# NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - MARCH 2023

| S/N | NDA REGISTRATION NUMBER | LICENSE HOLDER | LOCAL TECHNICAL REPRESENTATIVE | NAME OF DRUG | GENERIC NAME OF DRUG | STRENGTH OF DRUG | MANUFACTURER | COUNTRY OF MANUFACTURE | DOSAGE FORM | PACK SIZE | REGISTRATION DATE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | NDA/MAL/HDP/0002 | ABACUS PARENTERAL DRUGS LIMITED. | ABACUS PARENTERAL DRUGS LIMITED | X-SONE-N | DEXAMETHASONE +NEOMYCIN | 0.1W/V+ 0.35W/V | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/2011 |
| 2 | NDA/MAL/HDP/0003 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | UMOXIL CLAV 625 | AMOXICILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | UNI MEDICOLABS-21-22 PHARMACITY SELAQUI DEHRADUN 248197 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2015 |

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| 3 | NDA/MAL/HDP/0006 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIAMIDE | GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE | 5MG + 500MG | HOVID BERHAD,-LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X12.0 TABLET BLISTER | 01/07/2014 |
| 4 | NDA/MAL/HDP/0007 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROCIP SYRUP | CYPROHEPTADINE HYDROCHLORIDE | 2MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/2013 |
| 5 | NDA/MAL/HDP/0012 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | PENGESIC SR | TRAMADOL HYDROCHLORIDE SR | 100MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 6 | NDA/MAL/HDP/0014 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | MONTELAIR 10MG TABLET | MONTELUKAST | 10MG | HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 7 | NDA/MAL/HDP/0016 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | CODIMEX-CT TABLETS | CETIRIZINE DIHYDROCHLORIDE | 10MG | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 8 | NDA/MAL/HDP/0017 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | S-HYDRO | HYDROCORTISONE | 100MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X7.5 ML VIAL | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 9 | NDA/MAL/HDP/0024 | KOPRAN LIMITED | TATA UGANDA LIMITED | AMPICLOXA | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 10 | NDA/MAL/HDP/0030 | UNOSOURCE PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | TRADMIN | TRAMADOL HYDROCHLORIDE | 50MG/ML | AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403 | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X2.0 ML AMPOULE | 01/07/2015 |
| 11 | NDA/MAL/HDP/0031 | MANKIND PHARM LTD | TATA UGANDA LIMITED | CEFTATIME-SB 1.5 | CEFTRIAXONE+SULBACTAM | 1000MG+500MG | MANKIND PHARMA LTD--VILLAGE KISHANPURA P.O JAMNI WALA TEHSIL PAONTA SAHIB DISTT SIRMOUR 173025 HIMACHAL PRADESH | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.5 G VIAL | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 12 | NDA/MAL/HDP/0033 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYVATE CREAM | BETAMETHASONE VALERATE | 0.1%W/W | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 13 | NDA/MAL/HDP/0041 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RECIM | CIMETIDINE | 200MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 14 | NDA/MAL/HDP/0045 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMOL CAPLETS | PARACETAMOL | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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| 15 | NDA/MAL/HDP/0051 | H. LUNDBECK A/S | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | CLOPIXOL ACUPHASE | ZUCLOPENTHIXOL ACETATE | 50MG/ML | H. LUNDBECK A/S - OTTILIAVEJ 9,2500 VALBY | DENMARK | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/2015 |
| 16 | NDA/MAL/HDP/0052 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | DISPERCAM | PIROXICAM | 0.5%W/V | MEDICAL UNION PHARMACEUTICAL CO.- PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/2014 |
| 17 | NDA/MAL/HDP/0053 | H. LUNDBECK A/S | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FLUANXOL DEPOT | FLUPENTIXOL DECANOATE | 20MG/ML | H. LUNDBECK A/S ,.,- OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN | DENMARK | PARENTERAL RETARD AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/2015 |

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| 18 | NDA/MAL/HDP/0054 | GOOD DAY PHARMACY LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | FUNGOAL | CLOTRIMAZOLE | 1%W/W | KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2013 |
| 19 | NDA/MAL/HDP/0055 | H.LUNDBECK A/S | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | CLOPIXOL DEPOT | ZUCLOPENTHIXOL DECANOATE | 200MG/ML | H. LUNDBECK A/S ,.,-OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN | DENMARK | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/2015 |
| 20 | NDA/MAL/HDP/0056 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | DYNAPAR QPS | DICLOFENAC | 4%W/V | TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA TROIKAA PHARMACEUTICALS LTD-BLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD-382170, GUJARAT STATE | INDIA | TOPICAL EXTERNAL SPRAYS WITHOUT GAS | 1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE | 01/07/2015 |

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| 21 | NDA/MAL/HDP/0059 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | VAGIBACT CREAM | CLINDAMYCIN PHOSPHATE | 2%W/W | NABIQASIM INDUSTRIES (PVT) LTDv-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN. | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X40.0 G TUBE + 1 APPLICATOR | 01/07/2006 |
| 22 | NDA/MAL/HDP/0060 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GONAL-F PEN 300 IU/0,5 ML (22 µG/0,5 ML) | FOLLITROPIN ALFA | 22 µG/0,5 ML | MERCK SERONO S.A - SUCCURSALE D'AUBONNE, ZONE INDUSTRIELLE DE L'OURIETTAZ, 1170 AUBONNE, SWITZERLAND MERCK SERONO SPA (BARI)- VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI | ITALY SWITZERLAND | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION | 01/07/2015 |
| 23 | NDA/MAL/HDP/0063 | HETERO LABS LTD | AIVEEN (U) LIMITED | ABACAVIR SULPHATE + LAMIVUDINE | ABACAVIR SULFATE + LAMIVUDINE | 600MG + 300MG | HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2015 |

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| 24 | NDA/MAL/HDP /0064 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GONAL-F PEN 450 IU/ IE 0,75 ML (33 µG) | FOLLITROPIN ALFA | 33µG/ 0.7ML | MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND MERCK SERONO SPA (BARI)- VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI | SWITZERLAND | PARENTERAL ORDINARY CARTRIDGES | 1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION | 01/07/2015 |
| 25 | NDA/MAL/HDP /0065 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | ALENDRONATE 70MG | ALENDRONATE SODIUM | 70MG | HOVID BHD-LOT 56442 7 1/2 MILES JALAN IPOH / CHEMOR 31200 CHEMOR | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2015 |
| 26 | NDA/MAL/HDP /0069 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | LIPITOR | ATORVASTATIN | 10MG | PFIZER LABORATORIES-GODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X28.0 TABLET BLISTER | 01/07/1999 |

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| 27 | NDA/MAL/HDP/0070 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | LIPITOR | ATORVASTATIN | 20MG | PFIZER LABORATORIES-GODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X28.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/1999 |
| 28 | NDA/MAL/HDP/0075 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | SYNRIAM | ARTEROLANE MALEATE + PIPERAQUINE PHOSPHATE | 150 MG + 750 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED - INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2014 |
| 29 | NDA/MAL/HDP/0077 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | X-SONE | DEXAMETHASONE SODIUM PHOSPHATE | 0.1 % W/V | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL | 01/07/2015 |

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| 30 | NDA/MAL/HDP/0079 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | REVOKE 72 | LEVONORGESTREL | 750MCG | MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..--PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2014 |
| 31 | NDA/MAL/HDP/0083 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ZINNIA-F | LEVONORGESTREL & ETHINYLESTRADIOL + FERROUS FUMARATE | 150MCG + 30MCG + 75MG | MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..--PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X28.0 TABLET BLISTER | 01/07/2014 |
| 32 | NDA/MAL/HDP/0088 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | D-LYTE CO-PACK | ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE/ZINC,ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSI | 2.7MG+0.52MG+0.58MG+0.30MG+20MG PER 200ML,6.75MG+1.30MG+1.45MG+0.75MG+20MG PER 500ML SACHET,13.5MG+2.60MG+2.90MG+1.50MG+20MG PER 1000ML SACHET | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY COMBINATION PACK POWDERS/GRANULES | 4.0X500.0 ML SACHET + 1*10 BLISTERS,10.0X200.0 ML SACHET + 1*10 BLISTERS,2.0X1000.0 ML SACHET + 1*10 BLISTERS | 01/07/2015 |

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| 33 | NDA/MAL/HDP/0097 | MSN LABORATORIES LTD | METRO PHARMACEUTICALS LIMITED | SAFELEVO 750 | LEVOFLOXACIN | 750MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 34 | NDA/MAL/HDP/0098 | MSN LABORATORIES LTD | STAR PHARMACEUTICALS LTD | ATOREM 10 | ATORVASTATIN | 10MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 35 | NDA/MAL/HDP/0101 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOTETRA CAPSULES | TETRACYCLINE HYDROCHLORIDE | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/1998 |

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| 36 | NDA/MAL/HDP/0102 | MSN LABORATORIES PRIVATE LIMITED, | GOOD DAY PHARMACY LIMITED | SILMELT 100 | SILDENAFIL CITRATE | 100MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X2.0 TABLET BLISTER | 01/07/2014 |
| 37 | NDA/MAL/HDP/0103 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | ATOREM 20 | ATORVASTATIN | 20MG | MSN LABORATORIES LTD-PLOT N0.42, ANRICH INDUSTRIAL ESTATE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 38 | NDA/MAL/HDP/0104 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | SILMELT 50 | SILDENAFIL CITRATE | 50MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X2.0 TABLET BLISTER | 01/07/2014 |

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| 39 | NDA/MAL/HDP/0105 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOSPRIN TABLETS | ACETYL SALICYLIC ACID | 300MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 40 | NDA/MAL/HDP/0107 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | ASUNRA | DEFERASIROX | 400MG | NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFAUSERTRASSE | SWITZERLAND | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X5.0X6.0 TABLET BLISTER | 01/07/2015 |
| 41 | NDA/MAL/HDP/0110 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SAFETELMI 40 | TELMISARTAN | 40MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 42 | NDA/MAL/HDP/0111 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SAFETELMI 80 | TELMISARTAN | 80MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 43 | NDA/MAL/HDP/0112 | NORVATIS PHARMA AG | SURGIPHARM (U) LIMITED | EXFORGE 5MG/160MG | AMLODIPINE + VALSARTAN | 5 MG + 160 MG | NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFAUSERTRASSE NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2007 |
| 44 | NDA/MAL/HDP/0114 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | BREATHEZY 4 | MONTELUKAST SODIUM | 4MG | MSN LABORATORIES LTD - PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRIC 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 45 | NDA/MAL/HDP/0116 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | BREATHEZY CW 5 | MONTELUKAST SODIUM | 5MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 46 | NDA/MAL/HDP/0117 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ZOCEF 1.5G | CEFUROXIME SODIUM | 1.5G | ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205 SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.5 G VIAL + 1 AMPOULE OF WFI | 01/07/2013 |
| 47 | NDA/MAL/HDP/0118 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ZOCEF 750MG | CEFUROXIME SODIUM | 750MG | ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205 SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X750.0 MG VIAL + 1 AMPOULE WFI | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 48 | NDA/MAL/HDP/0119 | DAWA LIMITED | SUPER MEDIC LTD | DACOLD | CAFFEINE ANHYDROUS+CHLORPHENIRAMINE MALEATE+PARACETAMOL+PSEUDOEPHEDRINE | 30MG+4MG+400MG+30MG | DAWA LIMITED -BABA DOGO RWARAKA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 49 | NDA/MAL/HDP/0121 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | PEDZINC | ZINC SULPHATE | 20MG | BETA HEALTH CARE INTERNATIONAL LIMITED/- PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2015 |
| 50 | NDA/MAL/HDP/0124 | DAWA LIMITED | SUPER MEDIC LTD | AMPECIN | AMPICILLIN TRIHYDRATE | 125MG/5ML | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 51 | NDA/MAL/HDP/0125 | DAWA LIMITED | SUPER MEDIC LTD | SULPHUR OINTMENT | SULPHUR | 10%W/W | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE | 01/07/2013 |
| 52 | NDA/MAL/HDP/0127 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | CORYCARDON | IRBESARTAN + HYDROCHLOROTHIAZIDE | 300MG + 12.5MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 53 | NDA/MAL/HDP/0128 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | CORYCARDON | IRBESARTAN + HYDROCHLOROTHIAZIDE | 150MG + 12.5MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 54 | NDA/MAL/HDP/0135 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | HEMOVIT SYRUP | IRON + FOLIC ACID + PYRIDOXINE + CYANOCOBALAMIN + ZINC | 200MG + 1.5MG + 0.5MG + 50 MCG + 2.33MG | BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2013 |
| 55 | NDA/MAL/HDP/0139 | DAWA LIMITED- | SUPER MEDIC LTD | MOXAFORTE | FLUCLOXACILLIN SODIUM + AMOXICILLIN TRIHYDRATE | 250MG + 250MG | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 56 | NDA/MAL/HDP/0141 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | NYCOSTAT SUSPENSION | NYSTATIN | 100,000 I.U/ML | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 57 | NDA/MAL/HDP/0152 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | RYCARDON 150 | IRBESARTAN | 150MG | DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 58 | NDA/MAL/HDP/0153 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | RYCARDON 300 | IRBESARTAN | 300MG | DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 59 | NDA/MAL/HDP/0155 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | ASTHATOR 10 | MONTELUKAST SODIUM | 10MG | TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 60 | NDA/MAL/HDP /0157 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RECODIN | CODEINE PHOSPHATE + CHLORPHENIRAMINE MALEATE | 10MG + 4MG /5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2015 |
| 61 | NDA/MAL/HDP /0158 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | KIPEL 10 | MONTELUKAST SODIUM | 10MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 62 | NDA/MAL/HDP /0160 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | TIZIGESIC | TIZANIDINE HYDROCHLORIDE | 2MG | UNICHEM LABORATORIES LIMITED-C–31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 63 | NDA/MAL/HDP /0161 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | TRAMAREN | TRAMADOL HYDROCHLORIDE | 50MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 64 | NDA/MAL/HDP /0162 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | COSYP-D LINCTUS | DEXTROMETHORPHAN HYDROBROMIDE + CHLORPHENAMINE MALEATE | 10MG +4MG /5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2015 |
| 65 | NDA/MAL/HDP /0163 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | PHENAREN | PROMETHAZINE HYDROCHLORIDE | 5MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 66 | NDA/MAL/HDP/0164 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | RENPRESS | PROPRANOLOL | 40MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 67 | NDA/MAL/HDP/0165 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | TOLANZ 5 | OLANZAPINE ORODISPERSIBLE TABLETS | 5MG | TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 68 | NDA/MAL/HDP/0166 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | X-PEL | MEBENDAZOLE | 100MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 69 | NDA/MAL/HDP/0167 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | TOLANZ 10 | OLANZAPINE ORODISPERSIBLE TABLETS | 10MG | TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 70 | NDA/MAL/HDP/0168 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | FEBUDAY | FEBUXOSTAT | 80MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 71 | NDA/MAL/HDP/0175 | BAYER SCHERING PHARMA | SURGIPHARM (U) LIMITED | XARELTO 10MG | RIVAROXABAN | 10MG | BAYER HEALTHCARE AG,-D-51368, LEVERKUSEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 72 | NDA/MAL/HDP/0178 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | COLDCAP DAYTIME AND NIGHT TIME CAPSULE | DAY TIME(PARACETAMOL +CAFFEINE ANHYDROUS+PSEUDOEPHEDRINE HCL) AND NIGHT TIME(PARACETAMOL +CHLORPHENIRAMINE MALEATE) | DAY TIME (500MG + 30MG + 30MG) AND NIGHT TIME (500MG +2MG) | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X8.0 CAPSULE BLISTER | 01/07/2013 |
| 73 | NDA/MAL/HDP/0182 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | FEBUDAY 40 | FEBUXOSTAT | 40MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 74 | NDA/MAL/HDP/0186 | WIDE SPECTRUM ENTERPRISES (U) LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BBC SPRAY | BENZOCAINE+BENZYDAMINE+CATALKONIUM CHLORIDE | 1.5%W/V+0.15%W/V+0.0413%W/V | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | ORAL TOPICAL SPRAYS WITHOUT GAS | 1.0X25.0 ML BOTTLE | 01/07/2014 |

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| 75 | NDA/MAL/HDP/0187 | AMOUN PHARMACEUTICAL COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | KAPRON TABLET | TRANEXAMIC ACID | 500 MG | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2014 |
| 76 | NDA/MAL/HDP/0188 | AMOUN PHARMACEUTICALS LTD | BOOTS PHARMACEUTICALS LIMITED | LEVOXIN | LEVOFLOXACIN | 500MG | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0 TABLET BLISTER | 01/07/2014 |
| 77 | NDA/MAL/HDP/0191 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | CLEDOMOX 228.5 | AMOXICILLIN + CLAVULANATE | 200 MG + 28.5 MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 78 | NDA/MAL/HDP/0192 | AMOUN PHARMACEUTICALS COMPANY | BOOTS PHARMACEUTICALS LIMITED | AMOCOMB CREAM | NEOMYCIN + TRIAMCINOLONE ACETONIDE + GRAMICIDIN | 0.25GM + 0.1G + 100000IU + 0.025G/100G | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2014 |
| 79 | NDA/MAL/HDP/0193 | MEDOPHARM, INDIA | PLANET PHARMACEUTICALS UGANDA LTD | CLEDOMOX 625 | AMOXICILLIN + CLAVULANIC ACID | 500 MG + 125 MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET STRIP | 01/07/2013 |
| 80 | NDA/MAL/HDP/0196 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LAMIVUDINE AND ZIDOVUDINE TABLETS | LAMIVUDINE/ZIDOVUDINE | 150MG/300MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA | UGANDA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2013 |

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| 81 | NDA/MAL/HDP/0203 | GLAXOSMITHLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | SERETIDE EVOHALER 250 | SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE | 25MCG + 250MCG | GLAXO WELLCOME-PRODUCTION ZONE INDUSTRIELLE NO. 2 23, RUE LAVOISIER 27000 EVREUX | FRANCE | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2015 |
| 82 | NDA/MAL/HDP/0204 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | TIVICAY | DOLUTEGRAVIR SODIUM | 50MG | GLAXO OPERATIONS UK LTD-WARE SG120DJ UNITED KINGDOM GLAXOSMITHKLINE PHARMACEUTICALS SA-GRUNWALDZKA 189 STREET, 60-322 POZNANA | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2015 |
| 83 | NDA/MAL/HDP/0205 | MACLEODS PHARMACEUTICALS LTDS LTD | VITACARE LIMITED | TENOFOVIR DISOPROXIL FUMARATE | TENOFOVIR DISOPROXIL FUMARATE | 300MG | MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2013 |

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| 84 | NDA/MAL/HDP/0207 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 300MG +300MG | MACLEODS PHARMACEUTICALS LTD--- PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401 MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2013 |
| 85 | NDA/MAL/HDP/0209 | HETERO LABS LTD | AIVEEN (U) LIMITED | ABACAVIR SULPHATE ORAL SOLUTION | ABACAVIR SULPHATE | 20MG/ML | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X240.0 ML BOTTLE | 01/07/2013 |
| 86 | NDA/MAL/HDP/0210 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | HEPATICUM | SILYMARIN | 140MG | MEDICAL UNION PHARMACEUTICAL CO.- PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2011 |

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| 87 | NDA/MAL/HDP/0212 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | HEPATICUM | SILYMARIN | 1G/100ML | MEDICAL UNION PHARMACEUTICAL CO.- PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X120.0 ML BOTTLE | 01/07/2012 |
| 88 | NDA/MAL/HDP/0217 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | PALETHER | ARTEMETHER | 80MG/ML | LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT | INDIA | PARENTERAL ORDINARY I M AMPOULES | 2.0X3.0X1.0 ML AMPOULE | 01/07/2014 |
| 89 | NDA/MAL/HDP/0221 | DAWA LIMITED | SUPER MEDIC LTD | AMPICLO-DAWA | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |

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| 90 | NDA/MAL/HDP/0222 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | AVIR-200 | ACYCLOVIR | 200MG | LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT S KANT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 91 | NDA/MAL/HDP/0227 | AMOUM PHARMACEUTICALS LTD | BOOTS PHARMACEUTICALS LIMITED | CYRINOL SYRUP | PHOLCODINE+EPHEDRINE HCL +CARBINOXAMINE MALEATE | 4MG+7MG+2MG/5ML | AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2014 |
| 92 | NDA/MAL/HDP/0230 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | COMBIART | ARTHEMETHER + LUMEFANTRINE | 20MG +120MG | STRIDES PHARMA SCIENCE LIMITED (STRIDES SHASUN)-KRS GARDENS, PLOT 36/7 SURAGAJKKANAHALLI, INDLAWADI CROSS, ANKAL TALUK, BANGALORE SOUTH - 562106, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X6.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X1.0X24.0 TABLET BLISTER,1.0X24.0 TABLET | 01/07/2013 |

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| 93 | NDA/MAL/HDP/0232 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | BRANTA | LOSARTAN POTASSIUM + AMLODIPINE BESILATE | 50MG + 5MG | TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 94 | NDA/MAL/HDP/0233 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | CEFIMED 400 | CEFIXIME TRIHYDRATE | 400MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOUS LIMASSOL CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0 TABLET BLISTER | 01/07/2014 |
| 95 | NDA/MAL/HDP/0234 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | CEFIMED 200 | CEFIXIME TRIHYDRATE | 200MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X8.0 TABLET BLISTER,1.0X2.0X5.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 96 | NDA/MAL/HDP/0235 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | AXETINE 500 | CEFUROXIME AXETIL | 500MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2014 |
| 97 | NDA/MAL/HDP/0239 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | KOMEFAN 140 | ARTEMETHER + LUMEFANTRINE | 20 MG+ 120 MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X3.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER | 01/07/2014 |
| 98 | NDA/MAL/HDP/0248 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | PANTONEX DR-40 | PANTOPRAZOLE | 40 MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 99 | NDA/MAL/HDP/0252 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | VAST-40 | ATORVASTATIN | 40MG | LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 100 | NDA/MAL/HDP/0254 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR 5 | BISOPROLOL HEMIFUMARATE | 5MG | MERCK KGAA-250 FRANKFRUTER STRASSE 250-64293 DARMSTADT WINTHROP PHARMACEUTICALS(PTY) LTD,-315 WATLOO ROAD,WATLOO,PRETORIA,SOUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE) | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 101 | NDA/MAL/HDP/0256 | HETERO LABS LTD | AIVEEN (U) LIMITED | CAPETERO 500 | CAPECITABINE | 500MG | HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X120.0 TABLET CONTAINER | 01/07/2015 |

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| 102 | NDA/MAL/HDP/0266 | ASTRA PHARMA (UK) LTD | ASTRA PHARMA (U) LIMITED | BENZATHINE PENICILLIN INJECTION | BENZATHINE PENICILLIN | 2.400.000 IU | CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0 VIAL CARTON | 01/07/2001 |
| 103 | NDA/MAL/HDP/0269 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | VOMISTAT-8 | ONDANSETRON | 8MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 104 | NDA/MAL/HDP/0270 | HETERO LABS LTD | AIVEEN (U) LIMITED | LEVIN 500MG | LEVOFLOXACIN HEMIHYDRATE | 500MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 105 | NDA/MAL/HDP/0271 | BIOLOGICAL E. LTD | GITTOES PHARMACEUTICALS LIMITED | BETT | TETANUS VACCNE ADSORBED | 40 I.U | BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078 | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X20.0X10.0 ML AMPOULE,1.0X24.0X10.0 ML AMPOULE,1.0X5.0 ML VIAL (10 DOSES) | 01/07/2015 |
| 106 | NDA/MAL/HDP/0275 | GLAXO SMITHLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | ZENTEL | ALBENDAZOLE | 400MG | GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A (PTY) LIMITED-39 HAWKINS AVENUE, EPPING INDUSTRIA 1, 7460, CAPE TOWN, SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2011 |
| 107 | NDA/MAL/HDP/0276 | MICRO LABS LTD | LABOREX UGANDA LIMITED | MELANOV 80 | GLICLAZIDE | 80MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 108 | NDA/MAL/HDP/0278 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CHLORPROMAZINE TABLETS B.P 100MG | CHLORPROMAZINE HYDROCHLORIDE | 100MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER | 01/07/1998 |
| 109 | NDA/MAL/HDP/0283 | DAWA LIMITED | SUPER MEDIC LTD | AMPICLO-DAWA | AMPICILLIN + CLOXACILLIN | 125 MG + 125 MG | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 110 | NDA/MAL/HDP/0288 | UNIVERSAL CORPORATION LTD | PHARMA VILLE LIMITED | DUXCOSPAN | HYOSCINE BUTYL BROMIDE | 10MG | UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 111 | NDA/MAL/HDP/0290 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | NATOA | MEBENDAZOLE | 100MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 112 | NDA/MAL/HDP/0293 | HETERO LABS LTD | AIVEEN (U) LIMITED | DARUNAVIR | DARUNAVIR | 600 MG | HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2014 |
| 113 | NDA/MAL/HDP/0296 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | PRAZITEL TABLETS | PRAZIQUANTEL | 600MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 114 | NDA/MAL/HDP/0301 | HETERO LABS LTD | AIVEEN (U) LIMITED | MONAST 10 | MONTELUKAST SODIUM | 10MG | HETERO LABS LTD. UNIT (V)-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 115 | NDA/MAL/HDP/0303 | HETERO LABS LTD | AIVEEN (U) LIMITED | ABACAVIR SULPHATE | ABACAVIR SULPHATE | 300MG | HETERO DRUGS LTD, UNIT III - 22-110, IDA, JEEDIMETLA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2014 |
| 116 | NDA/MAL/HDP/0305 | SAKAR HEALTH CARE PVT .LTD | ROYAL PHARMA 2011 LIMITED | CEFAX-250 DRY SYRUP | CEFALEXIN | 250MG/5ML | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 117 | NDA/MAL/HDP/0307 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | LAMIVUDINE ORAL SOLUTION | LAMIVUDINE | 10MG/ML | HETERO DRUGS LTD, UNIT III - 22-110, IDA, JEEDIMETLA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X240.0 ML CONTAINER | 01/07/2013 |
| 118 | NDA/MAL/HDP/0311 | MARTINDALE PHARMACEUTICALS LTD | LABOREX UGANDA LIMITED | FENTANYL | FENTANYL CITRATE | 50MCG/ML | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2013 |
| 119 | NDA/MAL/HDP/0312 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | CLOXISPA ORAL SOLUTION 125 | CLOXACILLIN | 125MG/5ML | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |

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| 120 | NDA/MAL/HDP/0314 | MARTINDALE PHARMACEUTICALS LTD | LABOREX UGANDA LIMITED | SUXAMETHONIUM CHLORIDE SOLUTION FOR INJECTION | SUXAMETHONIUM CHLORIDE | 50MG/ML | MARTINDALE PHARMA - BAMPTON ROAD, HAROLD HILL,ROMFORD,RM3844 | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2013 |
| 121 | NDA/MAL/HDP/0318 | DAWA LIMITED | SUPER MEDIC LTD | SABULIN | SALBUTAMOL | 4MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 122 | NDA/MAL/HDP/0320 | DAWA LIMITED | SUPER MEDIC LTD | DAZOLE | CLOTRIMAZOLE | 1%W/W | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 123 | NDA/MAL/HDP/0322 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILONG-5 | NEBIVOLOL HCL | 5MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |
| 124 | NDA/MAL/HDP/0326 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | OSTEBON | CALCIUM + COLECALCIFEROL | 250MG + 125 IU | ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 01/07/2014 |
| 125 | NDA/MAL/HDP/0333 | KOPRAN LIMITED | TATA UGANDA LIMITED | CLAVAMYN-625 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 500MG +125MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 126 | NDA/MAL/HDP/0335 | GOOD DAY PHARMACY LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | NEOMYCIN SULPHATE CREAM USP | NEOMYCIN SULPHATE CREAM USP | 0.5%WW | KREMOINT PHARMA PVT LTD-B-8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE | 01/07/2013 |
| 127 | NDA/MAL/HDP/0337 | IND-SWIFT | PLANET PHARMACEUTICALS UGANDA LTD | SWAZI *500 | AZITHROMYCIN | 500MG | IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2014 |
| 128 | NDA/MAL/HDP/0339 | IND-SWIFT | PLANET PHARMACEUTICALS UGANDA LTD | SWAZI *250 | AZITHROMYCIN | 250MG | IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 129 | NDA/MAL/HDP/0341 | IND SWIFT LTD | PLANET PHARMACEUTICALS UGANDA LTD | TELSWIFT- H 40 | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 130 | NDA/MAL/HDP/0342 | IND SWIFT LTD | PLANET PHARMACEUTICALS UGANDA LTD | TELSWIFT- H 80 | TELMISARTAN + HYDROCHLOROTHIAZIDE | 80MG + 12.5MG | IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 131 | NDA/MAL/HDP/0348 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | XBETA | BETAMETHASONE SODIUM PHOSPHATE | 0.1%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 132 | NDA/MAL/HDP/0349 | SWISS PARENTERALS PVT LTD | SHREEJI CARE LIMITED | CLAXY 1.2 G | COAMOXICLAV | 1.2G | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.2 G VIAL | 01/07/2013 |
| 133 | NDA/MAL/HDP/0350 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | CETRIREN | CETIRIZINE HYDROCHLORIDE | 10MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |
| 134 | NDA/MAL/HDP/0351 | MANKIND PHARM LTD | TATA UGANDA LIMITED | DEPREGDINA | LEVONORGESTREL | 1.5MG | ACME FORMULATION PVT LTD.-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2014 |

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| 135 | NDA/MAL/HDP/0353 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DEROX-10 | AMLODIPINE BESILATE | 10MG | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X3.0X1.0X10.0 TABLET BLISTER | 01/07/2015 |
| 136 | NDA/MAL/HDP/0354 | KOPRAN LIMITED | TATA UGANDA LIMITED | LEVOKOP | LEVOFLOXACIN | 500MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 137 | NDA/MAL/HDP/0355 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | BICO VITA | THIAMINE HCL + RIBOFLAVIN + PYRIDOXINE HCL + NICOTINAMIDE | 10MG + 0.1MG + 1MG + 10MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2015 |

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| 138 | NDA/MAL/HDP/0356 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | LEVO DENK 500 | LEVOFLOXACIN HEMIHYDRATE | 500MG | ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61 59320 ENNIGERLOH GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 139 | NDA/MAL/HDP/0358 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | STREPTOCIN | STREPTOMYCIN SULPHATE | 1GM | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY I M VIALS | 1.0X1.0 G VIAL | 01/07/2014 |
| 140 | NDA/MAL/HDP/0360 | ASTRA ZENECA AB | MACNAUGHTON LIMITED | NEXIUM 20MG | ESOMEPRAZOLE | 20MG | ASTRA ZENECA AB, SODERTALJE-GARTUNAYEGEN, SODERTALJE | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER,1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 141 | NDA/MAL/HDP/0362 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | BUPI | BUPIVACAINE | 5 MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL | 01/07/2015 |
| 142 | NDA/MAL/HDP/0363 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | AGYCIN | AZITHROMYCIN | 250MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2014 |
| 143 | NDA/MAL/HDP/0365 | UNIVERSAL CORPORATION LTD | PHARMA VILLE LIMITED | SULFRAN- DS | TRIMETHOPRIM/SULFAMETHOXAZOLE | 160MG/800MG | UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 144 | NDA/MAL/HDP/0366 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | AGYCIN 500 | AZITHROMYCIN | 500MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2014 |
| 145 | NDA/MAL/HDP/0370 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILONG-H | NEBIVOLOL + HYDROCHLOROTHIAZIDE | 5MG + 12.5MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2010 |
| 146 | NDA/MAL/HDP/0372 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | LEZYNCET | LEVOCETIRIZINE | 5MG | UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER,5.0X2.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 147 | NDA/MAL/HDP/0376 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ASOMEX-D | AMLODIPINE + HYDROCHLOROTHIAZIDE | 2.5 MG + 12.5 MG | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 148 | NDA/MAL/HDP/0382 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | KETAMINE FRESENIUS | KETAMINE HYDROCHLORIDE | 50MG/ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY VIALS | 1.0X10.0X10.0 ML VIAL | 01/07/2014 |
| 149 | NDA/MAL/HDP/0383 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | MANNITOL FRESENIUS | MANNITOL | 20%W/V | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY INFUSION BAGS | 1.0X500.0 ML BAG | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 150 | NDA/MAL/HDP/0388 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | AZUCLOX | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE STRIP,1.0X250.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 151 | NDA/MAL/HDP/0389 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | SANMOL INFUSION IV | PARACETAMOL | 1000MG/100ML | PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG | INDONESIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2014 |
| 152 | NDA/MAL/HDP/0394 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | DOXYLEB | DOXYCYCLINE | 100MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 153 | NDA/MAL/HDP/0397 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ASOMEX-LT | AMLODIPINE + LOSARTAN POTASSIUM | 2.5 MG + 50 MG | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 154 | NDA/MAL/HDP/0401 | FOURRTS (INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | L MONTUS | LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM | 5MG + 10MG | FOURRTS (INDIA) LABORATORIES (PVT) LTD-FOURRTS AVENUE, VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2015 |
| 155 | NDA/MAL/HDP/0403 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | SUPRIDOL | TRAMADOL HYDROCHLORIDE | 50MG/ML | NEON LABORATORIES LTD -- PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA | INDIA | PARENTERAL ORDINARY I V AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 156 | NDA/MAL/HDP/0404 | GLAXOSMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ACTIFED WET COUGH & COLD | TRIPLORIDINE HCL/PSEUDOEPHEDRINE/GUAIPHENESIN | 1.25MG/30MG/100MG | GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X2.0 L JERRYCAN | 01/07/1997 |
| 157 | NDA/MAL/HDP/0406 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | EVATOCIN | OXYTOCIN | 10 I.U./ ML | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY I V AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 01/07/2015 |
| 158 | NDA/MAL/HDP/0407 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | NEOROF | PROPOFOL | 1%W/V | NEON LABORATORIES LTD --PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 159 | NDA/MAL/HDP/0408 | MSN LABORATORIES LTD | STAR PHARMACEUTICALS LTD | ALGIC - P | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 160 | NDA/MAL/HDP/0409 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | TYDE-S* | CHLORAMPHENICOL SODIUM SUCCINATE | 1G/VIAL | NEON LABORATORIES LTD -- PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2013 |
| 161 | NDA/MAL/HDP/0410 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | LDNIL 20 | ROSUVASTATIN CALCIUM | 20MG | MSN LABORATORIES LTD-PLOT N0.42, ANRICH INDUSTRIAL ESTATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 162 | NDA/MAL/HDP/0411 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | JADELLE SINE | LEVONORGESTREL | 150MG | BAYER OY-PANSIONATE 47 20210 TURKU FINLAND | FINLAND | PARENTERAL RETARD IMPLANTS | 1.0X10.0X1.0X2.0X 75.0 MG IMPLANT | 01/07/2003 |
| 163 | NDA/MAL/HDP/0413 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | XSPAS | HYOSCINE BUTYLBROMIDE | 20MG/ML | NEON LABORATORIES LTD -- PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA | INDIA | PARENTERAL ORDINARY I V AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 01/07/2013 |
| 164 | NDA/MAL/HDP/0415 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | RELEX | DIPHENHYDRAMINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SODIUM CITRATE+MENTHOL | 14.03MG+138MG+57.03MG+0.90MG | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 165 | NDA/MAL/HDP/0418 | ASTRA ZENECA | MACNAUGHTON LIMITED | KOMBIGLYZE XR 5MG/1000 | SAXAGLIPTIN + METFORMIN | 5MG + 1000MG | ASTRAZENECA PHARMACEUTICALS LP.-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA | UNITED STATES | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE,1.0X4.0X7.0 TABLET BLISTER | 01/07/2013 |
| 166 | NDA/MAL/HDP/0419 | ASTRAZENECA | MACNAUGHTON LIMITED | KOMBIGLYZE XR 2.5MG/1000MG | SAXAGLIPTIN + METFORMIN | 2.5MG + 1000MG | ASTRAZENECA PHARMACEUTICALS LP.-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA | UNITED STATES | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2013 |
| 167 | NDA/MAL/HDP/0421 | MSN LABORATORIES PRIVATE LIMITED | STAR PHARMACEUTICALS LTD | PREGASAFE 150 | PREGABALIN | 150MG | MSN LABORATORIES LTD-PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2014 |

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| 168 | NDA/MAL/HDP/0422 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PARAFLAM | IBUPROFEN + PARACETAMOL | 100MG + 162.5MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2013 |
| 169 | NDA/MAL/HDP/0423 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOTRAM | TRAMADOL | 50MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 X10.0 CAPSULE BLISTER | 01/07/2013 |
| 170 | NDA/MAL/HDP/0424 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CHLORPROMAZINE TABLETS B.P 25MG | CHLORPROMAZINE | 25MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER | 01/07/1998 |

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| 171 | NDA/MAL/HDP/0427 | MICRO LABS LTD | LABOREX UGANDA LIMITED | AMLOZAAR -H | LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOROTHIAZIDE | 50MG + 5MG + 12.5MG | MICRO LABS LTD ..-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIIL NADU | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 172 | NDA/MAL/HDP/0428 | MICRO LABS LTD | LABOREX UGANDA LIMITED | MICROMOX-400 | MOXIFLOXACIN | 400MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X5.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 173 | NDA/MAL/HDP/0429 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | FLEXON MR | IBUPROFEN + PARACETAMOL + CHLORZOXAZONE | 400MG + 325MG + 250MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X1.0X10.0 TABLET BLISTER,1.0X10.0X 1.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 174 | NDA/MAL/HDP/0430 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO ACECLO PLUS | ACECLOFENAC+PARACETAMOL | 100MG+500MG | ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X15.0X10.0 TABLET BLISTER | 01/07/2013 |
| 175 | NDA/MAL/HDP/0432 | FOURRTS (INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | K MAC ORAL SOLUTION | POTASSIUM CITRATE + MAGNESIUM CITRATE | 22MG + 7.5MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X200.0 ML BOTTLE | 01/07/2013 |
| 176 | NDA/MAL/HDP/0433 | PT SAMBE FARMA | MEDVIN PHARMA LIMITED | PROANES MCT/LCT | PROPOFOL | 1%W/V | PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG | INDONESIA | PARENTERAL ORDINARY I V AMPOULES | 1.0X5.0X20.0 ML AMPOULE | 01/07/2014 |

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| 177 | NDA/MAL/HDP /0434 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | PROHIBIN | GASTRO-RESISTANT OMEPRAZOLE CAPSULES BP 20 | 20 MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0X 10.0 CAPSULE STRIP | 01/07/2010 |
| 178 | NDA/MAL/HDP /0435 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | LIGNOCAINE HCL FRESENIUS | LIGNOCAINE HYDROCHLORIDE | 2%W/V | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY VIALS | 1.0X10.0X20.0 ML VIAL | 01/07/2015 |
| 179 | NDA/MAL/HDP /0437 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | NALOXONE HCL NEONATAL FRESENIUS | NALOXONE HYDROCHLORIDE | 0.02MG/ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2014 |

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| 180 | NDA/MAL/HDP/0439 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | NALOXONE HCL FRESENIUS 0.4MG/1ML | NALOXONE HYDROCHLORIDE | 0.4MG/1ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2015 |
| 181 | NDA/MAL/HDP/0440 | AGIO PHARMACEUTICALS LTD | ROYAL PHARMA 2011 LIMITED | AGICLOB-GM | CLOBETASOL/GENTAMICIN/MICONAZOLE | 0.5MG+3.4MG+20MG/1G | AGIO PHARMACEUTICALS LTD-PLOT NO. T-81, 82 MIDC, BHOSARI, PUNE-26 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2014 |
| 182 | NDA/MAL/HDP/0441 | AGIO PHARMACEUTICALS LTD | ROYAL PHARMA 2011 LIMITED | AGISEC | SECNIDAZOLE | 1GM | AGIO PHARMACEUTICALS LTD-PLOT NO. T-81, 82 MIDC, BHOSARI, PUNE-26 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 183 | NDA/MAL/HDP/0444 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | NEOSTIGMINE METHYLSUIPHATE FRESENIUS | NEOSTIGMINE METHYLSULPHATE | 2.5MG\ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2015 |
| 184 | NDA/MAL/HDP/0447 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | SANEXON®125 | METHYLPREDNISOLONE SODIUM SUCCINATE | 125MG/VIAL | PT SANBE FARMA UNIT 3.-JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG | INDONESIA | PARENTERAL ORDINARY DRY VIALS | 1.0X125.0 MG VIAL + 1*2ML AMPOULE OF WFI | 01/07/2014 |
| 185 | NDA/MAL/HDP/0449 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AMINOGUARD GRANULES | CYANOCOBALAMIN | 5MCG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY GRANULES | 1.0X10.0X5.0 G SACHET | 01/07/2013 |

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| 186 | NDA/MAL/HDP /0451 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | SANEXON®500 | METHYLPREDNISOLONE SODIUM SUCCINATE | 500MG/VIAL | PT SANBE FARMA UNIT 3.-JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG | INDONESIA | PARENTERAL ORDINARY DRY VIALS | 1.0X500.0 MG VIAL + 1*8ML AMPOULE OF WFI | 01/07/2014 |
| 187 | NDA/MAL/HDP /0453 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AMINOGUARD LIQUID | AMINO ACIDS + MULTIVITAMINS | MULTI INGREDIENTS | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X200.0 ML BOTTLE | 01/07/2013 |
| 188 | NDA/MAL/HDP /0454 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | LEVOCIN INFUSION | LEVOFLOXACIN HEMIHYDRATE | 500 MG | PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG | INDONESIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2014 |

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| 189 | NDA/MAL/HDP/0456 | LEBEN LABORATORIES PVT. LTD | MALIX PHARMA (U) LIMITED | METROLEB | METRONIDAZOLE | 125MG/5ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2014 |
| 190 | NDA/MAL/HDP/0457 | UNIVERSAL CORPORATION LTD | DELMAW ENTERPRISES LIMITED | UNIBROL 250MG | AMINOSIDINE | 250MG | UNIVERSAL CORPORATION LTD-UNIVERSAL CORPORATION LTD | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X6.0 TABLET BLISTER,1.0X4.0X6.0 TABLET BLISTER | 01/07/2012 |
| 191 | NDA/MAL/HDP/0460 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | AMBRODIL | AMBROXOL HYDROCHLORIDE | 7.5MG/ML | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X15.0 ML BOTTLE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 192 | NDA/MAL/HDP/0463 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TOPHEN | PHENYTOIN | 100MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2011 |
| 193 | NDA/MAL/HDP/0467 | DAWA PHARMACEUTICALS LIMITED | SUPER MEDIC LTD | CURAMOL PLUS | PARACETAMOL/CAFFEINE | 500MG/60MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 50.0X2.0 TABLET STRIP | 01/07/1997 |
| 194 | NDA/MAL/HDP/0468 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | CEFUAXIT 750 | CEFUROXIME | 750MG | NECTAR LIFESCIENCES LIMITED-VILL. BHATOLIKALAN, ADJOININGJHARMJRI, P.O BAROTIWALA DIST SOLAN H.P 173205 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X750.0 MG VIAL + 10ML WFI AMPOULE | 01/07/2013 |

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| 195 | NDA/MAL/HDP/0470 | NOVO NORDISK PHARMA GULF FZ-LC | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NOVOMIX 30 FLEXPEN | INSULIN ASPART | 100I.U/ML | NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - | DENMARK | PARENTERAL ORDINARY DRY PRE-FILLED PENS | 1.0X5.0X3.0 ML PREFILLED PEN | 01/07/2014 |
| 196 | NDA/MAL/HDP/0471 | NOVO NORDISK PHARMA GULF FZ-LC | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NOVORAPID FLEXPEN | INSULIN ASPART | 100 I.U/ML | NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - | DENMARK | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X5.0X3.0 ML PREFILLED PEN | 01/07/2014 |
| 197 | NDA/MAL/HDP/0472 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | BCG VACCINE (FREEZE DRIED) | BCG VACCINE(FREEZE DRIED) | 1.33*100000 C.F.U/0.1ML | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA SERUM INSTITUTE OF INDIA PRIVATE LIMITED-PLOT NO.: 105-110, MANJARI BUDRUK, TAL-HAVELI, PUNE - 412 307, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 ML VIAL,1.0X0.5 ML VIAL | 01/07/2015 |

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| 198 | NDA/MAL/HDP/0475 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | TINI-500 | TINIDAZOLE | 500MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X25.0X4.0 TABLET BLISTER | 01/07/2015 |
| 199 | NDA/MAL/HDP/0477 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | VOMISTAT-4 | ONDANSETRON | 4MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 200 | NDA/MAL/HDP/0482 | LEBEN LABORATORIES PVT. LTD | MALIX PHARMA (U) LIMITED | AZILEB-500 | AZITHROMYCIN | 500MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X3.0 TABLET BLISTER | 01/07/2014 |

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| 201 | NDA/MAL/HDP /0483 | FOUNTIL LIFE SCIENCES PVT LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ULGICID TABLETS | ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE+ MAGNESIUM TRISILICATE + SIMETICONE | 200MG + 250MG + 250MG + 250MG + 125MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 202 | NDA/MAL/HDP /0489 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | CEBAY-200 DT | CEFIXIME | 200MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 203 | NDA/MAL/HDP /0491 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABCHLOR EYE DROPS | CHLORAMPHENICOL | 0.5% W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X5.0 ML VIAL,1.0X10.0 ML VIAL | 01/07/2013 |

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| 204 | NDA/MAL/HDP/0496 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | MYPRODOL | PARACETAMOL + IBUPROFEN + CODEINE PHOSPHATE | 250MG + 200MG + 10MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X20.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER | ########## |
| 205 | NDA/MAL/HDP/0497 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | KEMOXYL DRY SUSPENSION | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | LABORATORY & ALLIED LTD-PLOT NO. 209/10349<br>OFF MOMBASA ROAD, NAIROBI<br>P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 206 | NDA/MAL/HDP/0502 | STEDMAN PHARMACEUTICALS LTD | VEERAM HEALTHCARE (U) LIMITED | DREZ GARGLE | IODINATED POVIDONE | 2%W/V | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2013 |

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| 207 | NDA/MAL/HDP/0507 | FOURRTS (INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | FILDILOL 12.5 | CARVEDILOL | 12.5 MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 208 | NDA/MAL/HDP/0509 | FOURRTS (INDIA) LABORATORIES (PVT) LTD | DELMAW ENTERPRISES LIMITED | FILDILOL 25 | CARVEDILOL | 25MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 209 | NDA/MAL/HDP/0510 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | LIZOLID-600 | LINEZOLID | 600MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X4.0 TABLET STRIP | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 210 | NDA/MAL/HDP /0512 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | FILSTAT 10 | ATORVASTATIN CALCIUM | 10MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 211 | NDA/MAL/HDP /0515 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | FILSTAT 20 | ATORVASTATIN | 20MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 212 | NDA/MAL/HDP /0518 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | CYCLOREN | ACICLOVIR | 200MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2014 |

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| 213 | NDA/MAL/HDP/0520 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | FILSTAT 40 | ATORVASTATIN CALCIUM | 40MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 214 | NDA/MAL/HDP/0521 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PAN 40 | PANTOPRAZOLE SODIUM | 40MG | ALKEM LABORATORIES LTD .-VILLAGE THANA BADDI TEHSIL NALAGARH DIST SOLAN HIMACHAL PRADESH EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 215 | NDA/MAL/HDP/0522 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | VAZORTAN 50 | LOSARTAN POTASSIUM | 50MG | MEDLEY PHARMACEUTICALS LTD -PLOT NO. 18 AND 19, SURVEY NO. 378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM , DAMAN-396 210, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 216 | NDA/MAL/HDP /0526 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | AMILEB- 25 | AMITRIPTYLINE | 25MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2014 |
| 217 | NDA/MAL/HDP /0531 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | ENDERM-GM | CLOBETASOL PROPIONATE + GENTAMYCIN + MICONAZOLE NITRATE | 0.05%W/W + 0.10%W/W + 2.0%W/W | LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE,1.0X15.0 G TUBE | 01/07/2014 |
| 218 | NDA/MAL/HDP /0538 | MICRO LABS LTD | LABOREX UGANDA LIMITED | XONADINE 180 | FEXOFENADINE HYDROCHLORIDE | 180 MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X1 0.0 TABLET BLISTER | 01/07/2013 |

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| 219 | NDA/MAL/HDP/0540 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | HYDRICORT | HYDROCORTISONE SODIUM SUCCINATE | 100MG | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X100.0 MG VIAL | 01/07/2014 |
| 220 | NDA/MAL/HDP/0541 | MICRO LABS LTD | LABOREX UGANDA LIMITED | XONADINE 120 | FEXOFENADINE HYDROCHLORIDE | 120MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 221 | NDA/MAL/HDP/0542 | DAWA LIMITED | SUPER MEDIC LTD | PHENBITAL | PHENOBARBITAL | 30MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 222 | NDA/MAL/HDP/0543 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | GLIMERYL 2 | GLIMEPIRIDE | 2MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 223 | NDA/MAL/HDP/0544 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | DOLOWIN PLUS | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 224 | NDA/MAL/HDP/0547 | NAARI LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | MISO-KARE | MISOPROSTOL | 200MCG | NAARI PHARMA PRIVATE LIMITED-PLOT NO. 14-16 &55-57, SECTOR-5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0 TABLET BLISTER (COMBIPACK),1.0X3.0X4.0 TABLET BLISTER | 01/07/2013 |

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| 225 | NDA/MAL/HDP/0548 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNICAST | MONTELUKAST | 5MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .--P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY | JORDAN | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 226 | NDA/MAL/HDP/0550 | DAWA LIMITED | SUPER MEDIC LTD | DA-ZEPAM | DIAZEPAM | 5MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2014 |
| 227 | NDA/MAL/HDP/0553 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | EQUIRAB | RABIES ANTISERUM | 1000IU/ 5ML | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X5.0 ML VIAL (5 DOSE VIAL) | 01/07/2013 |

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| 228 | NDA/MAL/HDP/0555 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | CARZEPIN | CARBAMAZEPINE | 200MG | HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 229 | NDA/MAL/HDP/0558 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABGENTA EYE DROPS | GENTAMICIN SULPHATE | 0.3% W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE,1.0X5.0 ML VIAL | 01/07/2014 |
| 230 | NDA/MAL/HDP/0559 | HOVID BHD | MEDICAL ACCESS (UGANDA) LIMITED | DIABETMIN RETARD | METFORMIN HYDROCHLORIDE | 850MG | HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA | MALAYSIA | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 231 | NDA/MAL/HDP/0560 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | GLIMERYL 1 | GLIMEPIRIDE | 1MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .--P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 232 | NDA/MAL/HDP/0563 | IND SWIFT LTD | PLANET PHARMACEUTICALS UGANDA LTD | EZO 40 | ESOMEPRAZOLE MAGNESIUM | 40MG | IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI | INDIA | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 233 | NDA/MAL/HDP/0568 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | FLUOXIREN | FLUOXETINE | 20MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |

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| 234 | NDA/MAL/HDP/0570 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | TETGLOB 250 I.U | HUMAN TETANUS IMMUNOGLOBULIN | 250IU | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY I M VIALS | 1.0X1.0X2.0 ML VIAL (1 DOSE VIAL) | 01/07/2013 |
| 235 | NDA/MAL/HDP/0572 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | AZARGA | BRINZOLAMIDE + TIMOLOL | 10MG/ML + 5MG/ML | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML VIAL | 01/07/2010 |
| 236 | NDA/MAL/HDP/0573 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL PARACETAMOL-250 | PARACETAMOL | 250MG/5ML | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 237 | NDA/MAL/HDP/0574 | IPCA LABORATOIES LTD | MEDVIN PHARMA LIMITED | ARTESUNATE AND AMODIAQUINE TABLETS 100/270 | ARTESUNATE AND AMODIAQUINE | 100MG+270MG | IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER | 01/07/2013 |
| 238 | NDA/MAL/HDP/0576 | GLAXO SMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | DUODART | DUTASTERIDE + TAMSULOSIN | 0.5MG + 0.4MG | CATALENT GERMANY SCHONDORF GMBH - STEINBEISSTRASSE 1-2, 73614 SCHORNDORF, GERMANY | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X30.0 CAPSULE CONTAINER | 01/07/2015 |
| 239 | NDA/MAL/HDP/0580 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | FLUCAP | MULTINGREDIENT | MULTINGREDIENT | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |

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| 240 | NDA/MAL/HDP/0582 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ACECLO SERA | ACECLOFENAC+PARACETAMOL+SERRATIOPEPTIDASE | 100MG + 500MG + 15MG | ARISTO PHARMACEUTICALS PVT LTD-VILLAGE: MAKHNUMAJRA P.O. BHUD BADDI DISTRIC: SOLAN (H.P) 173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |
| 241 | NDA/MAL/HDP/0584 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | TRIGLIMIPREX 1 | GLIMEPIRIDE+PIOGLITAZONE+METFORMIN HYDROCHLORIDE | 1MG+15MG+500MG | ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 242 | NDA/MAL/HDP/0587 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | CADIGREL | CLOPIDOGREL | 75MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 243 | NDA/MAL/HDP/0588 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROFORT | PREDNISOLONE ACETATE | 1%W/V | AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA | INDIA | OPHTHALMIC SUSPENSIONS | 1.0X5.0 ML BOTTLE | 01/07/2013 |
| 244 | NDA/MAL/HDP/0589 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | TRIGLIMIPREX 2 | GLIMEPIRIDE+PIOGLITAZONE+METFORMIN HYDROCHLORIDE | 2MG+15MG+500MG | ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2014 |
| 245 | NDA/MAL/HDP/0592 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROCHROME | CROMOLYN SODIUM | 2%W/V | AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA | INDIA | OPHTHALMIC LIQUIDS | 1.0X10.0 ML CONTAINER | 01/07/2013 |

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| 246 | NDA/MAL/HDP/0593 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | PANTOP-D | PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE CAPSULES | 20MG+10MG | ARISTO PHARMACEUTICALS PVT LTD .-MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP,1.0X3.0X10.0 CAPSULE STRIP | 01/07/2014 |
| 247 | NDA/MAL/HDP/0595 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ORNOF | ORNIDAZOLE + OFLOXACIN | 500MG + 200MG | ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 248 | NDA/MAL/HDP/0596 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ARBITEL-H | TELMISARTAN/HYDROCHLOROTHIAZIDE | 40MG/12.5MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2011 |

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| 249 | NDA/MAL/HDP/0598 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | LIPICURE-20 | ATORVASTATIN | 20MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2003 |
| 250 | NDA/MAL/HDP/0599 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | GRAMOCEF-O-400 | CEFIXIME | 400MG | MICROLABS LIMITED-PLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 251 | NDA/MAL/HDP/0600 | DENK PHARM GMBH&CO.KG | BENLE CONSULT LIMITED | CARVEDI-DENK 6.25 | CARVEDILOL | 6.25MG | ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 252 | NDA/MAL/HDP/0603 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | GROMIN SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/1999 |
| 253 | NDA/MAL/HDP/0605 | DENK PHARM GMBH&CO.KG | BENLE CONSULT LIMITED | CARVEDI-DENK 25 | CARVEDILOL | 25MG | ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 254 | NDA/MAL/HDP/0609 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | CLOPI-DENK 75 | CLOPIDOGREL BESYLATE | 75MG | ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 255 | NDA/MAL/HDP/0610 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | PYLOR KIT | LANSOPRAZOLE DELAYED RELEASE + CLARITHROMYCIN + TINIDAZOLE | 30MG + 250MG + 500MG | LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS) | 01/07/2016 |
| 256 | NDA/MAL/HDP/0614 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CLAVULIN | AMOXICILLIN + CLAVULANIC ACID | 125MG/5ML + 31.25MG/5ML | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1998 |
| 257 | NDA/MAL/HDP/0617 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | SILVEX | SILVER SULFADIAZINE + CHLORHEXIDINE | 1%W/W + 0.2%W/W | LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2014 |

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| 258 | NDA/MAL/HDP /0618 | HETERO LABS LTD | AIVEEN (U) LIMITED | VALSAR 160 | VALSARTAN | 160MG | HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |
| 259 | NDA/MAL/HDP /0619 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | D10 | GLUCOSE | 10%W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2013 |
| 260 | NDA/MAL/HDP /0621 | HETERO LABS LTD | AIVEEN (U) LIMITED | ALZER | DONEPEZIL HYDROCHLORIDE | 10MG | HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 261 | NDA/MAL/HDP/0623 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | GELCID | MAGNESIUM SULPHATE | 50%W/V | LINCOLN PHARMACEUTICALS LTD--11 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X5.0X10.0 ML AMPOULE,1.0X10.0X5.0X5.0 ML AMPOULE IN BLISTER PACK,1.0X5.0 ML AMPOULE IN BLISTER PACK | 01/07/2015 |
| 262 | NDA/MAL/HDP/0626 | KPI INDUSTRIES(1996) LTED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | CARDIPAC-10 | AMLODIPINE BESILATE | 10MG | KPI INDUSTRIES (1996) LTD-PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |
| 263 | NDA/MAL/HDP/0627 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | AMOXIKID | AMOXICILLIN TRIHYDRATE | 125MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 264 | NDA/MAL/HDP/0633 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | CIPROCIN | CIPROFLOXACIN | 0.3%W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/2013 |
| 265 | NDA/MAL/HDP/0634 | MEDLEY PHARMACEUTICALS | MEDVIN PHARMA LIMITED | TRISOLIV | ANDROGRAPHOLIDES/TRICHOLINE CITRATE | 50MCG+50MG/ML | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2014 |
| 266 | NDA/MAL/HDP/0635 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-AMIN | AMINOPHYLLINE | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 267 | NDA/MAL/HDP/0636 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | REVOKE-1.5 | LEVONORGESTREL | 1.5MG | MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2014 |
| 268 | NDA/MAL/HDP/0637 | NABIQASIM INDUSTRIES (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | ZUDICORT | FUSIDIC ACID + BETAMETHASONE VALERATE | 20MG + 1MG/G | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2014 |
| 269 | NDA/MAL/HDP/0638 | PHARMACIE BETHEL | ABACUS PARENTERAL DRUGS LIMITED | ABLOL-5 EYE DROPS | TIMOLOL MALEATE | 0.5% W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL | 01/07/2013 |

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| 270 | NDA/MAL/HDP/0639 | NEM LABORATORIES (PVT) LTD | RENE PHARMACY LTD | RHEUMATIC CREAM | MULTI-INGREDIENT | MULTI-INGREDIENT | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 271 | NDA/MAL/HDP/0654 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | GALVUS MET | VILDAGLIPTIN / METFORMIN | 50MG/500MG | NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2013 |
| 272 | NDA/MAL/HDP/0657 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | GALVUS MET | VILDAGLIPTIN / METFORMIN | 50MG / 850MG | NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 273 | NDA/MAL/HDP /0658 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | GALVUS MET | VILDAGLIPTIN/ METFORMIN | 50MG/1000MG | NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER | 01/07/2013 |
| 274 | NDA/MAL/HDP /0665 | HETERO LABS LTD | AIVEEN (U) LIMITED | IRBIS 150 | IRBESARTAN | 150MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 275 | NDA/MAL/HDP /0666 | HETERO LABS LTD | AIVEEN (U) LIMITED | IRBIS-H 300 | IRBESARTAN | 300MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 276 | NDA/MAL/HDP/0668 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | TELI 40 | TELMISARTAN | 40MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 277 | NDA/MAL/HDP/0669 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXEL FUNGICORT CREAM | MICONAZOLE NITRATE + HYDROCORTISONE | 2% W/W + 1% W/W | KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X5.0 G TUBE,1.0X15.0 G TUBE | 01/07/2013 |
| 278 | NDA/MAL/HDP/0670 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FLUNAZ-200 | FLUCONAZOLE | 200MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0 CAPSULE BLISTER,1.0X5.0X4.0 CAPSULE BLISTER | 01/07/2014 |

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| 279 | NDA/MAL/HDP/0672 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGONOR TABLETS | NORFLOXACIN | 400MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER | 01/07/2013 |
| 280 | NDA/MAL/HDP/0674 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGODAPS-100 | DAPSONE | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2013 |
| 281 | NDA/MAL/HDP/0675 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL METRONIDAZOLE 400 | METRONIDAZOLE | 400MG | KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 282 | NDA/MAL/HDP/0677 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | DOPAMET | METHYLDOPA | 250MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 283 | NDA/MAL/HDP/0678 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL HYDROCORTISONE CREAM | HYDROCORTISONE | 1%W/W | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/2014 |
| 284 | NDA/MAL/HDP/0679 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | MEFENA-250 CAPSULES | MEFENAMIC ACID | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 X10.0 CAPSULE BLISTER | 01/07/2013 |

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| 285 | NDA/MAL/HDP/0681 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ELAXIM 40 | TENECTEPLASE (RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR) | 40MG/VIAL | GENNOVA BIOPHARMACEUTICALS LIMITED-BLOCK 1, PLOT NO. P-1 AND P-2, ITBT PARK, PHASE II, MIDC, HINJAWADI, PUNE - 411057 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X40.0 MG VIAL , 1*8 ML VIAL OF WFI | 01/07/2013 |
| 286 | NDA/MAL/HDP/0685 | FERRER INTERNACIONAL S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SOMAZINA | CITICOLINE | 1000MG | FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | PARENTERAL RETARD I M AMPOULES | 1.0X5.0X4.0 ML AMPOULE | 01/07/2015 |
| 287 | NDA/MAL/HDP/0687 | FERRER INTERNACIONAL S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SOMAZINA | CITICOLINE | 1000MG | FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | ORAL LIQUID ORDINARY LIQUIDS | 1.0X6.0X10.0 ML SACHET | 01/07/2015 |

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| 288 | NDA/MAL/HDP/0688 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | HBB | HYOSCINE BUTYLBROMIDE | 10MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 289 | NDA/MAL/HDP/0689 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGONAL | NALIDIXIC ACID | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 290 | NDA/MAL/HDP/0690 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | HEALTHEASE CREAM | BECLOMETHASONE DIPROPRIONATE + PHENYLEPHRINE HCL + LIGNOCAINE HCL + CHLOROCRESOL | 0.025%W/W + 0.1%W/W + 2.5%W/W + 0.1%W/W | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/2014 |

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| 291 | NDA/MAL/HDP/0691 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | OLMAT-20 | OLMESARTAN MEDOXOMIL | 20 MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 292 | NDA/MAL/HDP/0692 | DAWA LIMITED | SUPER MEDIC LTD | DAWACLOX - 250 | CLOXACILLIN SODIUM | 250MG | DAWA LIMITED -BABA DOGO RWARAKA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2015 |
| 293 | NDA/MAL/HDP/0693 | DAWA LIMITED | SUPER MEDIC LTD | MOXACIL -250 | AMOXYCILLIN TRIHYDRATE | 250MG | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 294 | NDA/MAL/HDP /0694 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | DT ZINC-20 TABLETS | ZINC SULPHATE | 20MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET CARTON | 01/07/2013 |
| 295 | NDA/MAL/HDP /0696 | BYANSI SERVICES LIMITED | AIVEEN (U) LIMITED | RITONAVIR | RITONAVIR | 100MG | HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2014 |
| 296 | NDA/MAL/HDP /0698 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | WHITFIELD'S OINTMENT | BENZOIC ACID+SALICYLIC CID | 6%W/W + 3%W/W | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE | 01/07/2003 |

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| 297 | NDA/MAL/HDP/0700 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | VAXIRAB N | INACTIVATED RABIES VIRUS(PITMAN MOORE STRAIN) | >2.5 I.U | CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 ML VIAL + 1ML AMPOULE OF WFI(1 DOSE VIAL) | 01/07/2015 |
| 298 | NDA/MAL/HDP/0702 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | SEPTOCIN | STREPTOMYCIN SULPHATE | 1GM | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X1.0 G VIAL,1.0X100.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL | 01/07/2014 |
| 299 | NDA/MAL/HDP/0703 | GOOD DAY PHARMACY LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | DICLODAY GEL | DICLOFENAC DIETHYLAMINE+ LINSEED OIL+ METHYL SALICYLATE +MENTHOL | 11.6MG + 30MG + 100MG + 50MG | KREMOINT PHARMA PVT LTD---B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506 | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 300 | NDA/MAL/HDP/0704 | HETERO LABS LTD UNIT IX | AIVEEN (U) LIMITED | M-FLOX | MOXIFLOXACIN HYDROCHLORIDE | 400MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD-UNIT II & III BADDI THE NALAGARH DIST SOLAN H.P | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X 5.0 TABLET BLISTER | 01/07/2013 |
| 301 | NDA/MAL/HDP/0705 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | ACICLOVIR | ACICLOVIR | 5%W/W | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 01/07/2011 |
| 302 | NDA/MAL/HDP/0706 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | ROVAS 5 | ROSUVASTATIN | 5MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 303 | NDA/MAL/HDP/0710 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | ROVAS 20 | ROSUVASTATIN | 20MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 304 | NDA/MAL/HDP/0712 | GLAXOSMITHKLINE PHARMACEUTICALS KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZENTEL | ALBENDAZOLE | 100MG/5ML | ASPEN BAD OLDESLOE GMBH, INDUSTRIESTRASSE-INDUSTRIESTRASSE 32-36, 23843 BAD OLDESLOE | FRANCE | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X20.0 ML BOTTLE | 01/07/1997 |
| 305 | NDA/MAL/HDP/0713 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | PANTO-DENK 20 | PANTOPRAZOLE SODIUM SESQUIHYDRATE | 20MG | ADVANCE PHARMA GMBH..-WALLENRODER STR.12-14, 13435 BERLIN | GERMANY | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2015 |

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| 306 | NDA/MAL/HDP/0715 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | PANTO-DENK 40 | PANTOPRAZOLE SODIUM SESQUIHYDRATE | 40MG | ADVANCE PHARMA GMBH..-WALLENRODER STR.12-14, 13435 BERLIN | GERMANY | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2015 |
| 307 | NDA/MAL/HDP/0718 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | GLYMET-2 | GLIMEPIRIDE+METFORMIN HYDROCHLORIDE | 2MG + 500MG | LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X10.0 TABLET BLISTER | 01/07/2014 |
| 308 | NDA/MAL/HDP/0719 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | WEPOX 4000 | RECOMBINANT HUMAN ERYTHROPOIETIN | 4000 I.U | WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.4 ML PRE-FILLED SYRINGE | 01/07/2011 |

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| 309 | NDA/MAL/HDP/0720 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | JUSDEE 400 DROPS | COLECALCIFEROL | 400 I.U/ML | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE | 01/07/2013 |
| 310 | NDA/MAL/HDP/0721 | MISSION PHARMA | METRO PHARMACEUTICALS LIMITED | ARH-A | ARTEMETHER | 80MG/ML | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X2.0X3.0X1.0 ML AMPOULE,1.0X1.0X6.0 ML AMPOULE | 01/07/2014 |
| 311 | NDA/MAL/HDP/0722 | FDC LTD | AIVEEN (U) LIMITED | IOTIM 0.5% | TIMOLOL MALEATE | 0.5% W/V | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2014 |

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| 312 | NDA/MAL/HDP/0726 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | T DOL RAPID | TRAMADOL HYDROCHLORIDE | 50MG | TROIKAA PHARMACEUTICALS LTD-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2014 |
| 313 | NDA/MAL/HDP/0727 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | STOMACH FIT SYRUP | BISMUTH AMMONIUM CITRATE+BELLADONA DRY EXTRACT+THYMOL+MENTHOL | 140MG+9MG+0.15MG+0.2/5ML | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X225.0 ML BOTTLE | 01/07/2013 |
| 314 | NDA/MAL/HDP/0728 | IPCA LABORATOIES LTD | MEDVIN PHARMA LIMITED | ARTESUNATE AND AMODIAQUINE 25/67.5 | ARTESUNATE+AMODIAQUINE | 25MG+67.5MG | IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 01/07/2013 |

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| 315 | NDA/MAL/HDP/0731 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | ARTESUNATE AND AMODIAQUINE 50/135 | ARTESUNATE + AMODIAQUINE | 50/135MG | IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 01/07/2013 |
| 316 | NDA/MAL/HDP/0732 | AIVEEN (U) LIMITED | AIVEEN (U) LIMITED | VOLTAMED-100 | DICLOFENAC | 100 MG | MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |
| 317 | NDA/MAL/HDP/0734 | AIVEEN (U) LIMITED | AIVEEN (U) LIMITED | OMMED -20 | OMEPRAZOLE | 20MG | MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/2015 |

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| 318 | NDA/MAL/HDP /0736 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MABRON 50 | TRAMADOL HYDROCHLORIDE | 50MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 319 | NDA/MAL/HDP /0737 | SANOFI AVENTIS | SURGIPHARM (U) LIMITED | TAXOTERE 80MG | DOCETAXEL TRIHYDRATE | 80MG/4ML | SANOFI-AVENTIS DEUTSCHLAND GMBH - INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFURT AM MAIN, GERMANY | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X4.0 ML VIAL | 01/07/2014 |
| 320 | NDA/MAL/HDP /0740 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | COTRIM | CO-TRIMOXAZOLE | 960MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X17.0X6.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2013 |

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| 321 | NDA/MAL/HDP/0742 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | BROT | METFORMIN HYDROCHLORIDE | 500MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 322 | NDA/MAL/HDP/0745 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | TELI 80 | TELMISARTAN | 80MG | B. BRAUN MELSUNGEN - MISTELWEG-1389, TRABAD ROAD, DHOLKA 387 810, DISTRICT AHMEDABAD, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 323 | NDA/MAL/HDP/0746 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | DTS-Z KIT | TABLET-ZINC, SACHET-NACL + KCL + TRISODIUM CITRATE + ANHYDROUS GLUCOSE | TABLET-54.89MG , SACHET 1.3G + 0.75G + 1.45G + 6.75G | COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA | KENYA | ORAL LIQUID ORDINARY UNIT DOSE POWDERS | 1.0X4.0X10.3 G SACHET + 1.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 324 | NDA/MAL/HDP /0748 | BAYER PHARMA | SURGIPHARM (U) LIMITED | XARELTO 15MG | RIVAROXABAN | 15MG | BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X14.0 TABLET BLISTER | 01/07/2013 |
| 325 | NDA/MAL/HDP /0750 | BAYER PHARMA | SURGIPHARM (U) LIMITED | XARELTO 20MG | RIVAROXABAN | 20MG | BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X14.0 TABLET BLISTER | 01/07/2013 |
| 326 | NDA/MAL/HDP /0754 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | TORAS DENK 10 | TORASEMIDE | 10MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 327 | NDA/MAL/HDP/0759 | MICRO LABS LTD | PHARMA VILLE LIMITED | COTRIMOXAZOLE | COTRIMOXAZOLE | 960MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 328 | NDA/MAL/HDP/0760 | BEIJING HOLLEY-COTEC PHARMACEUTICALS CO.,LTD | SUPER PHARMACEUTICALS LIMITED | CEFAX | CEFTRIAXONE | 1G | REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100 REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X1.0 G VIAL | 01/07/2013 |
| 329 | NDA/MAL/HDP/0764 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | CORVADIL 5 | AMLODIPINE | 5MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 330 | NDA/MAL/HDP/0768 | FDC LTD | AIVEEN (U) LIMITED | PYRIMON EYE DROP | DEXAMETHASONE/CHLORAMPHENICOL | 1%W/V + 0.1%W/V | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1999 |
| 331 | NDA/MAL/HDP/0770 | BEIJING HOLLEY COTEC PHARMA CHINA | SUPER PHARMACEUTICALS LIMITED | AMPIL-500 | AMPICILLIN | 500MG | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X500.0 MG VIAL | 01/07/2013 |
| 332 | NDA/MAL/HDP/0772 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | LIGABA - 150 | PREGABALIN | 150MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2014 |

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| 333 | NDA/MAL/HDP/0775 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | LIGABA - 75 | PREGABALIN | 75MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 334 | NDA/MAL/HDP/0776 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | FREMOL TABLETS | PARACETAMOL TABLETS | 500MG | FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1999 |
| 335 | NDA/MAL/HDP/0781 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | TRICOLD | PARACETAMOL/PHENYLEPHRINE HYDROCHLORIDE/CAFFEINE ANHYDROUS/CHLORPHENIRAMINE | 500MG/10MG/30MG/2MG | TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4.0 TABLET BLISTER | 01/07/2013 |

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| 336 | NDA/MAL/HDP /0783 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | CYPOLIVE | CYPROHEPTADINE HYDROCHLORIDE | 4 MG | TRIVENI FORMULATIONS LIMITED--PLOT NO: 52,53,54, 62,63 & 64 ALEAP INDUSTRIAL ESTATE SURAMPALI VILLAGE, GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X50.0 TABLET BLISTER | 01/07/2013 |
| 337 | NDA/MAL/HDP /0784 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | HEMOSAN | FERROUS FUMERATE | 300MG | COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 338 | NDA/MAL/HDP /0786 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | DERMA 1 | GRISEOFULVIN | 500MG | TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 339 | NDA/MAL/HDP /0796 | HETERO LABS LTD | AIVEEN (U) LIMITED | AMLOSIN 5 | AMLODIPINE BESILATE | 5MG | HETERO DRUGS LTD. - VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, TEHSIL NALAGARH, DIST. SOLAN, HIMACHAL PRADESH PIN: 173 205 HETERO LABS LTD. UNIT (V) .-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 340 | NDA/MAL/HDP /0798 | HETERO LABS LTD | AIVEEN (U) LIMITED | AMLOSIN 10 | AMLODIPINE BESILATE | 10MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 341 | NDA/MAL/HDP /0802 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | EXFORGE HCT 5MG/ 160MG/12.5MG | AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE | 5MG+ 160MG+ 12.5MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 01/07/2015 |

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| 342 | NDA/MAL/HDP/0808 | PIRAMAL HEALTHCARE LTD | TATA UGANDA LIMITED | ISOFLURANE | ISOFLURANE | 250ML | PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH | INDIA | OTHER SYSTEMIC LIQUID INHALATIONS | 1.0X250.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2005 |
| 343 | NDA/MAL/HDP/0811 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | DOLOWIN -SR | ACECLOFENAC | 200MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 344 | NDA/MAL/HDP/0816 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | GLIMEPIRIDE DENK 2 | GLIMEPIRIDE | 2MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 345 | NDA/MAL/HDP/0821 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | GLIMEPIRIDE DENK 3 | GLIMEPIRIDE | 3MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 346 | NDA/MAL/HDP/0822 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | CLOXCIN-500 | CLOXACILLIN SODIUM | 500MG | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X0.5 G VIAL,1.0X100.0X0.5 G VIAL,1.0X10.0X0.5 G VIAL | 01/07/2014 |
| 347 | NDA/MAL/HDP/0824 | I CARE PHARMA LIMITED | VITACARE LTD | CLOXACILLIN | CLOXACILLIN | 250MG | MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2013 |

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| 348 | NDA/MAL/HDP/0826 | I CARE PHARMA LIMITED | VITACARE LTD | AMOXYCILLIN | AMOXYCILLIN | 250MG | MEDICO REMEDIES PVT LTD,.-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2013 |
| 349 | NDA/MAL/HDP/0830 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | EUTHYROX 25 MCG | LEVOTHYROXINE SODIUM | 25 MCG | MERCK KGAA - - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X30.0 TABLET BLISTER,1.0X4.0X25.0 TABLET BLISTER | 01/07/2015 |
| 350 | NDA/MAL/HDP/0831 | I CARE PHARMA LIMITED | VITACARE LTD | AMPICILLIN CAPSULES | AMPICILLIN | 250MG | MEDICO REMEDIES PVT LTD,.-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2013 |

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| 351 | NDA/MAL/HDP/0832 | MERCK | UNITED HEALTHCARE DISTRIBUTORS LTD | EUTHYROX 100MCG | LEVOTHYROXINE | 100MCG | MERCK KGAA - - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30.0 TABLET BLISTER | 01/07/2015 |
| 352 | NDA/MAL/HDP/0834 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | VOMI-6 | DOXYLAMINE SUCCINATE & PYRIDOXINE HYDROCHLORIDE | 10MG + 10MG | LINCOLN PHARMACEUTICALS LIMITED.-TRIMUL ESTATE NEAR KHATRAJ CHOKADI KHATRAJ 382721 GHANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 353 | NDA/MAL/HDP/0835 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOBIS | BISACODYL | 5MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2013 |

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| 354 | NDA/MAL/HDP/0836 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | CALBONE-500 | CALCIUM CARBONATE + COLECALCIFEROL | 1250MG + 250 I.U | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2012 |
| 355 | NDA/MAL/HDP/0841 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ETHOMID | ETHIONAMIDE | 250MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2013 |
| 356 | NDA/MAL/HDP/0842 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | SAC | SECNIDAZOLE | 1000MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X2.0 TABLET BLISTER | 01/07/2013 |

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| 357 | NDA/MAL/HDP/0843 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | COXERIN | CYCLOSERINE | 250MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/2013 |
| 358 | NDA/MAL/HDP/0845 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | OLEVO-500 | LEVOFLOXACIN | 500 MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0X10.0 TABLET BLISTER,1.0X5.0X1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 359 | NDA/MAL/HDP/0846 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MOXIMAC | MOXIFLOXACIN | 400MG | MACLEODS PHARMACEUTICALS LTD-- PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0 TABLET BLISTER | 01/07/2014 |

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| 360 | NDA/MAL/HDP/0848 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MACROZIDE 500 | PYRAZINAMIDE | 500MG | MACLEODS PHARMACEUTICALS LTD---PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER | 01/07/2014 |
| 361 | NDA/MAL/HDP/0850 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | LCT KIT | LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE | 30MG + 250MG + 500MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS) | 01/07/2012 |
| 362 | NDA/MAL/HDP/0853 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | BRUSTAN GEL | IBUPROFEN + LEVOMENTHOL | 5% W/W+ 3%W/W | SUN PHARMACEUTICAL IND. LTD-PLOT NO. B-2, MADKAI INDUSTRIAL ESTATE, PONDA-GOA, INDIA-403404 | INDIA | TOPICAL EXTERNAL LOTIONS | 1.0X50.0 G CONTAINER | 01/07/2012 |

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| 363 | NDA/MAL/HDP/0855 | HETERO LABS LTD | AIVEEN (U) LIMITED | LAZINE | LEVOCETIRIZINE DIHYDROCHLORIDE | 5MG | HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 364 | NDA/MAL/HDP/0857 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDID-V6 VAGINAL TABLETS | CLOTRIMAZOLE | 100MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | VAGINAL TABLETS | 1.0X6.0 PESSARY STRIP | 01/07/2000 |
| 365 | NDA/MAL/HDP/0858 | ASTRA ZENECA | MACNAUGHTON LIMITED | PLENDIL | FELODIPINE | 5MG | ASTRAZENECA SWEDEN OPERATIONS-ASTRAZENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2001 |

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| 366 | NDA/MAL/HDP/0864 | HETERO LABS LTD UNIT IX | AIVEEN (U) LIMITED | PANTIN-40 | PANTOPRAZOLE SODIUM | 40 MG | HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 ?OLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOBNAGAR ?DISTRICT). PIN 509301 | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 367 | NDA/MAL/HDP/0868 | SAKAR HEALTH CARE PVT .LTD | ROYAL PHARMA 2011 LIMITED | VARMIKA-500 | AMIKACIN | 500MG | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X2.0X6.0X2.0 ML VIAL | 01/07/2013 |
| 368 | NDA/MAL/HDP/0869 | SAKAR HEALTH CARE PVT .LTD | ROYAL PHARMA 2011 LIMITED | LARTRM | ARTEMETHER | 80MG/ML | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X6.0X1.0 ML AMPOULE | 01/07/2013 |

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| 369 | NDA/MAL/HDP/0870 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TROY-K | PHYTOMENADIONE | 10MG/ML | TROIKAA PHARMACEUTICALS LIMITED-THOL, DIST. MEHSANA-382728, GUJARAT,INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2010 |
| 370 | NDA/MAL/HDP/0873 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | OXYTOCIN INJECTION | OXYTOCIN | 10I.U/ML | SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2009 |
| 371 | NDA/MAL/HDP/0874 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | LEBASMA-4 | SALBUTAMOL | 4MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2014 |

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| 372 | NDA/MAL/HDP/0877 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | ANTAGIT DS GEL MINT FLAVOUR | DRIED ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE | 400MG + 400MG + 50MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X170.0 ML BOTTLE | 01/07/2007 |
| 373 | NDA/MAL/HDP/0879 | COSMOS LTD. | ASTRA PHARMA (U) LIMITED | TRIBEES FORTE FILM COATED TABLETS | THIAMINE + PYRIDOXINE + CYANOCOBALAMIN | 200MG + 50MG +1000MCG | COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2012 |
| 374 | NDA/MAL/HDP/0882 | MERCK | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOVANCE 500MG/2.5MG | METFORMIN + GLIBENCLAMIDE | 500MG + 2.5MG | MERCK SANTE S.A.S-CENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER | 01/07/2012 |

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| 375 | NDA/MAL/HDP/0883 | MERCK | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOVANCE 500MG/5MG | METFORMIN + GLIBENCLAMIDE | 500MG + 5MG | MERCK SANTE S.A.S-CENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER | 01/07/2012 |
| 376 | NDA/MAL/HDP/0889 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | DNS | SODIUM CHLORIDE + GLUCOSE | 0.9%W/V + 5% W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/2012 |
| 377 | NDA/MAL/HDP/0894 | HETERO LABS LTD | AIVEEN (U) LIMITED | GIAGRA 100 | SILDENAFIL CITRATE | 100MG | HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER | 01/07/2014 |

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| 378 | NDA/MAL/HDP/0895 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | HYORTH | SODIUM HYALURONATE | 10MG/1ML | VIRCHOW BIOTECH PVT, LTD-SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X2.0 ML PRE-FILLED SYRINGE | 01/07/2015 |
| 379 | NDA/MAL/HDP/0897 | VIRCHOW HEALTHCARE PVT LTD | LEGIT MEDEQ 2007 LIMITED | DEBRIDACE | PAPAIN + UREA | 521700UNITS+100 MG/G | VIRCHOW BIOTECH PVT, -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2015 |
| 380 | NDA/MAL/HDP/0899 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | VIRIAXONE | CEFTRIAXONE | 1G | INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 10 ML VIAL WFI | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 381 | NDA/MAL/HDP/0902 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPINE SR | NIFEDIPINE | 20MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 382 | NDA/MAL/HDP/0905 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | NECPOD | CEFPODOXIME PROXETIL | 200MG | NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2013 |
| 383 | NDA/MAL/HDP/0906 | VIRCHOW HEALTHCARE PVT LTD | LEGIT MEDEQ 2007 LIMITED | IONSIL | SILVER NITRATE | 0.2%W/W | VIRCHOW BIOTECH PVT, - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 384 | NDA/MAL/HDP/0907 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | CEFUAXIT | CEFUROXIME AXETIL | 250MG | NECTAR LIFE SCIENCES LTD--UNIT VI BHATOLIKALAN DIST SOLAN H.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2013 |
| 385 | NDA/MAL/HDP/0909 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | FIXINECT | CEFIXIME | 100MG | NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2013 |
| 386 | NDA/MAL/HDP/0911 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | HEALACE | RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR -B | 100MCG/G | VIRCHOW BIOTECH PVT, LTD-SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 387 | NDA/MAL/HDP/0914 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | OSTEOTIDE | TERIPARATIDE [RECOMBINANT HUMAN PARATHYROID HORMONE (1-34)] INJECTION | 250MCG/ML | VIRCHOW BIOTECH PVT LTD - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH | INDIA | PARENTERAL ORDINARY VIALS | 1.0X3.0 ML VIAL,1.0X3.0 ML PREFILLED PEN | 01/07/2015 |
| 388 | NDA/MAL/HDP/0920 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BUPITROY HEAVY | BUPIVACAINE HYDROCHLORIDE | 5MG/ML | TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X5.0X4.0 ML VIAL | 01/07/2012 |
| 389 | NDA/MAL/HDP/0926 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | BACTOCLAV-375 | AMOXICILLIN +CLAVULANATE POTASSIUM | 250MG + 125MG | MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET STRIP,1.0X2.0X10.0 TABLET STRIP | 01/07/2004 |

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| 390 | NDA/MAL/HDP/0928 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | INSTACLOP 75 | CLOPIDOGREL | 75MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 391 | NDA/MAL/HDP/0929 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | DUOQUIN | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 40MG +320MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X1.0X9.0 TABLET BLISTER,10.0X1.0X8.0 TABLET BLISTER | 01/07/2012 |
| 392 | NDA/MAL/HDP/0934 | CADILA HEALTH CARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ODIMONT 4 | MONTELUKAST | 4MG | CADILA HEALTHCARE LTD SARKHEJ-BAVLA NH NO.8A MORAIYA TAL SANAND DISTRICT AHMEDABAD 382210 | INDIA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |

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| 393 | NDA/MAL/HDP /0941 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ZAHA | AZITHROMYCIN | 200MG/5ML | AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X15.0 ML BOTTLE | 01/07/2013 |
| 394 | NDA/MAL/HDP /0948 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | LORHISTINA SYRUP 5MG/5ML | LORATADINE | 5MG/5ML | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X60.0 ML BOTTLE | 01/07/2013 |
| 395 | NDA/MAL/HDP /0952 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | EFECTAL | CEFTRIAXONE | 1G | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 396 | NDA/MAL/HDP/0953 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | CIZCAN | CISPLATIN | 10MG/10ML | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 01/07/2013 |
| 397 | NDA/MAL/HDP/0954 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | ANAWIN | BUPIVACAINE | 50MG/20ML | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL RETARD OTHER VIALS | 1.0X20.0 ML VIAL | 01/07/2013 |
| 398 | NDA/MAL/HDP/0957 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | LYRED SYRUP | VITAMINE A + VITAMINE E ACETATE + ASCORBIC ACID + SELENIUM + ZINC | 2500 IU + 10 IU + 50MG + 35MCG + 3MG | TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2012 |

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| 399 | NDA/MAL/HDP/0959 | AJANTA PHARMA LTD 31-0 | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN DISPERSIBLE 20/120 | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X12.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X30.0X 6.0 TABLET BLISTER,1.0X30.0X 12.0 TABLET BLISTER | 01/07/2013 |
| 400 | NDA/MAL/HDP/0969 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ASOMEX-2.5 | AMLODIPINE BESILATE | 2.5MG | EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2005 |
| 401 | NDA/MAL/HDP/0981 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | CLOFENAC SR TABLETS | DICLOFENAC SODIUM | 100MG | HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA | MALAYSIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 402 | NDA/MAL/HDP/0988 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | CADITOR 20 | ATORVASTATIN | 20MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 403 | NDA/MAL/HDP/0990 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FUSIDERM CREAM | FUSIDIC ACID | 2%W/W | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |
| 404 | NDA/MAL/HDP/0995 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | FLUCOMOL | PARACETAMOL + PHENYLEPHRINE HCL + DEXTROMETHORPHAN HBR + CHLORPHENIRAMINE MALEATE | 250MG + 5MG + 10MG + 2MG | LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2014 |

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| 405 | NDA/MAL/HDP/0999 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | THIOEVA | THIOTIC ACID | 600MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2014 |
| 406 | NDA/MAL/HDP/1000 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TROYCURIUM | ATRACURIUM | 10MG/ML | TROIKAA PHARMACEUTICALS LIMITED-THOL, DIST. MEHSANA-382728, GUJARAT,INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X3.0 ML AMPOULE,1.0X5.0 X2.5 ML AMPOULE | 01/07/2012 |
| 407 | NDA/MAL/HDP/1001 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | THIOEVA | THIOTIC ACID | 300MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 408 | NDA/MAL/HDP /10030 | SAKAR HEALTHCARE LIMITED - | TATA UGANDA LIMITED | NISTAN | NYSTATIN | 100,000IU | SAKAR HEALTHCARE PVT LTD- BLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 17/05/2022 |
| 409 | NDA/MAL/HDP /10031 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROFOLICK | FOLIC ACID | 5 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 410 | NDA/MAL/HDP /10032 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ACICRO-200 | ACICLOVIR | 200 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 411 | NDA/MAL/HDP/10033 | MEDOPHARM | PLANET PHARMACEUTICALS UGANDA LTD | EMCAR | CARBAMAZEPINE | 200 MG | MEDOPHARM-NO. 34B, INDUSTRIAL AREA, MALUR-563160, KARNATAKA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X10.0 TABLET BLISTER,1.0X100.0X1.0X10.0 TABLET BLISTER | 06/07/2022 |
| 412 | NDA/MAL/HDP/10034 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | M-FLOX | MOXIFLOXACIN HYDROCHLORIDE | 0.5 %W/V | AUROLAB LIMITED-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 06/07/2022 |
| 413 | NDA/MAL/HDP/10035 | MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES | SWASTIK PHARMACEUTICAL LTD | OXYTOCIN 10 IU | OXYTOCIN ACETATE | 10 IU/ AMPOULE | MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES-MINA STREET, 03RD INDUSTRIAL ZONE A2-10TH OF RAMADHAN CITY EGYPT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X10.0 I.U AMPOULE | 06/07/2022 |

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| 414 | NDA/MAL/HDP/10036 | MEDOPHARM | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOL | PARACETAMOL | 500 MG | MEDOPHARM-NO. 34B, INDUSTRIAL AREA, MALUR-563160, KARNATAKA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X10.0 TABLET BLISTER,1.0X100.0X1.0X10.0 TABLET BLISTER | 06/07/2022 |
| 415 | NDA/MAL/HDP/10037 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BORINI-K | LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN | 30 MG + 500 MG + 250 MG | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0X1.0X6.0 TABLET STRIP | 06/07/2022 |
| 416 | NDA/MAL/HDP/10038 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | CLEDOMOX 312.5 MG/5 ML | AMOXILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 312.5 MG/5 ML | MEDOPHARM PVT LIMITED-NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY-603202 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML CONTAINER | 06/07/2022 |

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| 417 | NDA/MAL/HDP /10039 | LEGIT MEDEQ 2007 LIMITED | LEGIT MEDEQ 2007 - SMC LTD | ZENMIC | TRANEXAMIC ACID | 500MG/5 ML | ZEN PHARMA PVT LTD-75/1, GIDC. VAPI-396 195 GUJARAT, | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X5.0 ML AMPOULE | 06/07/2022 |
| 418 | NDA/MAL/HDP /10040 | NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | CARBAMAZEPINE TABLETS USP 200 MG | CARBAMAZEPINE | 200 MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 419 | NDA/MAL/HDP /10041 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | PUMPINOX | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 20MG | PHARMA INTERNATIONAL CO. LTD -AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN | JORDAN | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X1.0X14.0 TABLET CONTAINER | 06/07/2022 |

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| 420 | NDA/MAL/HDP/10042 | GLOBELA PHARMA PVT. LTD. | SHREEJI CARE LIMITED | BACIPRO | CIPROFLOXACIN HYDROCHLORIDE | 500 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 421 | NDA/MAL/HDP/10043 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROYO-ADRENALINE | ADRENALINE ACID TARTRATE | 1 MG/ML | SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X1.0 ML AMPOULE | 06/07/2022 |
| 422 | NDA/MAL/HDP/10044 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | TERBI RO 250 | TERBINAFINEHYDROCHLORIDE | 250 MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 423 | NDA/MAL/HDP /10045 | PHARMACTIV FZCO | JEET PHARMACEUTICALS LIMITED | SURGITEC | CEFOTAXIME SODIUM | 1 G/VIAL | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 1*5ML, WFI IN A CLEAR GLASS AMPOULE | 06/07/2022 |
| 424 | NDA/MAL/HDP /10046 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ARTEMETHER INJECTION 80 MG/ML | ARTEMETHER | 80 MG/ ML | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X6.0X1.0 ML AMPOULE | 06/07/2022 |
| 425 | NDA/MAL/HDP /10047 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | ARCELIA CHLORAMPHENICOL SODIUM SUCCINATE FOR INJECTION USP 1000 MG | CHLORAMPHENICOL SODIUM SUCCINATE | 1000 MG/VIAL | SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1000.0 MG VIAL | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 426 | NDA/MAL/HDP /10048 | JOSHPA AFRICA LTD | AAFIYA (A) LIMITED | AAFISUNATE 60 MG | ARTESUNATE | 60 MG/VIAL | SANJAR PHARMACEUTICALS LIMITED-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*1ML, CLEAR GLASS AMPOULE OF 5% W/V SODIUM BICARBONATE + 1*5ML CLEAR GLASS AMPOULE OF 0.9% W/V SODIUM CHLORIDE | 06/07/2022 |
| 427 | NDA/MAL/HDP /10049 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ERYTHROMYCIN ESTOLATE ORAL SUSPENSION USP 125 MG/5ML | ERYTHROMYCIN ESTOLATE | 125 MG/5ML | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 06/07/2022 |
| 428 | NDA/MAL/HDP /10050 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | ROTAVIRUS VACCINE, LIVE ATTENUATED (ORAL) ROTASIIL LIQUID | LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT [G1, G2, G3, G4 AND G9] | ≥105.6 FFU / SEROTYPE PER DOSE (2 ML) | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X2.0 ML VIAL,1.0X50.0X2.0 ML VIAL | 06/07/2022 |

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| 429 | NDA/MAL/HDP/10051 | UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD) | PLANET PHARMACEUTICALS UGANDA LTD | PENIMAX 100 | SILDENAFIL CITRATE | 100MG | UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 06/07/2022 |
| 430 | NDA/MAL/HDP/10052 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HI DEE 5000 IU | CHOLECALCIFEROL | 5,000IU | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X30.0 CAPSULE CONTAINER | 06/07/2022 |
| 431 | NDA/MAL/HDP/10053 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | NADIMIX CREAM | NADIFLOXACIN + MICONAZOLE NITRATE + MOMETASONE FUROATE | 10 MG + 20 MG + 01 MG | WOCKHARDT LIMITED-PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X7.5 G TUBE | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 432 | NDA/MAL/HDP /10054 | LEGIT MEDEQ 2007 LIMITED | LEGIT MEDEQ 2007 LIMITED | HEMCROZ | IRON SUCROSE COMPLEX | 20 MG/ML | ZEN PHARMA PVT LTD-75/1, GIDC. VAPI-396 195 GUJARAT, | INDIA | PARENTERAL ORDINARY I V AMPOULES | 1.0X1.0X5.0X5.0 ML AMPOULE | 06/07/2022 |
| 433 | NDA/MAL/HDP /10055 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | FIMABUTE-400 | CEFIXIME TRIHYDRATE | 400MG | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/07/2022 |
| 434 | NDA/MAL/HDP /10056 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | AVARIN | SIMETHICONE+ ALVERINE CITRATE | 300 MG + 60 MG | MEGA LIFESCIENCES PUBLIC CO. LTD-PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X5.0X1.0X10.0 CAPSULE BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 435 | NDA/MAL/HDP /10057 | ZIM LABORATORIES LTD | REDDYS PHARMA LIMITED | ZIMLOX 500 | LEVOFLOXACIN HEMIHYDRATE | 500 MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 06/07/2022 |
| 436 | NDA/MAL/HDP /10058 | NEOMI PHARMACEUTICALS PVT LTD - | REDDYS PHARMA LIMITED | REDMENTIN 625 | AMOXICILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | CHIROS PHARMA-VILLAGE LOHARON, P.O. GHATTI, DISTT. - SOLAN, HIMACHAL PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X2.0X7.0 TABLET BLISTER | 06/07/2022 |
| 437 | NDA/MAL/HDP /10059 | SAGA LIFESCIENCES LTD | ABACUS PHARMA (AFRICA) LIMITED | FULCOVER | ITRACONAZOLE | 100 MG | SAGA LABORATORIES .-198/2 & 198/3, CHACHRAWADI, VASNA NO. CLARIS LIFE SCIENCE, TA SANAND, DIST. DIST: AHMEDABAD | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X4.0 CAPSULE STRIP | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 438 | NDA/MAL/HDP/1006 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TRIPRIDE-2 | GLIMEPIRIDE + PIOGLITAZONE+ METFORMIN | 2MG+15MG+500MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 439 | NDA/MAL/HDP/10060 | EMCURE PHARMACEUTICALS LTD - | HARLEYS UGANDA LIMITED | VIROPIL | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50 MG + 300 MG + 300 MG | EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 06/07/2022 |
| 440 | NDA/MAL/HDP/10061 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | INSTACLOP PLUS | CLOPIDOGREL + ASPIRIN | 75 MG + 75 MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 441 | NDA/MAL/HDP/10062 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRUCLOX-500 | CLOXACILLIN SODIUM | 500MG | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 06/07/2022 |
| 442 | NDA/MAL/HDP/10063 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | CARDIONE 25 | SPIRONOLACTONE | 25MG | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 443 | NDA/MAL/HDP/10064 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROSUVAT 20 | ROSUVASTATIN CALCIUM | 20MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 444 | NDA/MAL/HDP /10065 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 MG/ 300 MG/ 300 MG | EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 600 MG + 300 MG + 300 MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X90.0 TABLET BOTTLE,1.0X30.0 TABLET BOTTLE | 06/07/2022 |
| 445 | NDA/MAL/HDP /10066 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FEMPRO | LETROZOLE | 2.5MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 446 | NDA/MAL/HDP /10067 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | TRITINI | TINIDAZOLE | 500MG | TRIVENI FORMULATIONS LTD-PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X25.0X4.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 447 | NDA/MAL/HDP /10068 | LEGIT MEDEQ 2007 LIMITED | LEGIT MEDEQ 2007 - SMC LTD | Z- ENOX | ENOXAPARIN SODIUM | 10 MG/0.1 ML | ZEN PHARMA PVT LTD-75/1, GIDC. VAPI-396 195 GUJARAT, | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.4 ML PRE-FILLED SYRINGE,1.0X0.6 ML PRE- FILLED SYRINGE | 06/07/2022 |
| 448 | NDA/MAL/HDP /10069 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | OPELAN ODT 5 | OLANZAPINE | 5 MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 449 | NDA/MAL/HDP /1007 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | ZINCOS DISPERSIBLE TABLETS 20MG | ZINC SULPHATE | 20MG | COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA | KENYA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 450 | NDA/MAL/HDP/10070 | ZIM LABORATORIES LTD | ESCORTS PHARMACEUTICALS LTD - WILSON ROAD | TELCARD H | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 451 | NDA/MAL/HDP/10071 | ARTURA PHARMACEUTICALS PVT LTD | SWASTIK PHARMACEUTICAL LTD | FENAPAR | PARACETAMOL + ACECLOFENAC | 500 MG + 100 MG | ARTURA PHARMACEUTICALS PRIVATE LIMITED-NO. 1505, PORTIA ROAD SRI CITY SEZ, SATYAVEDU MANDAL, CHITTOOR DIST-517 588, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 452 | NDA/MAL/HDP/10072 | EMCURE PHARMACEUTICALS LTD - | HARLEYS UGANDA LIMITED | INBEC | ABACAVIR SULPHATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE | 600 MG + 50 MG + 300 MG | EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 453 | NDA/MAL/HDP /10073 | NATIONAL PHARMACEUTICAL INDUSTRIES CO. | HARLEYS UGANDA LIMITED | OMACILLIN 500 | AMOXICILLIN TRIHYDRATE | 500 MG | NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMAN-P.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN | OMAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 06/07/2022 |
| 454 | NDA/MAL/HDP /10074 | TAURUS CHEMICALS (P) LTD. | HEALTH CARE LTD | MAGACID SUSPENSION | ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE | (215 MG + 80 MG + 25 MG)/5ML | AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X120.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE | 06/07/2022 |
| 455 | NDA/MAL/HDP /10075 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | TELPER 80 | TELMISARTAN | 80 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 456 | NDA/MAL/HDP /10076 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RO-CID INJ | OMEPRAZOLE SODIUM | 40MG | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 MG VIAL + 10 ML WATER FOR INJECTION AMPOULE | 06/07/2022 |
| 457 | NDA/MAL/HDP /10077 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | STREPTOMYCIN | STREPTOMYCIN SULPHATE | 1G | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X1.0 G VIAL | 08/06/2022 |
| 458 | NDA/MAL/HDP /10080 | COMED CHEMICALS LTD. | LEGIT MEDEQ 2007 - SMC LTD | LYSER-D | DICLOFENAC SODIUM + SERRATIOPEPTIDASE | 50 MG + 10 MG | COMED CHEMICALS LTD (UNIT-III)-VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 06/07/2022 |

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| 459 | NDA/MAL/HDP/10081 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICAL LTD | IO-NEPA | NEPAFENAC | 0.1%W/V | INDIANA OPHTHALMICS-135, 136, 137, GIDC ESTATE, WADHWAN-363035 | INDIA | OPHTHALMIC SUSPENSIONS | 1.0X1.0X5.0 ML BOTTLE | 06/07/2022 |
| 460 | NDA/MAL/HDP/10082 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICAL LTD | NECIDEX EYE DROPS | NEOMYCIN SULPHATE + DEXAMETHASONE SODIUM PHOSPHATE | 0.5%W/V + 0.1%W/V | INDIANA OPHTHALMICS-135, 136, 137, GIDC ESTATE, WADHWAN-363035 | INDIA | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML BOTTLE | 06/07/2022 |
| 461 | NDA/MAL/HDP/10083 | THE SEARLE COMPANY LIMITED | HEALTHCARE LTD. | MORCET | ESCITALOPRAM OXALATE | 20 MG | SEARLE PAKISTAN LTD..-F-319, S.I.T.E., OPP. KESC POWER STATION, KARACHI | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 462 | NDA/MAL/HDP /10084 | M/S HETERO LABS LIMITED | AIVEEN (U) LIMITED | SEDAFOL | PROPOFOL | 10 MG/ ML | ASPIRO PHARMA LIMITED-SY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X200.0 MG VIAL | 06/07/2022 |
| 463 | NDA/MAL/HDP /10085 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICAL LTD | DORZY-T | DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE | 2.0 % W/V + 0.5 % W/V | INDIANA OPHTHALMICS-135, 136, 137, GIDC ESTATE, WADHWAN-363035 | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X5.0 ML BOTTLE | 06/07/2022 |
| 464 | NDA/MAL/HDP /10086 | NEOMI PHARMACEUTICALS PVT LTD - | ROYAL PHARMA 2011 LIMITED | NEOMICLAV-DS | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | (200 MG + 28.5 MG)/5 ML | CHIROS PHARMA-VILLAGE LOHARON, P.O. GHATTI, DISTT. - SOLAN, HIMACHAL PRADESH - INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X60.0 ML BOTTLE | 06/07/2022 |

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| 465 | NDA/MAL/HDP /10087 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | AZUNATE | ARTESUNATE | 60 MG/VIAL | MACLEODS PHARMACEUTICALS LTD. ..- UNIT I/UNIT II, PLOT 25-27, SR. NO. 366, PREMIER IND. ESTATE, KACHIGAM, DAMAN (U.T) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X60.0 MG VIAL + 1* 1ML CLEAR GLASS AMPOULE OF 5%W/V SODIUM BICARBONATE + 1*5ML CLEAR GLASS AMPOULE OF 0.9%W/V SODIUM CHLORIDE | 06/07/2022 |
| 466 | NDA/MAL/HDP /10089 | NABIQASIM INDUSTRIES (PVT) LIMITED | HEALTHCARE LTD. | CEFEXOL DS SUSPENSION | CEFIXIME TRIHYDRATE | 200 MG/5 ML | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML BOTTLE | 06/07/2022 |
| 467 | NDA/MAL/HDP /1009 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BUPITROY 0.5% | BUPIVACAINE | 5MG/ML | TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 468 | NDA/MAL/HDP/10090 | NABIQASIM INDUSTRIES (PVT) LIMITED | HEALTHCARE LTD. | CEFEXOL SUSPENSION | CEFIXIME TRIHYDRATE | 100 MG/5 ML | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML BOTTLE | 06/07/2022 |
| 469 | NDA/MAL/HDP/10091 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | PG-150 | PREGABALIN | 150 MG | ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 06/07/2022 |
| 470 | NDA/MAL/HDP/10092 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROTHISTRONE 5 | NORETHISTERONE | 5 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 471 | NDA/MAL/HDP /10093 | CADILA HEALTHCARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MUCOSIL BR | SALBUTAMOL + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL | 2.0 MG + 4.0 MG + 100 MG + 1.0 MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 06/07/2022 |
| 472 | NDA/MAL/HDP /10094 | TAKEDA PHARMA A/S | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ADCETRIS 50 MG | BRENTUXIMAB VEDOTIN | 50 MG/VIAL | BSP PHARMACEUTICALS S.P.A.-VIA APPIA KM 65, 561 LATINA SCALO (LT), 04013 | AUSTRIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X50.0 MG VIAL | 06/07/2022 |
| 473 | NDA/MAL/HDP /10095 | COMED CHEMICALS LTD. | LEGIT MEDEQ 2007 LIMITED | RAPCO -20 | RABEPRAZOLE SODIUM | 20 MG | COMED CHEMICALS LTD (UNIT-III)-VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 474 | NDA/MAL/HDP /10096 | COMED CHEMICALS LTD. | LEGIT MEDEQ 2007 LIMITED | ZACY- SR | ACECLOFENAC | 200 MG | COMED CHEMICALS LTD (UNIT-III)-VILL: DASSOMATRA BADDI, NALAGARGH ROAD DISTRICT: SOLAN, PIN.173205 HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 475 | NDA/MAL/HDP /10097 | ALKEM LABORATORIES LTD. - | ABACUS PHARMA (AFRICA) LIMITED | NULOC 20 | ESOMEPRAZOLE MAGNESIUM | 20 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 476 | NDA/MAL/HDP /10098 | ALKEM LABORATORIES LTD. - | ABACUS PHARMA (AFRICA) LIMITED | NULOC 40 | ESOMEPRAZOLE MANESIUM | 40 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 477 | NDA/MAL/HDP /10099 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | GLYFERON 1000 | METFORMIN HYDROCHLORIDE | 1000 MG | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 478 | NDA/MAL/HDP /10100 | HETERO LABS LTD | AIVEEN (U) LIMITED | PANTIN | PANTOPRAZOLE SODIUM SESQUIHYDRATE | 40 MG/VIAL | ASPIRO PHARMA LIMITED-SY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X40.0 MG VIAL | 06/07/2022 |
| 479 | NDA/MAL/HDP /10101 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | VILDARIL 50 | VILDAGLIPTIN | 50 MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 480 | NDA/MAL/HDP /10102 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | VILDARIL 100 | VILDAGLIPTIN | 100 MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 481 | NDA/MAL/HDP /10103 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | COLDPIL | PARACETAMOL +PHENYLEPHRINE HYDROCHLORIDE + CHLORPEHNAMIN E MALEATE | 650 MG + 5 MG + 2 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 482 | NDA/MAL/HDP /10104 | IND-SWIFT LIMITED | PLANET PHARMACEUTICA LS UGANDA LTD | TELSWIFT 40 | TELMISARTAN | 40 MG | IND-SWIFT LIMITED /-VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB | INDIA | TABLETS (COATED | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 483 | NDA/MAL/HDP /10105 | IND-SWIFT LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | TELSWIFT 80 | TELMISARTAN | 80 MG | IND-SWIFT LIMITED /-VILL-JAWAHARPUR, OFF NH21, DERABASSI DIST: MOHALI, PUNJAB | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 06/07/2022 |
| 484 | NDA/MAL/HDP /10106 | VEERAM HEALTHCARE (U) LIMITED | VEERAM HEALTHCARE (U) LIMITED | SERAFEN | DICLOFENAC POTASSIUM + SERRATIOPEPTIDASE | 50 MG + 10 MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 06/07/2022 |
| 485 | NDA/MAL/HDP /10107 | VEERAM HEALTHCARE (U) LIMITED | VEERAM HEALTHCARE (U) LIMITED | EXPECT | AMBROXOL HYDROCHLORIDE + TERBUTALINE SULPHATE + GUAIFENESIN | (15 MG + 1.25 MG + 50 MG)/ 5 ML | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X30.0 ML BOTTLE | 06/07/2022 |

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| 486 | NDA/MAL/HDP /10108 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PIRO 20 | PIROXICAM | 20 MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 06/07/2022 |
| 487 | NDA/MAL/HDP /10109 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RO MIFEN 500 | MEFENAMIC ACID | 500 MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 488 | NDA/MAL/HDP /1011 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | DABORAL SYRUP | AMINOSIDINE | 125MG/5ML | COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 489 | NDA/MAL/HDP/10110 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RO TAMIC 500 | TRANEXAMIC ACID | 500 MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 490 | NDA/MAL/HDP/10111 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | NEPEXTO | ETANERCEPT | 50 MG/ML | LUPIN LIMITED (BIOTECH DIVISION)-GAT NO. 1156, GHOTAWADDE - VILLAGE, MULSHI-TALUKA, PUNE - 412 115 | INDIA | PARENTERAL ORDINARY PRE-FILLED AUTOINJECTORS | 1.0X1.0X1.0 ML PREFILLED PEN | 06/07/2022 |
| 491 | NDA/MAL/HDP/10112 | KESAR PHARMA | ABACUS PHARMA (AFRICA) LIMITED | KESKETO | KETOCONAZOLE | 2 % W/W | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 06/07/2022 |

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| 492 | NDA/MAL/HDP /10113 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RO-PERICEM | PIROXICAM | 20 MG | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |
| 493 | NDA/MAL/HDP /10114 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 300/300 MG | LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 300 MG + 300 MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 06/07/2022 |
| 494 | NDA/MAL/HDP /10115 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ASPIRIN DELAYED RELEASE TABLETS USP 75MG | ASPIRIN | 75 MG | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 495 | NDA/MAL/HDP/10116 | RATNAMANI HEALTHCARE PVT. LTD | VIDA AFRICA LTD | ZENEGRA 50 | SILDENAFIL CITRATE | 50 MG | RATNAMANI HEALTHCARE PRIVATE LIMITED-SURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 06/07/2022 |
| 496 | NDA/MAL/HDP/10117 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VENOSMIL | HIDROSMIN | 200 MG | FAES FARMA SA-MAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN | SPAIN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 06/07/2022 |
| 497 | NDA/MAL/HDP/1012 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | LOX 2% | LIDOCAINE | 2% W/V | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY OTHER VIALS | 1.0X50.0 ML VIAL,1.0X20.0 ML VIAL | 01/07/2013 |

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| 498 | NDA/MAL/HDP /10129 | HETERO LABS LTD | AIVEEN (U) LIMITED | DARUNAVIR AND RITONAVIR TABLETS 400 MG/50 MG | DARUNAVIR ETHANOLATE + RITONAVIR | 400 MG + 50 MG | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 06/07/2022 |
| 499 | NDA/MAL/HDP /1013 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | THIOSOL | THIOPENTAL SODIUM | 500MG | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X20.0 ML VIAL | 01/07/2013 |
| 500 | NDA/MAL/HDP /10132 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | ATCOBETA-N | BETAMETHASONE SODIUM PHOSPHATE + NEOMYCIN SULPHATE | 0.1% W/V + 0.5% W/V | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | OPHTHALMIC DROPS | 1.0X1.0X7.5 ML BOTTLE | 06/07/2022 |

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| 501 | NDA/MAL/HDP /10134 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ISONIAZID/ RIFAPENTINE COATED TABLETS 300 MG + 300 MG | ISONIAZID + RIFAPENTINE | 300MG +300MG | OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X12.0 TABLET STRIP | 06/07/2022 |
| 502 | NDA/MAL/HDP /10135 | RAPTAKOS, BRETT & CO. LTD. | EUROPA HEALTHCARE (U) LTD | ZEVAC SYRUP | ZINC ACETATE (AS DIHYDRATE) | 20MG/5ML | RAPTAKOS BRETT & CO.LTD-1ST POKHRAN ROAD,THANE 400 606 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 06/07/2022 |
| 503 | NDA/MAL/HDP /10137 | UNISON PHARMACEUTICALS PVT. LTD. | HARLEYS UGANDA LIMITED | MBSON-SL | MECOBALAMIN | 1500 MCG | UNISON PHARMACEUTICALS PRIVATE LIMITED – UNIT 1-UNIT I, C/6, STEEL TOWN, OPP. NOVA PETRO, MORAIYA, TA. SANAND, DIST.: AHMEDABAD - 382213, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/07/2022 |

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| 504 | NDA/MAL/HDP /10138 | NABIQASIM INDUSTRIES (PVT) LIMITED | HEALTHCARE LTD. | CLARITHRO TABLETS | CLARITHROMYCIN | 500MG | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/07/2022 |
| 505 | NDA/MAL/HDP /10139 | NABIQASIM INDUSTRIES (PVT) LIMITED | HEALTHCARE LTD. | CLARITHRO GRANULES FOR SUSPENSION | CLARITHROMYCIN | 125 MG/ 5 ML | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS | 1.0X60.0 ML BOTTLE | 06/07/2022 |
| 506 | NDA/MAL/HDP /1014 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | TIDAZOL TABLETS | TINIDAZOLE | 500MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X4.0 TABLET BLISTER | 01/07/2015 |

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| 507 | NDA/MAL/HDP /10140 | UNICHEM LABORATORIES LIMITEDv | EUROPA HEALTHCARE (U) LTD | ALDROL 5 | DONEPEZIL HYDROCHLORIDE | 5MG | UNICHEM LABORATORIES BADI-UNIT II-VILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 508 | NDA/MAL/HDP /10141 | UNICHEM LABORATORIES LIMITEDv | EUROPA HEALTHCARE (U) LTD | ALDROL 10 | DONEPEZIL HYDROCHLORIDE | 10MG | UNICHEM LABORATORIES BADI-UNIT II-VILLAGE BHATAULI, BADDI HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/07/2022 |
| 509 | NDA/MAL/HDP /10142 | GALENICUM HEALTH S.L. | GOODMAN INTERNATIONAL LTD | ROSUVITAE 10 MG | ROSUVASTATIN | 10MG | BIOFARM SP. Z.O.O-UL. WALBRZYSKA 13, 60-198 POZNAN - POLAND | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 06/07/2022 |

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| 510 | NDA/MAL/HDP /10143 | GALENICUM HEALTH S.L. | GOODMAN INTERNATIONAL LTD | ROSUVITAE 40 MG | ROSUVASTATIN | 40MG | BIOFARM SP. Z.O.O-UL. WALBRZYSKA 13, 60-198 POZNAN - POLAND | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 06/07/2022 |
| 511 | NDA/MAL/HDP /10144 | VIRCHOW BIOTECH PVT LTD, | SURGIPHARM (U) LIMITED | CLASIPRO | BACILLUS CLAUSII SPORES | 2 X 10^9 SPORES/ 5 ML | VIRCHOW BIOTECH PRIVATE LIMITED-SURVEY NO. 172 PART, GAGILLAPUR, QUTHBULLPUR, RR DISTRICT, TELANGANA-500043 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X5.0 ML AMPOULE | 06/07/2022 |
| 512 | NDA/MAL/HDP /10146 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | UMBILICA GEL | CHLORHEXIDINE GLUCONATE | 4%W/W | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | TOPICAL EXTERNAL GELS AND SOLS | 1.0X10.0 G TUBE | 06/07/2022 |

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| 513 | NDA/MAL/HDP /10147 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | FLUOMIZIN | DEQUALINIUM CHLORIDE | 10MG | ROTTENDORF PHARMA GMBH-OSTENFELDER STRABE 51-61, 59320 ENNIGERLOH | GERMANY | VAGINAL TABLETS | 1.0X1.0X6.0 PESSARY BLISTER | 06/07/2022 |
| 514 | NDA/MAL/HDP /10148 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | RALEF 60 | ETORICOXIB | 60MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 06/07/2022 |
| 515 | NDA/MAL/HDP /10149 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | RALEF 90 | ETORICOXIB | 90MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 516 | NDA/MAL/HDP /10150 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | RALEF 120 | ETORICOXIB | 120MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 06/07/2022 |
| 517 | NDA/MAL/HDP /10151 | S KANT HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | FUNGARIN | MICONAZOLE | 2%W/W | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE | 06/07/2022 |
| 518 | NDA/MAL/HDP /10152 | BIOFARMA PLASMA LIMITED LIABILITY COMPANY | ONCOPHARM (U) LTD | ALBUMIN-BIOPHARMA | HUMAN ALBUMIN | 20G/100ML | BIOPHARMA PLASMA LIMITED LIABILITY COMPANY-37-V KYIVSKA ST., BILA TSERKVA, KYIV REGION, 09100 - UKRAINE | UKRAINE | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML VIAL | 06/07/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 519 | NDA/MAL/HDP /10154 | MEDIPAK LIMITED | HEALTHCARE LTD. | MEDISOL S | SODIUM CHLORIDE + DEXTROSE | 0.9%W/V + 5%W/V | MEDIPAK LTD-132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE | PAKISTAN | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 02/09/2022 |
| 520 | NDA/MAL/HDP /10155 | MEDIPAK LIMITED | HEALTHCARE LTD. | MEDISOL NS | SODIUM CHLORIDE | 0.9%W/V | MEDIPAK LTD-132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE | PAKISTAN | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 02/09/2022 |
| 521 | NDA/MAL/HDP /10156 | MEDIPAK LIMITED | HEALTHCARE LTD. | MEDISOL 5% | DEXTROSE | 5%W/V | MEDIPAK LTD-132/2/ INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE | PAKISTAN | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 02/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 522 | NDA/MAL/HDP /10157 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | MOXIPEN ORAL SUSPENSION | AMOXICILLIN | 125MG/5ML | XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA | MALAYSIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 29/08/2022 |
| 523 | NDA/MAL/HDP /10158 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | ERYSOL ORAL SUSPENSION | ERYTHROMYCIN ETHYLSUCCINATE | 200MG/5ML | XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA | MALAYSIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 29/08/2022 |
| 524 | NDA/MAL/HDP /10159 | MARTIN DOW MARKER LTD | HEALTHCARE LTD. | KLARIBACT | CLARITHROMYCIN | 500MG | MARTIN DOW MARKER LIMITED-7, JAIL ROAD, QUETTA - PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 23/01/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 525 | NDA/MAL/HDP /1016 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ASCORBIC ACID | ASCORBIC ACID | 200MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER | 01/07/2014 |
| 526 | NDA/MAL/HDP /10160 | MARTIN DOW MARKER LTD | HEALTHCARE LTD. | KLARIBACT | CLARITHROMYCIN | 250MG | MARTIN DOW MARKER LIMITED-7, JAIL ROAD, QUETTA - PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 23/01/2023 |
| 527 | NDA/MAL/HDP /10161 | MARTIN DOW MARKER LTD | HEALTHCARE LTD. | KLARIBACT | CLARITHROMYCIN | 125MG/5ML | MARTIN DOW MARKER LIMITED-7, JAIL ROAD, QUETTA - PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 23/01/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 528 | NDA/MAL/HDP /10162 | MARTIN DOW MARKER LTD | HEALTHCARE LTD. | LEVOMERC | LEVOFLOXACIN | 500MG | MARTIN DOW MARKER LIMITED-7, JAIL ROAD, QUETTA - PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 23/01/2023 |
| 529 | NDA/MAL/HDP /10164 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ASPIRIN TABLETS | ACETYLSALICYCLIC ACID | 300MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET STRIP,1.0X200.0 TABLET TIN,1.0X1000.0 TABLET TIN | 02/09/2022 |
| 530 | NDA/MAL/HDP /10165 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYTETRA | TETRACYCLINE HYDROCHLORIDE | 250MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER | 02/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 531 | NDA/MAL/HDP/10166 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYTETRA | TETRACYCLINE HYDROCHLORIDE | 3%W/W | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 02/09/2022 |
| 532 | NDA/MAL/HDP/10167 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | HEDAPAN TABLET | ASPIRIN/PARACETAMOL/CAFFEINE | 400MG/500MG/50MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 02/09/2022 |
| 533 | NDA/MAL/HDP/10168 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | LYFE | ORAL REHYDRATION SALT | N/A | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X14.0 G SACHET,1.0X28.0 G SACHET | 02/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 534 | NDA/MAL/HDP/10169 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ORODAR | SULFADOXINE+PYRIMETHAMINE | 500MG+25MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0X3.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 02/09/2022 |
| 535 | NDA/MAL/HDP/1017 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYCLOX | AMPICILLIN/CLOXACILLIN | 125MG/125MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2015 |
| 536 | NDA/MAL/HDP/10170 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | PREDNISOLONE TABLETS | PREDNISOLONE | 5MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 02/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 537 | NDA/MAL/HDP /10171 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | QUININE TABLETS | QUININE SULPHATE | 300MG | ELYS CHEMICAL INDUSTRIES LIMITED,-OFF ENTERPRISE ROAD, OPP HILLLOCK-INN ROAD B, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 02/09/2022 |
| 538 | NDA/MAL/HDP /10172 | SURGE LABORATORIES (PVT.) LTD. | HEALTHCARE LTD. | XTRACEF 2G INJECTION | CEFOPRAZONE SODIUM + SULBACTUM SODIUM | (1G + 1G)/VIAL | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X2.0 G VIAL + 10ML WFI CLEAR GLASS AMPOULE | 04/10/2022 |
| 539 | NDA/MAL/HDP /10173 | APAROZA PHARMA LTD | APAROZA PHARMA LIMITED | ESCAPELLE | LEVONORGESTREL | 1.5MG | GEDEON RICHTER PLC-H-1103 BUDAPEST, GYOMROI UT 19-21 HUNGARY | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 29/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 540 | NDA/MAL/HDP/10174 | STRIDES PHARMA SCIENCE LIMITED | DELMAW ENTERPRISES LIMITED | DOLUTEGRAVIR TABLETS 50 MG | DOLUTEGRAVIR SODIUM | 50 MG | STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 29/09/2022 |
| 541 | NDA/MAL/HDP/10175 | ESKAYEF PHARMACEUTICALS LTD | SWASTIK PHARMACEUTICAL LTD | LAXITOL | LACTITOL MONOHYDRATE | 10 MG | ESKAYEF BANGLADESH LTD-TONGI PLANT-400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH | BANGLADESH | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X10.0X1.0X10.0 MG SACHET | 04/10/2022 |
| 542 | NDA/MAL/HDP/10176 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CLINDAMYCIN HYDROCHLORIDE CAPSULES USP 300 MG | CLINDAMYCIN HYDROCHLORIDE | 300 MG | CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 35-37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR – 401404, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 29/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 543 | NDA/MAL/HDP/10177 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | METOCLOPRAMIDE TABLETS BP 10 MG | METOCLOPRAMIDE HYDROCHLORIDE | 10 MG | CIRON DRUGS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 35-37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR – 401404, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 544 | NDA/MAL/HDP/10178 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | BETAMET OINTMENT | BETAMETHASONE VALERATE | 0.1% W/W | ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700 | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X15.0 G TUBE | 29/09/2022 |
| 545 | NDA/MAL/HDP/10179 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LEDOBOOK 10 | LENALIDOMIDE | 10 MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X7.0 CAPSULE BLISTER | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 546 | NDA/MAL/HDP/1018 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM CHLOR | CHLORAMPHENICOL | 250MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 100.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE CONTAINER | 01/07/1997 |
| 547 | NDA/MAL/HDP/10180 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | POLYMOL RAPID | PARACETAMOL | 500 MG | M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 03/10/2022 |
| 548 | NDA/MAL/HDP/10181 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | POLYMOL ADVANCE | PARACETAMOL | 650 MG | M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 549 | NDA/MAL/HDP /10182 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | CYCLOSERINE 250 MG | CYCLOSERINE | 250 MG | MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 04/10/2022 |
| 550 | NDA/MAL/HDP /10183 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | TEXAKIND | TRANEXAMIC ACID | 500MG/5ML | MANKIND PHARMA LIMITED-UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X4.0X5.0 ML AMPOULE | 29/09/2022 |
| 551 | NDA/MAL/HDP /10184 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ROFAST 20 | ROSUVASTATIN CALCIUM | 20 MG | AUROBINDO PHARMA LTD, UNIT VII-SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 552 | NDA/MAL/HDP/10185 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TURBOVAS-10 | ROSUVASTATIN CALCIUM | 10MG | MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 553 | NDA/MAL/HDP/10186 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | AARLOFLOX OZ | OFLOXACIN + ORNIDAZOLE | 200 MG + 500 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X10.0 TABLET BLISTER | 29/09/2022 |
| 554 | NDA/MAL/HDP/10187 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | AARCET 5 | CETIRIZINE HYDROCHLORIDE | 5 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 555 | NDA/MAL/HDP/10188 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | AARLEFLOX 750 | LEVOFLOXACIN HEMIHYDRATE | 750 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X1.0 TABLET BLISTER | 29/09/2022 |
| 556 | NDA/MAL/HDP/10189 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | ETRICOX 120 | ETORICOXIB | 120 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 557 | NDA/MAL/HDP/10190 | ORCHIDIA PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TWINZOL | DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE | (20 MG + 5 MG)/ML | ORCHIDIA PHARMACEUTICAL INDUSTRIES-AL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT | EGYPT | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML CONTAINER | 29/09/2022 |

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| 558 | NDA/MAL/HDP /10191 | M/S HETERO LABS LIMITED | AIVEEN (U) LTD | VALSAR HT 160/25 | VALSARTAN + HYDROCHLORTHIA ZIDE | 160MG + 25MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/10/2022 |
| 559 | NDA/MAL/HDP /10192 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | INFUTAXIM 1 GM | CEFOTAXIME SODIUM | 1 G/ VIAL | ZEISS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) | INDIA | PARENTERAL RETARD DRY VIALS | 1.0X1.0X1.0 G VIAL | 29/09/2022 |
| 560 | NDA/MAL/HDP /10193 | UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VIVAZAC PLUS | IRBESARTAN + HYDROCHLOROTHI AZIDE | 300 MG + 12.5 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 561 | NDA/MAL/HDP/10194 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BETOLINA | BUPIVACAINE HYDROCHLORIDE | 0.5%W/V | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X20.0 ML VIAL | 03/10/2022 |
| 562 | NDA/MAL/HDP/10195 | DEV LIFE CORPORATION | PLANET PHARMACEUTICALS UGANDA LTD | ABZODEV | ACTIVATED CHARCOAL | 250 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER | 29/09/2022 |
| 563 | NDA/MAL/HDP/10196 | CONCEPT PHARMACEUTICAL LTD | QUALITY CHEMICALS LTD | PANTEC-DSR | PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE | 40 MG + 30 MG | CONCEPT PHARMACEUTICALS LIMITED-KISHANPUR JAMALPUR ROORKEE DIST HARIDWAR - 247667 UTTARAKHAND, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 29/09/2022 |

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| 564 | NDA/MAL/HDP/10197 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LIMITED | LEVOZINE | LEVOCETIRIZINE DIHYDROCHLORIDE | 5 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 565 | NDA/MAL/HDP/10198 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LIMITED | FORMET 500 SR | METFORMIN HYDROCHLORIDE | 500 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 566 | NDA/MAL/HDP/10199 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | GOFEN 200 | IBUPROFEN | 200 MG | MEGA LIFESCIENCES PUBLIC CO. LTD-PLANT 1; 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280 THAILAND | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X6.0X1.0X1.0X10.0 CAPSULE BLISTER | 29/09/2022 |

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| 567 | NDA/MAL/HDP/1020 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | PA-12 | PARACETAMOL SUSTAINED RELEASE | 1000MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID RETARD LAYERED TABLETS | 1.0X10.0X1.0X12.0 TABLET BLISTER | 01/07/2012 |
| 568 | NDA/MAL/HDP/10200 | UNITED PHARMACEUTICALS MANUFACTURING LIMITED COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SENERGY PLUS 5/160/12.5 MG | AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTHIAZIDE | 5 MG + 160 MG + 12.5 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 569 | NDA/MAL/HDP/10201 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | ETRICOX 60 | ETORICOXIB | 60 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 570 | NDA/MAL/HDP/10202 | ESKAYEF PHARMACEUTICALS LTD | SWASTIK PHARMACEUTICAL LTD | PRED | PREDNISOLONE ACETATE | 10 MG/ML | ESKAYEF BANGLADESH LTD-TONGI PLANT-400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH | BANGLADESH | OPHTHALMIC LIQUIDS | 1.0X1.0X5.0 ML BOTTLE | 29/09/2022 |
| 571 | NDA/MAL/HDP/10203 | MARCYRL PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SAVIBLEED | TRANEXAMIC ACID | 500 MG | MARCYRL PHARMACEUTICAL INDUSTRIES -WESTERN EXTEENSION-PARTS NUMBER 5/6/7/8/9/10/11/12-BLOCK 20005, EL OBOUR CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/09/2022 |
| 572 | NDA/MAL/HDP/10204 | SAGA LIFESCIENCES LTD | ABACUS PHARMA (AFRICA) LIMITED | NOVACEF 100 DT | CEFIXIME TRIHYDRATE | 100 MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 573 | NDA/MAL/HDP/10206 | PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD) | ROYAL PHARMA 2011 LIMITED | PRILIS 5 | LISINOPRIL DIHYDRATE | 5 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 574 | NDA/MAL/HDP/10207 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | TACROTAS-1 | TACROLIMUS MONOHYDRARE | 1 MG | INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER,1.0X30.0 CAPSULE CONTAINER | 29/09/2022 |
| 575 | NDA/MAL/HDP/10208 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | KENZOPRAZOL | ESOMEPRAZOLE SODIUM | 40MG PER VIAL | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X40.0 MG VIAL | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 576 | NDA/MAL/HDP /10209 | FERRER INTERNATIONAL, S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TRAMAPA FORT 75MG/650MG | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 75 MG + 650 MG | FERRER INTERNATIONAL, S.A-C/ JOAN BUSCALLA, 1-9 08173 SANT CUGAT DEL VALLES, | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/09/2022 |
| 577 | NDA/MAL/HDP /10210 | FDC LTD | AIVEEN (U) LTD | IOPROST EYE DROPS | LATANOPROST | 0.005%W/V | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X5.0 ML BOTTLE | 29/09/2022 |
| 578 | NDA/MAL/HDP /10211 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | SPAZNOL | DICLOFENAC SODIUM + PARACETAMOL + CHLORZOXAZON | 50 MG + 325 MG + 250 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 29/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 579 | NDA/MAL/HDP /10212 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | SPASNIL P | MEFENAMIC ACID + PARACETAMOL | 500 MG + 325 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 580 | NDA/MAL/HDP /10213 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | PANTAKIND-40 | PANTOPRAZOLE SODIUM | 40 MG | MANKIND PHARMA LIMITED-UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 29/09/2022 |
| 581 | NDA/MAL/HDP /10214 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ILAXTEN 20 MG TABLETS | BILASTINE | 20MG | A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRL-VIA CAMPO DI PILE 67100 L'AQUILA (AQ) | ITALY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 04/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 582 | NDA/MAL/HDP/10215 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ABAMOL | PARACETAMOL | 10 MG/ML | ABARIS HEALTHCARE PVT. LTD-SURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT-382740 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML CONTAINER | 05/10/2022 |
| 583 | NDA/MAL/HDP/10216 | CURETECH SKINCARE | AARON PHARMACEUTICALS LIMITED | LULIZOL CREAM | LULICONAZOLE | 1%W/W | CURETECH SKINCARE-PLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 29/09/2022 |
| 584 | NDA/MAL/HDP/10217 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | MIXIF 200 | CEFIXIME TRIHYDRATE | 200 MG | DAR AL DAWA DEVELOPMENT & INVESTMENT CO. LTD - P.O.BOX 9364, AMMAN 11191, JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X8.0 CAPSULE BLISTER | 04/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 585 | NDA/MAL/HDP/10218 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | COMIT-100 | SILDENAFIL CITRATE | 100 MG | BLISS GVS PHARMA LIMITED-10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR,MAHARASHTRA 401404,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 29/09/2022 |
| 586 | NDA/MAL/HDP/10219 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | COMIT-50 | SILDENAFIL CITRATE | 50 MG | BLISS GVS PHARMA LIMITED-10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR,MAHARASHTRA 401404,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 29/09/2022 |
| 587 | NDA/MAL/HDP/1022 | EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES - | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CONVENTIN | GABAPENTIN | 300MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 588 | NDA/MAL/HDP/10220 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | AZIRO-250 | AZITHROMYCIN | 250 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 29/09/2022 |
| 589 | NDA/MAL/HDP/10222 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROYALPINE-10 | AMLODIPINE BESYLATE | 10 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 590 | NDA/MAL/HDP/10223 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROMIPHENE 50 | CLOMIPHENE CITRATE | 50 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 29/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 591 | NDA/MAL/HDP/10224 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ITRO-100 | ITRACONAZOLE | 100 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 29/09/2022 |
| 592 | NDA/MAL/HDP/10227 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROYALPINE-5 | AMLODIPINE BESYLATE | 5 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 593 | NDA/MAL/HDP/10228 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | SEPTOPRIM 960 | TRIMETHOPRIM + SULFAMETHOXAZOLE | 160 MG + 800 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 594 | NDA/MAL/HDP/10229 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | SEPTOPRIM - S | TRIMETHOPRIM + SULFAMETHOXAZOLE | (40 MG + 200 MG)/5 ML | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 29/09/2022 |
| 595 | NDA/MAL/HDP/1023 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ZINNIA P | LEVONORGESTREL + ETHINYLESTRADIOL | 150MCG + 30MCG | MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X28.0 TABLET BLISTER,3.0X28.0 TABLET BLISTER | 01/07/2013 |
| 596 | NDA/MAL/HDP/10230 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | MBEN | MEBENDAZOLE | 100 MG/5 ML | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X30.0 ML BOTTLE | 29/09/2022 |

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| 597 | NDA/MAL/HDP /10231 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | MBEN 100 | MEBENDAZOLE | 100 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0X6.0 TABLET BLISTER | 29/09/2022 |
| 598 | NDA/MAL/HDP /10232 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | TOPGYL | METRONIDAZOLE BENZOATE | 125 MG/5 ML | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 29/09/2022 |
| 599 | NDA/MAL/HDP /10233 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | PAINFORCE 400 | IBUPROFEN | 400 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 600 | NDA/MAL/HDP /10234 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | TERBINAFORCE 250 | TERBINAFINEHYDROCHLORIDE | 250 MG | MANKIND PHARMA LIMITED-UNIT - II, VILLAGE KISHANPURA, P.O. JAMNIWALA, TEHSIL PAONTA SAHIB, DISTRICT SIRMOUR - 173025, HIMACHAL PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 601 | NDA/MAL/HDP /10235 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | LOFNAC GEL | LINSEED OIL + DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + MENTHOL | 3.00%W/W + 1.16% W/W + 10.00%W/W + 5.00%W/W | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE | 04/10/2022 |
| 602 | NDA/MAL/HDP /10236 | ESKAYEF PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | CARDOBIS 5 | BISOPROLOL FUMARATE | 5 MG | ESKAYEF BANGLADESH LTD-TONGI PLANT-400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 603 | NDA/MAL/HDP /10237 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | METHOTREXATE 500 MG/50ML | METHOTREXATE DISODIUM | 500 MG/50 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X50.0 ML VIAL | 29/09/2022 |
| 604 | NDA/MAL/HDP /10238 | CCL PHARMACEUTICALS (PVT.)LTD. | HARLEYS UGANDA LIMITED | NEO-KLAR | CLARITHROMYCIN | 500MG | CCL PHARMACEUTICALS (PVT) LTD-62- INDUSTRIAL ESTATE, KOT LAKHPHAT, LAHORE- 54770, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 19/09/2022 |
| 605 | NDA/MAL/HDP /10239 | GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD | TRIDEM PHARMA UGANDA LIMITED | ZITMYC | AZITHROMYCIN | 500MG | CSPC OUYI PHARMACEUTICAL CO. LTD.-WORKSHOPS 112,113 AND 117 PLOT NO. 88 YANGZI ROAD,ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 25/01/2023 |

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| 606 | NDA/MAL/HDP /10240 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | OLMESAR 40 | OLMESARTAN MEDOXOMIL | 40MG | MACLEODS PHARMACEUTICALS LIMITED, UNIT VI-VILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH–174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 03/10/2022 |
| 607 | NDA/MAL/HDP /10241 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | LARIACT FORTE | ARTEMETHER + LUMEFANTRINE | 80 MG + 480 MG | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 19/09/2022 |
| 608 | NDA/MAL/HDP /10242 | EMCURE PHARMACEUTICALS LTD - | HARLEYS UGANDA LIMITED | INSTGRA | DOLUTEGRAVIR SODIUM | 50MG | EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 19/09/2022 |

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| 609 | NDA/MAL/HDP /10243 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | OXALIPLATIN 100MG/20ML | OXALIPLATIN | 100 MG/20 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X20.0 ML VIAL | 29/09/2022 |
| 610 | NDA/MAL/HDP /10244 | ZYDUS DISCOVERY DMCC | ABACUS PHARMA (AFRICA) LIMITED | LIPAGLYN | SAROGLITAZAR MAGNESIUM | 4MG | CADILA HEALTHCARE LTD. - PLOT NO. 417, 419 & 420, SARKHEJ-BAVLA N.H. NO. 8A, MORAIYA, TAL: SANAND, DIST. AHMEDABAD - 382210, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 19/09/2022 |
| 611 | NDA/MAL/HDP /10245 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | METHOTREXATE 5000 MG/50ML | METHOTREXATE DISODIUM | 5000 MG/50 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X50.0 ML VIAL | 29/09/2022 |

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| 612 | NDA/MAL/HDP /10246 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | GLENDES | DESLORATADINE | 5MG | GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. S - 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 613 | NDA/MAL/HDP /10247 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | MOXIKIND-CV 228.5 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 200MG/5ML + 28.5MG/5ML | COPMED PHARMACEUTICALS PVT LTD-UNIT II. ,-PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH-173025, INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |
| 614 | NDA/MAL/HDP /10248 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LEVOKILZ 750 | LEVOFLOXACIN | 750MG | AUROBINDO PHARMA LTD, UNIT VII-SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 19/09/2022 |

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| 615 | NDA/MAL/HDP /10249 | FDC LTD | AIVEEN (U) LIMITED | IOPROST – T | LATANOPROST + TIMOLOL MALEATE | (50 MCG + 5 MG)/ML | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | OPHTHALMIC DROPS | 1.0X1.0X2.5 ML BOTTLE | 19/09/2022 |
| 616 | NDA/MAL/HDP /10250 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SINUTAB SINUS PAIN EXTRA STRENGTH | CODEINE PHOSPHATE +CHLORPHENIRAMINE MALEATE +PSEUDOEPHEDRINE HYDROCHLORIDE + PARACETAMOL | 10 MG + 2 MG + 30 MG + 500 MG | JOHNSON & JOHNSON (PTY) LTD-241 MAIN ROAD, RETREAT, 7945, CAPE TOWN | SOUTH AFRICA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 19/09/2022 |
| 617 | NDA/MAL/HDP /10251 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CITADONE | BETAMETHASONE | 0.6 MG/5 ML | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |

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| 618 | NDA/MAL/HDP/10252 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | ATCAM | LORNOXICAM | 8MG | ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700 | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 19/09/2022 |
| 619 | NDA/MAL/HDP/10253 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | LINEZOLID DENK 2 MG/ML | LINEZOLID | 2MG/ML | PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI | POLAND | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X300.0 ML BAG | 19/09/2022 |
| 620 | NDA/MAL/HDP/10254 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LIMITED | AZICEN 500 | AZITHROMYCIN | 500MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 03/10/2022 |

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| 621 | NDA/MAL/HDP /10255 | AKRITI PHARMACEUTICALS PVT LTD | PHARMA VILLE LIMITED | HOTGRA 100 | SILDENAFIL CITRATE | 100 MG | AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 29/09/2022 |
| 622 | NDA/MAL/HDP /10256 | AKRITI PHARMACEUTICALS PVT LTD | PHARMA VILLE LIMITED | HOTGRA 50 | SILDENAFIL CITRATE | 50 MG | AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 29/09/2022 |
| 623 | NDA/MAL/HDP /10257 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FENTEX® | PHENYTOIN | 250MG/5ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X10.0X5.0 ML VIAL | 19/09/2022 |

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| 624 | NDA/MAL/HDP /10258 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SENERGY PLUS 5/160 25 MG | AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTHIAZIDE | 5 MG + 160 MG + 25 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 625 | NDA/MAL/HDP /10259 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SENERGY PLUS 10/160 12.5 MG | AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTHIAZIDE | 10 MG + 160 MG + 12.5 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 626 | NDA/MAL/HDP /10260 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | OPELAN ODT 10 | OLANZAPINE | 10MG | MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 627 | NDA/MAL/HDP /10261 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | NTCLOT-C75 | CLOPIDOGREL BILSULFATE | 75 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 29/09/2022 |
| 628 | NDA/MAL/HDP /10262 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROFLOX | OFLOXACIN | 0.3%W/V | AUROLAB LIMITED-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 19/09/2022 |
| 629 | NDA/MAL/HDP /10263 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | WORMAID ORAL SUSPENSION | ALBENDAZOLE | 200 MG/5ML | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X10.0 ML BOTTLE | 29/09/2022 |

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| 630 | NDA/MAL/HDP /10264 | RUSAN PHARMA LTD | NORVIK ENTERPRISES LIMITED | ADDTREX 765 IMPLANT | NALTREXONE | 765 MG/APPLICATOR | RUSAN PHARMA LIMITED-PLOT NO. 59 - 65, SECTOR II, KANDLA SPECIAL ECONOMIC ZONE, GANDHIDHAM KUTCH 370 230 GUJARAT | INDIA | IMPLANTS (ASEPTICALLY FILLED) | 1.0X1.0X1.0X2.0 TABLET IMPLANT (THE IMPLANTATION TABLETS ARE CONTAINED IN A 3ML SYRINGE) | 17/11/2022 |
| 631 | NDA/MAL/HDP /10265 | MYLAN LABORATORIES LIMITED- | KIMSY MEDS LTD | MYVORCON 200 MG | VORICONAZOLE | 200 MG | MYLAN LABORATORIES LTD .-F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X15.0 TABLET BLISTER | 19/09/2022 |
| 632 | NDA/MAL/HDP /10266 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | TELCARD H 40 | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40 MG + 12.5 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 633 | NDA/MAL/HDP/10267 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | PROTOZOX-500 | NITAZOXANIDE | 500MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 03/10/2022 |
| 634 | NDA/MAL/HDP/10268 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | WORMAID TABLET | ALBENDAZOLE | 400 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 29/09/2022 |
| 635 | NDA/MAL/HDP/10269 | NATIONAL PHARMACEUTICAL INDUSTRIES CO. | MEDVIN PHARMA LIMITED | DIOCLAV 625 MG | AMOXICILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMAN-P.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN | OMAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET STRIP | 19/09/2022 |

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| 636 | NDA/MAL/HDP /10270 | GLENMARK PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | MALAGLEN | ATOVAQUONE + PROGUANIL HYDROCHLORIDE | 250 MG + 100 MG | GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. S - 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 19/09/2022 |
| 637 | NDA/MAL/HDP /10271 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | PACLITAXEL | PACLITAXEL | 100MG PER VIAL OF 16.7ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 MG VIAL | 04/10/2022 |
| 638 | NDA/MAL/HDP /10272 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | POWERCEF S | CEFTRIAXONE SODIUM + SULBACTAM SODIUM | 1.5 GM /VIAL | ZEISS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.5 G VIAL + 1.0X1.0X10ML AMPOULE OF WFI | 03/10/2022 |

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| 639 | NDA/MAL/HDP /10273 | KESAR PHARMA | SWASTIK PHARMACEUTICA L LTD | ASPIRIN 81 MG USP | ASPIRIN | 81 MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 640 | NDA/MAL/HDP /10274 | TAKEDA PHARMACEUTICAL S U.S.A INC | PHILLIPS PHARMACEUTICA LS (UGANDA) LIMITED | VIPDOMET | ALOGLIPTIN BENZOATE + METFORMIN HYDROCHLORIDE | 12.5MG + 1000MG | TAKEDA GMBH, PLANT ORANIENBURG-PLANT ORANIENBURG, LEHNITZSTRASSE 70-98, DE – 16515, GERMANY TAKEDA IRELAND LIMITED-BRAY BUSINESS PARK, KILRUDDERY, CO. WICKLOW - IRELAND | GERMANY IRELAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X8.0X7.0 TABLET BLISTER | 19/09/2022 |
| 641 | NDA/MAL/HDP /10275 | KESAR PHARMA | SWASTIK PHARMACEUTICA L LTD | METFORZIDE | GLICLAZIDE + METFORMIN HYDROCHLORIDE | 80 MG + 500 MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 642 | NDA/MAL/HDP/10276 | TAKEDA PHARMACEUTICALS U.S.A INC | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VIPIDIA | ALOGLIPTIN BENZOATE | 25MG | TAKEDA IRELAND LIMITED-BRAY BUSINESS PARK, KILRUDDERY, CO. WICKLOW - IRELAND | IRELAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 19/09/2022 |
| 643 | NDA/MAL/HDP/10277 | KESAR PHARMA | SWASTIK PHARMACEUTICAL LTD | CLOPASPRIN | CLOPIDOGREL BISULFATE + ASPIRIN | 75 MG + 75 MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |
| 644 | NDA/MAL/HDP/10278 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROTRAMIC | TRANEXAMIC ACID | 100 MG/ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY AMPOULES | 1.0X1.0X5.0X5.0 ML AMPOULE | 04/10/2022 |

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| 645 | NDA/MAL/HDP/10279 | PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD) | ROYAL PHARMA 2011 LIMITED | CLARIPSA | CLARITHROMYCIN | 500 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 646 | NDA/MAL/HDP/10280 | INDCHEMIE HEALTH SPECIALITIES PVT. LTD. | NUMED STORES SMC LIMITED | ZENOXIM 500 | CEFUROXIME AXETIL | 500 MG | INDCHEMIE HEALTH SPECIALITIES PVT. LTD-VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 19/09/2022 |
| 647 | NDA/MAL/HDP/10281 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | H- CURE ES | ESOMEPRAZOLE MAGNESIUM + CLARITHROMYCIN + TINIDAZOLE | 40MG + 500MG + 500MG | FREDUN PHARMACEUTICALS LIMITED,-14,15,16 - ZORABIAN INDUSTRIAL COMPLEX, VEOOR, PALGHAR (E), THANE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X7.0X1.0X6.0 TABLET BLISTER | 29/09/2022 |

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| 648 | NDA/MAL/HDP /10282 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | MUPIWAYS | MUPIROCIN | 2.0 W/W | NEXT WAVE-RAMPUR GHAT ROAD, POANTA SAHIB, DISTRICT SIRMOUR 173025 (H.P) | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X10.0 G TUBE | 29/09/2022 |
| 649 | NDA/MAL/HDP /10283 | DAWA LIMITED- | SUPER MEDIC LTD | DAZOLE | CLOTRIMAZOLE | 100MG | DAWA LIMITED-PLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA | KENYA | VAGINAL TABLETS | 1.0X1.0X6.0 PESSARY BLISTER | 19/09/2022 |
| 650 | NDA/MAL/HDP /10284 | NATIONAL PHARMACEUTICAL INDUSTRIES CO. | MEDVIN PHARMA LIMITED | MACROMAX 500 | AZITHROMYCIN | 500MG | NATIONAL PHARMACEUTICAL INDUSTRIES COMPANY OMAN-P.O.BOX 120, RUSAYL, POSTAL CODE-124, SULTANATE OF OMAN | OMAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 19/09/2022 |

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| 651 | NDA/MAL/HDP /10285 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10MG | DOLUTEGRAVIR SODIUM | 10 MG | MACLEODS PHARMACEUTICALS LTD ,.- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X90.0 TABLET CONTAINER | 29/09/2022 |
| 652 | NDA/MAL/HDP /10286 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PERLEX 250 | CEFALEXIN MONOHYDRATE | 250 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 29/09/2022 |
| 653 | NDA/MAL/HDP /10287 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | VILDA DENK 50 MG | VILDAGLIPTIN | 50 MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 03/10/2022 |

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| 654 | NDA/MAL/HDP /10288 | AGIO PHARMACEUTICALS LTD | REDDYS PHARMA LIMITED | AZIAGIO 200 | AZITHROMYCIN DIHYDRATE | 200 MG/5 ML | AGIO PHARMACEUTICALS LIMITED.-T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X15.0 ML BOTTLE | 19/09/2022 |
| 655 | NDA/MAL/HDP /10289 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICAL LTD | POLZIN EYE OINTMENT | POLYMYXIN B SULFATE + BACITRACIN ZINC + NEOMYCIN SULFATE | (5000 IU + 400 IU + 3400 IU)/G | INDIANA OPHTHALMICS-135, 136, 137, GIDC ESTATE, WADHWAN-363035 | INDIA | OPHTHALMIC OINTMENTS | 1.0X1.0X5.0 G TUBE | 19/09/2022 |
| 656 | NDA/MAL/HDP /10290 | KESAR PHARMA | SWASTIK PHARMACEUTICAL LTD | PHENYTOIN TABLETS BP 100 MG | PHENYTOIN SODIUM | 100 MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 657 | NDA/MAL/HDP/10291 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICAL LTD | CIPROCON EYE DROPS | CIPROFLOXACIN HYDROCHLORIDE | 0.3% W/V | INDIANA OPHTHALMICS-135, 136, 137, GIDC ESTATE, WADHWAN-363035 | INDIA | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML BOTTLE | 19/09/2022 |
| 658 | NDA/MAL/HDP/10292 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | SPASMOTRIT | DICYCLOMINE HYDROCHLORIDE + PARACETAMOL | 20MG + 500MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 659 | NDA/MAL/HDP/10294 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | ALTCIP | CIPROFLOXACIN | 200MG | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |

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| 660 | NDA/MAL/HDP /10296 | AIVEEN (U) LIMITED | AIVEEN (U) LIMITED | RIFAMPIN, ISONIAZID, PYRAZINAMIDE, ETHAMBUTOL HYDROCHLORID E TABLETS USP150/75/400 /275MG | RIFAMPIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE | 150MG + 75MG + 400MG + 275MG | LUPIN LTD-A-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD-431210, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X14.0 TABLET BLISTER | 19/09/2022 |
| 661 | NDA/MAL/HDP /10297 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | ACECLAV 1000 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 875 MG + 125 MG | MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 29/09/2022 |
| 662 | NDA/MAL/HDP /10298 | ZOTA HEALTHCARE LTD | HARLEYS UGANDA LIMITED | COXZOTA 90 | ETORICOXIB | 90 MG | ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 663 | NDA/MAL/HDP /10299 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | ACECLAV 625 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 500 MG + 125 MG | MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/09/2022 |
| 664 | NDA/MAL/HDP /1030 | LABORATORIOS SALVAT SA | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MALACUR | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 40MG + 320MG | CIRON DRUGS PHARMACEUTICALS PRIVATE LTD,-35-37, 43-45, CFC-B DEWAN UDYOG NAGAR, ALIYALI, DIST - PALGHAR 401 404, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER | 01/07/2014 |
| 665 | NDA/MAL/HDP /10300 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | ACECLAV 375 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 250 MG + 125 MG | MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/09/2022 |

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| 666 | NDA/MAL/HDP/10301 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LETRODAY 2.5 | LETROZOLE | 2.5 MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 667 | NDA/MAL/HDP/10302 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MYOTRAM-P 37.5/325 | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 37.5MG + 325MG | AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 668 | NDA/MAL/HDP/10303 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DAPZIN-5 | DAPAGLIFLOZIN | 5 MG | MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 669 | NDA/MAL/HDP/10304 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DAPZIN-10 | DAPAGLIFLOZIN | 10 MG | MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 670 | NDA/MAL/HDP/10305 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | SPASMO PONALGIC | DICYCLOMINE HYDROCHLORIDE + MEFENAMIC ACID | 10 MG + 250 MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/10/2022 |
| 671 | NDA/MAL/HDP/10306 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | OMEZOLE | OMEPRAZOLE SODIUM | 40 MG | SWISS PARENTERALS LIMITED (UNIT-1)-808, 809, 810, KERALA INDUSTRIAL ESTATE, GIDC, NR. BAVLA, AHMEDABAD - 382220, GUJARAT - INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X40.0 MG VIAL + 1.0X1.0X10.0ML AMPOULE OF WFI | 19/09/2022 |

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| 672 | NDA/MAL/HDP /10307 | ZOTA HEALTHCARE LTD | HARLEYS UGANDA LIMITED | DESLOZED-5 | DESLORATADINE | 5 MG | ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 673 | NDA/MAL/HDP /10308 | WALLACE PHARMACEUTICALS PVT. LTD | SURGIPHARM (U) LIMITED | ZN20 | ZINC GLUCONATE | 20MG/5ML | WALLACE PHARMACEUTICALS PVT LTD-BHATIAN, NALAGARH, DIST. SOLAN HP 174101 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |
| 674 | NDA/MAL/HDP /10309 | INDASI LIFESCIENCE PVT. LTD | ROYAL PHARMA 2011 LIMITED | OMEPRAZOLE FOR INJECTION | OMEPRAZOLE SODIUM | 40 MG | BLISS INDASI LIFESCIENCE PRIVATE LIMITED-PLOT NO. 73 TO 76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN-396 210 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X40.0 MG VIAL | 19/09/2022 |

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| 675 | NDA/MAL/HDP /1031 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MOXIFLOX | MOXIFLOXACIN | 400MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 01/07/2013 |
| 676 | NDA/MAL/HDP /10310 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ZINRO INFUSION | ORNIDAZOLE | 500MG/100ML | ABACUS PARENTERAL DRUGS LIMITED-PLOT 114, BLOCK 191, KINGA | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |
| 677 | NDA/MAL/HDP /10311 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | LOPINAVIR AND RITONAVIR TABLETS USP | LOPINAVIR + RITONAVIR | 200MG + 50MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X120.0 TABLET BOTTLE | 19/09/2022 |

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| 678 | NDA/MAL/HDP /10312 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | DICLOTRIX | DICLOFENAC DIETHYLAMINE + VIRGIN LINSEED OIL + METHYL SALICYLATE + MENTHOL | 1.0%W/W + 3.0%W/W + 10.0%W/W + 5.0%W/W | NANZ MED SCIENCE PHARMA PVT. LTD-RAMPUR GHAT, PAONTA SAHIB, DISTRICT SIRMOUR-173025, HIMACHAL PRADESH, INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X20.0 G TUBE | 04/10/2022 |
| 679 | NDA/MAL/HDP /10313 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | LOPINAVIR AND RITONAVIR TABLETS USP | LOPINAVIR + RITONAVIR | 100MG + 25MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 19/09/2022 |
| 680 | NDA/MAL/HDP /10314 | AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD | ROYAL PHARMA 2011 LIMITED | SPIRONOLACTONE TABLETS BP 25 MG | SPIRONOLACTONE | 25MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 681 | NDA/MAL/HDP /10315 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | INDOMETHACIN | INDOMETHACIN | 25MG | M/S SCOTT-EDIL PHARMACIA LIMITED-56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE TIN,1.0X500.0 CAPSULE TIN, 1.0X10.0X10.0 CAPSULE BLISTER | 13/01/2023 |
| 682 | NDA/MAL/HDP /10316 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TELFOCUS 20 | TELMISARTAN | 20 MG | AUROBINDO PHARMA LTD, UNIT VII-SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 683 | NDA/MAL/HDP /10317 | Y.S.P. INDUSTRIES (M) SDN. BHD. | ROYAL PHARMA 2011 LIMITED | VOREN SUPPOSITORY 100 MG | DICLOFENAC SODIUM | 100MG | Y.S.P INDUSTRIES (M) SDN BHN.-LOT 3, 5 & 7, JALAN P/7, SECTION 13, KAWASAN PENDUSTRIAN BANDAR BARU BANGI, 43000, KAJANG, SELANGOR, MALAYSIA | MALAYSIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY STRIP | 03/10/2022 |

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| 684 | NDA/MAL/HDP /10318 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TELFOCUS 40 | TELMISARTAN | 40 MG | AUROBINDO PHARMA LTD, UNIT VII-SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 685 | NDA/MAL/HDP /10319 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TELFOCUS 80 | TELMISARTAN | 80 MG | AUROBINDO PHARMA LTD, UNIT VII-SY. NO. 411/P, 425/P, 434/P, 435/P & 458/P, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (SEZ), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/09/2022 |
| 686 | NDA/MAL/HDP /10320 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | METROSCOT 125MG/5ML | METRONIDAZOLE BENZOATE | 125MG/5ML | M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 03/10/2022 |

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| 687 | NDA/MAL/HDP/10321 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | CYPROVIT | CYPROHEPTADINE HYDROCHLORIDE + VITAMIN A + COLECALCIFEROL (VITAMIN D3) + THIAMINE HYDROCHLORIDE + RIBOFLAVIN + CYANOCOBALAMIN + NICOTINAMIDE + CALCIUM | 4 MG + 1500 IU + 300 IU + 2 MG + 2 MG + 5 MCG + 10 MG + 5 MG + 20 MG + 50 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 04/10/2022 |
| 688 | NDA/MAL/HDP/10322 | CACHET PHARMACEUTICALS PVT LIMITED | ASTRA PHARMA (U) LIMITED | ORAFLOX | LEVOFLOXACIN HEMIHYDRATE | 500MG | CACHET PHARMACEUTICAL PVT LTD.-VILLAGE-THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH-173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 19/09/2022 |
| 689 | NDA/MAL/HDP/10323 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | XELTIN | TOFACITINIB CITRATE | 5MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 690 | NDA/MAL/HDP/10325 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | ONCET | CETIRIZINE DIHYDROCHLORIDE | 5MG/5ML | MEDLEY PHARMACEUTICALS LTD-PLOT 18 & 19 SURVEY NO. 378/7&8, 379/2&3 ZARI CAUSEWAY ROAD, KACHIGAM DAMAN-396210, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 19/09/2022 |
| 691 | NDA/MAL/HDP/10326 | SUNRISE INTERNATIONAL LABS LTD | ROYAL PHARMA 2011 LIMITED | RISEOL 50 | TRAMADOL HYDROCHLORIDE | 50MG | SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 19/09/2022 |
| 692 | NDA/MAL/HDP/10327 | ESKAYEF PHARMACEUTICALS LTD. | SWASTIK PHARMACEUTICAL LTD | DUMAX 30 | DAPOXETINE HYDROCHLORIDE | 30MG | ESKAYEF BANGLADESH LTD-TONGI PLANT-400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X4.0 TABLET BLISTER | 19/09/2022 |

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| 693 | NDA/MAL/HDP/10329 | ESKAYEF PHARMACEUTICALS LTD. | SWASTIK PHARMACEUTICAL LTD | TAMENOL | PARACETAMOL + TRAMADOL HYDROCHLORIDE | 325 MG + 37.5 MG | ESKAYEF BANGLADESH LTD-TONGI PLANT-400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 19/09/2022 |
| 694 | NDA/MAL/HDP/1033 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DYNAMOGEN | GLUTODINE (CYPROHEPTADINE ALPHA-KETOGLUTARATE) + ARGININE ASPARTATE | 3MG +1G | FAES FARMA, S.A -MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA | SPAIN | ORAL LIQUID ORDINARY LIQUIDS | 1.0X20.0X10.0 ML SACHET | 01/07/2015 |
| 695 | NDA/MAL/HDP/10333 | PHARMA BAVARIA INTERNACIONAL PORTUGAL | GOODMAN INTERNATIONAL LTD | FLUCAVEX | PARACETAMOL + ASCORBIC ACID + PHENIRAMINE MALEATE | 500 MG + 25 MG + 200 MG | FARMEA-10 RUE BOUCHE THOMAS, ZAC D'ORGEMONT, 49007 ANGERS CEDEX 01 | FRANCE | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X8.0 SACHET CARTON | 03/10/2022 |

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| 696 | NDA/MAL/HDP/10335 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | PRIDOCAINE | LIDOCAINE + PRILOCAINE | 2.5% W/W + 2.5%W/W | GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY | EGYPT | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 19/09/2022 |
| 697 | NDA/MAL/HDP/10336 | BIOLOGICAL E. LIMITED- | GITTOES PHARMACEUTICALS LIMITED | MEASLES AND RUBELLA VACCINE (LIVE) (ATTENUATED, FREEZE DRIED) | MEASLES VIRUS (CAM-70 STRAIN) + RUBELLA VIRUS (WISTAR RA 27/3 STRAIN) | (≥ 1000 CCID50 + ≥ 1000 CCID50)/0.5 ML( DOSE) | BIOLOGICAL E. LIMITED - PLOT NO. 1, BIOTECH PARK, PHASE-II, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELENGANA STATE, 500078 - INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X5.0 DOSE VIAL + 1*50*2.5ML AMPOULE OF NACL,1.0X50.0X10.0 DOSE VIAL + 1*50*5ML AMPOULE OF NACL | 03/10/2022 |
| 698 | NDA/MAL/HDP/10338 | NEOMI PHARMACEUTICALS PVT LTD - | ROYAL PHARMA 2011 LIMITED | ROART 20/120 | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X24.0 TABLET BLISTER | 19/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 699 | NDA/MAL/HDP/1034 | VOGEN LABORATORIES LTD | BUFFALO HEALTH CARE LTD | DURAMOX | AMOXICILLIN | 250MG/5ML | VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS | CYPRUS | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 700 | NDA/MAL/HDP/10340 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | KERELLA | BETAMETHASONE DIPROPIONATE + SALICYLIC ACID | (0.5 MG+ 220 MG)/G | GLOBAL NAPI PHARMACEUTICALS-2ND INDUSTRIAL ZONE, ST 18, 6TH OCTOBER CITY | EGYPT | TOPICAL EXTERNAL LOTIONS | 1.0X1.0X30.0 ML BOTTLE | 19/09/2022 |
| 701 | NDA/MAL/HDP/10342 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RHINOMAX | BUDESONIDE | 64MCG/ DOSE | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | NASAL TOPICAL METERED DOSE AEROSOLS | 1.0X120.0 METERED DOSE BOTTLE | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 702 | NDA/MAL/HDP /10343 | DAWA LIMITED- | SUPER MEDIC LTD | KENAZOLE | KETOCONAZOLE | 2%W/W | DAWA LIMITED-PLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 19/09/2022 |
| 703 | NDA/MAL/HDP /10346 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 2011 LIMITED | LACTORIV | LACTULOSE | 10 G/15 ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X120.0 ML BOTTLE | 19/09/2022 |
| 704 | NDA/MAL/HDP /10347 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 2011 LIMITED | PENTARIV-40 | PANTOPRAZOLE SODIUM | 40MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | PARENTERAL RETARD DRY VIALS | 1.0X1.0X40.0 MG VIAL + 1*10ML LDPE AMPOULE OF NACL | 19/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 705 | NDA/MAL/HDP /10349 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | GLUMAC | ARTEMETHER + LUMEFANTRINE | 80MG + 480MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 19/09/2022 |
| 706 | NDA/MAL/HDP /1035 | B&O PHARM | TRIDEM PHARMA UGANDA LIMITED | G-CIPROX | CIPROFLOXACIN | 500MG | GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 707 | NDA/MAL/HDP /10350 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ANCOLIN-ME | PREGABALIN + METHYLCOBALAMIN | 75 MG + 750 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 708 | NDA/MAL/HDP /10351 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROYALTRIM 160 MG + 800 MG | TRIMETHOPRIM + SULFAMETHOXAZOLE | 160 MG + 800 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 709 | NDA/MAL/HDP /10352 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROYALTRIM 80 MG + 400 MG | TRIMETHOPRIM + SULFAMETHOXAZOLE | 80 MG + 400 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 710 | NDA/MAL/HDP /10353 | CENTURION LABORATORIES PVT. LTD. | MEDIWORLD PHARMA AFRICA LTD | PAINAID | PARACETAMOL + IBUPROFEN + CAFFEINE | 400 MG + 325 MG + 40 MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 19/09/2022 |

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| 711 | NDA/MAL/HDP /10354 | AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD | ROYAL PHARMA 2011 LIMITED | C-STOL | MISOPROSTOL | 200MCG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 712 | NDA/MAL/HDP /10355 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | RIVATAS 15 | RIVAROXABAN | 15 MG | INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/10/2022 |
| 713 | NDA/MAL/HDP /10356 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | RIVATAS 20 | RIVAROXABAN | 20MG | INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X0.01 TABLET BLISTER | 03/10/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 714 | NDA/MAL/HDP /10357 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROMOXI 125 | AMOXICILLIN TRIHYDRATE | 125 MG/5ML | PIL PHARMACEUTICALS (PVT) LIMITED-PLOT NO. 71 & 72, SECTOR -6A, IIE, SIDCUL, HARIDWAR- 249403( UTTARAKHARD) | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 19/09/2022 |
| 715 | NDA/MAL/HDP /10358 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | VOLDIC - K | DICLOFENAC POTASSIUM | 50MG | PHARMA INTERNATIONAL CO. LTD -AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 19/09/2022 |
| 716 | NDA/MAL/HDP /10360 | KESAR PHARMA | SWASTIK PHARMACEUTICAL LTD | TERBIQUITE | TERBINAFINE HYDROCHLORIDE | 1.0% W/W | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 19/09/2022 |

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| 717 | NDA/MAL/HDP /10361 | AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD | ROYAL PHARMA 2011 LIMITED | AFRICAL | CALCIUM LACTATE | 300 MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 718 | NDA/MAL/HDP /10363 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RO - AMIKACIN | AMIKACIN SULFATE | 500 MG/2 ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X2.0 ML VIAL | 19/09/2022 |
| 719 | NDA/MAL/HDP /10364 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROYO-CORT INJ | HYDROCORTISONE SODIUM SUCCINATE | 100 MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X100.0 MG VIAL | 19/09/2022 |

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| 720 | NDA/MAL/HDP /10365 | MYLAN LABORATORIES LIMITED- | KIMSY MEDS LTD | MYLTEGA DT | DOLUTEGRAVIR SODIUM | 10MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X90.0 TABLET BOTTLE | 19/09/2022 |
| 721 | NDA/MAL/HDP /10367 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | SUVITRA – 750 | LEVETIRACETAM | 750MG | MICRO LABS LIMITED, HOSUR-NO. 92, SIPCOT INDUSTRIAL COMPLEX, HOSUR 635126 TAMIL NADU - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 722 | NDA/MAL/HDP /10368 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SITAPRIL 25 | SITAGLIPTIN PHOSPHATE MONOHYDRATE | 25MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 723 | NDA/MAL/HDP /10369 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SITAPRIL 50 | SITAGLIPTIN PHOSPHATE MONOHYDRATE | 50MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 724 | NDA/MAL/HDP /10370 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SITAPRIL 100 | SITAGLIPTIN PHOSPHATE MONOHYDRATE | 100MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 725 | NDA/MAL/HDP /10371 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROLEXIN 250 | CEFALEXIN MONOHYDRATE | 250MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 19/09/2022 |

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| 726 | NDA/MAL/HDP /10372 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | IPOPRIN 2 | POMALIDOMIDE | 2MG | MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY DISTRICT, PIN CODE, 509 228, TELENGANA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X21.0 CAPSULE BOTTLE | 19/09/2022 |
| 727 | NDA/MAL/HDP /10373 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | IPOPRIN 4 | POMALIDOMIDE | 4MG | MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY DISTRICT, PIN CODE, 509 228, TELENGANA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X21.0 CAPSULE BOTTLE | 19/09/2022 |
| 728 | NDA/MAL/HDP /10374 | B&O PHARM | TRIDEM PHARMA UGANDA LIMITED | FERLIX ®FOLIX | FERROUS SULFATE + FOLIC ACID | 200 MG + 0.4 MG | BIO NOVA PHARMACEUTICALS PVT.LTD-C-66/1, OKHLA INDUSTRIAL AREA, PHASE –II, NEW DELHI INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 729 | NDA/MAL/HDP /10375 | AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD | ROYAL PHARMA 2011 LIMITED | AFRI-FLU | PARACETAMOL + CAFFEINE + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMINE MALEATE | 500 MG + 15 MG + 5 MG + 2 MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 730 | NDA/MAL/HDP /10376 | SURGE LABORATORIES (PVT.) LTD. | HEALTHCARE LTD. | XTRACEF 1G INJECTION | CEFOPRAZONE SODIUM + SULBACTUM SODIUM | 0.5G + 0.5G | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL + 1*5ML AMPOULE OF WFI | 21/09/2022 |
| 731 | NDA/MAL/HDP /10377 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AROXICAM 15 | MELOXICAM | 15MG | AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 732 | NDA/MAL/HDP /10378 | CENTURION LABORATORIES PVT. LTD. | VRUSHIK INVESTMENT LIMITED | ESOMIZAP | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 40MG | CENTURION LABORATORIES PVT LTD-PLOT NO 2, BIO-TECH PARK, MANJUSAR, TAL-SAVLI VADODARA, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 733 | NDA/MAL/HDP /10379 | LITHA PHARMA (PTY) LTD. | LABOREX UGANDA LIMITED | ORATANE® 10 MG | ISOTRETINOIN | 10MG | SWISS CAPS AG-HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND DOUGLAS MANUFACTURING LIMITED-CORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND | NEW ZEALAND SWITZERLAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X4.0X15.0 CAPSULE BLISTER | 19/09/2022 |
| 734 | NDA/MAL/HDP /10380 | LITHA PHARMA (PTY) LTD. | LABOREX UGANDA LIMITED | ORATANE® 20 MG | ISOTRETINOIN | 20MG | SWISS CAPS AG-HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND DOUGLAS MANUFACTURING LIMITED-CORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND | NEW ZEALAND SWITZERLAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X4.0X15.0 CAPSULE BLISTER | 19/09/2022 |

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| 735 | NDA/MAL/HDP /10381 | LITHA PHARMA (PTY) LTD. | LABOREX UGANDA LIMITED | ORATANE® 40 MG | ISOTRETINOIN | 40MG | SWISS CAPS AG-HUSENSTRASSE 35, CH-9533 KIRCHBERG (SG) - SWITZERLAND DOUGLAS MANUFACTURING LIMITED-CORNER TE PAI PLACE AND CENTRAL PARK DRIVE, LINCOLN, AUCKLAND 0610 - NEW ZEALAND | NEW ZEALAND SWITZERLAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X2.0X15.0 CAPSULE BLISTER | 19/09/2022 |
| 736 | NDA/MAL/HDP /10382 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | PINN-TRYPTILLIN | AMITRIPTYLINE HYDROCHLORIDE | 25MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 19/09/2022 |
| 737 | NDA/MAL/HDP /10383 | AGIO PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | IBUPEN PLUS SUSPENSION | IBUPROFEN + PARACETAMOL | (100MG + 162.5 MG)/ 5ML | AGIO PHARMACEUTICALS LIMITED.-T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X60.0 ML BOTTLE | 19/09/2022 |

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| 738 | NDA/MAL/HDP/10384 | SANJAR PHARMA LLP. | MOTI PHARMA (UGANDA) LIMITED | MOFENAC | DICLOFENAC SODIUM | 75MG/3ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X3.0 ML AMPOULE | 19/09/2022 |
| 739 | NDA/MAL/HDP/10385 | XL LABORATORIES PRIVATE LIMITED- | ROYAL PHARMA 2011 LIMITED | SOFKOF | DEXTROMETHORPHAN HYDROBROMIDE + PHENYLEPHRINE HYDROCHLORIDE + CHORPHENIRAMINE MALEATE | 10MG + 5MG + 2MG | XL LABORATORIES PRIVATE LIMITED-A-141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA) | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 19/09/2022 |
| 740 | NDA/MAL/HDP/10386 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | OLMAC 5 | OLANZAPINE | 5MG | MACLEODS PHARMACEUTICALS LIMITED, UNIT VI-VILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH–174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |

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| 741 | NDA/MAL/HDP /10387 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | OLMAC 10 | OLANZAPINE | 10MG | MACLEODS PHARMACEUTICALS LIMITED, UNIT VI-VILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH–174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 19/09/2022 |
| 742 | NDA/MAL/HDP /10388 | AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD | HEALTHCARE LTD. | DEXOMETH-N CREAM | NEOMYCIN SULPHATE + DEXAMETHASONE SODIUM PHOSPHATE | (5MG + 1MG)/ G | AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 19/09/2022 |
| 743 | NDA/MAL/HDP /10389 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 2011 LIMITED | VIREXIM INJECTION | CEFTRIAXONE SODIUM | 1G | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 1*10ML AMPOULE OF WFI | 19/09/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 744 | NDA/MAL/HDP /10390 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN DT 40/240 | ARTEMETHER + LUMEFANTRINE | 40MG + 240MG | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 19/09/2022 |
| 745 | NDA/MAL/HDP /10391 | SANDOZ GMBH . | SURGIPHARM (U) LIMITED | HYDROXYUREA 100MG | HYDROXYCARBAMIDE | 100MG | HAUPT PHARMA AMAREG GMBH-DONAUSTAUFER STRASSE 378, 93055 REGENSBURG SIEGFRIED BARBERA, S.L.-RONDA SANTA MARIA 158, 08210 BARBERA DEL VALLES, BARCELONA, SPAIN. | GERMANY SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X60.0 TABLET BOTTLE,1.0X1.0X90.0 TABLET BOTTLE,1.0X1.0X120.0 TABLET BOTTLE | 19/09/2022 |
| 746 | NDA/MAL/HDP /10392 | SANDOZ GMBH . | SURGIPHARM (U) LIMITED | HYDROXYUREA 1000MG | HYDROXYCARBAMIDE | 1000MG | HAUPT PHARMA AMAREG GMBH-DONAUSTAUFER STRASSE 378, 93055 REGENSBURG SIEGFRIED BARBERA, S.L.-RONDA SANTA MARIA 158, 08210 BARBERA DEL VALLES, BARCELONA, SPAIN. | GERMANY SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 19/09/2022 |

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| 747 | NDA/MAL/HDP /10393 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENDOKEY 25 | BENDAMUSTINE HYDROCHLORIDE | 25MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X1.0X25.0 MG VIAL | 19/09/2022 |
| 748 | NDA/MAL/HDP /10394 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENDOKEY 100 | BENDAMUSTINE HYDROCHLORIDE | 100MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X1.0X100.0 MG VIAL | 19/09/2022 |
| 749 | NDA/MAL/HDP /10395 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENDOKEY | BENDAMUSTINE HYDROCHLORIDE | 100MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X4.0 ML VIAL | 19/09/2022 |

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| 750 | NDA/MAL/HDP /10417 | CADILA HEALTHCARE LIMITED | ABACUS PHARMA (A) LIMITED | DUONAS | AZELASTINE HYDROCHLORIDE + FLUTICASONE PROPIONATE | 137MCG/50MCG PER ACTUATION | CADILA HEALTHCARE LIMITED, PLOT NO. 417, 419, 420, SARKHEJ-BAVLA N.H. NO. 8A, VILLAGE: MORAIYA, TAL.: SANAND, DIST.: AHMEDABAD - 382 210, INDIA | INDIA | NASAL SPRAY | 1.0X1.0X30.0 ML BOTTLE | 10/02/2023 |
| 751 | NDA/MAL/HDP /10418 | AJANTA PHARMA LIMITED | ABACUS PHARMA (A) LIMITED | KAMAGRA CT 100 | SILDENAFIL CITRATE | 100 MG | AJANTA PHARMA LIMITED, B-4-5-6, MIDC INDUSTRIAL AREA PAITHAN, AURANGABAD, 431148 AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 10/02/2023 |
| 752 | NDA/MAL/HDP /10419 | AJANTA PHARMA LIMITED | ABACUS PHARMA (A) LIMITED | SITAPRIL M 50/1000 | SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE | 50 MG + 1000 MG | AJANTA PHARMA LIMITED B-4-5-6, MIDC INDUSTRIAL AREA PAITHAN, AURANGABAD, 431148 DIST: AURANGABAD MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 753 | NDA/MAL/HDP/1042 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO TELVAS-H 80/12.5 | TELMISARTAN +HYDROCHLOROTHIAZIDE | 80MG +12.5 MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 754 | NDA/MAL/HDP/10420 | AJANTA PHARMA LIMITED | ABACUS PHARMA (A) LIMITED | SITAPRIL M 50/500 | SITAGLIPTIN PHOSPHATE MONOHYDRATE + METFORMIN HYDROCHLORIDE | 50 MG + 500 MG | AJANTA PHARMA LIMITED B-4-5-6, MIDC INDUSTRIAL AREA PAITHAN, AURANGABAD, 431148 DIST: AURANGABAD MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 755 | NDA/MAL/HDP/10421 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (A) LIMITED | MIOPOLOL ER 50 | METOPROLOL SUCCINATE | 50 MG | INVENTIA HEALTHCARE LIMITED F1-F1/1, F75/1 ADDITIONAL AMBERNATH M.I.D.C., AMBERNATH (EAST) - 421 506, DIST. THANE, INDIA | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 756 | NDA/MAL/HDP /10422 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (A) LIMITED | MIOPOLOL ER 25 | METOPROLOL SUCCINATE | 25 MG | INVENTIA HEALTHCARE LIMITED F1-F1/1, F75/1 ADDITIONAL AMBERNATH M.I.D.C., AMBERNATH (EAST) - 421 506, DIST. THANE, INDIA | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 757 | NDA/MAL/HDP /10423 | S KANT HEALTHCARE LTD | ABACUS PHARMA (A) LTD | MALAKANT DISPERSIBLE JUNIOR | SULFADOXINE + PYRIMETHAMINE | 250MG + 12.5MG | S KANT HEALTHCARE LIMITED FORMULATION BLOCK: PLOT NO. 1802-1805, G.I.D.C., PHASE III, VAPI 396195. GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X25.0X3.0 TABLET BLISTER | 10/02/2023 |
| 758 | NDA/MAL/HDP /10424 | S KANT HEALTHCARE LTD | ABACUS PHARMA (A) LTD | MALAKANT DISPERSIBLE | SULFADOXINE + PYRIMETHAMINE | 500MG + 25MG | S KANT HEALTHCARE LIMITED FORMULATION BLOCK: PLOT NO. 1802-1805, G.I.D.C., PHASE III, VAPI 396195. GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X25.0X3.0 TABLET BLISTER | 10/02/2023 |

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| 759 | NDA/MAL/HDP /10425 | SUPREME PHARMA HEALTHCARE PVT. LTD | ABACUS PHARMA (U) LTD | FLOXYPREME-500 | LEVOFLOXACIN HEMIHYDRATE | 500 MG | SAI MIRRA INNOPHARM PVT. LTD. 288 & 299, SIDCO ESTATE, CHENNAI, INDIA-600 098 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 760 | NDA/MAL/HDP /10426 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA(A) LIMITED | SUPAGREL 90 | TICAGRELOR | 90 MG | MSN LABORATORIES PRIVATE LIMITED - FORMULATIONS DIVISION FORMULATIONS DIVISION, UNIT-II, SURVEY NOS. 1277, 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANGAREDDY DISTRICT, TELANGANA 509228, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 761 | NDA/MAL/HDP /10427 | AJANTA PHARMA LIMITED | ABACUS PHARMA(A) LIMITED | CELMAC 400 | CELECOXIB | 40 MG | AJANTA PHARMA LIMITED, B-4-5-6, MIDC INDUSTRIAL AREA PAITHAN, AURANGABAD, 431148 DIST: AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 762 | NDA/MAL/HDP /10428 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | AMOXI-DENK 1000 | AMOXICILLIN TRIHYDRATE | 1000 MG | PENCEF PHARMA GMBH BREITENBACHSTR. 13-14 13509 BERLIN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 763 | NDA/MAL/HDP /10429 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | AMOXI-DENK 500 | AMOXICILLIN TRIHYDRATE | 500 MG | PENCEF PHARMA GMBH BREITENBACHSTR. 13-14 13509 BERLIN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 764 | NDA/MAL/HDP /10430 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | QUADRIMUNE | ABACAVIR + LAMIVUDINE + LOPINAVIR + RITONAVIR | 30 MG + 15 MG + 40 MG +10 MG | CIPLA LIMITED, GOA (UNIT VII) PLOT NO. S-103 TO S-105, S-107 TO S-112 & L-147, L-147/1 TO L-147/3, L-147/A & L-138 VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE, GOA – 403 722, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X120.0 CAPSULE CONTAINER | 10/02/2023 |

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| 765 | NDA/MAL/HDP /10431 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | CLAMOXIN 375 INJECTION | AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE | 250 MG + 125 MG/VIAL | MEDOPHARM PRIVATE LIMITED NO.50, KAYARAMBEDU VILLAGE, GUDUVANCHERY CHENGALPET DISTRICT TAMILNADU-INDIA 603 202. | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1*1, GLASS VIAL + 1*20 ML WFI IN LDPE | 10/02/2023 |
| 766 | NDA/MAL/HDP /10432 | GUFIC LIFESCIENCES PRIVATE LIMITED | EUROPA HEALTHCARE (U) LTD | VAMOCIN 500 | VANCOMYCIN HYDROCHLORIDE | 500MG PER VIAL | GUFIC BIOSCIENCES LIMITED (UNIT 2) SURVEY NO. 171, N.H. NO.8, NEAR GRID KABILPORE NAVSARI – 396424 GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1*1, GLASS VIAL | 10/02/2023 |
| 767 | NDA/MAL/HDP /10433 | BIOLOGICAL E. LIMITED | GITTOES PHARMACEUTICALS LTD | TETANUS ANTITOXIN 1500 IU/ML BP | TETANUS ANTITOXIN | 1500 IU/ML | BIOLOGICAL E LIMITED,18 / 1 & 3, AZAMABAD, HYDERABAD, TELANGANA, INDIA – 500 020 | INDIA | PARENTERAL ORDINARY VIALS | 1*1*20ML CLEAR GLASS VIAL | 10/02/2023 |

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| 768 | NDA/MAL/HDP/10434 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY | AZIBRU | AZITHROMYCIN DIHYDRATE | 200 MG/5 ML | BRAWN LABORATORIES LTD., 13, NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001, (HARYANA), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML BOTTLE | 10/02/2023 |
| 769 | NDA/MAL/HDP/10435 | PROFARMA SH.A | JOINT MEDICAL STORES | AFEBRIL 5 MG/2.5ML | DIAZEPAM | 5MG/2.5ML | PROFARMA SH.A.RRUGA: MYSLYM KETA TIRANA ALBANIA | ALBANIA | RECTAL SOLUTION | 1*5*1, 2.5 LDPE VIALS | 10/02/2023 |
| 770 | NDA/MAL/HDP/10436 | YICHANG HUMANWELL PHARMACEUTICAL CO., LTD. | KAIYUANTANG (U) LIMITED | PETHIDINE HYDROCHLORIDE INJECTION | PETHIDINE HYDROCHLORIDE | 50 MG/ML | YICHANG HUMANWELL PHARMACEUTICAL CO., LTD. NO. 19, DALIAN ROAD, DEVELOPMENT ZONE, YICHANG, HUBEI, CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X2.0 ML AMPOULES | 10/02/2023 |

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| 771 | NDA/MAL/HDP /10437 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD. | GEMCITABINE 200 MG/5ML | GEMCITABINE | 200 MG/5ML ARTWORK TO BE PRINTED | EBEWE PHARMA GES.M.B.H. NFG.KG MONDSEESTRAßE 11 A-4866 UNTERACH AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1*1, 100 ML CLEAR GLASS VIAL | 10/02/2023 |
| 772 | NDA/MAL/HDP /10438 | JANSSEN-CILAG INTERNATIONAL NV | MEDICAL ACCESS (U) LIMITED | ZABDENO | ADENOVIRUS TYPE 26 ENCODING THE ZAIRE EBOLAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN (GP), | NOT LESS THAN 8.75 LOG 10 INFECTIOUS UNITS (INF.U),/DOSE (0.5 ML) | IDT BIOLOGIKA GMBH AM PHARMAPARK, 06861 DESSAU-ROSSLAU GERMANY (MANUFACTURE) + JANSSEN BIOLOGICS B.V. EINSTEINWEG 101, 2333 CB LEIDEN THE NETHERLANDS ( BATCH RELEASE) | GERMANY | SUSPENSION FOR INJECTION | 1.0X20.0X0.5 ML VIAL | 10/02/2023 |
| 773 | NDA/MAL/HDP /10439 | JANSSEN-CILAG INTERNATIONAL NV | MEDICAL ACCESS (U) LIMITED | MVABEA | ONE DOSE (0.5 ML) CONTAINS:MODIFIED VACCINIA ANKARA BAVARIAN NORDIC VIRUS* ENCODING THE: ZAIRE EBOLAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN (GP), SUDAN | NOT LESS THAN 0.7 X 108 INFECTIOUS UNITS (INF.U), /DOSE (0.5 ML) | IDT BIOLOGIKA GMBH AM PHARMAPARK, 06861 DESSAU-ROSSLAU GERMANY (MANUFACTURE) + JANSSEN BIOLOGICS B.V. EINSTEINWEG 101, 2333 CB LEIDEN THE NETHERLANDS ( BATCH RELEASE) | GERMANY | SUSPENSION FOR INJECTION | 1.0X20.0X0.5 ML VIAL | 10/02/2023 |

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| 774 | NDA/MAL/HDP/1044 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ANGINET 80MG | VALSARTAN | 80MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 775 | NDA/MAL/HDP/10440 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | PHENIREX | CHLORPHENAMINE MALEATE | 4 MG | CENTURION LABORATORIES PVT. LTD, PLOT NO. P-2, SAVALI BIOTECH PARK, AT. MANJUSAR, TAL-SAVALI, CITY: MANJUSAR, DIST. - VADODARA, GUJARAT - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 776 | NDA/MAL/HDP/10441 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | PREDNOVA 5 | PREDNISOLONE | 5 MG | CENTURION LABORATORIES PVT. LTD, PLOT NO. P-2, SAVALI BIOTECH PARK, AT. MANJUSAR, TAL-SAVALI, CITY: MANJUSAR, DIST. - VADODARA, GUJARAT - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 777 | NDA/MAL/HDP /10442 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | ACECARB | CARBAMAZEPINE | 200 MG | CENTURION LABORATORIES PVT. LTD, PLOT NO. P-2, SAVALI BIOTECH PARK, AT. MANJUSAR, TAL-SAVALI, CITY: MANJUSAR, DIST. - VADODARA, GUJARAT - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 778 | NDA/MAL/HDP /10443 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | FUNGIDERM | CLOTRIMAZOLE | 1 % W/W | NANZ MED SCIENCE PHARMA PVT LTD VILLAGE RAMPUR GHAT, TEHSIL PAONTA SAHIB, DIST. SIRMOUR – 173025, HIMACHAL PRADESH, INDIA. | INDIA | TOPICAL EXTERNAL CREAM | 1*1*20G, LAMI TUBE | 10/02/2023 |
| 779 | NDA/MAL/HDP /10444 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | STERODERM OINTMENT | BETAMETHASONE VALERATE | 0.1 % W/W | NANZ MED SCIENCE PHARMA PVT LTD VILLAGE RAMPUR GHAT, TEHSIL PAONTA SAHIB, DIST. SIRMOUR – 173025, HIMACHAL PRADESH, INDIA. | INDIA | TOPICAL EXTERNAL OINTMENT | 1*1*15G, LAMI TUBE | 10/02/2023 |

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| 780 | NDA/MAL/HDP /10445 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | STERODERM CREAM | BETAMETHASONE VALERATE | 0.1 % W/W | NANZ MED SCIENCE PHARMA PVT LTD VILLAGE RAMPUR GHAT, TEHSIL PAONTA SAHIB, DIST. SIRMOUR – 173025, HIMACHAL PRADESH, INDIA. | INDIA | TOPICAL EXTERNAL CREAM | 1*1*15G, LAMI TUBE | 10/02/2023 |
| 781 | NDA/MAL/HDP /10446 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | ZITHROPLUS 500 | AZITHROMYCIN DIHYDRATE | 500 MG | BIOMATRIX HEALTHCARE PVT LTD. SURVEY NO. 624, SARKHEJ – BAVLA HIGHWAY, VIL.: RAJODA, TAL.: BAVLA, DIST.: AHMEDABAD – 382 220, GUJARAT, INDIA | INIDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X1.0X3.0 TABLET BLISTER | 10/02/2023 |
| 782 | NDA/MAL/HDP /10447 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | TRADOSIK | TRAMADOL HYDROCHLORIDE | 50 MG/ML | PT. SANBE FARMA STERILE PREPARATION PLANT JL. INDUSTRI CIMAREME NO. 8, DESA CIMAREME, KECAMATAN NGAMPRAH, KABUPATEN BANDUNG BARAT – INDONESIA (UNIT 3) | INDONESIA | PARENTERAL ORDINARY AMPOULES | 1*2*5, CLEAR GLASS AMPOULE | 10/02/2023 |

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| 783 | NDA/MAL/HDP /10448 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | DOLONES | LIDOCAINE + PRILOCAINE | (25 MG + 25 MG)/G | PT CAPRIFARMINDO LABS, JL. INDUSTRI CIMAREME NO. 8, DS. CIMAREME. KEC.PADALARANG, KABUPATEN BANDUNG BARAT, INDONESIA | INDONESIA | TOPICAL EXTERNAL CREAM | 1*1, 5 G ALUMINIUM COLLAPSIBLE TUBE | 10/02/2023 |
| 784 | NDA/MAL/HDP /10449 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | POLIDEMISIN | NEOMYCIN SULFATE + POLIMYXYN B SULFATE + DEXAMETHASONE | (3.5 MG + 6000 IU + 1 MG)ML | PT CAPRIFARMINDO LABS, JL. INDUSTRI CIMAREME NO. 8, DS. CIMAREME. KEC.PADALARANG, KABUPATEN BANDUNG BARAT, INDONESIA | INDONESIA | OPHTHALMIC SUSPENSION | 1.0X1.0X5.0 ML BOTTLE | 10/02/2023 |
| 785 | NDA/MAL/HDP /10450 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | MEFINAL 500 | MEFENAMIC ACID | 500 MG | PT CAPRIFARMINDO LABS, JL. INDUSTRI CIMAREME NO. 8, DS. CIMAREME. KEC.PADALARANG, KABUPATEN BANDUNG BARAT, INDONESIA | INDONESIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1*10*10, POLYCELLONIUM STRIP PACK | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 786 | NDA/MAL/HDP/10451 | LINCOLN PHARMACEUTICALS LIMITED | METRO PHARMACEUTICALS LTD | WAXFREE | SODIUM BICARBONATE | 5%W/V | LINCOLN PARENTERAL LIMITED<br>11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, GANDHINAGAR, GUJARAT, INDIA. | INDIA | NASAL DROPS | 1.0X1.0X10.0 ML BOTTLE | 10/02/2023 |
| 787 | NDA/MAL/HDP/10452 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA (U) LIMITED | OPTIPRED | PREDNISOLONE ACETATE | 1.0% W/V | JAMJOOM PHARMACEUTICALS COMPANY<br>PLOT NO. ME1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267,<br>JEDDAH-21442, KINGDOM OF SAUDI ARABIA | SAUDI ARABIA | OPHTHALMIC SUSPENSION | 1.0X1.0X5.0 ML BOTTLE | 10/02/2023 |
| 788 | NDA/MAL/HDP/10453 | SANJAR PHARMA LLP | NILKANTH PHARMACY LIMITED | ARTICURE 60MG | ARTESUNATE | 60MG PER VIAL | SANJAR PHARMA LLP<br>SURVEY NO. 622/2/1/4, DEDHROTA, TA – HIMATNAGAR, DISTRICT SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1, GLASS VIAL + 10ML OF 0.9% SODIUM CHLORIDE SOLUTION, LDPE AMPOULE + 1ML OF 5.0% SODIUM BICARBONATE SOLUTION, GLASS AMOULE | 10/02/2023 |

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| 789 | NDA/MAL/HDP /10454 | PAMAJITA INTERNATIONAL LPP | NILKANTH PHARMACY LIMITED | OMEZOLE | OMEPRAZOLE SODIUM | 40MG PER VIAL | SANJAR PHARMA LLP SURVEY NO. 622/2/1/4, DEDHROTA, TA – HIMATNAGAR, DISTRICT SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1, GLASS VIAL + 10ML OF WATER FOR INJECTION, GLASS AMPOULE | 10/02/2023 |
| 790 | NDA/MAL/HDP /10455 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | ENOXAMED 2000 IU ANTI-XA /0.2 ML | ENOXAPARIN SODIUM | 2000 IU ANTI-XA /0.2 ML (EQUIVALENT TO 20 MG PER 0.2 ML) | UNIMED LABORATORIES P.O.BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | TUNISIA | PARENTERAL ORDINARY PRE-FILLED SYRINGE | 1*1*2, 0.2 ML PRE-FILLED SYRINGE | 10/02/2023 |
| 791 | NDA/MAL/HDP /10456 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | ENOXAMED 4000 IU ANTI-XA /0.4 ML | ENOXAPARIN SODIUM | 4000 IU ANTI-XA /0.4 ML (EQUIVALENT TO 40 MG PER 0.4 ML) | UNIMED LABORATORIES P.O.BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | TUNISIA | PARENTERAL ORDINARY PRE-FILLED SYRINGE | 1*1*2, 0.4 ML PRE-FILLED SYRINGE | 10/02/2023 |

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| 792 | NDA/MAL/HDP /10457 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | ENOXAMED 6000 IU ANTI-XA /0.6 ML | ENOXAPARIN SODIUM | 6000 IU ANTI-XA /0.6 ML (EQUIVALENT TO 60 MG PER 0.6 ML) | UNIMED LABORATORIES P.O.BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | TUNISIA | PARENTERAL ORDINARY PRE-FILLED SYRINGE | 1*1*2, 0.4 ML PRE-FILLED SYRINGE | 10/02/2023 |
| 793 | NDA/MAL/HDP /10458 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | ENOXAMED 8000 IU ANTI-XA /0.8 ML | ENOXAPARIN SODIUM | 8000 IU ANTI-XA /0.8 ML (EQUIVALENT TO 80 MG PER 0.8 ML) | UNIMED LABORATORIES P.O.BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | TUNISIA | PARENTERAL ORDINARY PRE-FILLED SYRINGE | 1*1*2, 0.4 ML PRE-FILLED SYRINGE | 10/02/2023 |
| 794 | NDA/MAL/HDP /10459 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | PARAMED | PARACETAMOL | 1G/100ML | UNIMED LABORATORIES P.O.BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | TUNISIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1*6*1*1, 100 ML MULTILAYED PLASTIC BAG IN ALUMINIUM FILM SACHETS | 10/02/2023 |

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| 795 | NDA/MAL/HDP /10460 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | AERIALLERG 5MG | DESLORATIDINE | 5 MG | PHARMA INTERNATIONAL COMPANY –PIC AL QASTAL INDUSTRIAL ZONE P.O. BOX 334 AMMAN 11941 JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 796 | NDA/MAL/HDP /10461 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | AERIALLERG 0.5MG/ML | DESLORATIDINE | 0.5MG/ML | PHARMA INTERNATIONAL COMPANY –PIC AL QASTAL INDUSTRIAL ZONE P.O. BOX 334 AMMAN 11941 JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X125.0 ML BOTTLE | 10/02/2023 |
| 797 | NDA/MAL/HDP /10462 | AUROBINDO PHARMA LIMITED | PHILIPS PHARMACEUTICALS (U) LTD | TOR - LOOP 10 | ANHYDROUS TORASEMIDE | 10 MG | AUROBINDO PHARMA LIMITED (UNIT III), SURVEY NO. 313 AND 314, BACHUPALLY, BACHUPALLY MANDAL, MEDCHAL - MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 798 | NDA/MAL/HDP /10463 | FAES FARMA, S.A. | PHILLIPS PHARMACEUTICALS (U) LIMITED | DISFOR | METHOCARBAMOL | 500 MG | FAES FARMA, S.A.MÁXIMO AGUIRRE,14 48940 LEIOA (VIZCAYA) SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |
| 799 | NDA/MAL/HDP /10464 | JOHNSON & JOHNSON (PTY) LTD. | PHILLIPS PHARMACEUTICALS LTD | BENYLIN 4 FLU TABLETS | DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE | 12.5MG + 500MG + 22.5MG | SPECGX LLC GREENVILLE PLANT 100 LOUIS LATZER DRIVE GREENVILLE, IL 62246 USA<br>JANSSEN-CILAG DOMAINE DE MAIGREMONT F27100 VAL DE REUIL FRANCE<br>JOHNSON & JOHNSON (PTY) LTD, 241 MAIN ROAD, RETREAT, 7945, SOUTH AFRICA (FPP RELEASE RESPONSIBILITY) | UNITED STATES OF AMERICA<br>FRANCE | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X12.0 TABLET BLISTER | 10/02/2023 |
| 800 | NDA/MAL/HDP /10465 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS LTD | ZESBINA 200 | PROGESTERONE | 200 MG | EUGIA PHARMA SPECIALITIES LTD, SURVEY NO. 550, 551 & 552, KOLTHUR VILLAGE, SHAMIRPET MANDAL, MEDCHAL - MALKAJGIRI,TELANGANA, INDIA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 801 | NDA/MAL/HDP /10466 | ARCELIA LIFE SCIENCES LTD | PLUTO PHARMACEUTICALS LIMITED | ARCELIA CEFIXIME | CEFIXIME TRIHYDRATE | 400 MG | ASSOCIATED BIOTECH VILL-KISHANPURA, GURUMAJRA ROAD, BADDI, TEH. NALAGARH, DIST. SOLAN-174 101 (H.P.) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 802 | NDA/MAL/HDP /10467 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | RABIRIV-DSR | RABEPRAZOLE SODIUM + DOMPERIDONE | 20 MG + 30 MG | EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY, SELAQUI DEHRADUN-248 011 UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 803 | NDA/MAL/HDP /10468 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CORTIRIV-100 | HYDROCORTISONE SODIUM SUCCINATE | 100 MG/VIAL | EAST AFRICAN (INDIA) OVERSEAS PLOT NO.1, PHARMACITY, SELAQUI DEHRADUN-248 011 UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1, CLEAR GLASS AMPOULE + 5 ML WFI IN LDPE AMPOULE | 10/02/2023 |

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| 804 | NDA/MAL/HDP /10469 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AZIRIV-FS KIT | FLUCONAZOLE + AZITHROMYCIN DIHYDRATE + SECNIDAZOLE | 150 MG + 1 G + 1G | EAST AFRICAN (INDIA) OVERSEAS<br>PLOT NO.1, PHARMACITY, SELAQUI<br>DEHRADUN-248 011<br>UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY COMBINATION PACK TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 10/02/2023 |
| 805 | NDA/MAL/HDP /1047 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EXOFEN 180MG | FEXOFENADINE | 180MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN<br>NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X15.0 TABLET BLISTER | 01/07/2013 |
| 806 | NDA/MAL/HDP /10470 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LTD | ROYODOL | TRAMADOL HYDROCHLORIDE | 50 MG | PSYCHOTROPICS INDIA LIMITED<br>PLOT NO.12 & 12A, INDUSTRIAL PARK-II, PHASE-I, SALEMPUR, MEHDOOD-2, HARIDWAR-249403, (UTTARAKHAND), INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 807 | NDA/MAL/HDP /10471 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LTD | CIPROFLOXACIN-500 | CIPROFLOXACIN HYDROCHLORIDE | 500 MG | SCOTT-EDIL PHARMACIA LTD.<br>56 EPIP, PHASE-I JHARMAJRI, BADDI, DISTT. SOLAN (HP) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 808 | NDA/MAL/HDP /10472 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LTD | TRAMADOL HYDROCHLORIDE INJECTION 100 MG/2ML | TRAMADOL HYDROCHLORIDE | 100 MG/2 ML | SCOTT-EDIL PHARMACIA LTD.<br>56, EPIP, PHASE-I, JHARMAJRI, BADDI-173 205, (HP), INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X 2 ML AMPOULE | 10/02/2023 |
| 809 | NDA/MAL/HDP /10473 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LTD | POLYMOL SUSPENSION 125MG/5ML. | PARACETAMOL | 125MG/5ML. | SCOTT-EDIL PHARMACIA LTD.<br>56, EPIP, PHASE-I, JHARMAJRI, BADDI-173 205, (HP), INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 10/02/2023 |

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| 810 | NDA/MAL/HDP /10474 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LTD | POLYMOL EXTRA | PARACETAMOL + CAFFEINE | 500 MG + 30 MG | SCOTT-EDIL PHARMACIA LTD.<br>56, EPIP, PHASE-I, JHARMAJRI, BADDI-173 205, (HP), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 811 | NDA/MAL/HDP /10475 | MARCYRL PHARMACEUTICAL INDUSTRIES | SHREEJI PHARMACEUTICALS LIMITED | EVASTINE | EBASTINE | 10 MG | MARCYRL PHARMACEUTICAL INDUSTRIES. EL OBOUR CITY, THE WESTERN EXTENSION BLOCK 20005 EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |
| 812 | NDA/MAL/HDP /10476 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LTD | DEXCEN 10 | RAMIPRIL | 10 MG | CENTURION LABORATORIES PVT. LTD. CENTURION LABORATORIES PVT. LTD. P-2, BIO-TECH PARK, MANJUSAR, SAVLI, DIST. BARODA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 813 | NDA/MAL/HDP /10477 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LTD | PENACAM | PIROXICAM | 20 MG | CENTURION LABORATORIES PVT. LTD. CENTURION LABORATORIES PVT. LTD. P-2, BIO-TECH PARK, MANJUSAR, SAVLI, DIST. BARODA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 814 | NDA/MAL/HDP /10478 | SANDOZ KENYA C/ONOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LTD | FENTANYL SANDOZ 12 µG/H | FENTANYL | 12µG/HOUR | HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN GERMANY | GERMANY | TRANSDERMAL PATCHES | 1*5, ALUMINIUM FOIL | 10/02/2023 |
| 815 | NDA/MAL/HDP /10479 | SANDOZ KENYA C/ONOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LTD | FENTANYL SANDOZ 25 µG/H | FENTANYL | 25µG/HOUR | HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN GERMANY | GERMANY | TRANSDERMAL PATCHES | 1*5, ALUMINIUM FOIL | 10/02/2023 |

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| 816 | NDA/MAL/HDP /1048 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EXOFEN 120MG | FEXOFENADINE | 120MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X15.0 TABLET BLISTER | 01/07/2013 |
| 817 | NDA/MAL/HDP /10480 | SANDOZ KENYA C/ONOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LTD | FENTANYL SANDOZ 75 µG/H | FENTANYL | 75µG/HOUR | HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN GERMANY | GERMANY | TRANSDERMAL PATCHES | 1*5, ALUMINIUM FOIL | 10/02/2023 |
| 818 | NDA/MAL/HDP /10481 | SANDOZ KENYA C/ONOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LTD | FENTANYL SANDOZ 50 µG/H | FENTANYL | 50µG/HOUR | HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN GERMANY | GERMANY | TRANSDERMAL PATCHES | 1*5, ALUMINIUM FOIL | 10/02/2023 |

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| 819 | NDA/MAL/HDP /10482 | SANDOZ KENYA C/ONOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LTD | FENTANYL SANDOZ 100 µG/H | FENTANYL | 100µG/HOUR | HEXAL AG INDUSTRIESTRASSE 25 D-83607 HOLZKIRCHEN GERMANY | GERMANY | TRANSDERMAL PATCHES | 1*5, ALUMINIUM FOIL | 10/02/2023 |
| 820 | NDA/MAL/HDP /10483 | NVS KENYA LIMITED | SURGIPHARM UGANDA LIMITED | PATIZRA | RANIBIZUMAB | 10 MG/ML | NOVARTIS PHARMA STEIN AG SCHAFFHAUSERSTRASSE 4332 – STEIN SWITZERLAND (MANUFACTURER)/ NOVARTIS PHARMA AG LICHTSTRASSE 35 CH-4056 (QUALITY CONTROL) | SWITZERLAND | PARENTERAL ORDINARY VIALS | 1*1, CLEAR GLASS VIAL | 10/02/2023 |
| 821 | NDA/MAL/HDP /10484 | INDIANA OPHTHALMICS | SWASTIK PHARMACEUTICALS LTD | TETROP | TETRACYCLINE HYDROCHLORIDE | 1%W/W | INDIANA OPHTHALMICS 136-137 PHASE 2 GIDC, WADHWANCITY - 363035 SURENDRANAGAR GUJARAT – INDIA | INDIA | OPHTHALMIC OINTMENT | 1*1*5 G, ALUMINIUM COLLAPSIBLE TUBE | 10/02/2023 |

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| 822 | NDA/MAL/HDP/10485 | ESKAYEF PHARMACEUTICALS LIMITED | SWASTIK PHARMACEUTICALS LTD | RIVAROX 15 | RIVAROXABAN | 15 MG | ESKAYEF PHARMACEUTICALS LIMITED, 400 SQUIBB ROAD, TONGI INDUSTRIAL AREA, TONGI, GAZIPUR 1711, BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |
| 823 | NDA/MAL/HDP/10486 | ESKAYEF PHARMACEUTICALS LIMITED | SWASTIK PHARMACEUTICALS LTD | RIVAROX 20 | RIVAROXABAN | 20 MG | ESKAYEF PHARMACEUTICALS LIMITED, 400 SQUIBB ROAD, TONGI INDUSTRIAL AREA, TONGI, GAZIPUR 1711, BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |
| 824 | NDA/MAL/HDP/10487 | ESKAYEF PHARMACEUTICALS LIMITED | SWASTIK PHARMACEUTICALS LTD | KETONIC 30 | KETOROLAC TROMETHAMINE | 30 MG/ AMPOULE | ESKAYEF PHARMACEUTICALS LIMITED, 400 SQUIBB ROAD, TONGI INDUSTRIAL AREA, TONGI, GAZIPUR 1711, BANGLADESH | BANGLADESH | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X1.0 ML AMPOULE + 3 ML SYRINGE | 10/02/2023 |

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| 825 | NDA/MAL/HDP/10488 | ESKAYEF PHARMACEUTICALS LIMITED | SWASTIK PHARMACEUTICALS LTD | GTN 2.6 SR | DILUTED NITROGLYCERIN | 2.6 MG | ESKAYEF PHARMACEUTICALS LIMITED, 400 SQUIBB ROAD, TONGI INDUSTRIAL AREA, TONGI, GAZIPUR 1711, BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 10/02/2023 |
| 826 | NDA/MAL/HDP/10489 | GLOBAL NAPI PHARMACEUTICALS | SWASTIK PHARMACEUTICALS LTD | TERBIN | TERBINAFINE HYDROCHLORIDE | 250 MG | GLOBAL NAPI PHARMACEUTICALS, 2ND INDUSTRIAL ZONE, ST. 18, NO. 40, 6TH OCTOBER CITY - EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 10/02/2023 |
| 827 | NDA/MAL/HDP/1049 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVATE | BETAMETHASONE VALERATE | 0.1%W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2013 |

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| 828 | NDA/MAL/HDP/10490 | GLOBAL NAPI PHARMACEUTICALS | SWASTIK PHARMACEUTICALS LTD | BISOCARD PLUS 5MG/12.5MG | BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE | 5MG + 12.5MG | GLOBAL NAPI PHARMACEUTICALS, 2ND INDUSTRIAL ZONE, ST. 18, NO. 40, 6TH OCTOBER CITY - EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 829 | NDA/MAL/HDP/10491 | GLAXOSMITHKLINE LIMITED | UNITED HEALTHCARE DICTRIBUTERS (UHD) LIMITED | APRETUDE 30 MG | CABOTEGRAVIR | 30 MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS) PRIORY STREET WARE HERTFORDSHIRE SG12 0DJ UNITED KINGDOM (MANUFACTURE) + GLAXO WELLCOME, S.A. AVDA. EXTREMADURA, 3 ARANDA DE DUERO, BURGOS 09400 SPAIN (BATCH RELEASE) | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 10/02/2023 |
| 830 | NDA/MAL/HDP/10492 | MACLEODS PHARMACEUTICALS LIMITED | VITACARE LIMITED | DOLUTEGRAVIR SODIUM TABLETS 50 MG | DOLUTEGRAVIR SODIUM | 50 MG | MACLEODS PHARMACEUTICALS LIMITED, PLOT NO. 25 – 27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN, PIN – 396210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 10/02/2023 |

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| 831 | NDA/MAL/HDP/10493 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LIMITED | ROUNOX | TRAMADOL HYDROCHLORIDE | 50 MG | CENTURION LABORATORIES PVT. LTD. PLOT NO.2, SAVLI BIO-TECH PARK, MANJUSAR, SAVLI, DIST. VADODARA, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 832 | NDA/MAL/HDP/10494 | CENTURION LABORATORIES PVT. LTD. | SHREEJI PHARMACEUTICALS LIMITED | FORMET 1000 | METFORMIN HYDROCHLORIDE | 1000 MG | CENTURION LABORATORIES PVT. LTD. PLOT NO.2, SAVLI BIO-TECH PARK, MANJUSAR, SAVLI, DIST. VADODARA, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 833 | NDA/MAL/HDP/10495 | EGYPHAR | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HELI-CURE | CLARITHROMYCIN + OMEPRAZOLE + TINIDAZOLE | 250 MG + 20 MG + 500 MG | EGYPHAR, INDUSTRIAL ZONE (A), PARTS NO. 9 & 10, BLOCK 13026 – EL OBOUR CITY, EGYPT | EGYPT | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X7.0X2.0 TABLET BLISTER | 10/02/2023 |

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| 834 | NDA/MAL/HDP /10496 | THE UNITED PHARMACEUTICALS MFG. CO. LTD. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | IRIS SYRUP | DESLORATADINE | 0.5 MG/ML | THE UNITED PHARMACEUTICALS MFG. CO. LTD.<br>NUZHAT SAHAB, AL-RAQEEM-NEAR PUBLIC SECURITY HOUSING<br>PO BOX 69<br>AMMAN11591JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 10/02/2023 |
| 835 | NDA/MAL/HDP /10497 | EGYPHAR | WIDE SPECTRUM ENTERPRISES (U) LTD | ZISROCIN | AZITHROMYCIN | 500MG | EGYPHAR<br>BLOCK NO. 13026, PIECE NO. 9,10, INDUSTRIAL ZONE (A), EL-OBOUR CITY, EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X3.0 CAPSULE BLISTER | 10/02/2023 |
| 836 | NDA/MAL/HDP /10498 | ADWIA CO. | WIDE SPECTRUM ENTERPRISES (U) LTD | URIPAN | OXYBUTYNIN HYDROCHLORIDE | 5MG/ML | ADWIA S.A.E.<br>1ST INDUSTRIAL ZONE A1, 10TH OF RAMADAN CITY - EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X120.0 ML BOTTLE | 10/02/2023 |

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| 837 | NDA/MAL/HDP /10499 | AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES | WIDESPECTRUM ENTERPRISES (U) LTD. | TIRATAM 500 MG XR | LEVETIRACETAM | 500 MG | AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES, PART NO. 7/6, 6TH INDUSTRIAL AREA, 6TH OF OCTOBER CITY, EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |
| 838 | NDA/MAL/HDP /1050 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | AMTAS-10 | AMLODIPINE | 10MG | INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 839 | NDA/MAL/HDP /10502 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (U) LTD | VORIOLE 200 | VORICONAZOLE | 200 MG | MSN LABORATORIES PRIVATE LIMITED - FORMULATIONS DIVISION PLOT NO.: 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 840 | NDA/MAL/HDP /10503 | AUROBINDO PHARMA LIMITED | PHILIPS PHARMACEUTICALS (U) LTD | HI-ALFA SR 10 | ALFUZOSIN HYDROCHLORIDE | 10 MG | AUROBINDO PHARMA LIMITED (UNIT-III), SURVEY NO. 313 & 314, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, TELANGANA STATE. ZIP CODE: 500090, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 841 | NDA/MAL/HDP /10504 | INFUGEN PHARMA PVT LTD | TATA UGANDA LILITED | INFUROXIM 1.5 G | CEFUROXIME SODIUM | 1.5 G/VIAL | ZEISS PHARMACEUTICALS PVT. LTD. 72, EPIP, PHASE-I, JHARMAJRI, BADDI, 173205, DIST. SOLAN, H.P, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.5 G VIAL | 10/02/2023 |
| 842 | NDA/MAL/HDP /10505 | ABACUS PARENTERAL DRUGS LTD | ABACUS PARENTERAL DRUGS LTD | OPTOR EYE DROPS | KETOROLAC TROMETHAMINE | 0.5 %W/V | ABACUS PARENTERAL DRUGS LTD (APDL). BLOCK 191, PLOT 114, KINGA MUKONO. P.O.BOX 31376, KAMPALA, UGANDA | UGANDA | OPHTHALMIC SOLUTION | 1.0X1.0X10.0 ML BOTTLE | 10/02/2023 |

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| 843 | NDA/MAL/HDP /10506 | PHARMATHEN S.A | GOODMAN INTERNATIONAL LIMITED | A-CNOTREN® 10MG | ISOTRETINOIN | 10 MG | PHARMATHEN S.A., DERVENAKION 6, 15351 PALLINI, ATTIKI, GREECE | GREECE | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 844 | NDA/MAL/HDP /10507 | AUROLAB | SWASTIK PHARMACEUTICALS LIMITED | TOB - DEX | TOBRAMYCIN SULFATE + DEXAMETHASONE SODIUM PHOSPHATE | 0.3%W/V + 0.1%W/V | AUROLAB NO 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI – 625020, TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 10/02/2023 |
| 845 | NDA/MAL/HDP /10508 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY | FIMABUTE-100 | CEFIXIME TRIHYDRATE | 100 MG/5 ML | BRAWN LABORATORIES LTD., 13, NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001, (HARYANA), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X60.0 ML BOTTLE | 10/02/2023 |

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| 846 | NDA/MAL/HDP/10509 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY | PANTRO INJECTION | PANTOPRAZOLE SODIUM | 40 MG | BRAWN LABORATORIES LTD. 13, NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001, HARYANA, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1*40 MG, CLEAR GLASS VIAL + 1*1*10ML OF SODIUM CHLORIDE SOLUTION IN CLEAR GLASS AMPOULE | 10/02/2023 |
| 847 | NDA/MAL/HDP/10510 | ZIM LABORATORIES LIMITED | GITTOES PHARMACEUTICALS LIMITED | NEUROZIM 75 | PREGABALIN | 75 MG | ZIM LABORATORIES LIMITED, B-21/22, M.I.D.C. AREA, KALMESHWAR, NAGPUR 441501, MAHARASHTRA STATE, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 848 | NDA/MAL/HDP/10511 | VRUSHIK INVESTMENT (U) LTD | SHREEJI PHARMACEUTICALS LIMITED | METO | METOCLOPRAMIDE HYDROCHLORIDE | 10 MG | CENTURION LABORATORIES PVT. LTD. PLOT NO.2, SAVLI BIO-TECH PARK, MANJUSAR, SAVLI, DIST. VADODARA, 391775, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 849 | NDA/MAL/HDP /10512 | VRUSHIK INVESTMENT (U) LTD | SHREEJI PHARMACEUTICALS LIMITED | FINADOL ULTRA | PARACETAMOL + CAFFEINE | 500 MG + 30 MG | CENTURION LABORATORIES PVT. LTD. PLOT NO.2, SAVLI BIO-TECH PARK, MANJUSAR, SAVLI, DIST. VADODARA, 391775, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 850 | NDA/MAL/HDP /10513 | MS PHARMA JORDAN CO.LTD. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EXITINE 0.5MG/5ML | FLUMAZENIL | 0.5MG/5ML | MS PHARMA JORDAN - KING ABDULLAH II INDUSTRIAL ESTATE P.O. BOX 34 SAHAB 11512 AMMAN – JORDAN | JORDAN | SOLUTION OF INJECTION | 1*5*5 ML CLEAR GLASS VIAL | 10/02/2023 |
| 851 | NDA/MAL/HDP /10514 | ARTURA PHARMACEUTICALS PVT LTD | SWASTIK PHARMACEUTICALS LTD | ORITA-100 | SILDENAFIL CITRATE | 100 MG | ARTURA PHARMACEUTICALS PVT LTD NO. 1505 PORTIA ROAD, SRI CITY SEZ, SATYAVEDU MANDAL CHITTOOR DIST.- 517 588, ANDHRA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 10/02/2023 |

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| 852 | NDA/MAL/HDP /10515 | TAKEDA PHARMA A/S | PHILIPS PHARMACEUTICALS (U) LTD | NINLARO 2.3 MG | IXAZOMIB CITRATE | 2.3 MG | HAUPT PHARMA AMAREG GMBH DONAUSTAUFER STRAßE 378 93055 REGENSBURG GERMANY (MANUFACTURER) TAKEDA PHARMA A/S DYBENDAL ALLE 10 2630 TAASTRUP DENMARK (BATCH RELEASER) | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X1.0X1.0 CAPSULE BLISTER | 10/02/2023 |
| 853 | NDA/MAL/HDP /10516 | TAKEDA PHARMA A/S | PHILIPS PHARMACEUTICALS (U) LTD | NINLARO 3.0 MG | IXAZOMIB CITRATE | 3.0 MG | HAUPT PHARMA AMAREG GMBH DONAUSTAUFER STRAßE 378 93055 REGENSBURG GERMANY (MANUFACTURER) TAKEDA PHARMA A/S DYBENDAL ALLE 10 2630 TAASTRUP DENMARK (BATCH RELEASER) | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X1.0X1.0 CAPSULE BLISTER | 10/02/2023 |
| 854 | NDA/MAL/HDP /10517 | BRAWN LABORATORIES LTD | GOOOD DAY PHARMACY | BRULEXIN-250 | CEFALEXIN MONOHYDRATE | 250 MG | BRAWN LABORATORIES LTD. 13, N.I.T. INDUSTRIAL AREA, FARIDABAD-121 001, (HARYANA), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 855 | NDA/MAL/HDP /10518 | ARTURA PHARMACEUTICALS PVT LTD | SWASTIK PHARMACEUTICALS LTD | GLYCOFORM 500 | METFORMIN HYDROCHLORIDE | 500 MG | ARTURA PHARMACEUTICALS PVT LTD<br>NO. 1505 PORTIA ROAD, SRI CITY SEZ,<br>SATYAVEDU MANDAL<br>CHITTOOR DIST.- 517 588,<br>ANDHRA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 856 | NDA/MAL/HDP /10519 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | PLASMINEX | TRANEXAMIC ACID | 500 MG | PT. SANBE FARMA<br>UNIT 1, JL. INDUSTRI I NO. 9 RT.01 RW.08, KELURAHAN UTAMA, KECAMATAN CIMAHI SELATAN, CIMAHI, INDONESIA | INDONESIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 857 | NDA/MAL/HDP /1052 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | MICLOGEN | MICONAZOLE NITRATE+CLOBETASOLE PROPIONATE+GENTAMICIN SULPHATE | 2.0%W/W+0.05% W/W+0.1W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |

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| 858 | NDA/MAL/HDP /10520 | ENCORE HEALTHCARE PVT. LTD. | REDDY'S PHARMA LIMITED | ENCOBLOC | PROPRANOLOL HYDROCHLORIDE | 40 MG | ENCORE HEALTHCARE PVT. LTD<br>D-5, M.I.D.C. AREA, PAITHAN, 431148 DIST. AURANGABAD, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 859 | NDA/MAL/HDP /10521 | SCOTT-EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD | ROYAL PHARMA LIMITED | SCOTXONE PLUS | CEFTRIAXONE SODIUM + SULBACTAM SODIUM | 1000 MG + 500 MG | SCOTT – EDIL ADVANCE RESEARCH LABORATORIES & EDUCATION LTD.<br>HILL TOP INDUSTRIAL AREA, BHATOLI KALAN, BADDI-173205, (H.P.) INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1*1500MG, CLEAR GLASS VIAL | 10/02/2023 |
| 860 | NDA/MAL/HDP /10522 | ZIM LABORATORIES LIMITED | GITTOES PHARMACEUTICALS LIMITED | CEFRIM 500 | CEFUROXIME AXETIL | 500 MG | ZIM LABORATORIES LIMITED, B-21/22, MIDC AREA, KALMESHWAR, NAGPUR 441501, MAHARASHTRA STATE,<br>INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 861 | NDA/MAL/HDP /10523 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LIMITED | SYNRIAM DT | ARTEROLANE MALEATE + PIPERAQUINE PHOSPHATE | 37.5 MG + 187.5 MG | SUN PHARMACEUTICAL INDUSTRIES LTD, PLOT NO. B-2 MADKAI INDUSTRIAL ESTATE, PONDA, GOA - 403404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X3.0 TABLET BLISTER | 10/02/2023 |
| 862 | NDA/MAL/HDP /10524 | AGIO PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | DICLOGEN RETARD 100 | DICLOFENAC SODIUM | 100 MG | AGIO PHARMACEUTICALS LTD T-82, MIDC, BHOSARI, PUN, 411026, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 863 | NDA/MAL/HDP /10525 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (A) LIMITED | PRELYNCA 50 MG | PREGABALIN | 50 MG | PHARMATHEN INTERNATIONAL S.A. INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE | GREECE | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X7.0 CAPSULE BLISTER | 10/02/2023 |

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| 864 | NDA/MAL/HDP /10526 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (A) LIMITED | PRELYNCA 75 MG | PREGABALIN | 75 MG | PHARMATHEN INTERNATIONAL S.A. INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE | GREECE | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X7.0 CAPSULE BLISTER | 10/02/2023 |
| 865 | NDA/MAL/HDP /10527 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (A) LIMITED | PRELYNCA 150 MG | PREGABALIN | 150 MG | PHARMATHEN INTERNATIONAL S.A. INDUSTRIAL PARK SAPES, RODOPI PREFECTURE, BLOCK NO. 5, RODOPI 69300 - GREECE | GREECE | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 10/02/2023 |
| 866 | NDA/MAL/HDP /10528 | THE SEARLE COMPANY LIMITED | HEALTHCARE LIMITED | EZIUM 20 MG | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 20 MG | THE SEARLE COMPANY LIMITED, F-319, S.I.T.E, KARACHI PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X7.0 CAPSULE BLISTER | 10/02/2023 |

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| 867 | NDA/MAL/HDP /10529 | THE SEARLE COMPANY LIMITED | HEALTHCARE LIMITED | EZIUM 40 MG | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 40 MG | THE SEARLE COMPANY LIMITED, F-319, S.I.T.E, KARACHI PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X7.0 CAPSULE BLISTER | 10/02/2023 |
| 868 | NDA/MAL/HDP /10530 | ZOTA HEALTHCARE LTD | HARLEY'S (U) LTD | COXZOTA 120 | ETORICOXIB | 120 MG | ZOTA HEALTHCARE LTD. PLOT NO: 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN, SURAT-394 230, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 869 | NDA/MAL/HDP /10531 | GLAXOSMITHKLINE LIMITED | UNITED HEALTHCARE DICTRIBUTERS (UHD) LIMITED | ENO CALCIUM ANTACID TABLETS | CALCIUM CARBONATE | 500 MG | GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC 320 SOUTH BROADWAY ST. LOUIS, MISSOURI 63102 USA (MANUFACTURE OF BULK) GLAXOSMITHKLINE LIMITED LIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, NAIROBI KENYA (PACKAGING AND RELEASE) | USA + KENYA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER 1.0X2.0X10.0 TABLET BLISTER | 10/02/2023 |

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| 870 | NDA/MAL/HDP /10532 | ALKEM LABORATORIES LTD | ABACUS PHARMA (U) LTD | TAXIM-O | CEFIXIME TRIHYDRATE | 400 MG | EAST AFRICAN (INDIA) OVERSEAS, PLOT N. 1, PHARMACITY, SELAQUI, DEHRADUN (INDIA)-248011 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X5.0 CAPSULE BLISTER | 10/02/2023 |
| 871 | NDA/MAL/HDP /10533 | CELON LABORATORIES PRIVATE LIMITED | GENERAL ANESTHETIC | HYPRO 200 | PROPOFOL | V | CELON LABORATORIES PRIVATE LIMITED PLOT NO.2, ALEAP INDUSTRIAL ESTATE, GAJULARAMARAM, RANGA REDDY, MEDCHAL DISTRICT - 500090, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1*1*20 ML, CLEAR GLASS VIAL | 10/02/2023 |
| 872 | NDA/MAL/HDP /10534 | PSYCHOTROPICS INDIA LTD. | ABACUS PHARMA (U) LTD | KETAMINE HYDROCHLORIDE INJECTION USP 50MG/ML | KETAMINE HYDROCHLORIDE | 50MG/ML | PSYCHOTROPICS INDIA LIMITED PLOT NO.12 & 12A, INDUSTRIAL PARK-II, PHASE-I, SALEMPUR, MEHDOOD-2, HARIDWAR-249403, (UTTARAKHAND), INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X10.0 ML VIAL | 10/02/2023 |

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| 873 | NDA/MAL/HDP /10535 | FERRER INTERNACIONAL | PHILLIPS PHARMACEUTICALS (U) LIMITED | ANGINOVAG | DEQUALINIUM CHLORIDE + TYROTHRICIN + B - GLYCYRRHETINIC ACID (ENOXOLONE) + HYDROCORTISONE ACETATE + LIDOCAINE HYDROCHLORIDE | 100MG + 400MG + 60MG + 60MG+100MG) PER 100 ML | FERRER INTERNACIONAL, S.A. JOAN BUSCALLÀ 1-9 08173-SANT CUGAT DEL VALLÈS (BARCELONA) SPAIN | SPAIN | ORAL TOPICAL SPRAYS WITHOUT GAS | 1.0X1.0X10.0 ML BOTTLE | 10/02/2023 |
| 874 | NDA/MAL/HDP /10536 | KLM LABORATORIES PVT. LTD. | REDDY'S PHARMA LIMITED | MUPISOFT OINTMENT | MUPIROCIN | 2.0% W/W | CURETECH SKINCARE PLOT NO-33 & 34, PHASE-IV, BHATOLI KALAN, BADDI, DISTT.- SOLAN (HP) INDIA | INDIA | TOPICAL EXTERNAL OINTMENT | 1*1*5 G, LAMI TUBE | 10/02/2023 |
| 875 | NDA/MAL/HDP /10537 | KLM LABORATORIES PVT. LTD. | REDDY'S PHARMA LIMITED | NIOSOL OINTMENT | CLOBETASOL PROPIONATE | 0.05%W/W | CURETECH SKINCARE PLOT NO-33 & 34, PHASE-IV, BHATOLI KALAN, BADDI, DISTT.- SOLAN (HP) INDIA | INDIA | TOPICAL EXTERNAL OINTMENT | 1*1*30 G, LAMI TUBE | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 876 | NDA/MAL/HDP /10538 | KLM LABORATORIES PVT. LTD. | REDDY'S PHARMA LIMITED | SUDIF CREAM | FUSIDIC ACID | 2.0 %W/W | CURETECH SKINCARE PLOT NO-33 & 34, PHASE-IV, BHATOLI KALAN, BADDI, DISTT.- SOLAN (HP) INDIA | INDIA | TOPICAL EXTERNAL CREAM | 1.0X1.0X10.0 GTUBE | 10/02/2023 |
| 877 | NDA/MAL/HDP /10539 | ZOTA HEALTHCARE LTD | REDDY'S PHARMA LIMITED | ZOTAMET-850 | METFORMIN HYDROCHLORIDE | 850 MG | ZOTA HEALTHCARE LTD., PLOT NO: 169, SURAT SPECIAL ECONOMIC ZONE, , SACHIN, SURAT-394 230, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 878 | NDA/MAL/HDP /10540 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | ATAZANAVIR AND RITONAVIR TABLETS | ATAZANAVIR SULFATE + RITONAVIR | 300MG + 100MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED VILLAGE: GANGUWALA, PAONTA SAHIB, DISTRICT SIRMOUR – 173025, HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE, 1.0X1.0X90.0 TABLET BOTTLE | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 879 | NDA/MAL/HDP /10541 | GALENICUM HEALTH S.L. | GOODMAN INTERNATIONAL UGANDA LTD | ROSUVASTATIN | ROSUVASTATIN | 20MG | BIOFARM SP.Z O.O WALBRZYSKA 13, 60-198 POZNAN POLAND | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X7.0 TABLET BLISTER | 10/02/2023 |
| 880 | NDA/MAL/HDP /10542 | SANDOZ GMBH, KUNDL | KIMSY MEDS LIMITED | PACLITAXEL 6 MG /1 ML | PACLITAXEL | 300MG /50ML | EBEWE PHARMA GESMBH NFG.KG MONDSEESTRASSE 11 4866 UNTERACH AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1*1*50 ML, CLEAR GLASS VIAL | 10/02/2023 |
| 881 | NDA/MAL/HDP /10543 | ADWIA CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ADWIFLAM | DICLOFENAC POTASSIUM | 75 MG | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO.) PART NO. 44-A/11-FIRST INDUSTRIAL ZONE – 6TH OF OCTOBER CITY, EGYPT | EGYPT | RECTAL SUPPOSITORIES | 1*1*5, PVC/PVC STRIP PACK | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 882 | NDA/MAL/HDP /10544 | AUROLAB | SWASTIK PHARMACEUTICALS LIMITED | ATROP | ATROPINE SULFATE | 1%W/V | AUROLAB NO 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI – 625020, TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 10/02/2023 |
| 883 | NDA/MAL/HDP /10545 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEY'S (U) LTD | BRAMOL | PARACETAMOL | 10 MG/ML | BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 PAKISTAN | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML VIAL | 10/02/2023 |
| 884 | NDA/MAL/HDP /10546 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEY'S (U) LTD | OXOFERIN | TETRACHLORODECAOXIDE | 100ML OF TCDO FORMING "REACTION PRODUCT" HAS A BIOLOGICAL ACTIVITY: 138.0 X 10^6 PMOL | BROOKES PHARMA (PRIVATE) LIMITED 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 PAKISTAN | PAKISTAN | TOPICAL EXTERNAL LIQUIDS | 1*1*50 ML, LDPE CONATINER | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 885 | NDA/MAL/HDP /10547 | PROFARMA SH.A | JOINT MEDICAL STORES | HALOPERIDOL SOLUTION FOR INJECTION 5MG/ML | HALOPERIDOL | 5MG/ML | PROFARMA SH.A. RRUGA : MYSLYM KETA TIRANË - ALBANIA | ALBANIA | PARENTERAL ORDINARY VIALS | 1*2*5*1ML, AMBER GLASS VIAL | 10/02/2023 |
| 886 | NDA/MAL/HDP /1055 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | ROZITTA 40 | ROSUVASTATIN CALCIUM | 40MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 887 | NDA/MAL/HDP /10550 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (U) LTD | AZADUAL 100 | AZACITIDINE | 100 MG/VIAL | MSN LABORATORIES PRIVATE LIMITED FORMULATIONS DIVISION, UNIT-II, SURVEY NOS. 1277, 1319 TO 1324, NANDIGAMA (VILLAGE& MANDAL), RANGAREDDY DISTRICT, TELANGANA 509228, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X100 MG VIAL | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 888 | NDA/MAL/HDP /10551 | SANJAR PHARMA LLP | MOTI PHARMA (U) LTD | ADRENLIN | ADRENALINE ACID TARTRATE | 1 MG/VIAL | SANJAR PHARMA LLP SURVEY NO. 622/2/1/4, DEDHROTA, HIMATNAGAR, DIST-SABARKANTHA, GUJARAT - INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X1.0 ML AMPOULES | 10/02/2023 |
| 889 | NDA/MAL/HDP /10552 | MACLEODS PHARMACEUTICALS LIMITED | VITACARE LIMITED | ZOPIMAC 2 | ESZOPICLONE | 2MG | MACLEODS PHARMACEUTICALS LIMITED BLOCK NO.: 2, VILLAGE THEDA P.O. LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH, 174101 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X100.0 TABLET BOTTLE | 10/02/2023 |
| 890 | NDA/MAL/HDP /10553 | ACINO AG | GOODMAN INTERNATIONAL LIMITED | TITANAFIL 5 | TADALAFIL | 5 MG | PHARMACTIVE İLAÇ SAN. VE TIC. A.Ş. ÇERKEZKÖY ORGANIZE SANAYI BÖLGESI KARAAĞAÇ MAH. FATIH BULV. NO:32 KAPAKLI / TEKIRDAĞ TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 10/02/2023 |

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| 891 | NDA/MAL/HDP /10554 | ACINO AG | GOODMAN INTERNATIONAL LIMITED | TITANAFIL 20 | TADALAFIL | 20 MG | PHARMACTIVE İLAÇ SAN. VE TIC. A.Ş.<br>ÇERKEZKÖY ORGANIZE SANAYI BÖLGESI KARAAĞAÇ MAH. FATIH BULV. NO:32<br>KAPAKLI / TEKIRDAĞ<br>TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 10/02/2023 |
| 892 | NDA/MAL/HDP /10555 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS LTD | ZESBINA 200 | PROGESTERONE | 200 MG | EUGIA PHARMA SPECIALITIES LTD,<br>SURVEY NO. 550, 551 & 552,<br>KOLTHUR VILLAGE,<br>SHAMIRPET MANDAL,<br>MEDCHAL - MALKAJGIRI,<br>TELANGANA,<br>INDIA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 893 | NDA/MAL/HDP /10556 | KESAR PHARMA (P) LIMITED | SWASTIK PHARMACEUTICALS LIMITED | PIADIN | POVIDONE IODINE | 5.0 W/W | KESAR PHARMA (P) LIMITED.<br>PLT NO.50-P/2, AT VILLAGE,<br>BILESHWARPURA. PO<br>CHHATRAL-382729.<br>TAL. KALOL, DIST.<br>GANDHINAGAR, GUJARAT<br>INDIA | INDIA | TOPICAL EXTERNAL OINTMENT | 1.0X1.0X10.0 GTUBE | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 894 | NDA/MAL/HDP /10557 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | LOFNAC-50 | DICLOFENAC SODIUM | 50 MG | BLISS GVS PHARMA LIMITED, 10, DEWAN UDYOG NAGAR, ALIYALI, PALGHAR, DISTRICT THANE 401404, MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 895 | NDA/MAL/HDP /10558 | KLM LABORATORIES PVT. LTD. | REDDY'S PHARMA LIMITED | NEOCLEAN GEL | CLINDAMYCIN PHOSPHATE + NICOTINAMIDE | 1.0 %W/W + 4.0%W/W | CURETECH SKINCARE PLOT NO-33 & 34, PHASE-IV, BHATOLI KALAN, BADDI 173205 , DISTT.- SOLAN (HP) INDIA | INDIA | TOPICAL EXTERNAL GEL | 1.0X1.0X10.0 GTUBE | 10/02/2023 |
| 896 | NDA/MAL/HDP /10559 | KLM LABORATORIES PVT. LTD. | REDDY'S PHARMA LIMITED | NIOSALIC OINTMENT | CLOBETASOL PROPIONATE + SALICYLIC ACID | 0.05%W/W + 3.00W/W | CURETECH SKINCARE PLOT NO-33 & 34, PHASE-IV, BHATOLI KALAN, BADDI 173205 , DISTT.- SOLAN (HP) INDIA | INDIA | TOPICAL EXTERNAL OINTMENT | 1*1*30 G, LAMINATED TUBE | 10/02/2023 |

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| 897 | NDA/MAL/HDP /1056 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVATE-N OINTMENT | BETAMETHASONE + NEOMYCIN | 0.1%W/W + 0.5% W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X15.0 G TUBE | 01/07/2013 |
| 898 | NDA/MAL/HDP /10560 | LEBEN LABORATORIES PVT. LTD. | MALIX PHARMA (U) LTD | WHITFIELD'S OINTMENT | BENZOIC ACID + SALICYLIC ACID | 6%W/W + 3%W/W | LEBEN LABORATORIES LTD. PLOT NO. L-4 & L-15, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | TOPICAL EXTERNAL OINTMENT | 1*1*20G, LAMINATED TUBE | 10/02/2023 |
| 899 | NDA/MAL/HDP /10561 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA II LTD | WORIV | ALBENDAZOLE | 400 MG | EAST AFRICAN (INDIA) OVERSEAS, PLOT N. 1, PHARMACITY, SELAQUI, DEHRADUN - 248011 - INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 10/02/2023 |

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| 900 | NDA/MAL/HDP /10562 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 11 LIMITED | ACESON-P | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | EAST AFRICAN (INDIA) OVERSEAS, PLOT N. 1, PHARMACITY, SELAQUI, DEHRADUN - 248011 - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 10/02/2023 |
| 901 | NDA/MAL/HDP /10563 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ENARIV-10 | ENALAPRIL MALEATE | 10 MG | EAST AFRICAN (INDIA) OVERSEAS, PLOT N. 1, PHARMACITY, SELAQUI, DEHRADUN - 248011 - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 10/02/2023 |
| 902 | NDA/MAL/HDP /10564 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ISONIAZID/PYRIDOXINE HYDROCHLORIDE/SULFAMETHOXAZOLE TRIMETHOPRIM TABLETS 300 MG/25 MG/800 MG/160 MG | ISONIAZID + PYRIDOXINE HYDROCHLORIDE + SULFAMETHOXAZOLE + TRIMETHOPRIM | 300 MG + 25 MG + 800 MG + 160 MG | MYLAN LABORATORIES LIMITED, PLOT NO. 11,12 AND 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775, DIST.DHAR, MADHYA PRADESH,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER + 1.0X1.0X30.0 TABLET CONTAINER | 10/02/2023 |

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| 903 | NDA/MAL/HDP /10565 | AUROLAB | SWASTIK PHARMACEUTICALS LIMITED | PILO | PILOCARPINE NITRATE | 2%W/V | AUROLAB<br>NO 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI – 625020, TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 10/02/2023 |
| 904 | NDA/MAL/HDP /10566 | AUROLAB | SWASTIK PHARMACEUTICALS LIMITED | AUROCARPINE | PILOCARPINE NITRATE | 0.5 % W/V | AUROLAB<br>NO 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI – 625020, TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1*5*1 ML, AMBER GLASS VIAL | 10/02/2023 |
| 905 | NDA/MAL/HDP /10567 | AJANTA PHARMA LIMITED | ABACUS PHARMA (A) LIMITED | CELMAC 200 | CELECOXIB | 200 MG | AJANTA PHARMA LIMITED<br>B-4-5-6, MIDC INDUSTRIAL AREA<br>PAITHAN, AURANGABAD, 431148,<br>MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 906 | NDA/MAL/HDP /10568 | AJANTA PHARMA LIMITED | ABACUS PHARMA (U) LTD | AMADAY PL 5/4 | AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE | 5 MG + 4 MG | AJANTA PHARMA LTD. MIRZA - PALASHBARI ROAD VILLAGE: KOKJHAR DIST: KAMPUR, GUWAHATI ASSAM-781128 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 907 | NDA/MAL/HDP /10569 | AJANTA PHARMA LIMITED | ABACUS PHARMA (U) LTD | AMADAY PL 5/8 | AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE | 5 MG + 8 MG | AJANTA PHARMA LTD. MIRZA - PALASHBARI ROAD VILLAGE: KOKJHAR DIST: KAMPUR, GUWAHATI ASSAM-781128 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 908 | NDA/MAL/HDP /1057 | NECTAR LIFESCIENCES LTD | SUPER MEDIC LTD | FIXINECT-200MG | CEFIXIME | 200MG | NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2013 |

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| 909 | NDA/MAL/HDP /10570 | AJANTA PHARMA LIMITED | ABACUS PHARMA (U) LTD | AMADAY PL 10/4 | AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE | 10 MG + 4 MG | AJANTA PHARMA LTD. MIRZA - PALASHBARI ROAD VILLAGE: KOKJHAR DIST: KAMPUR, GUWAHATI ASSAM-781128 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 910 | NDA/MAL/HDP /10571 | AJANTA PHARMA LIMITED | ABACUS PHARMA (U) LTD | AMADAY PL 10/8 | AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE | 10 MG + 8 MG | AJANTA PHARMA LTD. MIRZA - PALASHBARI ROAD VILLAGE: KOKJHAR DIST: KAMPUR, GUWAHATI ASSAM-781128 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 911 | NDA/MAL/HDP /10572 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED | ABACUS PHARMA (U) LTD | NAT-B FORTE | THIAMINE MONONITRATE (VITAMIN B1) + PYRIDOXINE HYDROCHLORIDE (VITAMIN B6) + METHYLCOBALAMIN (VITAMIN B12) + FOLIC ACID + D-ALPHA-TOCOPHEROL ACETATE + | 100 MG + 200 MG + 500 MCG + 200 MCG + 153.84 MG + 200 IU + 13.33 MG + 5000 IU + 0.4 MG + 400 IU + 2.512 MG + 1.0 MG +1.609 MG + 0.20 MG + 75.0 MG + 15.0 MG | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED, 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |

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| 912 | NDA/MAL/HDP /10573 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (U) LTD | DABIFIB 110 | DABIGATRAN ETEXILATE | 110 MG | MSN LABORATORIES PRIVATE LIMITED - FORMULATIONS DIVISION, UNIT-II, SURVEY NOS. 1277, 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANGA REDDY DISTRICT, TELANGANA 509228, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 913 | NDA/MAL/HDP /10574 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (U) LTD | DABIFIB 150 | DABIGATRAN ETEXILATE | 150 MG | MSN LABORATORIES PRIVATE LIMITED - FORMULATIONS DIVISION, UNIT-II, SURVEY NOS. 1277, 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANGA REDDY DISTRICT, TELANGANA 509228, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 10/02/2023 |
| 914 | NDA/MAL/HDP /10575 | AUROBINDO PHARMA LIMITED | PHILIPS PHARMACEUTICALS (U) LTD | BINOVEN 75 | VENLAFAXINE HYDROCHLORIDE | 75 MG | AUROBINDO PHARMA LIMITED (UNIT III), SURVEY NO. 313 AND 314, BACHUPALLY, BACHUPALLY MANDAL, MEDCHAL - MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 10/02/2023 |

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| 915 | NDA/MAL/HDP /10576 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS LTD | QUITIDE 100 | QUETIAPINE FUMARATE | 100MG | AUROBINDO PHARMA LIMITED (UNIT III), SURVEY NO. 313 AND 314, BACHUPALLY, BACHUPALLY MANDAL, MEDCHAL - MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 10/02/2023 |
| 916 | NDA/MAL/HDP /10577 | ARCELIA LIFE SCIENCES LTD | PLUTO PHARMACEUTICALS LIMITED | ARCELIA MEROPENEM | MEROPENEM TRIHYDRATE | 1G/VIAL | REYOUNG PHARMACEUTICAL CO., LTD. NO. 1, RUIYANG ROAD, YIYUAN COUNTY, SHANDONG PROVINCE, CHINA. POST CODE: 256100 | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1*1,CLEAR GLASS VIAL | 10/02/2023 |
| 917 | NDA/MAL/HDP /10578 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | OCORTIN | HYDROCORTISONE | 1%W/W | KREMOINT PHARMA PVT.LTD. B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH INDIA | INDIA | TOPICAL EXTERNAL CREAM | 1*1*30G, LAMI TUBE | 10/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 918 | NDA/MAL/HDP /10579 | RENE INDUSTRIES LTD | RENE INDUSTRIES LTD | BENZYL BENZOATE APPLICATION BP | BENZYL BENZOATE | 25%W/V | RENE INDUSTRIES LTD. PO BOX 6034, PLOT NO.680, KAMULI, KIREKA, KAMPALA, UGANDA | UGANDA | TOPICAL EXTERNAL EMULSION | 1.0X1.0X100.0 ML BOTTLE | 10/02/2023 |
| 919 | NDA/MAL/HDP /10580 | ASHISH LIFE SCIENCE PVT LIMITED | ASHISH LIFE SCIENCE UGANDA LTD | ASHIVER FORTE | IVERMECTIN + CLORSULON | (10MG + 100MG)/ML | ASHISH LIFE SCIENCE PVT LIMITED J-137, M.I.D.C., TARAPUR, BOISAR - 401501, TAL & DIST – PALGHAR, MAHARASHTRA, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X50.0 ML BOTTLE, 1.0X1.0X250.0 ML BOTTLE | 10/02/2023 |
| 920 | NDA/MAL/HDP /10581 | NEOGEN CHEMICALS UGANDA LIMITED | NEOGEN CHEMICALS UGANDA LIMITED | OXY-GEN® | OXYTETRACYCLINE HYDROCHLORIDE | 3.15%W/V | HEBEI NEW CENTURY PHARMACEUTICAL CO., LTD NO. 189 TAIHANG STREET., SHIJIAZHUANG, HEBEI CHINA | CHINA | PARENTERAL ORDINARY VIALS | 1.0X1.0X100.0 ML BOTTLE, 1.0X1.0X250.0 ML BOTTLE, 1.0X1.0X500.0 ML BOTTLE | 10/02/2023 |

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| 921 | NDA/MAL/HDP /10582 | ZOETIS BELGIUM SA | ERAM UGANDA LTD | POULVAC MAREK CVI + HVT (RISPENS-HVT) FROZEN | MAREK'S DISEASE CHICKEN HERPES VIRUS-INFECTED CELL SUSPENSION (CVI 988 STRAIN) + MAREK'S DISEASE TURKEY HERPES VIRUS-INFECTED CELL SUSPENSION (FC #126 STRAIN) | (≥1,046 PFU + ≥992 PFU)/ DOSE | ZOETIS INC. 2000 ROCKFORD ROAD, CHARLES CITY, IOWA 50616, USA | UNITED STATES OF AMERICA | PARENTERAL ORDINARY DRY AMPOULES | 1*5*1000 DOSES, GLASS AMPOULES + 1*200ML OF DILUENT IN GLASS VIALS OR PLASTIC BAGS | 10/02/2023 |
| 922 | NDA/MAL/HDP /10583 | VETCARE KENYA LTD | VETCARE UGANDA LTD | TYLODOXY 200 | TYLOSIN TARTRATE + DOXYCYCLINE HYCLATE | (100MG + 100MG)/ GRAM | VETCARE KENYA LTD UNITS 7 AND 8, PLOT NO.336/202, WINSFORD PARK, BABA DOGO ROAD, RUARAKA, NAIROBI, KENYA. | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X10.0X25.0 G SACHET, 1.0X12.0X100.0 G SACHET, 1.0X1.0X1000.0 G JAR | 10/02/2023 |
| 923 | NDA/MAL/HDP /10584 | VETCARE KENYA LTD | VETCARE UGANDA LTD | WORMIFAS DRENCH | LEVAMISOLE HYDROCHLORIDE + OXYCLOZANIDE + COBALT (II) CARBONATE | (15MG + 30MG + 1.5MG) PER ML | VETCARE KENYA LTD UNITS 7 AND 8, PLOT NO.336/202, WINSFORD PARK, BABA DOGO ROAD, RUARAKA, NAIROBI, KENYA. | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X150.0 ML BOTTLE, 1.0X1.0X500.0 ML BOTTLE, 1.0X1.0X1000.0 ML BOTTLE | 10/02/2023 |

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| 924 | NDA/MAL/HDP /10585 | VETCARE KENYA LTD | VETCARE UGANDA LTD | WORMIFAS MZITO SUSPENSION | LEVAMISOLE HYDROCHLORIDE + OXYCLOZANIDE + COBALT (II) CARBONATE + SODIUM SELENITE | (30MG + 60MG + 3.0MG + 0.32MG) PER ML | VETCARE KENYA LTD UNITS 7 AND 8, PLOT NO.336/202, WINSFORD PARK, BABA DOGO ROAD, RUARAKA, NAIROBI, KENYA. | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X125.0 ML BOTTLE, 1.0X1.0X500.0 ML BOTTLE, 1.0X1.0X1000.0 ML BOTTLE | 10/02/2023 |
| 925 | NDA/MAL/HDP /10586 | VETCARE KENYA LTD | VETCARE UGANDA LTD | WORMITREX 7.5 POULTRY | LEVAMISOLE HYDROCHLORIDE | 7.5%W/V | VETCARE KENYA LTD UNITS 7 AND 8, PLOT NO.336/202, WINSFORD PARK, BABA DOGO ROAD, RUARAKA, NAIROBI, KENYA. | KENYA | ORAL LIQUID ORDINARY SOLUTION | 1.0X50.0 ML BOTTLE 1.0X100.0 ML BOTTLE 1.0X500.0 ML BOTTLE 1.0X1000.0 ML BOTTLE 1.0X5000.0 ML BOTTLE | 10/02/2023 |
| 926 | NDA/MAL/HDP /10587 | INTERCHEMIE WERKEN 'DE ADELAAR' B.V. | VET CENTRE (U) LTD | XYLA | XYLAZINE HYDROCHLORIDE | 20MG/ML | INTERCHEMIE WERKEN 'DE ADELAAR' B.V., METAALWEG 8, 5804 CG VENRAY, THE NETHERLANDS | THE NETHERLANDS | PARENTERAL ORDINARY VIALS | 1.0X1.0X50.0 ML BOTTLE | 10/02/2023 |

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| 927 | NDA/MAL/HDP /10589 | PSYCHOTROPICS INDIA LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | PILECA-EZ | ATORVASTATIN + EZETIMIBE | 10 MG + 10 MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49, SECTOR-6A,IIE, SIDCUL,HARIDWAR - 249403( UTTARAKHARD) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 928 | NDA/MAL/HDP /10590 | MYLAN LABORATORIES LIMITED- | KIMSY MEDS LTD | ULCEREST 20 | ESOMEPRAZOLE MAGNESIUM | 20MG | MYLAN LABORATORIES LTD .-F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X28.0 TABLET BOTTLE | 06/03/2023 |
| 929 | NDA/MAL/HDP /10591 | MYLAN LABORATORIES LIMITED- | KIMSY MEDS LTD | ULCEREST 40 | ESOMEPRAZOLE MAGNESIUM | 40MG | MYLAN LABORATORIES LTD .-F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X28.0 TABLET BOTTLE | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 930 | NDA/MAL/HDP /10592 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | ASCARD-75 | ASPIRIN | 75MG | ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700 | PAKISTAN | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 931 | NDA/MAL/HDP /10593 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | MOMRIV | MOMETASONE FUROATE | 0.1%W/W | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 06/03/2023 |
| 932 | NDA/MAL/HDP /10597 | MEDISEL (K) LTD | AIVEEN (UGANDA) LIMITED | GABANERVE | GABAPENTIN + METHYLCOBALAMIN | 300MG + 500MCG | CORONA REMEDIES PVT LTD VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 20/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 933 | NDA/MAL/HDP /10598 | DAR AL DAWA DEVELOPMENT & INVESTMENT CO. LTD | KIMSY MEDS LTD | MIXIF | CEFIXIME TRIHYDRATE | 400MG | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD (DAD) PRINCE HASHEM BIN AL-HUSSEIN STREET, NA'UR AMMAN 11191 JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X5.0 CAPSULE BLISTER | 20/02/2023 |
| 934 | NDA/MAL/HDP /10599 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | BETAMET CREAM | BETAMETHASONE VALERATE | 0.1%W/W | ATCO LABORATORIES LIMITED-B-18, S.I.T.E, KARACHI - 74700 | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 06/03/2023 |
| 935 | NDA/MAL/HDP /10600 | MEDISEL (K) LTD | AIVEEN (U) LTD | OSTEOCERIN | GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE + METHL SULPHONYL METHANE (MSM) + DIACEREIN | 750MG + 250MG + 50MG | CORONA REMEDIES PVT LTD VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 20/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 936 | NDA/MAL/HDP/10601 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA(A) LTD | VORIOLE 50 | VORICONAZOLE | 50 MG | MSN LABORATORIES PRIVATE LIMITED – FORMULATIONS DIVISION PLOT NO.: 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, TELANGANA - 502 325, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 20/02/2023 |
| 937 | NDA/MAL/HDP/10602 | WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş. | GOODMAN INTERNATIONAL LTD | ZIROMIN 200 MG/5 ML | AZITHROMYCIN DIHYDRATE | 200 MG/5 ML | WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESI, CAMI YOLU CADDESI, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY | TURKEY | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML BOTTLE | 06/03/2023 |
| 938 | NDA/MAL/HDP/10603 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | ETOPOSIDE 200 MG/10ML | ETOPOSIDE | 200 MG/10ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0 ML AMPOULE | 06/03/2023 |

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| 939 | NDA/MAL/HDP /10604 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PIPERATAZ 4.5 | PIPERACILLIN + TAZOBACTAM | 4 G + 0.5 G | UNI MEDICOLABS-UNI MEDICOLABS, PLOT NO. 21-22, PHARMACITY, SELAQUI, DEHRADUN - 248011 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X4.5 G VIAL | 06/03/2023 |
| 940 | NDA/MAL/HDP /10605 | PSYCHOTROPICS INDIA LTD. | ABACUS PHARMA (A) LTD | HALOPAC | HALOPERIDOL | 5MG | PSYCHOTROPICS INDIA LTD. PLOT NO.46 & 49, SECTOR-6A, IIE, SIIDCUL, HARIDWAR- 249403 (UTTARAKHAND), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 20/02/2023 |
| 941 | NDA/MAL/HDP /10606 | MEDISEL (K) LTD | ALVEEN (U) LIMITED | EMADON SYRUP | ONDANSETRON HYDROCHLORIDE | 2MG/5ML | CORONA REMEDIES PVT LTD VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X30.0 ML BOTTLE | 20/02/2023 |

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| 942 | NDA/MAL/HDP /10607 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD | DOLAC | KETOROLAC TROMETHAMINE | 10 MG | CADILA PHARMACEUTICALS LIMITED<br>1389, TRASAD ROAD,<br>DHOLKA – 382225,<br>DIST:AHMEDABAD<br>GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 20/02/2023 |
| 943 | NDA/MAL/HDP /10608 | WILSHIRE LABORATORIES (PVT) LTD | HEALTHCARE LIMITED | QOSMET 500/50 | METFORMIN HYDROCHLORIDE+ SITAGLIPTIN MONOHYDRATE PHOSPHATE | 500MG + 50MG | WILSHIRE LABORATORIES (PVT) LTD, 124/1, INDUSTRIAL ESTATE, KOT LAKHPAT LAHORE PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X5.0 TABLET BLISTER | 20/02/2023 |
| 944 | NDA/MAL/HDP /10609 | FDC LIMITED | AIVEEN UGANDA LIMITED | OCUDOR | DORZOLAMIDE HYDROCHLORIDE | 2%W/V | FDC LIMITED<br>B-8, MIDC INDUSTRIAL AREA , WALUJ , AURANGABAD 431136<br>MAHARASHTRA , INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 20/02/2023 |

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| 945 | NDA/MAL/HDP /1061 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | BISACODYL TABLETS | BISACODYL | 5MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 946 | NDA/MAL/HDP /10610 | WORLD MEDICINE İLAÇ SAN. VE TIC. A.Ş. | GOODMAN INTERNATIONAL LTD | ESLOTIN | DESLORATADINE | 2.5 MG/5ML | WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESI, CAMI YOLU CADDESI, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY | TURKEY | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 06/03/2023 |
| 947 | NDA/MAL/HDP /10611 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | NEWSTAR 160/10 MG | VALSARTAN + AMLODIPINE BESYLATE | 160 MG + 10 MG | PHARMA INTERNATIONAL CO. LTD -AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 06/03/2023 |

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| 948 | NDA/MAL/HDP /10612 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | NEWSTAR 160/5 MG | VALSARTAN + AMLODIPINE BESYLATE | 160 MG + 5 MG | PHARMA INTERNATIONAL CO. LTD -AL QASTAL AIRPORT ROAD, P.O. BOX 334 AL JUBAIHA 11941, AMAAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 06/03/2023 |
| 949 | NDA/MAL/HDP /10613 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | SYNER-CEF 500 | CEFUROXIME AXETIL | 500MG | M/S SCOTT-EDIL ADVANCE RESEARCH LABORATORIES AND EDUCATION LIMITED-HILL-TOP, INDUSTRIAL AREA, BHATOLI KALAN, BADDI, DISTT. SOLAN (HP) - 173205, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/03/2023 |
| 950 | NDA/MAL/HDP /10614 | S KANT HEALTHCARE LTD - | ABACUS PHARMA (AFRICA) LIMITED | AVIRAX | ACICLOVIR | 5% W/W | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X10.0 G TUBE | 06/03/2023 |

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| 951 | NDA/MAL/HDP /10615 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | LEVOZIN 5 | LEVOCETIRIZINE DIHYDROCHLORIDE | 5MG | LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |
| 952 | NDA/MAL/HDP /10616 | COSMOS LTD. | ASTRA PHARMA (U) LIMITED | GLYSIT 5 | DAPAGLIFLOZIN | 5MG | COSMOS LTD..-RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 06/03/2023 |
| 953 | NDA/MAL/HDP /10617 | COSMOS LTD. | ASTRA PHARMA (U) LIMITED | GLYSIT 10 | DAPAGLIFLOZIN | 10MG | COSMOS LTD..-RANGWE ROAD OFF, LUNA LUNGA ROAD, INDUSTRIAL AREA - NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 06/03/2023 |

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| 954 | NDA/MAL/HDP /10618 | BHARAT SERUMS & VACCINES LTD. | ABACUS PHARMA (AFRICA) LIMITED | FOLIGRAF 150 I.U | RECOMBINANT - HUMAN FOLLICLE STIMULATING HORMONE (R-HFSH) | 150 I.U/1ML | BHARAT SERUM AND VACCINES LIMITED-PLOT NO. K-27 ADDITIONAL M.I.D.C INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0X1.0 ML PRE- FILLED SYRINGE | 06/03/2023 |
| 955 | NDA/MAL/HDP /10619 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | DEXIREN | DEXKETOPROFEN TROMETAMOL | 50MG/2ML | IDOL ILAC SAN. VE TIC A.S, 34010 TOPKAPI, ISTANBUL, TURKEY | TURKEY | PARENTERAL ORDINARY AMPOULES | 1*1*6*2 ML, AMBER GLASS AMPOULES | 20/02/2023 |
| 956 | NDA/MAL/HDP /1062 | VENUS REMEDIES LTD | HARLEYS UGANDA LIMITED | VANCONEX-CP | VANCOMYCIN | 500MG | VENUS REMEDIES LIMITED-UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI BADDI (HP) 173205 INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2013 |

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| 957 | NDA/MAL/HDP /10620 | RENE INDUSTRIES LTD | RENE INDUSTRIES LTD | BUSCOREN | HYOSCINE BUTYLBROMIDE | 10 MG | RENE INDUSTRIES LTD. P.O BOX 6034, PLOT NO 680, KAMULI, KIREKA, KAMPALA, UGANDA | UGANDA | ORAL SOLID ORDINARY SUGAR-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 20/02/2023 |
| 958 | NDA/MAL/HDP /10621 | RENE INDUSTRIES LTD | RENE INDUSTRIES LTD. | PENIREN | PHENOXYMETHYLP ENICILLIN POTASSIUM | 250MG | RENE INDUSTRIES LTD. PLOT NO 680, PO BOX 6034, KAMULI, KIREKA, KAMPALA, UGANDA. | UGANDA. | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 20/02/2023 |
| 959 | NDA/MAL/HDP /10622 | CENTURION LABORATORIES PVT. LTD | SHREEJI PHARMACEUTICA LS LTD | PANTOPRAM 40 | PANTOPRAZOLE SODIUM SESQUIHYDRATE | 40 MG | CENTURION LABORATORIES PVT. LTD. P-2, BIO-TECH PARK, MANJUSAR, SAVLI, DIST. BARODA, INDIA. | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |

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| 960 | NDA/MAL/HDP /10623 | RENE INDUSTRIES LTD | RENE INDUSTRIES LTD | STERIREN | CHLORHEXIDINE GLUCONATE | 5% W/V | RENE INDUSTRIES LTD. PO BOX 6034, PLOT NO.680, KAMULI, KIREKA, KAMPALA, UGANDA | UGANDA | TOPICAL EXTERNAL LIQUIDS | 1*5 L, HDPE CONTAINER | 20/02/2023 |
| 961 | NDA/MAL/HDP /10624 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (U) LTD | MIBZO | BORTEZOMIB | 3.5 MG/VIAL | MSN LABORATORIES PRIVATE LIMITED - FORMULATIONS DIVISION, FORMULATIONS DIVISION, UNIT-II, SURVEY NOS. 1277, 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANGAREDDY DISTRICT, TELANGANA 509216, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1*3.5 MG, CLEAR GLASS VIAL | 20/02/2023 |
| 962 | NDA/MAL/HDP /10625 | LA RENON HEALTHCARE PVT. LTD | AIVEEN (U) LTD | ESOGRESS 40 | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 40 MG | STANFORD LABORATORIES PRIVATE LIMITED (A SUBSIDIARY COMPANY OF LA RENON HEALTHCARE PRIVATE LIMITED, 8, INDUSTRIAL AREA, MEHATPUR - 174315, HIMACHAL PRADESH INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |

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| 963 | NDA/MAL/HDP /10626 | GAMA PHARMACEUTICALS (U) LTD | GAMA PHARMACEUTICALS (U) LTD | XAPRINE 5 | CYCLOBENZAPRINE HYDROCHLORIDE | 5 MG | BEIT JALA PHARMACEUTICAL CO. 81, AL-MADARESS STREET, P.O. BOX 58, BEIT JALA-PALESTINE | PALESTINE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 20/02/2023 |
| 964 | NDA/MAL/HDP /10627 | GAMA PHARMACEUTICALS (U) LTD | GAMA PHARMACEUTICALS (U) LTD | XAPRINE 10 | CYCLOBENZAPRINE HYDROCHLORIDE | 10 MG | BEIT JALA PHARMACEUTICAL CO. 81, AL-MADARESS STREET, P.O. BOX 58, BEIT JALA-PALESTINE | PALESTINE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 20/02/2023 |
| 965 | NDA/MAL/HDP /10628 | HILTON PHARMA (PVT.) LTD. | ASTRA PHARMA (U) LTD | SITAGLU MET 50/500 | SITAGLIPTIN PHOSPHATE + METFORMIN HYDROCHLORIDE | 50 MG + 500 MG | HILTON PHARMA (PVT.) LTD. PLOT NO.13-14, SECTOR 15, KORANGI INDUSTRIAL AREA KARACHI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 20/02/2023 |

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| 966 | NDA/MAL/HDP /10629 | HILTON PHARMA (PVT.) LTD. | ASTRA PHARMA (U) LTD | SITAGLU MET 50/500 | SITAGLIPTIN PHOSPHATE + METFORMIN HYDROCHLORIDE | 50 MG + 500 MG | HILTON PHARMA (PVT.) LTD. PLOT NO.13-14, SECTOR 15, KORANGI INDUSTRIAL AREA KARACHI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 20/02/2023 |
| 967 | NDA/MAL/HDP /10630 | INNOVA CAPTAB PVT. LTD | TATA UGANDA LTD | INFIXIME 400 | CEFIXIME TRIHYDRATE | 400MG | INNOVA CAPTAB PVT. LTD 1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP, PHASE-I, JHARMAJARI, BADDI, DIST. SOLAN (H.P.) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 20/02/2023 |
| 968 | NDA/MAL/HDP /10631 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LIMITED | RYALTRIS | OLOPATADINE HYDROCHLORIDE + MOMETASONE FUROATE | 665 MCG/25 MCG | GLENMARK PHARMACEUTICALS LIMITED (UNIT III), VILLAGE KISHANPURA, BADDI- NALAGARH ROAD, TEHSIL BADDI, DISTT. SOLAN HIMACHAL PRADESH-173205, INDIA | INDIA | NASAL TOPICAL SPRAYS WITHOUT GAS | HDPE BOTTLE | 20/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 969 | NDA/MAL/HDP /10632 | PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD.) | ROYAL PHARMA 2011 LTD | ROSUVAT 10 | ROSUVASTATIN CALCIUM | 10 MG | GLOBELA PHARMA PVT. LTD., 357, G.I.D.C., SACHIN, SURAT 394 230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 970 | NDA/MAL/HDP /10633 | MYLAN PHARMACEUTICAL PRIVATE LIMITED | KIMSY MEDS LTD | FULPHILA | PEGFILGRASTIM | 6 MG/0.6 ML | BIOCON LIMITED<br>SPECIAL ECONOMIC ZONE<br>PLOT NO: 2, 3, 4, 5, PHASE – IV<br>BOMMASANDRA JIGANI LINK ROAD<br>BOMMASANDRA POST<br>BANGALORE<br>KARNATAKA, 560099<br>INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1*1*1, 0.6 ML SINGLE DOSE PREFILLED SYRINGE | 20/02/2023 |
| 971 | NDA/MAL/HDP /10634 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | FLUSCOT | PARACETAMOL + CAFFEINE + CHLORPHENIRAMINE MALEATE + PHENYLEPHRINE HYDROCHLORIDE | 500MG + 30MG + 2MG + 10MG | M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 06/03/2023 |

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| 972 | NDA/MAL/HDP /10636 | UNICHEM LABORATORIES LIMITEDv | EUROPA HEALTHCARE (U) LTD | UNIPROEX ER 250 | DIVALPROEX SODIUM | 250MG | UNICHEM LABORATORIES LTD-PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511 | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 973 | NDA/MAL/HDP /10637 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | SETRIZIN | CETIRIZINE | 10MG | M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |
| 974 | NDA/MAL/HDP /10638 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE, GENTAMICIN SULPHATE CREAM | CLOTRIMAZOLE + BETAMETHASONE DIPROPIONATE + GENTAMICIN SULPHATE | (10 MG + 0.5 MG + 1 MG)/G | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 975 | NDA/MAL/HDP /10639 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CIROVIR | ACICLOVIR | 5%W/W | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X5.0 G TUBE | 06/03/2023 |
| 976 | NDA/MAL/HDP /10640 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DISTEM | METHOCARBAMOL + PARACETAMOL | 380 MG + 300 MG | FAES FARMA SA-MAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 06/03/2023 |
| 977 | NDA/MAL/HDP /10641 | BHARAT BIOTECH INTERNATIONAL LIMITED. | REDDYS PHARMA LIMITED | TYPBAR TCV | S. TYPHI TY 2 CONJUGATED TO TETANUS TOXOID | 25 MCG/0.5ML | BHARAT BIOTECH INTERNATIONAL LTD-GENOME VALLEY, SHAMEERPET MANDAL, RANGAREDDY, TELANGANA STATE-500078 INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0X1.0 PREFILLED SYRINGE CARTON | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 978 | NDA/MAL/HDP/10642 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PACSITA 150 | CAPECITABINE | 150MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/03/2023 |
| 979 | NDA/MAL/HDP/10643 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PACSITA 500 | CAPECITABINE | 500MG | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/03/2023 |
| 980 | NDA/MAL/HDP/10644 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | LORATYN 10 | LORATADINE | 10MG | HOVID BERHAD (IPOH SITE)-121, JALAN TUNKU ABDUL RAHMAN 30010 IPOH PERAK | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 981 | NDA/MAL/HDP /10645 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VINKAMINE | VANCOMYCIN HYDROCHLORIDE | 500MG | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X1.0X500.0 MG VIAL | 06/03/2023 |
| 982 | NDA/MAL/HDP /10646 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | ENZYSTAL P | PANCREAS POWDER | EQUIVALENT TO AMYLASE ACTIVITY 4200 PH. EUR UNITS, LIPASE ACTIVITY 3500 PH. EUR UNITS AND PROTEASE ACTIVITY 250 PH. EUR UNITS | TORRENT PHARMACEUTICALS LTD - VILLAGE: BHUD & MAKHNU MAJRA, TEHSIL: BADDI – 173205, DIST: SOLAN, HIMACHAL PRADESH, | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 06/03/2023 |
| 983 | NDA/MAL/HDP /10648 | CIPLA LTD | QUALITY CHEMICALS LTD | TENVIR-AF | TENOFOVIR ALAFENAMIDE FUMARATE | 25MG | CIPLA LIMITED-PLOT NO. A-33, A-2 & A-37/2/2 (UNIT-I), A-42(UNIT-II), MIDC PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 984 | NDA/MAL/HDP/10649 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | ESOCID 40 | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 40MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 985 | NDA/MAL/HDP/1065 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | SLIPIZEM-5 | DIAZEPAM | 5MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | RECTAL SYSTEMIC ADULT SUPPOSITORIES | 1.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 986 | NDA/MAL/HDP/10650 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | MEROPENEM FOR INJECTION USP | MEROPENEM TRIHYDRATE | 1G | CSPC OUYI PHARMACEUTICAL CO. LTD.-WORKSHOPS 112,113 AND 117 PLOT NO. 88 YANGZI ROAD,ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 987 | NDA/MAL/HDP /10651 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BROZELIN | AMBROXOL HYDROCHLORIDE + SALBUTAMOL + GUAIPHENESIN + MENTHOL | (30 MG + 2 MG + 50 MG + 1 MG)/5 ML | THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 06/03/2023 |
| 988 | NDA/MAL/HDP /10652 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | Z-OFLOX 200 | OFLOXACIN | 200MG | ZOTA HEATHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |
| 989 | NDA/MAL/HDP /10653 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | COXZOTA-60 | ETORICOXIB | 60MG | ZOTA HEATHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 990 | NDA/MAL/HDP /10654 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION | SODIUM LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE | 0.320%W/V + 0.600%W/V + 0.040%W/V + 0.027%W/V | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 06/03/2023 |
| 991 | NDA/MAL/HDP /10655 | HETERO LABS LTD | AIVEEN (U) LIMITED | TENOFOVIR ALAFENAMIDE TABLETS | TENOFOVIR ALAFENAMIDE HEMIFUMARATE | 25MG | HETERO LABS LIMITED (UNIT V)-SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 06/03/2023 |
| 992 | NDA/MAL/HDP /10658 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ATORKEY 40 | ATORVASTATIN CALCIUM TRIHYDRATE | 40MG | AUROBINDO PHARMA LIMITED, UNIT - XV-PLOT NO. 17A, E BONANGI (V), PARAWADA (M), VISAKHAPATNAM DISTRICT, ANDHRA PRADESH. PIN: 531021 | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 993 | NDA/MAL/HDP /10659 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | ACENAC-P | ACECLOFENAC + PARACETAMOL | 100MG + 500MG | MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 994 | NDA/MAL/HDP /10660 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | AZITOZ-250 | AZITHROMYCIN DIHYDRATE | 250MG | ZOTA HEATHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 06/03/2023 |
| 995 | NDA/MAL/HDP /10661 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | LIVOTA-750 | LEVOFLOXACIN HEMIHYDRATE | 750MG | ZOTA HEATHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 996 | NDA/MAL/HDP /10662 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LIMITED | TOMOZA | MOSAPRIDE CITRATE DIHYDRATE | 5MG | ZOTA HEATHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NEAR SACHIN RAILWAY STATION, SACHIN, CITY: SURAT, DIST: SURAT, GUJARAT STATE - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 997 | NDA/MAL/HDP /10663 | FERRER INTERNATIONAL,SA | PHILIPS PHARMACEUTICALS (U) LTD | TRAMAPA 37.5 MG/325 MG | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 37.5 MG/325 MG | FERRER INTERNACIONAL, S.A C/JOAN BUSCALLA, 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 20/02/2023 |
| 998 | NDA/MAL/HDP /10664 | FDC LIMITED | AIVEEN UGANDA LTD | OCUDORT-T | DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE | (20 MG + 5 MG)/ML | FDC LTD.<br>B-8, MIDC INDUSTRIAL AREA, WALUJ, AURANGABAD 431136<br>MAHARASHTRA, INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 20/02/2023 |

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| 999 | NDA/MAL/HDP /10665 | AUROBINDO PHARMA LIMITED | PHILIPS PHARMACEUTICALS (UGANDA) LIMITED | CIATUFF 10 | TADALAFIL | 10 MG | AUROBINDO PHARMA LIMITED, UNIT-VII, SEZ, TSIIC, PLOT NO. S1, SURVEY NO'S: 411/P, 425/P, 434/P, 435/P & 458/P, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOBNAGAR DISTRICT, TELANGANA STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X4.0 TABLET BLISTER | 20/02/2023 |
| 1000 | NDA/MAL/HDP /10666 | LINCOLN PHARMACEUTICALS LIMITED | METRO PHARMACEUTICALS LTD | VANCOLIN-500 | VANCOMYCIN HYDROCHLORIDE | 500 MG | LINCOLN PARENTERAL LIMITED, 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*10*500 MG CLEAR GLASS VIALS | 20/02/2023 |
| 1001 | NDA/MAL/HDP /10667 | VINS BIOPRODUCTS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LTD | VINRAB 1000 IU | EQUINE ANTIRABIES IMMUNOGLOBULIN FRAGMENTS F (AB') 2 | NOT LESS THAN 200 IU PER ML | VINS BIOPRODUCTS LIMITED, SURVEY NO.117, THIMMAPUR (V) KOTHUR MANDAL, RANGA REDDY-DIST., TELANGANA., INDIA 509325 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*1*5 ML, CLEAR GLASS VIAL | 20/02/2023 |

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| 1002 | NDA/MAL/HDP /10668 | LUPIN LIMITED | AIVEEN UGANDA LIMITED | DOLUTEGRAVIR SODIUM/LAMIV UDINE/TENOFO VIR DISOPROXIL FUMERATE 50MG/300MG/ 300MG | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXI | 50 MG + 300 MG + 300 MG | LUPIN LIMITED PLOT NO. 6A, SECTOR 17, SPECIAL ECONOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHSTRA, INDIA. (BLOCK 1). | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X60.0 TABLET BOTTLE | 20/02/2023 |
| 1003 | NDA/MAL/HDP /10669 | AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LTD | CARDIOTIMIDE 20 MG | TORSEMIDE | 20 MG | AL ANDALOUS FOR PHARMACEUTICAL INDUSTRIES ADDRESS: PART NO. 7/6, 6TH INDUSTRIAL AREA, 6TH OF OCTOBER CITY, EGYPT. | EGYPT | ORAL SOLID ORDINARY TABLETS | AL/OPAQUE(PVC/P VDC | 20/02/2023 |
| 1004 | NDA/MAL/HDP /1067 | MACK BROWN PHARMECEUTICAL S PVT LTD | SHURIK LTD | IBUPARA | IBUPROFEN+PARA CETAMOL | 200MG+ 250MG/10ML | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2010 |

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| 1005 | NDA/MAL/HDP /10670 | HILTON PHARMA (PVT.) LTD. | HEALTHCARE LIMITED | DOLGINA | DEXLANSOPRAZOL E | 30 MG | HILTON PHARMA (PVT.) LTD. PLOT NO.13-14, SECTOR 15, KORANGI INDUSTRIAL AREA KARACHI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 20/02/2023 |
| 1006 | NDA/MAL/HDP /10671 | HILTON PHARMA (PVT.) LTD. | HEALTHCARE LIMITED | TRANSAMIN-S | TRANEXAMIC ACID | 1000MG/10ML | HILTON PHARMA (PVT.) LTD. PLOT NO.13-14, SECTOR 15, KORANGI INDUSTRIAL AREA KARACHI, PAKISTAN | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1*2*5, CLEAR GLASS AMPOULES | 20/02/2023 |
| 1007 | NDA/MAL/HDP /10672 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDY'S PHARMA LTD | DNS | SODIUM CHLORIDE + ANHYDROUS GLUCOSE | 0.9%W/V & 5%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED, VILLAGE; VASANA – CHACHARWADI,TAL:SANAND , DIST;AHMEDABAD, 382 213, INDIA | INDIA | SOLUTION FOR INTRAVENOUS INFUSION | 1*1*500ML, LDPE BOTTLE | 20/02/2023 |

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| 1008 | NDA/MAL/HDP/10673 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 2011 LIMITED | CETARIV | CETIRIZINE HYDROCHLORIDE | 5MG/5ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 06/03/2023 |
| 1009 | NDA/MAL/HDP/10674 | VINS BIO PRODUCTS LIMITED | PHILLIPS PHARMACEUTICALS (U) LTD | AFRIVEN-10 | NAJA MELANOLEUCA+ NAJA NIGRICOLLIS + NAJA HAJE + DENDROASPIS POLYLEPIS + DENDROASPIS VIRIDIS + DENDROASPIS JAMESONI + BITIS GABONICA + BITIS ARIETANS + ECHIS | NOT LESS THAN 22 LD50 + 22 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 + 27.5 LD50 | VINS BIOPRODUCTS LIMITED, SURVEY NO.117, THIMMAPUR (V) KOTHUR MANDAL, RANGA REDDY-DIST., TELANGANA., INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*5, 10 ML CLEAR GLASS VIAL | 20/02/2023 |
| 1010 | NDA/MAL/HDP/10675 | THE SEARLE COMPANY LIMITED | HEALTHCARE LIMITED | JENTIN 50 | SITAGLIPTIN PHOSPHATE MONOHYDRATE | 50 MG | THE SEARLE COMPANY LIMITED, F-319, S. I.T.E. KARACHI PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1*2*7,ALU/ALU BLISTER PACK | 20/02/2023 |

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| 1011 | NDA/MAL/HDP /10676 | THE SEARLE COMPANY LIMITED | HEALTHCARE LIMITED | JENTIN 100 | SITAGLIPTIN PHOSPHATE MONOHYDRATE | 100 MG | THE SEARLE COMPANY LIMITED, F-319, S. I.T.E. KARACHI PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1*2*7,ALU/ALU BLISTER PACK | 20/02/2023 |
| 1012 | NDA/MAL/HDP /10677 | MEDOCHEMIE LTD | SHREEJI PHARMACEUTICALS LTD | MEDOCRIPTINE 2.5 MG | BROMOCRIPTINE MESILATE | 2.5 MG | MEDOCHEMIE LTD. (CENTRAL FACTORY), 1-10 CONSTANTINOUPOLEOS STREET, 3011 LIMASSOL, CYPRUS | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1013 | NDA/MAL/HDP /10678 | KESAR PHARMA (P) LIMITED, | ABACUS PHARMA (A) LIMITED | ARTELUM | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | KESAR PHARMA (P) LIMITED, PLOT SURVEY NO.50-P/2, VILLAGE, BILESHWARPURA, PO CHHATRAL-382729. TAL.KALOL, DIST. GANDHINAGAR, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1*1*24 ALU/PVC BLISTER PACK | 20/02/2023 |

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| 1014 | NDA/MAL/HDP /10679 | ZOTA HEALTHCARE LTD | REDDY`S PHARMA LTD, | PG-75 | PREGABALIN | 75 MG | ZOTA HEALTHCARE LTD., PLOT NO: 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN, SURAT-394 230, GUJARAT, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 20/02/2023 |
| 1015 | NDA/MAL/HDP /10680 | RAPTAKOS, BRETT & CO. LTD | EUROPA HEALTHCARE (U) LTD | NEOPEPTINE PLUS DROPS | ALPHA AMYLASE (BACTERIAL 1:800) + PAPAIN | (20MG + 10MG) PER ML | RAPTAKOS, BRETT & CO LTD 1ST POKHRAN ROAD, SHASTRI NAGAR, THANE 400606, INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X1.0X5.0 ML BOTTLE | 20/02/2023 |
| 1016 | NDA/MAL/HDP /10681 | BIODEAL LABORATORIES LTD | ABACUS PHARMA (U) LTD | PODOSAL OINTMENT | PODOPYLLUM RESIN + SALICYLIC ACID | 20%W/W + 25%W/W | BIODEAL LABORATORIES LTD, PLOT NO.123, LUNGA LUNGA ROAD, P.O BOX 32040-00600, NAIROBI KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1*1*10 GM , ALLUMINIUM COLLAPSIBLE TUBE | 20/02/2023 |

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| 1017 | NDA/MAL/HDP /10682 | HETERO LABS LIMITED | AIVEEN (U) LTD | RALTEGRAVIR TABLETS | RALTEGRAVIR POTASSIUM | 400 MG | HETERO LABS LIMITED UNIT – III (FORMULATIONS), 22 – 110, I.D.A JEEDIMETLA, HYDERABAD, TELANGANA, INDIA. PIN CODE 500 055 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1*60, HDPE CONTAINER | 20/02/2023 |
| 1018 | NDA/MAL/HDP /10683 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS LTD | MF-DAY ER 750 | METFORMIN HYDROCHLORIDE | 750 MG | AUROBINDO PHARMA LIMITED (UNIT III) SURVEY NO. 313 & 314, BACHUPALLY, BACHUPALLY MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1019 | NDA/MAL/HDP /10684 | GALENICUM HEALTH S.L. | GOODMAN INTERNATIONAL LTD | DUTASVITAE 0.5MG | DUTASTERIDE | 0.5MG | CYNDEA PHARMA, S.L-POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA) | SPAIN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1020 | NDA/MAL/HDP /10685 | AVACARE GLOBAL | GOODMAN INTERNATIONAL LTD | DEMOX | MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE PHOSPHATE | (5MG + 1MG)/ML | WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESI, CAMI YOLU CADDESI, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY | TURKEY | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 06/03/2023 |
| 1021 | NDA/MAL/HDP /10686 | HETERO LABS LTD | AIVEEN (U) LIMITED | CELOFEN 200 | CELECOXIB | 200MG | HETERO LABS LIMITED (UNIT V)-SY. NO. 439, 440, 441 & 458, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOOBNAGAR DISTRICT, PIN-509 301, TELANGANA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 06/03/2023 |
| 1022 | NDA/MAL/HDP /10687 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | IRNIZET 300 | IRINOTECAN HYDROCHLORIDE TRIHYDRATE | 300 MG/15ML | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X15.0 ML VIAL | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1023 | NDA/MAL/HDP /10688 | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED, | ABACUS PHARMA (A) LTD | UROKA | DUTASTERIDE | 0.5 MG | MEGA LIFESCIENCES PUBLIC COMPANY LIMITED, 384 MOO 4, SOI 6, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKAN 10280, THAILAND | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 20/02/2023 |
| 1024 | NDA/MAL/HDP /10689 | ZOTA HEALTHCARE LTD | REDDYS PHARMA LTD | LOSARZED-100 | LOSARTAN POTASSIUM | 100 MG | ZOTA HEALTHCARE LTD., PLOT NO: 169, SURAT SPECIAL ECONOMY ZONE, NR. SACHIN RAILWAY STATION, SACHIN, SURAT-394 230, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1025 | NDA/MAL/HDP /1069 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | K-ONE INJECTION | PHYTOMENADIONE | 10MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X1.0 ML AMPOULE | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1026 | NDA/MAL/HDP /10690 | SUNRISE INTERNATIONAL LABS LTD | ROYAL PHARMA 2011 LTD | PROTAC-40 | PANTOPRAZOLE SODIUM | 40 MG | SUNRISE INTERNATIONAL LABS LTD. PLOT NO. 100, LANE-5, SECTOR-II, PHASE II, IDA CHERLAPALLY, HYDERABAD 500051 INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1027 | NDA/MAL/HDP /10691 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NEUROGLOPENTIN 400 MG | GABAPENTIN | 400 MG | GLOBAL NAPI PHARMACEUTICALS 2ND INDUSTRIAL ZONE, 6TH OCTOBER CITY, GIZA, EGYPT | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 20/02/2023 |
| 1028 | NDA/MAL/HDP /10692 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NEUROGLOPENTIN 300 MG | GABAPENTIN | 300 MG | GLOBAL NAPI PHARMACEUTICALS 2ND INDUSTRIAL ZONE, 6TH OCTOBER CITY, GIZA, EGYPT | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 20/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1029 | NDA/MAL/HDP /10693 | SWISS PARENTERALS LTD | SHREEJI CARE LTD | GEN DEX EYE DROPS | GENTAMICIN SULFATE + DEXAMETHASONE SODIUM PHOSPHATE | 0.3% W/V + 0.1% W/V | SWISS PARENTERALS LTD. 808, 809, 810 KERALA INDUSTRIAL ESTATE, NR. BAVLA, DIST. AHMEDABAD - 382 220 GUJARAT, INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 20/02/2023 |
| 1030 | NDA/MAL/HDP /10694 | MYLAN LABORATORIES LIMITED- | KIMSY MEDS LTD | OTYCULF 500 MG | FLUCYTOSINE | 500MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X100.0 TABLET BOTTLE | 06/03/2023 |
| 1031 | NDA/MAL/HDP /10695 | UNIMED LABORATORIES | OMAB UGANDA LTD | GLUCOSE 5 % UNIMED | GLUCOSE ANHYDROUS | 5%W/V | UNIMED LABORATORIES P.O BOX: 38, I.Z 4060 KALAA KEBIRA TUNISIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1*100 ML, POLYOLEFIN BAG | 20/02/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1032 | NDA/MAL/HDP /10696 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | CELEBIB CAPSULES 200MG | CELECOXIB | 200MG | MACLEODS PHARMACEUTICALS LIMITED, UNIT VI-VILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL PRADESH–174101 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 06/03/2023 |
| 1033 | NDA/MAL/HDP /10697 | BHARAT SERUMS & VACCINES LTD. | ABACUS PHARMA (AFRICA) LIMITED | ASPORELIX | CETRORELIX ACETATE | 0.25MG | BHARAT SERUM AND VACCINES LIMITED-PLOT NO. K-27 ADDITIONAL M.I.D.C INDIA | INDIA | PARENTERAL ORDINARY I V VIALS | 1.0X0.25 MG VIAL + 1*1ML GLASS AMPOULE OF WFI | 06/03/2023 |
| 1034 | NDA/MAL/HDP /10698 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | PACLITAXEL 6 MG /1 ML | PACLITAXEL | 6 MG /1 ML | EBEWE PHARMA GES.M.B.H. NFG. KG MONDSEESTRASSE 11 4866 UNTERACH AM ATTERSEE AUSTRIA. | AUSTRIA. | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | EBEWE PHARMA GES.M.B.H. NFG. KG MONDSEESTRASSE 11 4866 UNTERACH AM ATTERSEE AUSTRIA. | 20/02/2023 |

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| 1035 | NDA/MAL/HDP /10699 | PHARMA BAVARIA INTERNACIONAL (PBI) | GOODMAN INTERNATIONAL LTD | RHINIZILL 50 | MOMETASONE FUROATE MONOHYDRATE | 50 MG/ACTUATION | FARMEA<br>10, RUE BOUCHÉ THOMAS<br>Z.A.C D'ORGEMONT<br>49000 ANGERS<br>FRANCE | FRANCE | NASAL TOPICAL SPRAYS WITHOUT GAS | 1*1, HDPE BOTTLE WITH 120 OR 140 ACTUATIONS, GLASS CONTAINER | 20/02/2023 |
| 1036 | NDA/MAL/HDP /10700 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | NEPEXTO 50 MG | ETANERCEPT (RDNA ORIGIN) | 50 MG/ML | LUPIN LIMITED (BIOTECH DIVISION)-GAT NO. 1156, GHOTAWADDE - VILLAGE, MULSHI-TALUKA, PUNE - 412 115 | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0X1.0 ML PRE- FILLED SYRINGE | 06/03/2023 |
| 1037 | NDA/MAL/HDP /10701 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | NEPEXTO 25 MG | ETANERCEPT | 25MG/0.5ML | LUPIN LIMITED (BIOTECH DIVISION)-GAT NO. 1156, GHOTAWADDE - VILLAGE, MULSHI-TALUKA, PUNE - 412 115 | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0X0.5 ML PRE- FILLED SYRINGE | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1038 | NDA/MAL/HDP /10702 | UNIMED LABORATORIES | OMAB UGANDA LIMITED | VAAMOX 1G/200 MG | SODIUM AMOXICILLIN + POTASSIUM CLAVULANATE. | (1 G + 200 MG)VIAL | UNIMED LABORATORIES I.Z KALAA KEBIRA P.O BOX 38 4060 TUNISIA | TUNISIA | PARENTERAL ORDINARY DRY VIALS | 1*1, CLEAR GLASS VIAL | 20/02/2023 |
| 1039 | NDA/MAL/HDP /10703 | MOTI PHARMA (U) LTD | MOTI PHARMA(U) LTD. | TOPSUNATE | TOPSUNATE | 60 MG | SANJAR PHARMA LLP SURVEY NO. 622/2/1/4, HIMATNAGAR - VIJAPUR HIGHWAY, DEDHROTA, HIMATNAGAR - 383 220, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1*[1, CLEAR GLASS VIAL + 5ML OF 0.9%W/V SODIUM CHLORIDE SOLUTION IN A CLEAR GLASS AMPOULE + 1ML OF 5%W/V SODIUM BICARBONATE SOLUTION IN A CLEAR GLASS | 20/02/2023 |
| 1040 | NDA/MAL/HDP /10704 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LTD | EMEFILM-4 | ONDANSETRON HYDROCHLORIDE | 4 MG | SHILPA THERAPEUTICS PRIVATE LIMITED (FORMERLY M/S NU THERAPEUTICS PVT. LTD.) PLOT NO. 118, PHASE III, IDA, CHERLAPALLY HYDERABAD-500 051, INDIA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1*5, ALU/ALU STRIP PACK | 20/02/2023 |

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| 1041 | NDA/MAL/HDP /10705 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | SUPADOL 500 | PARACETAMOL | 500 MG | BIOMATRIX HEALTHCARE PVT LTD. SURVEY NO. 624, SARKHEJ – BAVLA HIGHWAY, VIL.: RAJODA, TAL.: BAVLA, DIST.: AHMEDABAD – 382 220, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1042 | NDA/MAL/HDP /10706 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | NTSUGA 500 | METFORMIN HYDROCHLORIDE | 500 MG | BIOMATRIX HEALTHCARE PVT LTD. SURVEY NO. 624, SARKHEJ, BAVLA HIGHWAY, VIL.: RAJODA, TAL.: BAVLA, DIST.: AHMEDABAD, 382 220, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1043 | NDA/MAL/HDP /10707 | MACLEODS PHARMACEUTICALS LIMITEDAST, MUMBAI 400059 INDIA | VITACARE LIMITED | ZOPIMAC 3 | ESZOPICLONE | 3MG | MACLEODS PHARMACEUTICALS LIMITED BLOCK NO.: 2, VILLAGE THEDA P.O. LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH, 174101 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1*1*100, HDPE CONTAINER | 20/02/2023 |

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| 1044 | NDA/MAL/HDP /10708 | BETA HEALTHCARE INTERNATIONAL LIMITED | BETA HEALTHCARE UGANDA LIMITED | CAFENOL | ACETYLSALICYLIC ACID + CAFFEINE | 375MG + 25MG | BETA HEALTHCARE INTERNATIONAL LIMITED PLOT NO. LR 209/6554, MOGADISHU ROAD, INDUSTRIAL AREA, NAIROBI KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1*8*20, ALU-PVC BLISTER PACK | 20/02/2023 |
| 1045 | NDA/MAL/HDP /10709 | CADILA HEALTHCARE LIMITED | ABACUS PHARMA (A) LTD | VINGLYN M 50/850 | VILDAGLIPTIN + METFORMIN HYDROCHLORIDE | 50 MG + 850 MG | EAST AFRICAN (INDIA) OVERSEAS, PLOT NO. 1, PHARMACITY, SELAQUI DEHRADUN – 248011, UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 20/02/2023 |
| 1046 | NDA/MAL/HDP /1071 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CO-ANGINET 160/25MG | VALSARTAN + HYDROCHLOROTHIAZIDE | 160 MG + 25 MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 1047 | NDA/MAL/HDP /10710 | CADILA HEALTHCARE LIMITED; | ABACUS PHARMA (AFRICA) LIMITED | OXALGIN GEL | DICLOFENAC DIETHYLAMINE+ METHYL SALICYLATE + VIRGIN LINSEED OIL + CAPSAICIN + RACEMENTHOL | 1.0%W/W + 10.0%W/W + 3.0%W/W + 0.05%W/W + 5.0%W/W | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE | 06/03/2023 |
| 1048 | NDA/MAL/HDP /10711 | EAST AFRICAN (INDIA) OVERSEAS | ROYAL PHARMA 2011 LIMITED | VIREXIM-DS | CEFIXIME TRIHYDRATE | 100MG/5ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 06/03/2023 |
| 1049 | NDA/MAL/HDP /10713 | BIOMATRIX HEALTHCARE PVT LTD.- | MEDIWORLD PHARMA AFRICA LTD | IMMUNCEE 500 | ASCORBIC ACID + SODIUM ASCORBATE | 100MG + 450MG | BIOMATRIX HEALTHCARE PRIVATE LIMITED-SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 1050 | NDA/MAL/HDP /10714 | BIOMATRIX HEALTHCARE PVT LTD.- | MEDIWORLD PHARMA AFRICA LTD | DICLOTRIX PLUS | DICLOFENAC SODIUM + PARACETAMOL | 50MG + 500MG | BIOMATRIX HEALTHCARE PRIVATE LIMITED-SURVEY NO. 624, SARKHEJ - BAVLA HIGHWAY, VILLAGE: RAJODA, TAL. - BAVLA, DIST. - AHMEDABAD - 382 220, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1051 | NDA/MAL/HDP /10715 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | VILDARIL M 50/500 | VILDAGLIPTIN + METFORMIN HYDROCHLORIDE | 50 MG + 500MG | AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1052 | NDA/MAL/HDP /10716 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | VILDARIL M 50/850 | VILDAGLIPTIN + METFORMIN HYDROCHLORIDE | 50 MG + 850 MG | AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 1053 | NDA/MAL/HDP/10717 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | VILDARIL M 50/1000 | VILDAGLIPTIN + METFORMIN HYDROCHLORIDE | 50 MG + 1000 MG | AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1054 | NDA/MAL/HDP/10719 | HETERO LABS LTD | AIVEEN (U) LIMITED | GOAB 5 | SOLIFENACIN SUCCINATE | 5 MG | M/S. ANNORA PHARMA PRIVATE LIMITED-SY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1055 | NDA/MAL/HDP/1072 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CO-ANGINET 80/12.5MG | VALSARTAN + HYDROCHLOROTHIAZIDE | 80MG + 12.5MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .-57 UBAYBIN MUAATH STREET AL RAGEEM-SAHAB, AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |

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| 1056 | NDA/MAL/HDP /10720 | HETERO LABS LTD | AIVEEN (U) LIMITED | GOAB 10 | SOLIFENACIN SUCCINATE | 10MG | M/S. ANNORA PHARMA PRIVATE LIMITED-SY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELENGANA STATE – 502313, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1057 | NDA/MAL/HDP /10721 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | FLEXABENZ GEL | DICLOFENAC DIETHYLMAINE + LINSEED OIL + METHYL SALICYLATE + MENTHOL + CYCLOBENZAPRINE HYDROCHLORIDE | 1.0%W/W + 3.0%W/W + 10.0%W/W + 5.0%W/W + 2.0%W/W | OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL BADDI DIST: SOLAN (H.P.) PIN CODE: 174101 - INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE | 06/03/2023 |
| 1058 | NDA/MAL/HDP /10722 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MEDWIN | MEDROXYPROGESTERONE ACETATE | 150MG/ML | EUGIA PHARMA SPECIALITIES LIMITED-PLOT 5-38 SURVEY NO. 550, 551&552, KOLTHUR VILLAGE, SHAMEERPET MANDAL, MEDCHAL-MALKAJGIRI DISTRICT, TELANGANA, INDIA, 500078 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X1.0 ML VIAL | 06/03/2023 |

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| 1059 | NDA/MAL/HDP /10723 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | INSULIN H MIX | RECOMBINANT HUMAN INSULIN + RECOMBINANT PROTAMINE - HUMAN INSULIN | (30IU + 70IU)/ML | SOUTH EGYPT DRUG INDUSTRIES COMPANY (SEDICO)-FIRST INDUSTRIAL ZONE, 6TH OF OCTOBER CITY - EGYPT | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X1.0X10.0 ML VIAL | 06/03/2023 |
| 1060 | NDA/MAL/HDP /10725 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BESICOR 2.5 | BISOPROLOL FUMARATE | 2.5MG | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1061 | NDA/MAL/HDP /10726 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BESICOR 5 | BISOPROLOL FUMARATE | 5MG | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 1062 | NDA/MAL/HDP /10727 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BESICOR 10 | BISOPROLOL FUMARATE | 10MG | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1063 | NDA/MAL/HDP /10728 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | RAPI-COOL | CHOLINE SALICYLATE + LIDOCAINE HYDROCHLORIDE | 8.70% W/W + 2.00% W/W | LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X10.0 G TUBE | 06/03/2023 |
| 1064 | NDA/MAL/HDP /10729 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | BRISCORIL | SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN | (1MG + 2MG + 50MG ) PER 5ML | LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 06/03/2023 |

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| 1065 | NDA/MAL/HDP /10730 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | UNICHLOR 25 | CHLORTHALIDONE | 25MG | UNICHEM LABORATORIES LIMITED-C–31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1066 | NDA/MAL/HDP /10731 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | UNICHLOR 50 | | | UNICHEM LABORATORIES LIMITED-C–31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 06/03/2023 |
| 1067 | NDA/MAL/HDP /10732 | B&O PHARM | TRIDEM PHARMA UGANDA LIMITED | BREAZLAX | MONTELUKAST | 4MG | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 06/03/2023 |

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| 1068 | NDA/MAL/HDP /10733 | B&O PHARM | TRIDEM PHARMA UGANDA LIMITED | BREAZLAX | MONTELUKAST | 5MG | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 06/03/2023 |
| 1069 | NDA/MAL/HDP /10734 | B&O PHARM | TRIDEM PHARMA UGANDA LIMITED | BREAZLAX | MONTELUKAST | 10MG | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 06/03/2023 |
| 1070 | NDA/MAL/HDP /10735 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLADON PLUS | PARACETAMOL + DOXYLAMINE SUCCINATE + CAFFEINE + CODEINE PHOSPHATE | 450MG + 5MG + 30MG + 10MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X4.0X10.0 TABLET BLISTER | 06/03/2023 |

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| 1071 | NDA/MAL/HDP /10736 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | UNIPROEX ER 500 | DIVALPROEX SODIUM | 500MG | UNICHEM LABORATORIES LTD-PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511 | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER (ALU-ALU BLISTER),1.0X3.0X10.0 TABLET BLISTER (ACLAR – PVC BLISTER) | 06/03/2023 |
| 1072 | NDA/MAL/HDP /10737 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | ABACAVIR 600 MG AND LAMIVUDINE 300 MG FILM COATED TABLETS | ABACAVIR SULFATE + LAMIVUDINE | 600MG + 300MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE | 06/03/2023 |
| 1073 | NDA/MAL/HDP /10738 | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD | TATA UGANDA LIMITED | DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS | DOLUTEGRAVIR + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50 MG + 300 MG + 300 MG | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD-1479, ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE, SHANGHAI 201203 - CHINA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X1.0X90.0 TABLET BOTTLE | 06/03/2023 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1074 | NDA/MAL/HDP /1074 | NECTAR LIFESCIENCES LTD | SUPER MEDIC LTD | CEFUAXIT | CEFUROXIME | 500MG | NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2013 |
| 1075 | NDA/MAL/HDP /1075 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | NECPIME | CEFEPIME | 1000MG | NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL + 1*10 ML WATER FOR INJECTION | 01/07/2013 |
| 1076 | NDA/MAL/HDP /1076 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNICAST 4MG | MONTELUKAST SODIUM | 4MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 1077 | NDA/MAL/HDP /1077 | NECTAR LIFESCIENCES LTD | AIVEEN (U) LIMITED | NECTRAM | CEFTRIAXONE | 1G | NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL + 1*10 ML WFI AMPOULE | 01/07/2013 |
| 1078 | NDA/MAL/HDP /1078 | MICRO LABS LTD | LABOREX UGANDA LIMITED | LEVOBACT INFUSION | LEVOFLOXACIN HEMIHYDRATE | 500MG | AHLCON PARENTERALS (INDIA) LTD-SP-917-918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1079 | NDA/MAL/HDP /1079 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOG-QUININE SYRUP | QUININE HYDROCHLORIDE | 100MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2000 |

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| 1080 | NDA/MAL/HDP/1080 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ZOCEF 250 TABLETS | CEFUROXIME AXETIL | 250MG | ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2009 |
| 1081 | NDA/MAL/HDP/1082 | DAWA LIMITED | SUPER MEDIC LTD | DACOF PAEDIATRIC | DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE + MENTHOL | 75MG + 28.5MG + 0.55MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1082 | NDA/MAL/HDP/1084 | DAWA LIMITED | SUPER MEDIC LTD | DAWA-CPM | CHLORPHENIRAMINE MALEATE | 4MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 1083 | NDA/MAL/HDP /1086 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | SYNOGEN TABLETS | DIACEREIN + METHYL SULPHONYL METHANE + GLUCOSAMINE SULPHATE | 50MG +250MG + 750MG | NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1084 | NDA/MAL/HDP /1087 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCYCLINE | TETRACYCLINE | 3%W/W | AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2013 |
| 1085 | NDA/MAL/HDP /1093 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE | EMTRICITABINE+TENOFOVIR DISOPROXIL FUMARATE | 200MG+300MG | STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1086 | NDA/MAL/HDP /1094 | MICRO LABS LTD | LABOREX UGANDA LIMITED | GRAMOCEF-O-100 | CEFIXIME | 100MG/5ML | MICRO LABS LTD--NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1087 | NDA/MAL/HDP /1095 | MICRO LABS LTD | LABOREX UGANDA LIMITED | EROSTINE-20 | EBASTINE | 20MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1088 | NDA/MAL/HDP /1096 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | ARTEMETHER | ARTEMETHER | 80MG/ML | SANJAR PHARMA LLP HIMATNAGAR-VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA | CHINA | PARENTERAL ORDINARY I M AMPOULES | 1.0X6.0X1.0 ML AMPOULE,1.0X1.0X8.0X1.0 ML AMPOULE | 01/07/2014 |

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| 1089 | NDA/MAL/HDP/1099 | GLENMARK PHARMACEUTICAL LTD. | STAR PHARMACEUTICALS LTD | MOMATE F CREAM | FUSIDIC ACID+MOMETASONE FUROATE | 2.1%W/W + 0.1W/W | GLENMARK PHARMACEUTICALS LTD UNIT II.-UNIT II VILLAGE BHATTANWALA NALAGARH DIST SOLAN HIMACHAL PRADESH | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 01/07/2012 |
| 1090 | NDA/MAL/HDP/1100 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVIR SKIN CREAM | ACICLOVIR | 5% W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE,1.0X5.0 G TUBE | 01/07/2013 |
| 1091 | NDA/MAL/HDP/1103 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCIN CREAM | NEOMYCIN SULPHATE | 0.5% W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2014 |

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| 1092 | NDA/MAL/HDP /1104 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | LIPIDUCE 10 | ATORVASTATIN | 10MG | HOVID BERHAD,-LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X3.0 TABLET BLISTER | 01/07/2014 |
| 1093 | NDA/MAL/HDP /1106 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DIACEREIN | DIACEREIN | 50MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER,1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 1094 | NDA/MAL/HDP /1107 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | HEPATITIS B VACCINE(RDNA) (PAEDIATRIC)) | HEPATITIS B VACCINE(RDNA) | 10MCG /0.5ML | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY I M VIALS | 1.0X25.0X5.0 ML VIAL (10 DOSES),1.0X10.0X0.5 ML VIAL (1 DOSE) | 01/07/2005 |

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| 1095 | NDA/MAL/HDP /1109 | DAWA LIMITED | SUPER MEDIC LTD | DAWA-CPM | CHLORPHENIRAMINE MALEATE | 2MG/5ML | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2014 |
| 1096 | NDA/MAL/HDP /1111 | DAWA LIMITED | SUPER MEDIC LTD | FAST-ACT GEL | DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL CRYSTALS | 1.16%W/W + 10%W/W + 3%W/W + 5%W/W | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2013 |
| 1097 | NDA/MAL/HDP /1113 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | ALCID-YELLOW | MULTI-INGREDIENT | MULTI-INGREDIENT | TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1098 | NDA/MAL/HDP/1114 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | TRANGEL ULTRA | DICLOFENAC/METHYL SALICYLATE/MENTHOL/CAPSICUM OLEORESIN | 10MG/80MG/60MG/0.15MG | NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G CONTAINER | 01/07/2012 |
| 1099 | NDA/MAL/HDP/1117 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | TETRACYCLINE EYE OINTMENT USP 1% | TETRACYCLINE | 1%W/W | NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA | INDIA | OPHTHALMIC OINTMENTS | 1.0X20.0X3.5 G TUBE | 01/07/2013 |
| 1100 | NDA/MAL/HDP/1124 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO SCRUB | CHLORHEXIDINE GLUCONATE | 4%W/V | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL LIQUIDS | 1.0X1.0X500.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1101 | NDA/MAL/HDP/1125 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AUROXONE 1000 | CEFTRIAXONE | 1000MG | AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7-AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502307 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2009 |
| 1102 | NDA/MAL/HDP/1128 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | BTC KIT | FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE | 150MG + 1G + 1G | LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY COMBINATION PACK TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2013 |
| 1103 | NDA/MAL/HDP/1130 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | KLARO-500 | CLARITHROMYCIN TABLETS | 500MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1104 | NDA/MAL/HDP/1132 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | M-CALZ | CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFEROL | 1000MG+100MG+4MG+200.I.U | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2012 |
| 1105 | NDA/MAL/HDP/1136 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOSCAB APPLICATION | BENZYL BENZOATE | 25%W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL EMULSIONS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1106 | NDA/MAL/HDP/1138 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-CALAMINE | CALAMINE | 15%W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL LOTIONS | 1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1107 | NDA/MAL/HDP/1139 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVATE | BETAMETHASONE | 0.1%W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2012 |
| 1108 | NDA/MAL/HDP/1140 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVATE-N | BETAMETHASONE +NEOMYCIN SULPHATE | 0.1%W/W+0.5%W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |
| 1109 | NDA/MAL/HDP/1142 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CANDIZOL | CLOTRIMAZOLE | 1%W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1110 | NDA/MAL/HDP/1143 | LINCOLN P'CALS LTD | METRO PHARMACEUTICALS LIMITED | LOSA-H | LOSARTAN + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1111 | NDA/MAL/HDP/1149 | UNIVERSAL CORPORATION LTD | DELMAW ENTERPRISES LIMITED | NEUROBA | GABAPENTIN | 300MG | UNIVERSAL CORPORATION LTD..-PLOT 13777 CLUB ROAD, PAST KIKUYU | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2015 |
| 1112 | NDA/MAL/HDP/1154 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | BACQURE | IMIPENEM + CILASTATIN | 500MG + 500MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED-INDUSTRIAL AREA NO.3, A.B. ROAD DEWAS, 455001 (MP), INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X30.0 ML VIAL | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1113 | NDA/MAL/HDP /1155 | TRIVENI FORMULATIONS LIMITED | SUPER MEDIC LTD | DOXYCYCLINE | DOXYCYCLINE | 100 | TRIVENI FORMULATION LTD-PLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2012 |
| 1114 | NDA/MAL/HDP /1158 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | TRAMADOL | TRAMADOL | 50MG | TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2012 |
| 1115 | NDA/MAL/HDP /1160 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | DAFRACLAV | AMOXYCILLIN + CLAVULANIC ACID | 875MG+125MG | BILIM PHARMACEUTICALS--CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X5.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1116 | NDA/MAL/HDP /1162 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | WINKLOT | CLOPIDOGREL | 75MG | TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1117 | NDA/MAL/HDP /1163 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | FRUSEMIDE | FUROSEMIDE | 40MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1118 | NDA/MAL/HDP /1164 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | PIROXICAM | PIROXICAM | 20MG | TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1119 | NDA/MAL/HDP/1166 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | DOLZERO | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 37.5MG + 325MG | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1120 | NDA/MAL/HDP/1167 | CIRON DRUGS AND PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | METOCLOPRAMIDE INJECTION | METOCLOPRAMIDE | 5MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA. | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2010 |
| 1121 | NDA/MAL/HDP/1168 | DAWA LIMITED | SUPER MEDIC LTD | DAWA-CORT CREAM | HYDROCORTISONE | 1%W/W | DAWA LTD -BABA DOGO ROAD, RUARAKA P.O.BOX 16633-00620, NAIROBI KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1122 | NDA/MAL/HDP/1169 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | NEBI 5 | NEBIVOLOL HYDROCHLORIDE | 5MG | ARISTO PHARMACEUTCALS PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X3.0X3. 0X10.0 TABLET BLISTER | 01/07/2013 |
| 1123 | NDA/MAL/HDP/1170 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO MEGANEURON | METHYLCOBALAMIN | 500MCG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/2013 |
| 1124 | NDA/MAL/HDP/1172 | CIRON DRUGS AND PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | LIDOCAINE HYDROCHLORIDE | LIDOCAINE HYDROCHLORIDE | 20MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL,1.0X30.0 ML VIAL | 01/07/2010 |

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| 1125 | NDA/MAL/HDP/1176 | AMOUN PHARMACEUTICALS COMPANY | BOOTS PHARMACEUTICALS LIMITED | FUNGISAFE | TERBINAFINE HYDROCHLORIDE | 1%W/W | AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT | EGYPT | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |
| 1126 | NDA/MAL/HDP/1178 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | TENOFOVIR | TENOFOVIR DISOPROXIL FUMARATE | 300MG | HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2013 |
| 1127 | NDA/MAL/HDP/1179 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | OVITRELLE | CHORIOGONADOTROPIN ALFA | 250MCG/0.5ML | MERCK SERONO SA-1170 AUBONNE(SWITZERLAND) MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY | SWITZERLAND | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0 PREFILLED SYRINGE CARTON | 01/07/2015 |

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| 1128 | NDA/MAL/HDP/1182 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | ASTHATOR 5 | MONTELUKAST SODIUM | 5MG | TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD-382721, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1129 | NDA/MAL/HDP/1184 | DAWA LIMITED | SUPER MEDIC LTD | DACOF MUCOLYTIC | SALBUTAMOL + BROMHEXINE + GUAIPHENESIN + MENTHOL | 2.0MG + 4.0MG +100MG + 1.0MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1130 | NDA/MAL/HDP/1185 | DAWA LIMITED | SUPER MEDIC LTD | DACOF DRY | DIPHENHYDRAMINE + DEXTROMETHORPHAN + MENTHOL | 12.5MG + 6.5MG + 1.10MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1131 | NDA/MAL/HDP /1186 | DAWA LIMITED | SUPER MEDIC LTD | DACOF EXPECTORANT | DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE + SODIUM CITRATE + MENTHOL | 14.0MG + 135.0MG + 57.0MG + 1.10MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2013 |
| 1132 | NDA/MAL/HDP /1188 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | GMYCIN-80 | GENTAMYCIN SULPHATE | 80MG/2ML | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X100.0X2.0 ML AMPOULE | 01/07/2013 |
| 1133 | NDA/MAL/HDP /1189 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | DICLOMAX-75 | DICLOFENAC SODIUM | 75MG/ML | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X3.0 ML AMPOULE | 01/07/2013 |

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| 1134 | NDA/MAL/HDP/1194 | VENUS REMEDIES LTD | HARLEYS UGANDA LIMITED | PISA | PIPERACILLIN + TAZOBACTAM | 4000MG/VIAL + 500MG/VIAL | VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X30.0 ML VIAL | 01/07/2009 |
| 1135 | NDA/MAL/HDP/1195 | UNIVERSAL CORPORATION LTD | HARLEYS UGANDA LIMITED | ALTRINE | CETIRIZINE | 5MG/5ML | UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE | 01/07/2013 |
| 1136 | NDA/MAL/HDP/1196 | UNIVERSAL CORPORATION LTD | DELMAW ENTERPRISES LIMITED | ACNESOL | TRETINOIN | 0.05%W/W | UNIVERSAL CORPORATION LTD..-PLOT 13777 CLUB ROAD, PAST KIKUYU | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X25.0 G TUBE | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1137 | NDA/MAL/HDP/1205 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | EFAVIRENZ | EFAVIRENZ | 600MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2008 |
| 1138 | NDA/MAL/HDP/1206 | THE METHOLATUM CO. LTD | HARLEYS UGANDA LIMITED | DEEP RELIEF | IBUPROFEN + MENTHOL | 5%W/W + 3% W/W | THE MENTHOLATUM CO. LTD. -1 REDWOOD AVE PEEL PARK CAMPUS EAST KILBRIDE | UNITED KINGDOM | TOPICAL EXTERNAL OTHER GELS/SOLS | 1.0X50.0 G CONTAINER,1.0X15.0 G CONTAINER,1.0X30.0 G CONTAINER | 01/07/2013 |
| 1139 | NDA/MAL/HDP/1208 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | VISCO LIQUID | ALGINIC ACID + MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE + SIMETHICONE | 100 MG + 250 MG + 125 MG + 50 MG | ARISTO PHARMACEUTCALS PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2011 |

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| 1140 | NDA/MAL/HDP /1209 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ARBITEL-80 | TELMISARTAN | 80MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1141 | NDA/MAL/HDP /1211 | ASTRA ZENECA | MACNAUGHTON LIMITED | BRILINTA | TICAGRELOR | 90MG | ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN) | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X14.0 TABLET BLISTER | 01/07/2011 |
| 1142 | NDA/MAL/HDP /1214 | FERRER INTERNACIONAL S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NUCLEO C.M.P FORTE | CYTIDINE+URIDINE | 5MG+3MG | FERRER INTERNACIONAL, S.A-JOAN BUCSALA 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN | SPAIN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X15.0 CAPSULE BLISTER | 01/07/2013 |

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| 1143 | NDA/MAL/HDP/1215 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | GYNANFORT VAGINAL PESSARY | METRONIDAZOLE+NEOMYCIN SULPHATE+NYSTATIN | 500MG+65,000I.U+100,000I.U | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | VAGINAL SUPPOSITORIES | 1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1144 | NDA/MAL/HDP/1219 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | TORAS-DENK 5 | TORASEMIDE | 5MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1145 | NDA/MAL/HDP/1220 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | LONART | ARTEMETHER + LUMEFANTRINE | 180 MG + 1080 MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1146 | NDA/MAL/HDP/1223 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | WHITFIELD'S OINTMENT | BENZOIC ACID + SALICYLIC ACID | 6%W/W + 3%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X25.0 G TUBE | 01/07/1997 |
| 1147 | NDA/MAL/HDP/1226 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | SALBUTAMOL | SALBUTAMOL | 4MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1148 | NDA/MAL/HDP/1227 | AMOUN PHARMACEUTICALS COMPANY | BOOTS PHARMACEUTICALS LIMITED | FUNGISAFE | TERBINAFINE HCL | 250MG | AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0 TABLET STRIP | 01/07/2013 |

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| 1149 | NDA/MAL/HDP/1230 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | LOXAMP | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 1150 | NDA/MAL/HDP/1231 | NORVIK ENTERPRISES LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOX 125 | AMOXYCILLIN | 125MG/5ML | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2012 |
| 1151 | NDA/MAL/HDP/1234 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | BISACODYL TABLETS BP | BISACODYL | 5MG | MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2007 |

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| 1152 | NDA/MAL/HDP/1242 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TOPHEN-100 | PHENYTOIN | 100MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2013 |
| 1153 | NDA/MAL/HDP/1243 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | LEVO DENK 250 | LEVOFLOXACIN HEMIHYDRATE | 250MG | ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61 59320 ENNIGERLOH GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1154 | NDA/MAL/HDP/1244 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | FLEXILOR SR | LORNOXICAM | 16MG | GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205 | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 1155 | NDA/MAL/HDP/1245 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | FLEXILOR P8 | LORNOXICAM + PARACETAMOL | 8MG + 500MG | GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1156 | NDA/MAL/HDP/1247 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROCIP | CYPROHEPTADINE | 4MG | AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X5.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1157 | NDA/MAL/HDP/1252 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | ZOY | SILDENAFIL | 50MG | TORQUE PHAMACEAUTICALS PVT LTD-VILL ISSAPUR P.O DAPPAR INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2013 |

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| 1158 | NDA/MAL/HDP /1255 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | NIFELAT RETARD | NIFEDIPINE | 20MG | CIPLA LTD-MIDC PATALGANGA 410 220 DIST. RAIGAD | INDIA | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1159 | NDA/MAL/HDP /1259 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | CARDOZ- 6.25 | CARVEDILOL | 6.25MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2013 |
| 1160 | NDA/MAL/HDP /1261 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | CARDOZ-12.5 | CARVEDILOL | 12.5MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2013 |

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| 1161 | NDA/MAL/HDP/1264 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | OCUCYCLINE EYE OINTMENT | TETRACYCLINE HYDROCHLORIDE | 1%W/W | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE,1.0X3.5 G TUBE | 01/07/2000 |
| 1162 | NDA/MAL/HDP/1265 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | COMBIPLEX | VITAMIN B1 + VITAMIN B2 + NICOTINAMIDE + VITAMIN B6 | 1.0 MG + 1.0 MG + 15 MG + 0.5 MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 1163 | NDA/MAL/HDP/1275 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | NIFELAT 10 F.C TABLETS | NIFEDIPINE | 10MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 1164 | NDA/MAL/HDP/1278 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP | DIHYDROARTEMESININ + PIPERAQUINE PHOSPHATE | 40MG +320MG | GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X9.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X25.0X 1.0X9.0 TABLET BLISTER | 01/07/2013 |
| 1165 | NDA/MAL/HDP/1285 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANFUR-750 | CEFUROXIME | 750MG | SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X750.0 MG VIAL | 01/07/2012 |
| 1166 | NDA/MAL/HDP/1287 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANIX- DS 100 | CEFIXIME | 100MG/5ML | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2014 |

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| 1167 | NDA/MAL/HDP /1290 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANIX 400 CAP | CEFIXIME | 400MG | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 1168 | NDA/MAL/HDP /1291 | BAYER SCHERING PHARMA | SURGIPHARM (U) LIMITED | ULTRAVIST-300 | IOPROMIDE | 300MG/ML | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | PARENTERAL ORDINARY VIALS | 1.0X50.0 ML VIAL,1.0X100.0 ML VIAL | 01/07/2012 |
| 1169 | NDA/MAL/HDP /1293 | ZEE PHARMACEUTICALS LTD | ZEE PHARMACEUTICALS LIMITED | ZEEGRA - 100 | SILDENAFIL CITRATE | 100MG | THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2016 |

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| 1170 | NDA/MAL/HDP /1294 | BAYER SCHERING PHARMA | SURGIPHARM (U) LIMITED | ULTRAVIST 370 | IOPROMIDE | 370MG/ML | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | PARENTERAL ORDINARY VIALS | 1.0X100.0 ML VIAL,1.0X50.0 ML VIAL | 01/07/2012 |
| 1171 | NDA/MAL/HDP /1295 | SHAIGAN PHARMACEUTICALS (PVT) LTD | HARLEYS UGANDA LIMITED | ZEPAR | ALBENDAZOLE | 200MG | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/1997 |
| 1172 | NDA/MAL/HDP /1298 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | NEUROVIT FORTE | THIAMINE MONONITRATE/ PYRIDOXINE/ CYANOCOBALAMIN | 245.5MG/ 250MG/ 1.4MG | HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 1173 | NDA/MAL/HDP/1299 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANAXONE PLUS-1000 | CEFTRIAXONE+SULBACTAM | 1000MG+500MG | SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.5 G VIAL,1.0X50.0X1.0 VIAL CARTON | 01/07/2012 |
| 1174 | NDA/MAL/HDP/1302 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | HIPEN CAPSULES | AMOXYCILLIN | 250MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 1175 | NDA/MAL/HDP/1303 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FIBRAL | FINOFIBRATE | 200MG | MICRO LABS LTD ..-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIIL NADU | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |

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| 1176 | NDA/MAL/HDP /1304 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DIAPRIDE PLUS 2 | GLIMEPIRIDE+ METFORMIN | 2MG + 500MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1177 | NDA/MAL/HDP /1307 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ARBITEL 40 | TELMISARTAN | 40MG | MICRO LABS LTD ..-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1178 | NDA/MAL/HDP /1312 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | SLIPIZEM- 2.5 | DIAZEPAM | 2.5MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES | 1.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |

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| 1179 | NDA/MAL/HDP/1319 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | ZESTAVAL 200 F.C TABLETS | ALBENDAZOLE | 200MG | REMEDICA LTD-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 50.0X2.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER | 01/07/1997 |
| 1180 | NDA/MAL/HDP/1324 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | TOOTH HEAL | MULTI INGREDIENT | MULTI INGREDIENT | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X18.0 ML BOTTLE | 01/07/2005 |
| 1181 | NDA/MAL/HDP/1328 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ENGERIX-B VACCINE | HEPATITIS B SURFACE ANTIGEN | 20MCG/ML | GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY VIALS | 1.0X10.0X1.0 ML VIAL (1 DOSE),1.0X25.0X1.0 ML VIAL (1 DOSE) | 01/07/1997 |

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| 1182 | NDA/MAL/HDP/1330 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | RAPICLAV-625 | AMOXYCILLIN+CLAVULANIC ACID | 500MG+125MG | IPCA LABORATORIES LTD,.-PLOT 69 TO 72 (B), SECTOR II, KASEZ, GANDHIDHAM - 370230, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X2.0 TABLET STRIP,1.0X7.0X3.0 TABLET STRIP | 01/07/2003 |
| 1183 | NDA/MAL/HDP/1331 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | BETADERM N OINTMENT | BETAMETHASONE VALERATE + NEOMYCIN | 0.1%W/W + 0.5%W/W | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/1997 |
| 1184 | NDA/MAL/HDP/1335 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | PREGATAS | PREGABALIN | 75MG | INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2012 |

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| 1185 | NDA/MAL/HDP /1337 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | FOURTS B | THIAMINE +RIBOFLAVIN + PYRIDOXINE + NICOTINAMIDE + FOLIC ACID + ASCORBIC ACID + COLECALCIFEROL + ACETYL CYSTEINE + GLYCINE + GLUTAMIC ACID + CHROMIUM + VANADIUM + ZINC | 10MG + 10MG + 3MG + 50MG + 1MG + 75MG + 400IU + 25MG +25MG +MG +200MCG + 100MCG + 55MG +100MCG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2016 |
| 1186 | NDA/MAL/HDP /1338 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | GRISEBEN 500 | GRISEOFULVIN | 500 MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |
| 1187 | NDA/MAL/HDP /1341 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | G-FLOX | GATIFLOXACIN SESQUIHYDRATE | 0.3%W/V | AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA | INDIA | OPHTHALMIC LIQUIDS | 1.0X5.0 ML VIAL | 01/07/2016 |

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| 1188 | NDA/MAL/HDP /1343 | MICRO LABS LTD | PHARMA VILLE LIMITED | PRAZIQUANTEL | PRAZIQUANTEL | 600MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 MICRO LABS LIMITED, BOMMASANDRA (ML07),- PLOT 121-124, IV PHASE KIADB, BOMMASANDRA IND. AREA, JIGNI LINK ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER | 01/07/2009 |
| 1189 | NDA/MAL/HDP /1345 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SWICH-200 | CEFPODOXIME | 200MG | ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1190 | NDA/MAL/HDP /1347 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | ORNILOX | ORNIDAZOLE + OFLOXACIN | 500MG + 200MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2010 |

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| 1191 | NDA/MAL/HDP/1348 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | VALPARIN CHRONO 500 | SODIUM VALPROATE (CONTROLLED RELEASE) | 500MG | TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRA D-382721 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2009 |
| 1192 | NDA/MAL/HDP/1351 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | ATORIN | ATORVASTATIN CALCIUM | 20MG | MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1193 | NDA/MAL/HDP/1352 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | PLATFREE | CLOPIDOGREL | 75MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 1194 | NDA/MAL/HDP/1353 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | KITPYLO - C | LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN | 30MG +500MG + 250MG | MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS) | 01/07/2015 |
| 1195 | NDA/MAL/HDP/1355 | PIRAMAL HEALTHCARE LTD | MEDIWORLD PHARMA AFRICA LTD | SEVOFLURANE | SEVOFLURANE | 100% V/V | PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH | INDIA | OTHER SYSTEMIC LIQUID INHALATIONS | 1.0X250.0 ML BOTTLE | 01/07/2010 |
| 1196 | NDA/MAL/HDP/1359 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | DIFENAC-100 SR | DICLOFENAC SODIUM | 100MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA | UGANDA | ORAL SOLID RETARD CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1197 | NDA/MAL/HDP /1361 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | FALCI CARE | ARTESUNATE | 120MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X30.0 MG VIAL + 1*5ML OF 0.9%W/V NACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE | 01/07/2016 |
| 1198 | NDA/MAL/HDP /1362 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | BACTOCLAV-1000 | AMOXICILLIN + CLAVULANATE | 875 MG + 125 MG | MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X6.0 TABLET STRIP | 01/07/2013 |
| 1199 | NDA/MAL/HDP /1366 | F. HOFFMANN- LA ROCHE LTD | LABOREX UGANDA LIMITED | HERCEPTIN 440MG | TRASTUZUMAB | 440MG | F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST | SWITZERLAND | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X440.0 MG VIAL ,2OML VIAL OF SOLVENT | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1200 | NDA/MAL/HDP /1367 | DAWA LIMITED | SUPER MEDIC LTD | ACEPAR | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1201 | NDA/MAL/HDP /1368 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | D5 | GLUCOSE | 5%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2010 |
| 1202 | NDA/MAL/HDP /1370 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | STERILIZED WATER FOR INJECTION | WATER FOR INJECTION | NEUTRAL | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE,1.0X7.5 ML AMPOULE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1203 | NDA/MAL/HDP /1377 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | SUPER AMP | WATER FOR INJECTION | N/A | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0 ML AMPOULE | 01/07/2014 |
| 1204 | NDA/MAL/HDP /1380 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICA L INDUSTRIES 1996 LIMITED | HYCORT CREAM | HYDROCORTISONE | 1%W/W | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/1997 |
| 1205 | NDA/MAL/HDP /1382 | HOVID BERHAD | UNITED HEALTHCARE DISTRIBUTORS LTD | INOX CAPSULES | ITRACONAZOLE | 100MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY CAPSULES | 1.0X7.0X4.0 CAPSULE BLISTER | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1206 | NDA/MAL/HDP/1383 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | KETOFEN GEL | KETOPROFEN | 2.5%W/W | HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G CONTAINER | 01/07/2013 |
| 1207 | NDA/MAL/HDP/1384 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LAMIVUDINE AND ZIDOVUDINE TABLETS | LAMIVUDINE + ZIDOVUDINE | 30MG + 60MG | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2013 |
| 1208 | NDA/MAL/HDP/1387 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | LAN-30 | LANSOPRAZOLE | 30MG | INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X5.0X10.0 CAPSULE STRIP | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1209 | NDA/MAL/HDP/1391 | UNIVERSAL CORPORATION LTD | PHARMA VILLE LIMITED | UNIVIR 5% | ACYCLOVIR | 5%W/W | UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X10.0 G TUBE | 01/07/2010 |
| 1210 | NDA/MAL/HDP/1392 | ASTRA ZENECA | MACNAUGHTON LIMITED | ZOLADEX | GOSERELIN | 3.6MG | ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, | UNITED KINGDOM | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0 PREFILLED SYRINGE CARTON | 01/07/1997 |
| 1211 | NDA/MAL/HDP/1393 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANFUR | CEFUROXIME | 500MG | SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1212 | NDA/MAL/HDP/1394 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANPIME -1000 | CEFEPIME | 1000MG | SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X15.0 ML VIAL | 01/07/2010 |
| 1213 | NDA/MAL/HDP/1395 | ASTRA ZENECA AB | MACNAUGHTON LIMITED | NEXIUM 40MG IV | ESOMEPRAZOLE | 40MG/5ML | ASTRA ZENECA--KVARNBERGAGATAN12, SE-151 SODERTALIJE | SWEDEN | PARENTERAL ORDINARY VIALS | 1.0X1.0X5.0 ML VIAL,1.0X10.0X5.0 ML VIAL | 01/07/2010 |
| 1214 | NDA/MAL/HDP/1397 | ASTRA ZENECA | MACNAUGHTON LIMITED | PLENDIL | FELODIPINE | 10MG | ASTRAZENECA SWEDEN OPERATIONS-ASTRAZENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1215 | NDA/MAL/HDP /1399 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ASTHALIN | SALBUTAMOL | 100MCG/DOSE | CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X200.0 METERED DOSE CANNISTER | 01/07/2010 |
| 1216 | NDA/MAL/HDP /1400 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | PANFOR SR 500 | METFORMIN HYDROCHLORIDE | 500MG | INVENTIA HEALTHCARE PRIVATE LIMITED-F1-F1/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST), DISTRICT THANE, 421 0506, DIST. THANE, MAHARASHTRA, INDIA. | INDIA | ORAL SOLID RETARD TABLETS | 1.0X5.0X20.0 TABLET BLISTER | 01/07/2015 |
| 1217 | NDA/MAL/HDP /1402 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | PANFOR SR 1000 | METFORMIN HYDROCHLORIDE | 1000MG | INVENTIA HEALTHCARE PRIVATE LIMITED-F1-F1/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST), DISTRICT THANE, 421 0506, DIST. THANE, MAHARASHTRA, INDIA. | INDIA | ORAL SOLID RETARD TABLETS | 1.0X5.0X20.0 TABLET BLISTER | 01/07/2015 |

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| 1218 | NDA/MAL/HDP/1406 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | CEBAY DRY SYRUP | CEFIXIME TRIHYDRATE | 50MG/5ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2014 |
| 1219 | NDA/MAL/HDP/1409 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | ROMYCIN | AZITHROMYCIN | 200MG/5ML | NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN. | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X15.0 ML BOTTLE | 01/07/2007 |
| 1220 | NDA/MAL/HDP/1411 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | CIPIUM | CHLORPHENIRAMINE | 4MG | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |

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| 1221 | NDA/MAL/HDP /1415 | ASTRA ZENECA | MACNAUGHTON LIMITED | ATACAND | CANDESARTAN | 32MG | ASTRA ZENECA SWEDEN OPERATIONS-TABLET PRODUCTION SE-151 85, GARTUNAVAGEN, SODERTALJE | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2011 |
| 1222 | NDA/MAL/HDP /1417 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICA LS LTD | MILICAL TABLETS | CALCIUM CITRATE + VITAMIN D3 | 1000MG +200 I.U | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2001 |
| 1223 | NDA/MAL/HDP /1418 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | AMINOPHYLLIN E TABLETS | AMINOPHYLLINE | 100MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER | 01/07/2011 |

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| 1224 | NDA/MAL/HDP/1419 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SINOPRIL 10 | LISINOPRIL | 10MG | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1225 | NDA/MAL/HDP/1422 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | STAMIN | CETIRIZINE DIHYDROCHLORIDE | 10MG | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1226 | NDA/MAL/HDP/1425 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | L-TRIM | COTRIMOXAZOLE | 240MG/5ML | LEBEN LABORATORIES PVT. LTD-L-4, PHASE –III, M.I.D.C, | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2007 |

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| 1227 | NDA/MAL/HDP/1426 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | METROLEB | METRONIDAZOLE | 200MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |
| 1228 | NDA/MAL/HDP/1427 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TENA-50 | ATENOLOL | 50MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X28.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2011 |
| 1229 | NDA/MAL/HDP/1431 | INTAS PHARMACUITICALS LTD | NORVIK ENTERPRISES LIMITED | TORTAS 10 | TORSEMIDE | 10MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 1230 | NDA/MAL/HDP/1433 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | NORISTERAT | NORETHISTERONE ENANTATE | 200MG | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | PARENTERAL ORDINARY VIALS | 1.0 ML PRE- FILLED SYRINGE,1.0X100.0 X1.0 ML VIAL | 01/07/1997 |
| 1231 | NDA/MAL/HDP/1436 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR 10 | BISOPROLOL HEMIFUMARATE | 10MG | MERCK KGAA-250 FRANKFRUTER STRASSE 250-64293 DARMSTADT WINTHROP PHARMACEUTICALS(PTY) LTD,-315 WATLOO ROAD,WATLOO,PRETORIA,SOUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE) | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1232 | NDA/MAL/HDP/1445 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | AXONE 1000 | CEFTRIAXONE SODIUM | 1000MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1000.0 MG VIAL | 01/07/2003 |

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| 1233 | NDA/MAL/HDP/1446 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | VITAMIN B COMPLEX | VITAMINS B1 + B2 + B6 + NIACINAMIDE | 0.5 MG + 0.5MG + 7.5MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2015 |
| 1234 | NDA/MAL/HDP/1449 | SHAIGAN PHARMACEUTICALS (PVT) LTD | HARLEYS UGANDA LIMITED | ZEPAR SUSPENSION | ALBENDAZOLE | 200MG/5ML | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2000 |
| 1235 | NDA/MAL/HDP/1450 | GLAXOSMITHKLINE LIMITED LIKONI | UNITED HEALTHCARE DISTRIBUTORS LTD | VOLTAREN EMULGEL 1% | DICLOFENAC DIETHYLAMMONIUM | 1%W/V | GSK CONSUMER HEALTH SA-GSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND | SWITZERLAND | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE,1.0X50.0 G TUBE | 01/07/1997 |

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| 1236 | NDA/MAL/HDP/1451 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN INJECTION | DICLOFENAC | 25MG/ML | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. | SWITZERLAND | PARENTERAL ORDINARY AMPOULES | 1.0X3.0 ML AMPOULE | 01/07/1997 |
| 1237 | NDA/MAL/HDP/1454 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | PAINEX | PARACETAMOL + ASPIRIN + CAFFEINE | 500MG + 400MG + 50 MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X25.0X4.0 TABLET STRIP | 01/07/2003 |
| 1238 | NDA/MAL/HDP/1456 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | SUCRAFIL O GEL | SUCRALFATE + OXETACAINE | 10MG + 0.2MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/2013 |

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| 1239 | NDA/MAL/HDP /1457 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | DYSEN FORTE | SECNIDAZOLE | 1000MG | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2006 |
| 1240 | NDA/MAL/HDP /1458 | STRIDES PHARMA SCIENCE LIMITED | DELMAW ENTERPRISES LIMITED | CLAVICIN INJECTION | AMOXICILLIN + POTASSIUM CLAVULANATE | 1.2G | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.2 G VIAL | 01/07/2013 |
| 1241 | NDA/MAL/HDP /1459 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | TASIGNA 200 | NILOTINIB | 200MG | NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2014 |

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| 1242 | NDA/MAL/HDP/1463 | ARISTO PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | ARISTOZYME LIQUID | DIASTASE+PEPSIN | 50MG+10MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA. | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X200.0 ML BOTTLE | 01/07/2015 |
| 1243 | NDA/MAL/HDP/1464 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ORNIDA | ORNIDAZOLE | 500MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2014 |
| 1244 | NDA/MAL/HDP/1465 | NORVATIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTFAST 50MG | DICLOFENAC POTASSIUM | 50MG | MIPHARM S.P.A -VIA BERNARDO QUARANTA, 12-20141, MILANO ITALY. | ITALY | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X3.0 SACHET CARTON,9.0X1.0X3 .0X3.0 SACHET CARTON | 01/07/2014 |

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| 1245 | NDA/MAL/HDP/1468 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | OCID 20 | OMEPRAZOLE | 20MG | S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID RETARD CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/1998 |
| 1246 | NDA/MAL/HDP/1469 | VOGEN LABORATORIES LTD | BUFFALO HEALTH CARE LTD | DURAMOX 125 | AMOXICILLIN | 125MG/5ML | VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS | CYPRUS | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1247 | NDA/MAL/HDP/1474 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGODIC GEL | DICLOFENAC DIETHYLAMINE | 1%W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2016 |

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| 1248 | NDA/MAL/HDP/1476 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | SEPTOL | SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE | 1%W/W + 0.20W/W | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2016 |
| 1249 | NDA/MAL/HDP/1478 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | KAMAGRA | SILDENAFIL | 50MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2001 |
| 1250 | NDA/MAL/HDP/1484 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | CLYCIN.V | CLINDAMYCIN | 2%W/W | SHAIGAN PHARMACEUTICALS (PVT) LIMITED-14 KM ADYALA RD, RAWALPINDI, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL OTHER CREAMS | 1.0X40.0 G TUBE + APPLICATOR | 01/07/2004 |

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| 1251 | NDA/MAL/HDP /1485 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DICLOFEN 25 | DICLOFENAC | 25MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY BLISTER | 01/07/2011 |
| 1252 | NDA/MAL/HDP /1488 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DICLO-DENK 100 RECTAL | DICLOFENAC SODIUM | 100MG | HAUPT PHARMA WULFING GMBH.-BETHELNER LANDSTR. 18, 31028 GRONAU | GERMANY | RECTAL SYSTEMIC ADULT SUPPOSITORIES | 10.0X1.0X2.0X5.0 SUPPOSITORY STRIP,1.0X5.0 SUPPOSITORY STRIP | 01/07/2000 |
| 1253 | NDA/MAL/HDP /1492 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DICLO-DENK 75 INJECTION | DICLOFENAC SODIUM | 25MG/ML | HAUPT PHARMA WULFING GMBH;--BETHELNER LANDSTR. 18, 31028 GRONAULLEIRE, GERMANY. | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X3.0 ML AMPOULE | 01/07/1998 |

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| 1254 | NDA/MAL/HDP/1494 | FERRER INTERNACIONAL S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PEITEL 0.25% | PREDNICARBATE | 0.25%W/W | FERRER INTERNACIONAL, S.A-JOAN BUCSALA 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN | SPAIN | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/2013 |
| 1255 | NDA/MAL/HDP/1495 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | PELOX-400 | PEFLOXACIN | 400MG | WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET STRIP | 01/07/1997 |
| 1256 | NDA/MAL/HDP/1497 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LAEOVATE CREAM | BETAMETHASONE VALERATE | 0.1%W/W | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1257 | NDA/MAL/HDP /1499 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROMETHAZINE | PROMETHAZINE HYDROCHLORIDE | 25MG/ML | NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0 ML AMPOULE | 01/07/2005 |
| 1258 | NDA/MAL/HDP /1500 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | ATRIPLA | EFAVIRENZ+EMTRICITABINE + TENOFOVIR | 600MG +200MG+300MG | PATHEON INC-MISSISSAUGA,ON L5N 7K9 CANADA | NETHERLANDS | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2008 |
| 1259 | NDA/MAL/HDP /1503 | MEDICAL UNION PHARMACUITICALS | KARURI PHARMACEUTICALS LTD. | SEDIPROCT CREAM | HYDROCORTISONE +CINCHOCAINE | 0.5%W/W + 0.5%W/W | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | TOPICAL EXTERNAL OTHER CREAMS | 1.0X20.0 G TUBE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1260 | NDA/MAL/HDP/1505 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | SERETIDE EVOHALER | SALMETEROL/ FLUTICASONE PROPIONATE | 25/50 MCG | GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX | FRANCE | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X1.0 CANNISTER CARTON | 01/07/2007 |
| 1261 | NDA/MAL/HDP/1508 | DAWA LIMITED- | SUPER MEDIC LTD | WOMNIL | ALBENDAZOLE | 200MG/5ML | DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2009 |
| 1262 | NDA/MAL/HDP/1509 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | FEVEREX | PARACETAMOL | 500MG | BETA HEALTHCARE INTERNATIONAL LTD-PLOT LR 209/6554 MOGADISHU ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA NAIROBI, 00100, | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2007 |

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| 1263 | NDA/MAL/HDP/1514 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VERMOX | MEBENDAZOLE | 100MG | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE JOHNSON & JOHNSON (PTY) LTD-241 MAIN ROAD, RETREAT, 7945, CAPE TOWN | SOUTH AFRICA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/1997 |
| 1264 | NDA/MAL/HDP/1516 | WIN-MEDICARE LTD | SURGIPHARM (U) LIMITED | URGENDOL P | TRAMADOL/ PARACETAMOL | 37.5MG/ 325MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1265 | NDA/MAL/HDP/1517 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | VEST MENTAMU BALM | COMPOUND METHYLSALICYLATE | MULTI INGREDIENT | NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1266 | NDA/MAL/HDP /1523 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMPIREN | AMPICILLIN | 125MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1267 | NDA/MAL/HDP /1524 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMOXIREN | AMOXICILLIN TRIHYDRATE | 125 MG / 5 ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2008 |
| 1268 | NDA/MAL/HDP /1525 | CIPLA LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BENDEX | ALBENDAZOLE | 20MG/5ML | CIPLA LTD ,,-PLOT NO. 9,10,15 INDORE SPECIAL ECONOMIC ZONE PHASE II PITHAMPUR DISTRICT DHAR MADHYA PRADESH PIN. 454775 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2007 |

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| 1269 | NDA/MAL/HDP/1526 | FERRER INTERNACIONAL S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | GAMALATE B6 | MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6 | 75MG + 75MG + 37MG + 37MG | FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2015 |
| 1270 | NDA/MAL/HDP/1527 | MICRO LABS LTD | LABOREX UGANDA LIMITED | BACTOCLAV | AMOXICILLIN + CLAVULANATE POTASSIUM | 200MG + 28.5MG/5ML | MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2012 |
| 1271 | NDA/MAL/HDP/1528 | MICRO LABS LTD | LABOREX UGANDA LIMITED | BACTOCLAV-625 | AMOXYCILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 01/07/2007 |

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| 1272 | NDA/MAL/HDP /1529 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | PROVIRON | MESTEROLONE | 25MG | BAYER WEIMAR GMBH & CO. KG-DOBEREINERSTRASSE 20 D-99427 WEIMAR, GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1273 | NDA/MAL/HDP /1532 | BF BIOSCIENCES LTD | HARLEYS UGANDA LIMITED | NOVAPRESSIN | TERLIPRESSIN | 1MG/VIAL | BF BIOSCIENCES LTD. - RAIWIND,PAKISTAN | PAKISTAN | PARENTERAL ORDINARY VIALS | 1.0X1.0 MG VIAL | 01/07/2014 |
| 1274 | NDA/MAL/HDP /1533 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | 5D | GLUCOSE | 50G/L | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2007 |

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| 1275 | NDA/MAL/HDP /1535 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | FORTIWIN-4 | FORTIFIED PROCAINE PENICILLIN SODIUM | 4 M.U | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X4.0 MU VIAL,1.0X100.0X4.0 MU VIAL,1.0X10.0X4.0 MU VIAL | 01/07/2011 |
| 1276 | NDA/MAL/HDP /1537 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYZOLE | ALBENDAZOLE | 200MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0X2.0 TABLET BLISTER | 01/07/2005 |
| 1277 | NDA/MAL/HDP /1538 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYZOLE SUSPENSION | ALBENDAZOLE | 200MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2003 |

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| 1278 | NDA/MAL/HDP/1544 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROMETHAZINE HYDROCHLORIDE B.P | PROMETHAZINE HCL | 25MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |
| 1279 | NDA/MAL/HDP/1546 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LANPRO | LANSOPRAZOLE | 30MG | UNICHEM LABORATORIES LTD-UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD-PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X2.0X10.0 CAPSULE BLISTER | 01/07/1999 |
| 1280 | NDA/MAL/HDP/1551 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | CALOSHELL-500 | CALCIUM CARBONATE + VITAMIN D3 | 1250MG + 250IU | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |

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| 1281 | NDA/MAL/HDP/1553 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | VIFEX | SALBUTAMOL + BROMHEXINE + GUAIFENESIN | 1MG/5ML+2MG/5ML+50MG/5ML | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2004 |
| 1282 | NDA/MAL/HDP/1554 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL CETIRIZINE | CETIRIZINE DIHYDROCHLORIDE | 5MG/5ML | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL--382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | MALAYSIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2010 |
| 1283 | NDA/MAL/HDP/1555 | GALENTIC PHARMA LTD | VITACARE LIMITED | GALSCRUB | CHLORHEXIDINE | 4%W/W | GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA | INDIA | TOPICAL EXTERNAL LIQUIDS | 1.0X500.0 ML BOTTLE | 01/07/2008 |

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| 1284 | NDA/MAL/HDP/1556 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | VOMISTAT | ONDASENTRON | 2MG/ML | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2014 |
| 1285 | NDA/MAL/HDP/1557 | GLAXOSMITHKLINE | UNITED HEALTHCARE DISTRIBUTORS LTD | SYNFLORIX VACCINE | PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V,14,23F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPTHERIA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE | 1MCG+3MCG+13MCG+8MCG+5MCG+0.5MG | GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE),1.0X100.0X0.5 ML VIAL (1 DOSE) | 01/07/2010 |
| 1286 | NDA/MAL/HDP/1561 | LINCOLN P'CALS LTD | METRO PHARMACEUTICALS LIMITED | NEOVAG | NYSTATIN | 10000IU | LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA | INDIA | VAGINAL TABLETS | 1.0X14.0 PESSARY STRIP | 01/07/2004 |

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| 1287 | NDA/MAL/HDP/1563 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AMOXIL | AMOXYCILLIN | 125MG/5ML | GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE | FRANCE | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1288 | NDA/MAL/HDP/1566 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | VITAVIT | MULTI-INGREDIENT | MULTI-INGREDIENT | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | NULL | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2009 |
| 1289 | NDA/MAL/HDP/1571 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | RHOCLONE | MONOCLONAL ANTI-D IMMUNOGLOBULIN | 300MCG | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X2.0 ML VIAL (1 DOSE VIAL) | 01/07/2013 |

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| 1290 | NDA/MAL/HDP /1572 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | ROSUVAS 20 | ROSUVASTATIN | 20MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)-VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2011 |
| 1291 | NDA/MAL/HDP /1574 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | AMTAS-5 | AMLODIPINE | 5MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 2.0X2.0X7.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER | 01/07/2003 |
| 1292 | NDA/MAL/HDP /1579 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | PLASMINEX | TRANEXAMIC ACID | 100MG/ML | PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG | INDONESIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X5.0 ML AMPOULE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1293 | NDA/MAL/HDP/1581 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PANTOTAB | PANTOPRAZOLE | 40MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1294 | NDA/MAL/HDP/1584 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | UCLOX | CLOXACILLIN SODIUM | 500MG | UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X500.0 MG VIAL | 01/07/2015 |
| 1295 | NDA/MAL/HDP/1585 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | UDIHEP FORTE | URSODEOXYCHOLIC ACID | 300MG | WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1296 | NDA/MAL/HDP/1589 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | CENTACID SUSPENSION | MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIMETHICONE | 40MG+200MG+250MG/5ML | CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X170.0 ML BOTTLE | 01/07/1997 |
| 1297 | NDA/MAL/HDP/1591 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | CENTIPAR ELIXIR | PIPERAZINE CITRATE | 750ML/5ML | CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X30.0 ML BOTTLE | 01/07/1997 |
| 1298 | NDA/MAL/HDP/1598 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCIM 400 | CIMETIDINE | 400MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1299 | NDA/MAL/HDP/1605 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | ASPIRIN TABLETS | ACETYL SALICYLIC ACID | 300MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER | 01/07/2001 |
| 1300 | NDA/MAL/HDP/1615 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | APCALIS SX | TADALAFIL | 20MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X2.0 TABLET BLISTER | 01/07/2005 |
| 1301 | NDA/MAL/HDP/1616 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CEZIN | CETIRIZINE | 5MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1302 | NDA/MAL/HDP/1627 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDID-V GEL | CLOTRIMAZOLE | 2%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | VAGINAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2004 |
| 1303 | NDA/MAL/HDP/1629 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | CARVETAS 12.5 | CARVEDILOL | 12.5MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1304 | NDA/MAL/HDP/1631 | AUROBINDOM PHARMA LIMITED | GITTOES PHARMACEUTICALS LIMITED | NEVIRAPINE ORAL SUSPENSION | NEVIRAPINE | 50MG/5ML | AUROBINDO PHARMA LTD, UNIT III -SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X240.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1305 | NDA/MAL/HDP/1632 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | CLAVAM 1.2G | AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM | 1000MG +200MG | ALKEM LABS LTD.-VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1 AMPOULE OF WFI | 01/07/2005 |
| 1306 | NDA/MAL/HDP/1635 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | ORITAXIM 1000MG INJECTION | CEFOTAXIME SODIUM | 1GM | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 G VIAL | 01/07/1997 |
| 1307 | NDA/MAL/HDP/1636 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | VIGAMOX | MOXIFLOXACIN | 5MG/ML | S.A.ALCON COUVREUR N.V-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1308 | NDA/MAL/HDP/1638 | AMOUN PHARMACEUTICAL COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FLADAZOLE | SECNIDAZOLE | 500MG | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2005 |
| 1309 | NDA/MAL/HDP/1639 | GLAXO SMITHLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | PANADOL EXTRA WITH OPTIZORB | PARACETAMOL + CAFFEINE | 500MG + 65MG | GLAXOSMITHKLINE DUNGARAVAN LTD-KNOCKBRACK DUNGARVAN CO. WATERFORD GRANULES INDIA LIMITED-SY. NO. 160/A, 161/E, 162 & 174/A GAGILLAPUR VILLAGE, DUNDIGAL-GANDIMAISAMMA MANDAL, MEDCHAL - MALKHAJGIRI DISTRICT - 500043 TELENGANA | IRELAND | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON | 01/07/2003 |
| 1310 | NDA/MAL/HDP/1641 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | UNIENZYME C MPS | NICOTINAMIDE+SIMETHICONE+PAPAIN+FUNGAL DIASTASE+CHARCOAL | 25MG+50MG+30MG+20MG+75MG | UNICHEM LABORATORIES LIMITED-C–31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1311 | NDA/MAL/HDP/1642 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | EUCHLOR-1000 | CHLORAMPHENICOL SODIUM SUCCINNATE B.P | 1G | UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 G VIAL | 01/07/2004 |
| 1312 | NDA/MAL/HDP/1646 | BETA HEALTHCARE INTERNATIONAL LTD | BETA HEALTHCARE UGANDA LIMITED | BETROZOLE TABLETS | METRONIDAZOLE+DILOXANIDE | 200MG+250MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BLISTER | 01/07/2002 |
| 1313 | NDA/MAL/HDP/1650 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | TEGRETOL CR 200 | CARBAMAZEPINE | 200MG | NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY | ITALY | ORAL SOLID RETARD TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1314 | NDA/MAL/HDP/1651 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | MEGATRIM SUSPENSION | CO-TRIMOXAZOLE | 240MG/5ML | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1315 | NDA/MAL/HDP/1652 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | VALPARIN CHRONO 300 | SODIUM VALPROATE | 300MG | TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2009 |
| 1316 | NDA/MAL/HDP/1656 | AIVEEN (U) LIMITED | AIVEEN (U) LIMITED | AZIGYL-500 | AZITHROMYCIN | 500MG | MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1317 | NDA/MAL/HDP/1660 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCIM-200 | CIMEDITINE | 200MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET STRIP | 01/07/2005 |
| 1318 | NDA/MAL/HDP/1661 | ABBVIE (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | ALUVIA 100/25 | LOPINAVIR/ RITONAVIR | 100MG/25MG | ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY. | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2007 |
| 1319 | NDA/MAL/HDP/1663 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | ALCID-PINK | ALUMINIUM HYDROXIDE/MAGNESIUM TRISILICATE | 400MG+400MG/50ML | TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE | 01/07/2003 |

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| 1320 | NDA/MAL/HDP/1665 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOXIN CAPSULES | AMOXICILLIN TRIHYDRATE | 250MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1998 |
| 1321 | NDA/MAL/HDP/1675 | MERCK SHARP & DOHME BV | SURGIPHARM (U) LIMITED | GARDASIL | QUADRIVALENT HUMAN PAPILLOMAVIRUS RECOMBINANT VACCINE (TYPES 6, 11, 16, 18) | (20MCG+40MCG+40MCG+20MCG)/0.5ML | MERK & CO. INC-SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA | UNITED STATES | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE),1.0X10.0X0.5 ML VIAL (1 DOSE) | 01/07/2007 |
| 1322 | NDA/MAL/HDP/1676 | KOPRAN LIMITED | TATA UGANDA LIMITED | CLOXIN-250 | CLOXACILLIN | 250MG | KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |

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| 1323 | NDA/MAL/HDP /1679 | LEBEN LABORATORIES PVT. LTD | MALIX PHARMA (U) LIMITED | CIPROLEB | CIPROFLOXACIN | 500MG | LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1324 | NDA/MAL/HDP /1680 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | H-CORT | HYDROCORTISONE | 0.1%W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 1325 | NDA/MAL/HDP /1682 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | TOFLOX-200 | OFLOXACIN | 200MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X 1.0X10.0 TABLET BLISTER | 01/07/2005 |

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| 1326 | NDA/MAL/HDP/1690 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | FINALLERG | CETIRIZINE DIHYDROCHLORIDE | 1MG/ML | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2004 |
| 1327 | NDA/MAL/HDP/1691 | WIDE SPECTRUM ENTERPRISES (U) LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ZITHRORIV | AZITHROMYCIN | 500MG | RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0 CAPSULE BLISTER | 01/07/2011 |
| 1328 | NDA/MAL/HDP/1692 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CEFODOX 50MG/5ML SUSPENSION | CEFPODOXIME PROXETIL | 50MG/5ML | PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN | JORDAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X50.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1329 | NDA/MAL/HDP/1693 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | OPTIMAL (0.05%) CREAM | TRETINOIN USP | 0.5MG/1G | PHARMA INTERNATIONAL COMPANY .-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN | JORDAN | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE | 01/07/2005 |
| 1330 | NDA/MAL/HDP/1697 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | FINALLERG | CETIRIZINE DIHYDROCHLORIDE | 10MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1331 | NDA/MAL/HDP/1698 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | AZICIP 500 | AZITHROMYCIN | 500MG | CIPLA LTD ;-VILLAGE UPPER MALPUR P.O BHUD THE NALAGARH DIST. SOLAN HIMACHAL PRADESH PIN 173205 CIPLA LTD.-VERNA IND. ESTATE GOA 403 722 INDIA CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X3.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1332 | NDA/MAL/HDP/1701 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | FORMIN | METFORMIN HYDROCHLORIDE | 500MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1333 | NDA/MAL/HDP/1702 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | DELOR | CLOBETASOL PROPIONATE | 0.05%W/W | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | TOPICAL EXTERNAL OINTMENTS | 1.0X25.0 G TUBE | 01/07/2005 |
| 1334 | NDA/MAL/HDP/1704 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | DAFRACLAV | AMOXYCILLIN + POTASSIUM CLAVULANATE | 500MG + 125MG | BILIM ILAC SAN. VE. TIC. A.S.-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510 | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X5.0 TABLET BLISTER | 01/07/2011 |

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| 1335 | NDA/MAL/HDP /1707 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | FEBRICOL TABLETS | PARACETAMOL / PSEUDOEPHEDRIN E / CHLORPHENIRAMI NE | 500MG / 30MG /2MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN BLD -1-5 CHENG INDUSTRIAL ESTATE, 75250<br>MALEKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X1 0.0 TABLET BLISTER | 01/07/1997 |
| 1336 | NDA/MAL/HDP /1708 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | DENTAMOL | ACETAMINOPHEN | 500MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349<br>OFF MOMBASA ROAD, NAIROBI<br>P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1337 | NDA/MAL/HDP /1709 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | LUCIN CREAM | HYDROCORTISONE | 1%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE,1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/1997 |

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| 1338 | NDA/MAL/HDP /1711 | KOPRAN LIMITED | TATA UGANDA LIMITED | AMYN-250 | AMOXYCILLIN | 250MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |
| 1339 | NDA/MAL/HDP /1713 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LUMITER | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | OXALIS LABS -VILLAGE THEDA P.O LODHIMAJRA, THESIL BADDI DISTRICT SOLAN HIMACHAL PRADESH MACLEODS PHARMACEUTICALS LIMITED, UNIT II-PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN - 396210 (UT) - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X8.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X24.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X30.0X18.0 TABLET | 01/07/2007 |
| 1340 | NDA/MAL/HDP /1714 | REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN | HEALTHCARE LTD. | REMICOL EAR DROPS | CHLORAMPHENICOL | 1%W/V | REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM | PAKISTAN | OTIC DROPS | 1.0X10.0 ML BOTTLE | 01/07/1999 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1341 | NDA/MAL/HDP/1715 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | MUCOLYN SYRUP | AMMONIUM CHLORIDE+CHLORPHENIRAMINE+DEXTROMETHORPHAN+BROMHEXINE | 50MG+2MG+5MG+4MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2011 |
| 1342 | NDA/MAL/HDP/1723 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GROVIT MULTIVITAMIN DROPS | MULTI-INGREDIENT | MULTI-INGREDIENT | SAKAR HEALTHCARE PVT LTD-SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE | 01/07/2000 |
| 1343 | NDA/MAL/HDP/1724 | GLAXOSMITHKLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AVAMYS NASAL SPRAY | FLUTICASONE FUROATE | 27.5MCG/ACTUATION | GLAXO OPERATIONS UK LTD--HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK | UNITED KINGDOM | NASAL TOPICAL SPRAYS WITHOUT GAS | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1344 | NDA/MAL/HDP/1725 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | MYCORIL CREAM 1% | CLOTRIMAZOLE | 1%W/W | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2000 |
| 1345 | NDA/MAL/HDP/1728 | ARISTO PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | DELISPRIN 75MG | ASPIRIN | 75MG | ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046 | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X10.0X14.0 TABLET STRIP | 01/07/2007 |
| 1346 | NDA/MAL/HDP/1730 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | ZITHROX | AZITHROMYCIN | 500MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1347 | NDA/MAL/HDP/1731 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | MEDIVEN-S OINTMENT | BETAMETHASONE VALERATE + SALICYLIC ACID | 0.05%W/W + 3%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |
| 1348 | NDA/MAL/HDP/1732 | MICRO LABS LTD | LABOREX UGANDA LIMITED | CEFEX-250 | CEPHALEXIN | 250MG | MICROLABS LIMITED-PLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1999 |
| 1349 | NDA/MAL/HDP/1734 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMOMINT | COMPOUND MAGNESIUM TRISILICATE | 500MG | TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 10.0 TABLET CONTAINER,250.0 TABLET CONTAINER,500.0 TABLET CONTAINER,100.0 TABLET CONTAINER,1000.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1350 | NDA/MAL/HDP /1736 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | KLERIMED | CLARITHROMYCIN | 500MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2009 |
| 1351 | NDA/MAL/HDP /1738 | ALCON PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | TEARS NATURALE II | NATURAL TEARS | 15ML | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM ALCON SINGAPORE MANUFACTURING PTE. LIMITED-19 TUAS SOUTH AVENUE 14 - SINGAPORE | BELGIUM | OPHTHALMIC DROPS | 1.0X15.0 ML BOTTLE | 01/07/1997 |
| 1352 | NDA/MAL/HDP /1739 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MELOX | MELOXICAM | 15MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1353 | NDA/MAL/HDP /1741 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NEOPRED-P | PREDNISOLONE ACETATE + NEOMYCIN SULPHATE+ POLYMYXIN-B | 5MG/ML +5MG/ML + 1M I.U/ML | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |
| 1354 | NDA/MAL/HDP /1743 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | DAPRIL | LISINOPRIL DIHYDRATE | 10MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |
| 1355 | NDA/MAL/HDP /1745 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APIGEN | GENTAMYCIN SULPHATE | 0.3%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1356 | NDA/MAL/HDP/1747 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | PRESARTAN H 50 | LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 1357 | NDA/MAL/HDP/1750 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APIFLOX | NORFLOXACIN | 0.3%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |
| 1358 | NDA/MAL/HDP/1751 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OPTIFUCIN | FUSIDIC ACID | 1%W/V | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X5.0 ML AMPOULE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1359 | NDA/MAL/HDP /1753 | PHARMATEC PAKISTAN PVT LTD | HEALTHCARE LTD. | FLU-GONE-P. PLUS SYRUP | PARACETAMOL + PSEUDOEPHEDRIN E HCL + CHLORPHENIRAMI NE MALEATE | 120MG/5ML + 15MG/5ML + 1MG/5ML | PHARMATEC PKISTAN (PVT) LTD-D-86/A, S.I.T.E., KARACHI - 75700, PAKISTAN | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X120.0 ML BOTTLE | 01/07/2013 |
| 1360 | NDA/MAL/HDP /1754 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APIMOL | TIMOLOL MALEATE | 0.5%W/V | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML VIAL | 01/07/2005 |
| 1361 | NDA/MAL/HDP /1756 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APICROM 2% | SODIUM CROMOGLYCATE | 2%W/V | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |

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| 1362 | NDA/MAL/HDP/1758 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APICORT | PREDNISOLONE ACETATE | 0.12%W/V | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |
| 1363 | NDA/MAL/HDP/1759 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | AMLOPIN | AMLODIPINE | 5MG | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 07/01/2004 |
| 1364 | NDA/MAL/HDP/1760 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NEODEX | NEOMYCIN +DEXAMETHASONE | 0.5%W/V + 0.1%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OTIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1365 | NDA/MAL/HDP/1761 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ATAZOR-R | ATAZANAVIR + RITONAVIR | 300 MG + 100 MG | EMCURE PHARMACEUTICALS LTD .-PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2014 |
| 1366 | NDA/MAL/HDP/1762 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APITROPIN | ATROPINE | 1%W/V | AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN | JORDAN | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 01/07/2005 |
| 1367 | NDA/MAL/HDP/1763 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | ASPIRIN TABLETS BP | ACETYL SALICYLIC ACID | 300MG | LABORATORY & ALLIED LTD.-PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 1368 | NDA/MAL/HDP/1764 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FRESH BURST LISTERINE | ALCOHOL + THYMOL | 95 % W/V + 12 MG | JOHNSON&JOHNSON PTY LTD..-241 MAIN ROAD RETREAT 794 | SOUTH AFRICA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X250.0 ML CONTAINER,1.0X500.0 ML CONTAINER | 01/07/2006 |
| 1369 | NDA/MAL/HDP/1765 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | RILIF PLUS | ACECLOFENAC + PARACETAMOL | 100MG + 500MG | UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1370 | NDA/MAL/HDP/1766 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | COLDEASE CAPSULES | PARACETAMOL+CAFFEINE CITRATE+CHLORPHENIRAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE | 400MG+30MG+4MG+30MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2005 |

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| 1371 | NDA/MAL/HDP/1769 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ENGERIX-B VACCINE | HEPATITIS B SURFACE ANTIGEN | 10MCG/ML | GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY VIALS | 1.0X10.0X0.5 ML VIAL (1 DOSE),1.0X25.0X0.5 ML VIAL (1 DOSE) | 01/07/1997 |
| 1372 | NDA/MAL/HDP/1772 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | GESTID TABLETS | COMPOUND MAGNESIUM TRISILICATE | 385MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED,-INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X4.0 TABLET BLISTER | 01/07/2000 |
| 1373 | NDA/MAL/HDP/1773 | MICRO LABS LTD | LABOREX UGANDA LIMITED | LEVOBACT 500 | LEVOFLOXACIN HEMIHYDRATE | 500MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X5.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2005 |

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| 1374 | NDA/MAL/HDP/1777 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | NUZAC 20 | FLUOXETINE | 20MG | CIPLA LTD ..-PLOT NO. 910 & 15 INDORE SPECIAL ECONOMIC ZONE PHASE II PITHAMPUR DISTRICT DHAR MADHYA PRADESH 454775 CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2003 |
| 1375 | NDA/MAL/HDP/1779 | BROOKES PHARMACEUTICAL LABORATORIES L | HARLEYS UGANDA LIMITED | PYODINE SOLUTION | POVIDONE IODINE | 10.0G/100ML | BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN | PAKISTAN | TOPICAL EXTERNAL LIQUIDS | 1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/1999 |
| 1376 | NDA/MAL/HDP/1780 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENETRIM SUSPENSION | CO-TRIMOXAZOLE | 240MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1377 | NDA/MAL/HDP /1781 | ASTRAZENECA | MACNAUGHTON LIMITED | ARIMIDEX | ANASTROZOLE | 1MG | ASTRAZENECA PHARMACEUTICALS LP-NEWARK, DELAWARE | UNITED STATES | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2000 |
| 1378 | NDA/MAL/HDP /1782 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CO-METHER | ARTEMETHER + LUMEFANTRINE | PER 5ML: 15MG + 90MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE | 01/07/2010 |
| 1379 | NDA/MAL/HDP /1783 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LAEOVATE OINTMENT | BETAMETHASONE VALERATE | 0.1%W/W | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X15.0 G TUBE | 01/07/1997 |

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| 1380 | NDA/MAL/HDP/1784 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | AZICURE-500 | AZITHROMYCIN | 500MG | MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2005 |
| 1381 | NDA/MAL/HDP/1785 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | ACTION TABLETS | ACETYL SALICYLATE + CAFFEINE + PARACETAMOL | 600MG+50MG+300MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X200.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X110.0 TABLET STRIP,1.0X12.0 TABLET BLISTER | 01/07/1997 |
| 1382 | NDA/MAL/HDP/1790 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNITRIM TABLET | CO-TRIMOXAZOLE | 480MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 1383 | NDA/MAL/HDP/1792 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | LIPODAR | ATORVASTATIN | 20MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1384 | NDA/MAL/HDP/1795 | KOPRAN LIMITED | TATA UGANDA LIMITED | AMPIK-250 | AMPICILLIN | 250MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |
| 1385 | NDA/MAL/HDP/1796 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ZAHA 250 | AZITHROMYCIN | 250 MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1.0X6.0 TABLET BLISTER | 01/07/2006 |

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| 1386 | NDA/MAL/HDP/1797 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | AMPICILLIN+CLOXACILLIN | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-#14, II PHASE PIA, BANGALORE 560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL | 01/07/2010 |
| 1387 | NDA/MAL/HDP/1799 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | SECZOL DS | SECNIDAZOLE | 1GM | INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2001 |
| 1388 | NDA/MAL/HDP/1800 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AMLONG-10 | AMLODIPINE | 10MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1389 | NDA/MAL/HDP/1801 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | LABESTEN PESSARIES | CLOTRIMAZOLE | 100MG | LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | VAGINAL TABLETS | 1.0X1.0X6.0 PESSARY STRIP | 01/07/1997 |
| 1390 | NDA/MAL/HDP/1803 | ASTRA ZENECA AB | MACNAUGHTON LIMITED | NEXIUM 40MG | ESOMEPRAZOLE | 40MG | ASTRAZENECA AB.-GARTUNA & SNACKVIKEN STOCKHOLM | SWEDEN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON,1.0X28.0 TABLET CARTON | 01/07/2001 |
| 1391 | NDA/MAL/HDP/1804 | TORRENT PHARMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | LISTRIL | LISINOPRIL | 5MG | TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1392 | NDA/MAL/HDP/1807 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AMPICLOX NEONATAL DROPS | AMPICILLIN + CLOXACILLIN | 60 MG / 0.6 ML + 30 MG / 0.6 ML | MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X8.0 ML BOTTLE | 01/07/1997 |
| 1393 | NDA/MAL/HDP/1810 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOTRI | TRIFLUOPERAZINE | 5MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2010 |
| 1394 | NDA/MAL/HDP/1811 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DUOVIR TABLETS | ZIDOVUDINE+ LAMIVUDINE | 300MG + 150MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER,1.0X60.0 TABLET BOTTLE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1395 | NDA/MAL/HDP/1812 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REQUIN TABLETS | QUININE SULPHATE | 300MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2001 |
| 1396 | NDA/MAL/HDP/1813 | DAWA LIMITED | SUPER MEDIC LTD | MOXAFORTE | AMOXICILLIN + FLUCLOXACILLIN | 125 MG + 125MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2014 |
| 1397 | NDA/MAL/HDP/1815 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | SUPIROCIN OINTMENT | MUPIROCIN | 2%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL OTHER OINTMENTS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1398 | NDA/MAL/HDP/1816 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | DRESS UP CREAM | NEOMYCIN SULPHATE | 0.5%W/W | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/1998 |
| 1399 | NDA/MAL/HDP/1821 | BLUE CROSS LABORATORIES LTD | STAR PHARMACEUTICALS LTD | MEFTAL 500 TABLETS | MEFENAMIC ACID | 500MG | BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/1997 |
| 1400 | NDA/MAL/HDP/1822 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | EPHEDRINE | EPHEDRINE HYDROCHLORIDE | 30MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1401 | NDA/MAL/HDP/1825 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | COLDEASE SYRUP | PARACETAMOL+CHLORPHENIRAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE | 120MG+2MG+15MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2005 |
| 1402 | NDA/MAL/HDP/1827 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | ALBASOL SUSPENSION | ALBENDAZOLE | 200MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2006 |
| 1403 | NDA/MAL/HDP/1840 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | OVA-MIT | CLOMIPHENE | 50MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1404 | NDA/MAL/HDP/1841 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | FUNGNIL CREAM | CLOTRIMAZOLE | 1%W/W | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2000 |
| 1405 | NDA/MAL/HDP/1842 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | SUGAQUIN TABLETS | CHLOROQUINE PHOSPHATE | 250MG | KAMPALA PHARMACEUTICALS INDUSTIES-PLOT NO M44B STRETCHER ROAD INTINDA | UGANDA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2002 |
| 1406 | NDA/MAL/HDP/1843 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ECORIN-75 | ASPIRIN | 75MG | REMEDEX PHARMA-B-249/250 PEENYA INDUSTRIAL ESTATE BANGALORE 560 058 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1407 | NDA/MAL/HDP /1844 | GUILIN PHARMACEUTICALS CO.LTD | TRIDEM PHARMA UGANDA LIMITED | SULFAMETHOXAZOLE / TRIMETHOPRIM | SULFAMETHOXAZOLE / TRIMETHOPRIM | 800MG /160MG | GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 1408 | NDA/MAL/HDP /1846 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | ANTAGIT DS GEL ORANGE FLAVOUR | ALUMINIUM HYDROXIDE + MAGNESIUM + SIMETHICONE | 400MG + 400MG + 50MG | LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA. | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X170.0 ML BOTTLE | 01/07/2013 |
| 1409 | NDA/MAL/HDP /1847 | MICRO LABS | MALIX PHARMA (U) LIMITED | MOXILEB-250 CAPSULE | AMOXICILLIN | 250MG | LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1410 | NDA/MAL/HDP/1848 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | PARATAL | PARACETAMOL | 500MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1411 | NDA/MAL/HDP/1849 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | CIFIN | CIPROFLOXACIN | 0.2%W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 1412 | NDA/MAL/HDP/1850 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | ALZOL TABLETS | ALBENDAZOLE | 400MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1413 | NDA/MAL/HDP/1851 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | CAPSIFENAC GEL | CAPSAICIN + DICLOFENAC + LEVOMENTHOL + METHYL SALICYLATE | 0.438 G + 0.335 G + 0.135 G + 0.918 G | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | TOPICAL EXTERNAL EMULSION GELS | 1.0X1.0X20.0 G TUBE,1.0X1.0X10.0 G TUBE | 01/07/2011 |
| 1414 | NDA/MAL/HDP/1852 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | VERCEF ORAL SUSPENSION | CEFACLOR | 125MG/5ML | RANBAXY LABORATORIES-LABORATORIES LIMITED INDUSTRIAL AREA 3 DEWAS 455001 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1415 | NDA/MAL/HDP/1853 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | AERIUS ORAL SOLUTION | DESLORATADINE | 0.5MG/ML | MSD (PTY) LTD- LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG | BELGIUM | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X150.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1416 | NDA/MAL/HDP /1856 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | PROPRANOLOL TABLETS B.P. 40MG | PROPRANOLOL HYDROCHLORIDE | 40MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER | 01/07/1998 |
| 1417 | NDA/MAL/HDP /1861 | GUILIN PHARMACEUTICAL S CO LTD | TRIDEM PHARMA UGANDA LIMITED | SULFAMETHOX AZOLE / TRIMETHOPRIM | SULFAMETHOXAZ OLE / TRIMETHOPRIM | 400MG /80MG | GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000. 0 TABLET CONTAINER | 01/07/2011 |
| 1418 | NDA/MAL/HDP /1863 | AMOUN PHARMACEUTICAL S COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ORACURE GEL | LIDOCAINE HCL+CETYL PYRIDINUM CHLORIDE | 2 GM+0.1 GM | AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT. | EGYPT | ORAL TOPICAL GELS AND SOLS | 1.0X15.0 G TUBE | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1419 | NDA/MAL/HDP/1864 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | PATANOL | OLOPATADINE HYDROCHLORIDE | 0.1%W/V | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML VIAL | 01/07/2009 |
| 1420 | NDA/MAL/HDP/1877 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | MINT-O-COOL | DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE | 120MG + 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 1421 | NDA/MAL/HDP/1879 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPENIV | PHENOXYMETHYL PENICILLIN | 250MG | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |

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| 1422 | NDA/MAL/HDP/1880 | SPARSH BIO-TECH PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMCLOX | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2004 |
| 1423 | NDA/MAL/HDP/1881 | SPARSH BIO-TECH PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMOX | AMOXYCILLIN | 250MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0X10.0 CAPSULE BLISTER,1.0X1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2004 |
| 1424 | NDA/MAL/HDP/1882 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMCIL | AMPICILLIN | 250MG | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1425 | NDA/MAL/HDP/1887 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMADOL | PARACETAMOL | 500MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,100.0 TABLET CONTAINER,250.0 TABLET CONTAINER,500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET | 01/07/1997 |
| 1426 | NDA/MAL/HDP/1889 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM PREDSOL | PREDNISOLONE | 5MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON,1.0X10.0 TABLET CARTON | 01/07/1997 |
| 1427 | NDA/MAL/HDP/1891 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LEVOMAC 500 | LEVOFLOXACIN | 500MG | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X5.0 TABLET BLISTER | 01/07/2005 |

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| 1428 | NDA/MAL/HDP/1892 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LEVOMAC 250 | LEVOFLOXACIN | 250MG | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0X5.0 TABLET BLISTER | 01/07/2012 |
| 1429 | NDA/MAL/HDP/1894 | KOPRAN LIMITED | TATA UGANDA LIMITED | TRIM-480 | CO-TRIMOXAZOLE | 480MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 1430 | NDA/MAL/HDP/1895 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TRIMAGO (PAEDIATRIC) | CO-TRIMOXAZOLE | 100MG/20MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2007 |

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| 1431 | NDA/MAL/HDP /1898 | WIN-MEDICARE LTD | SURGIPHARM (U) LIMITED | ZAPACID - 30 | LANSOPRAZOLE | 30MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 3.0X10.0 CAPSULE BLISTER | 01/07/2001 |
| 1432 | NDA/MAL/HDP /1900 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOM 20 | OMEPRAZOLE | 20MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X 10.0 CAPSULE STRIP | 01/07/2007 |
| 1433 | NDA/MAL/HDP /1901 | AJANTA PHARMA LTD 31-0 | ABACUS PHARMA (AFRICA) LIMITED | IBUMOL | IBUPROFEN + PARACETAMOL | 100MG + 162.5 MG /5ML | AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2013 |

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| 1434 | NDA/MAL/HDP/1902 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMODIUM | LOPERAMIDE HYDROCHLORIDE | 2MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 1435 | NDA/MAL/HDP/1905 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | OXYTOCIN INJECTION | OXYTOCIN | 10I.U/ML | KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJIAKOU CITY, HEBEI PROVINCE | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE,1.0X100.0X1.0 ML AMPOULE | 01/07/2007 |
| 1436 | NDA/MAL/HDP/1911 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CODEINE PHOSPHATE TABLETS BP 30 | CODEINE PHOSPHATE | 30MG | COSMOS LIMITED -RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1437 | NDA/MAL/HDP/1912 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | D-WORM | ALBENDAZOLE | 200MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2008 |
| 1438 | NDA/MAL/HDP/1914 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | CHLORPHENIRAMINE | CHLORPHENIRAMINE | 4MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2003 |
| 1439 | NDA/MAL/HDP/1919 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDIDERM CREAM | BECLOMETASONE/CLOTRIMAZOLE/GENTAMYCIN | 0.025%W/W+1%W/W+0.1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X5.0 G TUBE,1.0X15.0 G TUBE | 01/07/1999 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1440 | NDA/MAL/HDP/1921 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ANTIMIN | LORATIDINE | 10MG | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1441 | NDA/MAL/HDP/1922 | IPCA LABORATORIES | MEDVIN PHARMA LIMITED | AZIFAST-500 | AZITHROMYCIN | 500MG | IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA IPCA LABORATORIES LTD, PLOT NO. T-139-PLOT NO. T-139, MIDC, INDUSTRIAL ESTATE, TARAPUR, BOISOR, DIST-PALGHAR, THANE 401506, MAHARASHTRA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X3.0 TABLET BLISTER | 01/07/2007 |
| 1442 | NDA/MAL/HDP/1924 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | AMPICILLIN SODIUM | AMPICILLIN SODIUM | 500MG | CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X500.0 MG VIAL | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1443 | NDA/MAL/HDP/1927 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | INTAPLEX TABLET | VITAMIN B COMPOUND | N/A | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1444 | NDA/MAL/HDP/1928 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | NEUTRAFLUX | ALGINIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE | 200MG + 250MG +250MG +250MG + 125MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1445 | NDA/MAL/HDP/1931 | ASTRAZENECA | MACNAUGHTON LIMITED | ZOLADEX LA | GOSERELIN ACETATE | 10.8MG | ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, | UNITED KINGDOM | PARENTERAL RETARD PRE-FILLED SYRINGES | 1.0X10.8 MG IMPLANT | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1446 | NDA/MAL/HDP /1932 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | CANDISTAT CREAM | CLOTRIMAZOLE | 1%W/W | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL TOPICAL CREAMS | 1.0X20.0 G TUBE | 01/07/2001 |
| 1447 | NDA/MAL/HDP /1934 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENECHLOR SUSPENSION | CHLORAMPHENICOL | 125MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2001 |
| 1448 | NDA/MAL/HDP /1937 | AUROBINDO PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | EFAVIRENZ | EFAVIRENZ | 600MG | AUROBINDO PHARMA LIMITED (UNIT III) -AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD-500090, ANDHERA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1449 | NDA/MAL/HDP/1938 | YURIA-PHARM LTD | PHARMA VILLE LIMITED | INFULGAN | PARACETAMOL | 10MG/ML | YURIA-PHARM LLC MANUFACTURING SITE NO. 1-108, KOBZARSKA STREET, CHERKASY, 18030 | UKRAINE | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE,1.0X20.0 ML BOTTLE | 01/07/2013 |
| 1450 | NDA/MAL/HDP/1941 | CADILA PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | RABELOC IV | RABEPRAZOLE | 20MG/VIAL | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X5.0 ML VIAL | 01/07/2005 |
| 1451 | NDA/MAL/HDP/1942 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | AMCLOREN | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0 CAPSULE CONTAINER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1452 | NDA/MAL/HDP /1943 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | NITROCONTIN 2.6 | NITROGLYCERIN (CONTROLLED RELEASE) | 2.6MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID RETARD TABLETS | 1.0X25.0 TABLET CONTAINER | 01/07/2009 |
| 1453 | NDA/MAL/HDP /1946 | WIN-MEDICARE LTD | SURGIPHARM (U) LIMITED | SOLUDOL TABLETS | DICLOFENAC SODIUM | 50MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 10.0X10.0 TABLET STRIP | 01/07/1998 |
| 1454 | NDA/MAL/HDP /1948 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | ZITHROMAX | AZITHROMYCIN DIHYDRATE | 500MG | HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE PFIZER LABORATORIES (PTY) LTD;--SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1455 | NDA/MAL/HDP /1949 | MACLEODS PHARMACEUTICALS LTDS LTD | VITACARE LIMITED | TRENAXA 500 | TRANEXAMIC ACID | 500MG | MACLEODS PHARMACEUTICALS -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X6.0 TABLET BLISTER | 01/07/2011 |
| 1456 | NDA/MAL/HDP /1951 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | CLOPI 75 | CLOPIDOGREL | 75MG | MACLEODS PHARMACEUTICALS -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA MACLEODS PHARMACEUTICALS LIMITED, UNIT VI-VILLAGE THEDA, KHARUNI LODHI MAJRA RD, TEHSIL BADDI N2, DISTRICT SOLAN, HIMACHAL | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1457 | NDA/MAL/HDP /1954 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | RAPEED-20 | RABEPRAZOLE | 20MG | ALKEM LABORATORIES LTD .- VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP,1.0X1.0X10.0 TABLET STRIP | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1458 | NDA/MAL/HDP/1956 | MILAN LABORATORIES LTD | GITTOES PHARMACEUTICALS LIMITED | MILOXY | AMOXYCILLIN | 250MG | MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI). | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2006 |
| 1459 | NDA/MAL/HDP/1958 | MILAN LABORATORIES LTD | GITTOES PHARMACEUTICALS LIMITED | MILOXY | AMOXYCILLIN | 125MG/5ML | MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI). | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2005 |
| 1460 | NDA/MAL/HDP/1959 | MILAN LABERATORIES PVT LTD | GITTOES PHARMACEUTICALS LIMITED | BETRIM 480 | CO-TRIMOXAZOLE | 480MG | MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI). | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1461 | NDA/MAL/HDP/1960 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | DIFENAC | DICLOFENAC SODIUM | 50MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2003 |
| 1462 | NDA/MAL/HDP/1961 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | MUILTIZEBEX | VITAMIN A + CHOLECALCIFEROL + THIAMINE + RIBOFLAVINE + PYRIDOXINE + NICOTINAMIDE | 2500 IU + 200IU + 1MG +1MG + 0.5MG +15MG | TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2014 |
| 1463 | NDA/MAL/HDP/1966 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | PARACIN | PARACETAMOL | 500MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1464 | NDA/MAL/HDP/1969 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN SR 75MG | DICLOFENAC SODIUM | 75MG | NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY-NA | ITALY | ORAL SOLID RETARD TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/1997 |
| 1465 | NDA/MAL/HDP/1970 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | CETRAMAC | CETIRIZINE | 10MG | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1466 | NDA/MAL/HDP/1971 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMPICLOX ORAL SUSPENSION | AMPICILLIN + CLOXACILLIN | 125 MG/5ML + 125 MG/5ML | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1467 | NDA/MAL/HDP/1975 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | BET-CODERM N | BETAMETHASONE + NEOMYCIN | 0.1 W/W + 0.5 W/W | LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2007 |
| 1468 | NDA/MAL/HDP/1977 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | LOSAR-H | LOSARTAN + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1469 | NDA/MAL/HDP/1984 | ELI-LILLY (SUISSE) SA | LABOREX UGANDA LIMITED | CIALIS | TADALAFIL | 20MG | LILLY SA, AVDA DE LA INDUSTRIA-LILLY SA, AVDA DE LA INDUSTRIA, 30 28108 ALCOBENDAS - MADRID | SPAIN | ORAL SOLID ORDINARY TABLETS | 2.0X2.0 TABLET BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1470 | NDA/MAL/HDP/1987 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | FOMYCETIN | CHLORAMPHENICOL | 250MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 1471 | NDA/MAL/HDP/1989 | FERRER INTERNACIONAL S.A | LABOREX UGANDA LIMITED | DERMOFIX | SERTACONAZOLE NITRATE | 2%W/W | FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2014 |
| 1472 | NDA/MAL/HDP/1990 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TAGERA FORTE | SECNIDAZOLE | 1G | UNICHEM LABORATORIES LTD-UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X2.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1473 | NDA/MAL/HDP/1997 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TENA-100 | ATENOLOL | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X1000.0 TABLET JAR (WITH STATEMENT "FOR HOSPITAL USE ONLY".) | 01/07/2011 |
| 1474 | NDA/MAL/HDP/1999 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | CARBATOL 200 | CARBAMAZEPINE | 200MG | TORRENT PHARMACEUTICALS LTD-INDRAD-382721, TAL KADI, AHMEDABAD, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,2.0X5.0X10.0 TABLET BLISTER | 01/07/2000 |
| 1475 | NDA/MAL/HDP/2000 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | CALCIGARD RETARD | NIFEDIPINE(SR) | 20MG | TORRENT PHARMACEUTICALS LTD-INDRAD-382721, TAL KADI, AHMEDABAD, INDIA | INDIA | ORAL SOLID RETARD TABLETS | 1.0X2.0X5.0X10.0 TABLET BLISTER | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1476 | NDA/MAL/HDP /2004 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | R.B.TONE | FERROUS GLUCONATE + VITAMIN C + VITAMIN B12 + VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + CALCIUM PANTOTHENATE + VITAMIN B3 + FOLIC ACID + DIBASIC CA PO4 + | 200MG + 38MG + 4MCG + 3MG + 2.5MG + 1MG + 2.5MG + 1MG + 2.5MG + 23MG + 0.5MG + 100MG + 33MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X15.0 CAPSULE BLISTER | 01/07/2008 |
| 1477 | NDA/MAL/HDP /2005 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | KAMAGRA-100 | SILDENAFIL CITRATE | 100MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2005 |
| 1478 | NDA/MAL/HDP /2008 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | CANDID -B-CREAM | CLOTRIMAZOLE + BECLOMETASONE DIPROPRIONATE CREAM | 1%W/W + 0.025%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1479 | NDA/MAL/HDP/2009 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | ZITHROX | AZITHROMYCIN | 200MG/5ML | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE | 01/07/2010 |
| 1480 | NDA/MAL/HDP/2011 | HETERO LABS LTD | AIVEEN (U) LIMITED | GIAGRA 50 | SILDENAFIL CITRATE | 50MG | HETERO LABS LTD. UNIT (V) .-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER,1.0X10.0X 1.0X4.0 TABLET BLISTER | 01/07/2013 |
| 1481 | NDA/MAL/HDP/2012 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | CANDID -B-LOTION | CLOTRIMAZOLE + BECLOMETHASONE DIPROPIONATE | 1%W/V + 0.025%W/V | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL LOTIONS | 1.0X15.0 ML BOTTLE | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1482 | NDA/MAL/HDP/2014 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | CANI-MAKS | CLOTRIMAZOLE | 1%W/W | S KANT HEALTHCARE LTD-1802-1805 GIDC OHASE II VAPS-396195, GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 01/07/2009 |
| 1483 | NDA/MAL/HDP/2016 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | CANDID CREAM | CLOTRIMAZOLE | 1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2000 |
| 1484 | NDA/MAL/HDP/2018 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | ORAXIN SYRUP | CYPROHEPTADINE +TRICHOLINE CITRATE | 2MG+275MG | CENTAUR PHARMACEUTICALS LTD,--KARASWADA MAPUSA GOA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1485 | NDA/MAL/HDP/2019 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOHAL | HALOPERIDOL | 10MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1486 | NDA/MAL/HDP/2020 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | QUINE | QUININE SULPHATE | 300MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER | 01/07/1997 |
| 1487 | NDA/MAL/HDP/2022 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | TORACTIN | CYPROHEPTADINE | 2MG/5ML | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |

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| 1488 | NDA/MAL/HDP/2024 | TORRENT PHARMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | NEXPRO - 40 | ESOMEPRAZOLE MAGNESIUM TABLET | 40MG | TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2004 |
| 1489 | NDA/MAL/HDP/2025 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | FERRO-B COMPLEX SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1490 | NDA/MAL/HDP/2026 | BROOKES PHARMACEUTICAL LABORATORIES L | HARLEYS UGANDA LIMITED | CORAM 10MG | AMLODIPINE BESYLATE | 10MG | BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1491 | NDA/MAL/HDP/2027 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CO-ANGINET 160/12.5MG | VALSARTAN + HYDROCHLOROTHIAZIDE | 160MG + 12.5MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1492 | NDA/MAL/HDP/2028 | SEARLE PAKISTAN LIMITED | HEALTHCARE LTD. | SELANZ - SR | LANSOPRAZOLE | 30MG | SEARLE PAKISTAN LIMITED-PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X7.0 CAPSULE BLISTER | 01/07/2005 |
| 1493 | NDA/MAL/HDP/2033 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ANGIZAAR-50 | LOSARTAN POTASSIUM | 50MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1494 | NDA/MAL/HDP/2035 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | NEOSIDAR | SULPHADOXINE + PYRIMETHAMINE | 500MG + 25MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X25.0X3.0 TABLET BLISTER,1.0X50.0X 3.0 TABLET BLISTER | 01/07/2004 |
| 1495 | NDA/MAL/HDP/2036 | ELI-LILLY (SUISSE) SA | LABOREX UGANDA LIMITED | HUMULIN REGULAR | HUMAN INSULIN | 100IU | ELI LILLY & COMPANY-LILLY TECHNOLOGY CENTER, 1555 S HARDING, INDIANAPOLIS, INDIANA, 46221 LILLY FRANCE SA-FRANCE | FRANCE | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 01/07/1998 |
| 1496 | NDA/MAL/HDP/2040 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN 20/120 | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0X12.0 TABLET BLISTER,1.0X3.0X8. 0 TABLET BLISTER,1.0X30.0X 24.0 TABLET BLISTER,1.0X30.0X 18.0 TABLET BLISTER,1.0X30.0X 6.0 TABLET BLISTER,1.0X1.0X6. 0 TABLET | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1497 | NDA/MAL/HDP /2042 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | BURNCURE | SILVER SULFADIAZINE | 1%W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 1498 | NDA/MAL/HDP /2043 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | DIASTOP TABLETS | ATTAPULGITE/ ALUMINIUM HYDROXIDE | N/A | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X25.0X4.0 TABLET STRIP | 01/07/1998 |
| 1499 | NDA/MAL/HDP /2046 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | LORHISTINA | LORATADINE | 10MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1500 | NDA/MAL/HDP/2047 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | RITONAVIR | RITONAVIR | 100MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET CONTAINER,1.0X30.0 TABLET BOTTLE | 01/07/2011 |
| 1501 | NDA/MAL/HDP/2049 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | KEFSTAR-500 | CEFUROXIME AXETIL | 500MG | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET STRIP,1.0X1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1502 | NDA/MAL/HDP/2053 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ASOMEX-5 | AMLODIPINE BESILATE | 5MG | EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1503 | NDA/MAL/HDP/2055 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | ARTESUN | ARTESUNATE | 120MG | GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X120.0 MG VIAL + 1 *2 ML AMPOULE OF 5% SODIUM BICARBONATE SOLUTION + 1*10 ML AMPOULE OF 0.9% SODIUM CHLORIDE | 01/07/2011 |
| 1504 | NDA/MAL/HDP/2056 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | BRO-ZEDEX | TERBUTALINE SULPHATE +BROMHEXINE HYDROCHLORIDE+ GUAIPHENESIN+MENTHOL | 1.25MG+ 4 MG+50 MG+2.5 MG/5 ML | WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1505 | NDA/MAL/HDP/2058 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | QUININE SULPHATE | QUININE SULPHATE | 300MG | MACLEODS PHARMACEUTICALS -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1506 | NDA/MAL/HDP/2062 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | MUCOLYN PAEDIATRIC SYRUP | DEXTROMETHORPHAN HYDROBROMIDE BP + CHLORPHENIRAMINE MALEATE BP + AMMONIUM CHLORIDE BP + PSEUDOEPHEDRINE HYDROCHLORIDE BP | (5MG + 2MG + 50MG + 10MG)/ 5ML | BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2006 |
| 1507 | NDA/MAL/HDP/2063 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | MICROGYNON FE | LEVONORGESTREL / ETHINYLESTRADIOL. | 0.15MG / 0.03MG | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X28.0 TABLET BLISTER | 01/07/1997 |
| 1508 | NDA/MAL/HDP/2066 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | METHOTREXATE | METHOTREXATE | 2.5MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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| 1509 | NDA/MAL/HDP/2067 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | ZYNCET | CETIRIZINE DIHYDROCHLORIDE | 10MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X5.0X10.0 TABLET BLISTER | 01/07/1999 |
| 1510 | NDA/MAL/HDP/2068 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | DOMADOL | TRAMADOL HYDROCHLORIDE | 50MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1999 |
| 1511 | NDA/MAL/HDP/2069 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | SK DERM | BETAMETHASONE + CLOTRIMOXAZOLE + GENTAMYCIN | 0.05%W/W + 1%W/W + 0.1%W/W | S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE,1.0X100.0 G TUBE,1.0X100.0 G TUBE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1512 | NDA/MAL/HDP/2070 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | MIRENA | LEVONORGESTREL | 52MG | BAYER OY-PANSIONATE 47 20210 TURKU FINLAND | FINLAND | PARENTERAL RETARD IMPLANTS | 1.0X1.0 IMPLANT CARTON | 01/07/2009 |
| 1513 | NDA/MAL/HDP/2071 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | CEFAMOR DRY SYRUP | CEFALEXIN | 125MG/5ML | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2000 |
| 1514 | NDA/MAL/HDP/2073 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | SII MEASLES VACCINE LIVE ATTENUATED(FREEZE-DRIED) | MEASLES VIRUS | NOT LESS THAN 1000CCID50/ DOSE | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 DOSE VIAL + 0.5ML AMPOULE OF STERILE WATER FOR INJECTION,1.0X10.0 DOSE VIAL + 5ML AMPOULE OF STERILE WATER FOR INJECTION | 01/07/1997 |

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| 1515 | NDA/MAL/HDP/2074 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOXIN ORAL SUSPENSION | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1998 |
| 1516 | NDA/MAL/HDP/2075 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPRED | PREDNISOLONE | 5MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1517 | NDA/MAL/HDP/2076 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMIDE | FUROSEMIDE | 40MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2006 |

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| 1518 | NDA/MAL/HDP/2077 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | AMBRODIL | AMBROXOL HYDROCHLORIDE | 30MG/5ML | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1519 | NDA/MAL/HDP/2083 | BIOLOGICAL E. LTD | GITTOES PHARMACEUTICALS LIMITED | BEVAC | PURIFIED HEPATITIS B SURFACE ANTIGEN | 20MCG | BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X35.0X1.0 ML VIAL (1 DOSE VIAL),1.0X24.0X10.0 ML VIAL (10 DOSE VIAL) | 01/07/2015 |
| 1520 | NDA/MAL/HDP/2087 | ABBVIE LOGISTICS BV | MEDICAL ACCESS (UGANDA) LIMITED | NORVIR | RITONAVIR | 100MG | ABBVIE DEUTSCHLAND GMBH & CO. KG.-KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY. | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1521 | NDA/MAL/HDP /2089 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIABETMIN XR 500MG | METFORMIN HCL EXTENDED RELEASE | 500MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1522 | NDA/MAL/HDP /2090 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | CIPROREN | CIPROFLOXACIN | 500MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1523 | NDA/MAL/HDP /2091 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | CAMSTON | CLOTRIMAZOLE | 1%W/W | KPI ( KAMPALA PHARMACEUTICAL INDUSTIRES LTD-PLOT M444 B STRETCHER ROAD NTINDA | UGANDA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2001 |

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| 1524 | NDA/MAL/HDP/2093 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | TRIGAN-D TABLET | PARACETAMOL + DICYCLOMINE | 500MG + 20MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET STRIP | 01/07/1999 |
| 1525 | NDA/MAL/HDP/2094 | MICRO LABS LTD | LABOREX UGANDA LIMITED | LEVOBACT-750 | LEVOFLOXACIN HEMIHYDRATE | 750MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1526 | NDA/MAL/HDP/2097 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | ALCLOX | CLOXACILLIN | 250MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1527 | NDA/MAL/HDP/2098 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO QUININE | QUININE SULPHATE | 300MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1528 | NDA/MAL/HDP/2099 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | HYDROCORTISONE 1% CREAM | HYDROCORTISONE | 1%W/W | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250<br>MALEKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1998 |
| 1529 | NDA/MAL/HDP/2101 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CARDISPRIN | ACETYL SALICYLIC ACID | 75MG | COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1530 | NDA/MAL/HDP/2104 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE DISPERSIBLE TABLETS | LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE | 30MG + 50MG + 60MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2009 |
| 1531 | NDA/MAL/HDP/2108 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYMOX CAPSULES 250MG | AMOXYCILLIN | 250MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |
| 1532 | NDA/MAL/HDP/2111 | HETERO LABS LTD | AIVEEN (U) LIMITED | LOPINAVIR / RITONAVIR | LOPINAVIR / RITONAVIR | 200MG /50MG | HETERO LABS LTD. UNIT (V) .-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET CONTAINER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1533 | NDA/MAL/HDP/2112 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LOPINAVIR + RITONAVIR | LOPINAVIR + RITONAVIR | 200MG + 50MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET CONTAINER | 01/07/2008 |
| 1534 | NDA/MAL/HDP/2116 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | AMLOVAS-10 | AMLODIPINE BESILATE | 10MG | MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET STRIP | 01/07/2005 |
| 1535 | NDA/MAL/HDP/2120 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MEGAPIME | CEFEPIME | 1G | ALKEM LABORATORIES LTD.-VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA. SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1536 | NDA/MAL/HDP/2122 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYMOL | PARACETAMOL | 120MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1537 | NDA/MAL/HDP/2124 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYMOX | AMOXYCILLIN | 125MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1538 | NDA/MAL/HDP/2125 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BECLATE 100 | BECLOMETASONE | 100MCG/DOSE | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | NASAL SYSTEMIC METERED-DOSE LIQUIDS | 1.0X200.0 METERED DOSE CANNISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1539 | NDA/MAL/HDP/2129 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CLAVODAR | AMOXICILLIN/CLAVULANIC ACID | 500MG/125MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2011 |
| 1540 | NDA/MAL/HDP/2132 | AUROBINDO PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | LOPINAVIR/ RITONAVIR | LOPINAVIR/ RITONAVIR | 200MG/ 50MG | AUROBINDO PHARMA LTD-UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET CONTAINER | 01/07/2010 |
| 1541 | NDA/MAL/HDP/2133 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ACTRAPID | HUMAN INSULIN | 100 I.U/ML | NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE | DENMARK | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1542 | NDA/MAL/HDP/2136 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | SEDIPROCT SUPOSITORY | HYDROCORTISONE + CINCHOCAINE+ ESCULOSIDE+ FRAMYCETIN | 5MG + 5MG +10MG +10MG | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | TOPICAL EXTERNAL SUPPOSITORIES | 1.0X6.0 SUPPOSITORY STRIP | 01/07/2003 |
| 1543 | NDA/MAL/HDP/2140 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | AVIRANZ | EFAVIRENZ | 600 | SUN PHARMACEUTICAL INDUSTRIES LIMITED-SUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGAON (EAST), MUMBAI, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2006 |
| 1544 | NDA/MAL/HDP/2141 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | INFLAZONE | MULTIINGREDIENT | N/A | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1545 | NDA/MAL/HDP /2143 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | GRISEOFIL | GRISEOFULVIN | 500MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1546 | NDA/MAL/HDP /2144 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPICOTIL | TENOXICAM | 20MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE | 01/07/2014 |
| 1547 | NDA/MAL/HDP /2145 | FOURRTS (INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | METFIL 500 | METFORMIN | 500MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1548 | NDA/MAL/HDP/2147 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | SUPER MEDIC LTD | DICLOFEN -50 | DICLOFENAC | 50MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1549 | NDA/MAL/HDP/2149 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | PRIMOLUT DEPOT | HYDROXYPROGESTERONE HEXANOATE | 250MG | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/1997 |
| 1550 | NDA/MAL/HDP/2150 | ELI-LILLY (SUISSE) SA | LABOREX UGANDA LIMITED | HUMULIN MIXTURE | HUMAN INSULIN | 70/30 I.U | LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,-INDIANA 46285 USA | UNITED STATES | PARENTERAL ORDINARY S C VIALS | 1.0X4.0 ML VIAL,1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1551 | NDA/MAL/HDP /2151 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GLYCOMET 850 | METFORMIN | 850MG | FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2000 |
| 1552 | NDA/MAL/HDP /2154 | ABACUS PHARMA (AFRICA) LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GLYNASE | GLIPIZIDE | 5MG | FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2000 |
| 1553 | NDA/MAL/HDP /2155 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | DOXEFIL | DOXYCYCLINE | 100MG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1554 | NDA/MAL/HDP/2160 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ACEM-500 | CLARITHROMYCIN | 500MG | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1555 | NDA/MAL/HDP/2161 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CYCLOVAX CREAM | ACICLOVIR | 5%W/W | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 01/07/1997 |
| 1556 | NDA/MAL/HDP/2164 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYCORT | HYDROCORTISONE | 1%W/W | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1557 | NDA/MAL/HDP/2165 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | TRAMAREN | TRAMADOL HYDROCHLORIDE | 50MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 1558 | NDA/MAL/HDP/2170 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ALSARTAN-AM | LOSARTAN + AMLODIPINE | 50MG + 5MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 01/07/2011 |
| 1559 | NDA/MAL/HDP/2173 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | GLEVO-500 | LEVOFLOXACIN | 500MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X5.0 TABLET BLISTER | 01/07/2003 |

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| 1560 | NDA/MAL/HDP/2175 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLADON | PARACETAMOL | 500MG | CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X12.0X4.0 TABLET STRIP,1.0X4.0X4.0 TABLET STRIP | 01/07/2005 |
| 1561 | NDA/MAL/HDP/2176 | INTAS PHARMACUITICALS LTD | NORVIK ENTERPRISES LIMITED | RISPITAS-2 | RISPERIDONE | 2MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1562 | NDA/MAL/HDP/2178 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL CEFUROXIME-250 | CEFUROXIME AXETIL | 250MG | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1563 | NDA/MAL/HDP/2181 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM PHEN | PHENOXYMETHYLPENICILLIN | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 100.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,500.0 TABLET CONTAINER,250.0 TABLET CONTAINER | 01/07/1997 |
| 1564 | NDA/MAL/HDP/2185 | GLAXOSMITHKLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ROTARIX | LIVE ATTENUATED RIX4414 STRAIN OF HUMAN ROTAVIRUS OF THE G1P[8] TYPE | NOT LESS THAN $10^6$ $CCID_{50}$ OF THE RIX4414 STRAIN | GLAXOSMITHKLINE AUSTRALIA.- GLAXOSMITHKLINE AUSTRALIA, 1061 MOUNTAIN HIGHWAY, BORONIA, VICTORIA, 3155 AUSTRALIA GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.5 ML TUBE (1 DOSE),1.0X50.0X1.5 ML TUBE (1 DOSE),1.0X7.5 ML TUBE (5-DOSE) FOR GAVI/UNICEF SUPPLY ONLY | 01/07/2009 |
| 1565 | NDA/MAL/HDP/2189 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL BETAMETHASONE | BETAMETHASONE | 0.1%W/W | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/2008 |

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| 1566 | NDA/MAL/HDP/2191 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | KLOXY | CLOXACILLIN | 250MG | LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 1567 | NDA/MAL/HDP/2195 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | EUDERM CREAM | UREA | 10%W/W | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250<br>MALEKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X45.0 G TUBE | 01/07/1997 |
| 1568 | NDA/MAL/HDP/2197 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | WHITFIELD'S OINTMENT | BENZOIC ACID + SALICYLIC ACID | 6%W/W + 3%W/W | LABORATORY & ALLIED LTD-PLOT NO. 209/10349<br>OFF MOMBASA ROAD, NAIROBI<br>P.O. BOX 42875, NAIROBI, KENYA. | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1569 | NDA/MAL/HDP/2199 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | EUTHYROX 50MCG | LEVOTHYROXINE SODIUM | 50MCG | MERCK KGAA - - FRANKFRUTER STRASSE 250, D-64293,DARMSTADT-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30.0 TABLET BLISTER | 01/07/2013 |
| 1570 | NDA/MAL/HDP/2201 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | CLYCIN | CLINDAMYCIN PHOSPHATE | 10MG/ML | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | TOPICAL EXTERNAL LOTIONS | 1.0X30.0 ML BOTTLE | 01/07/2008 |
| 1571 | NDA/MAL/HDP/2208 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL CEPHALEXIN | CEPHALEXIN MONOHYDRATE | 500MG | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2010 |

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| 1572 | NDA/MAL/HDP/2211 | GALENTIC PHARMA (PVT)LTD | VITACARE LIMITED | BENZYL BENZOATE | BENZYL BENZOATE | 25%W/W | GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE BELAPURNAVI MUMBAI 400 701 INDIA | INDIA | TOPICAL EXTERNAL EMULSIONS | 1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X1000.0 ML BOTTLE | 01/07/2005 |
| 1573 | NDA/MAL/HDP/2212 | DENK PHARMA | BENLE CONSULT LIMITED | CIPRO-DENK 500 | CIPROFLOXACIN | 500MG | ALLPHARMED PHARBIL ARZNEIMITTEL GMBH-12 D377081 | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1574 | NDA/MAL/HDP/2216 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | METOCLOPRAMIDE | METOCLOPRAMIDE | 5MG/ML | NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2005 |

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| 1575 | NDA/MAL/HDP/2219 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | PRIMOLUT N | NORETHISTERONE | 5MG | BAYER WEIMAR GMBH & CO. KG-DOBEREINERSTRASSE 20 D-99427 WEIMAR, GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET CONTAINER,1.0X2.0X15.0 TABLET BLISTER | 01/07/1997 |
| 1576 | NDA/MAL/HDP/2224 | VOGEN LABORATORIES LTD | BUFFALO HEALTH CARE LTD | DURAMOX 500 | AMOXICILLIN | 500MG | VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 1577 | NDA/MAL/HDP/2226 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | HEPA-MERZ GRANULES | L-ORNITHINE-L-ASPARTATE | 3G/5G | WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH | INDIA | ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES | 1.0X10.0X5.0 G SACHET | 01/07/2004 |

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| 1578 | NDA/MAL/HDP/2232 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNICAST | MONTELUKAST | 10MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1579 | NDA/MAL/HDP/2233 | ASTRAZENECA | MACNAUGHTON LIMITED | PULMICORT NEBULISER | BUDESONIDE | 0.25MG/ML | ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE-151-85,SWEDEN | SWEDEN | LUNG ADMINISTRATION LIQUID FOR INHALATION | 1.0X4.0X5.0X2.0 ML VIAL | 01/07/2011 |
| 1580 | NDA/MAL/HDP/2236 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | TEGRETOL 200 | CARBAMAZEPINE | 200MG | NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY | ITALY | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1581 | NDA/MAL/HDP/2237 | WOCKHARDT LTD | ABACUS PHARMA (AFRICA) LIMITED | WOSULIN-30/70 | INSULIN HUMAN(RECOMBINANT DNA ORIGIN) | 100I.U/ML | WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL,1.0X3.0 ML VIAL | 01/07/2006 |
| 1582 | NDA/MAL/HDP/2239 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | TEGRETOL SYRUP | CARBAMAZEPINE | 20MG/ML | DELPHARMA HUNINGUE S.A.S-26, RUE DE LA CHAPELLE, 68330 HUNINGUE, FRANCE | FRANCE | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2006 |
| 1583 | NDA/MAL/HDP/2242 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CYCLOVAX 200 TABLETS | ACYCLOVIR | 200MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1584 | NDA/MAL/HDP/2243 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | SIMDOL TABLETS | PARACETAMOL | 500MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 1585 | NDA/MAL/HDP/2245 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | X-PEL | MEBENDAZOLE | 100MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2008 |
| 1586 | NDA/MAL/HDP/2248 | GALENTIC PHARMA (PVT)LTD | VITACARE LIMITED | TETRACYCLINE OPHTHALMIC | TETRACYCLINE | 1%W/W | GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE, INDIA | INDIA | OPHTHALMIC OINTMENTS | 1.0X3.5 G TUBE,1.0X5.0 G TUBE | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1587 | NDA/MAL/HDP/2249 | WOCKHARDT LTD | ABACUS PHARMA (AFRICA) LIMITED | WOSULIN-R | INSULIN | 100ML | WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X3.0 ML VIAL,1.0X10.0 ML VIAL | 01/07/2006 |
| 1588 | NDA/MAL/HDP/2252 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VERMOX | MEBENDAZOLE | 500MG | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE JOHNSON & JOHNSON (PTY) LTD-241 MAIN ROAD, RETREAT, 7945, CAPE TOWN | SOUTH AFRICA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2000 |
| 1589 | NDA/MAL/HDP/2254 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | BURN CUR CREAM | ACRIFLAVINE/THYMOL | N/A | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1590 | NDA/MAL/HDP/2256 | GLAXOSMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AUGMENTIN 457MG/5ML | AMOXICILLIN + CLAVULANIC ACID | 400 MG + 57 MG / 5 ML | GLAXO WELLCOME PRODUCTION-ZI DE LA PEYENNIERE, 53100, MAYENNE | UNITED KINGDOM | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X70.0 ML BOTTLE | 01/07/2010 |
| 1591 | NDA/MAL/HDP/2258 | MYLAN LABORATORIES LIMITED (OTL) | KIMSY MEDS LTD | TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ | TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ | 300MG/300MG/600MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, | INDIA KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET BOTTLE,1.0X1.0X30.0 TABLET BOTTLE | 01/07/2009 |
| 1592 | NDA/MAL/HDP/2263 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | CELEMIN 10 PLUS | AMINO ACIDS/ELECTROLYTES | 10%W/V+10%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION BAGS | 1.0X500.0 ML BOTTLE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1593 | NDA/MAL/HDP /2265 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | TENOFOVIR/ LAMUVIDINE | TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE | 300MG + 300MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2010 |
| 1594 | NDA/MAL/HDP /2267 | MYLAN LABORATORIES LIMITED (OTL) | KIMSY MEDS LTD | TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE | TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE | 300MG+300MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2007 |
| 1595 | NDA/MAL/HDP /2269 | DAWA LIMITED | SUPER MEDIC LTD | DAWAMOX | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1596 | NDA/MAL/HDP/2271 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | ARTEMETHER 20MG/LUMEFANTRINE 120MG | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X3.0X6.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X10.0X1.0X6.0 TABLET BLISTER,1.0X10.0X2.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET | 01/07/2010 |
| 1597 | NDA/MAL/HDP/2272 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | CLARANTA -500 | CLARITHROMYCIN | 500MG | AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X2.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1598 | NDA/MAL/HDP/2281 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | LUMFORT | LORATADINE | 10MG | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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| 1599 | NDA/MAL/HDP/2282 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROPAN | PROPRANOLOL | 40MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 1600 | NDA/MAL/HDP/2283 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | SII DIPHTHERIA TETANUS PERTUSIS | DIPTHERIA TOXOID+TETANUS TOXOID+B.PERTUSIS ADSORBED ON ALUMINIUM PHOSPATE | >25LF(>30IU)+>5LF(>40IU)+<16OU(>4PU) ADSORBED ON ≥1.5MG | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE) | 01/07/1997 |
| 1601 | NDA/MAL/HDP/2287 | GLAXO WELLCOME (KENYA) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZINNAT | CEFUROXIME AXETIL | 250MG | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1602 | NDA/MAL/HDP/2290 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LAMIVUDINE + ZIDOVUDINE | LAMIVUDINE + ZIDOVUDINE | 150MG + 300MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD-431136 MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2008 |
| 1603 | NDA/MAL/HDP/2293 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TIOCON | TIOCONAZOLE | 1%W/W | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2005 |
| 1604 | NDA/MAL/HDP/2295 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | ROZITTA 10 | ROSUVASTATIN CALCIUM | 10MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |

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| 1605 | NDA/MAL/HDP/2297 | DAWA LIMITED | SUPER MEDIC LTD | SABULIN SYRUP | SALBUTAMOL SULPHATE | 2MG/5ML | DAWA LIMITED -BABA DOGO RWARAKA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2008 |
| 1606 | NDA/MAL/HDP/2298 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | SAFELEVO 500 | LEVOFLOXACIN | 500MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1607 | NDA/MAL/HDP/2299 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | ROZITTA 20 | ROSUVASTATIN CALCIUM | 20MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |

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| 1608 | NDA/MAL/HDP/2303 | MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZIAK 5/6.25 | BISOPROLOL + HYDROCHLOROTHIAZIDE | 5 MG + 6.25 MG | MERCK KGAA-FRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1609 | NDA/MAL/HDP/2304 | MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZIAK 10/6.25 | BISOPROLOL + HYDROCHLOROTHIAZIDE | 10 MG + 6.25 MG | MERCK KGAA-FRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1610 | NDA/MAL/HDP/2305 | MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZIAK 2.5/6.25 | BISOPROLOL + HYDROCHLOROTHIAZIDE | 2.5 MG + 6.25 MG | MERCK KGAA-FRANKFURTER STRASSE 250 64271 DARMSTADT GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |

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| 1611 | NDA/MAL/HDP /2306 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | MICROLUT | LEVONORGESTREL | 0.03MG | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X35.0 TABLET BLISTER | 01/07/2010 |
| 1612 | NDA/MAL/HDP /2312 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CLAVOMID 625 | AMOXICILLIN + CLAVULANIC ACID | 500 MG + 125 MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 2.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1613 | NDA/MAL/HDP /2313 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CLAVOMID 375 | AMOXICILLIN + CLAVULANIC ACID | 250 MG + 125 MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 2.0X10.0 TABLET BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1614 | NDA/MAL/HDP/2314 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RABEMAC-20 | RABEPRAZOLE SODIUM | 20MG | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2005 |
| 1615 | NDA/MAL/HDP/2315 | MICRO LABS LTD | LABOREX UGANDA LIMITED | GRAMOCEF-O-50 | CEFIXIME | 50MG/5ML | MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2006 |
| 1616 | NDA/MAL/HDP/2318 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DIAPRIDE-4 | GLIMEPIRIDE | 4MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2006 |

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| 1617 | NDA/MAL/HDP/2319 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | COSMOL | PARACETAMOL | 120MG/5ML | COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1998 |
| 1618 | NDA/MAL/HDP/2320 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ERO-125 DRY SYRUP | ERYTHROMYCIN ESTOLATE | 125MG/5ML | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2006 |
| 1619 | NDA/MAL/HDP/2322 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TREFLUCAN | FLUCONAZOLE | 150MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X1.0 CAPSULE STRIP | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1620 | NDA/MAL/HDP/2323 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ALPRIM | CO-TRIMOXAZOLE | 240MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X5.0 L JERRYCAN | 01/07/1997 |
| 1621 | NDA/MAL/HDP/2324 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | SWISSCLOXA | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X7.5 ML VIAL | 01/07/2011 |
| 1622 | NDA/MAL/HDP/2326 | EMCURE PHARMACEUTICALS LTD - | HARLEYS UGANDA LIMITED | SYLATE-500 | ETHAMSYLATE | 500MG | EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X6.0 TABLET STRIP | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1623 | NDA/MAL/HDP/2330 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | COARTEM | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | NOVARTIS PHARMA AG-SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESI IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X24.0 TABLET BLISTER,1.0X30.0X 24.0 TABLET BLISTER,1.0X30.0X 6.0 TABLET BLISTER,1.0X36.0X 6.0 TABLET BLISTER,1.0X3.0X8. 0 TABLET BLISTER,1.0X30.0X 12.0 TABLET BLISTER,1.0X30.0X | 01/07/2005 |
| 1624 | NDA/MAL/HDP/2333 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | SII DIPHTHERIA & TETANUS VACCINE ADSORBED(PEDIATRIC) | DIPTHERIA TOXOID+TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE | >25LF(>30IU)+>5LF (>40IU) ADSORBED ON ≥1.5MG | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE) | 01/07/1997 |
| 1625 | NDA/MAL/HDP/2334 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | SII MEASLES MUMPS & RUBELLA | MEASLES VIRUS+MUMPS VIRUS+RUBELLA VIRUS | NLT 1000 CCID50+NLT 5000 CCID50 +NLT1000 CCID50 | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 DOSE VIAL + 0.5ML OF THE DILUENT | 01/07/1997 |

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| 1626 | NDA/MAL/HDP/2337 | AUROBINDOM PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AUROXETIL-500 | CEFUROXIME AXETIL | 500MG | AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7-AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502307 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1627 | NDA/MAL/HDP/2338 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CLAVULIN | AMOXICILLIN + CLAVULANIC ACID | 200 MG + 28.5 MG | GLAXO WELLCOME PRODUCTION-ZI DE LA PEYENNIERE, 53100, MAYENNE | FRANCE | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE | 01/07/2003 |
| 1628 | NDA/MAL/HDP/2339 | AUROBINDO PHARMA LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KOACT-375 | AMOXICILLIN + CLAVULANATE POTASSIUM | 250 MG + 125 MG | AUROBINDO PHARMA LTD, UNIT XII,.-SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X5.0 TABLET BLISTER,1.0X20.0X5.0 TABLET BLISTER | 01/07/2007 |

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| 1629 | NDA/MAL/HDP/2342 | AUROBINDO PHARMA LTD UNIT VII | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KOACT-625 | AMOXICILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X5.0 TABLET BLISTER | 01/07/2007 |
| 1630 | NDA/MAL/HDP/2348 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | HEPATITIS B VACCINE(RDNA) ADULT | HEPATITIS B VACCINE(RDNA) ADULT | 20MCG/ML | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY I M VIALS | 1.0X10.0X10.0 ML VIAL (10 DOSE VIAL),1.0X50.0X1.0 ML VIAL (1 DOSE VIAL) | 01/07/2005 |
| 1631 | NDA/MAL/HDP/2350 | ASTRA ZENECA AB | MACNAUGHTON LIMITED | PULMICORT TURBUHALER | BUDESONIDE | 200MCG | ASTRAZENECA AB,-GARTUNA & SNACKVIKEN STOCKHOLM | SWEDEN | LUNG ADMINISTRATION METERED-DOSE INHALER | 1.0X100.0 DOSE CANNISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1632 | NDA/MAL/HDP/2352 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | COLDCAP DAY TIME | PARACETAMOL/PSEUDOEPHEDRINE HCL/CAFFEINE | 500MG+30MG+30MG | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X12.0 CAPSULE BLISTER | 01/07/2007 |
| 1633 | NDA/MAL/HDP/2353 | ASTRA ZENECA | MACNAUGHTON LIMITED | NEXIUM | ESOMEPRAZOLE (AS MAGNESIUM TRIHYDRATE) | 10MG | ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN) | SWEDEN | ORAL SOLID ORDINARY GRANULES | 1.0X28.0 SACHET CARTON | 01/07/2013 |
| 1634 | NDA/MAL/HDP/2356 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | QUININE | QUININE DIHYDROCHLORIDE | 600MG/2ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1635 | NDA/MAL/HDP /2357 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | TRABILIN- 50 CAPSULES | TRAMADOL | 50MG | MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2003 |
| 1636 | NDA/MAL/HDP /2359 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | ASPIREM 75 | ASPIRIN | 75MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X28.0 TABLET BLISTER | 01/07/2007 |
| 1637 | NDA/MAL/HDP /2360 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | FUNGISTIN PESSARIES | NYSTATIN | 100000 IU | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | INDIA | VAGINAL TABLETS | 1.0X14.0 PESSARY PACK,5.0X3.0 PESSARY STRIP,1.0X100.0 PESSARY CONTAINER | 01/07/2002 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1638 | NDA/MAL/HDP/2361 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CLAREM 500 | CLARITHROMYCIN | 500MG | REMEDICA LTD-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2007 |
| 1639 | NDA/MAL/HDP/2362 | GALENTIC PHARMA LTD | VITACARE LIMITED | CANDISTATIN OINTMENT | NYSTATIN | 100,000I.U | GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE | 01/07/2009 |
| 1640 | NDA/MAL/HDP/2363 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | GENTAMICIN SULPHATE | GENTAMICIN SULPHATE | 80MG/2ML | NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1641 | NDA/MAL/HDP/2364 | AIVEEN (U) LIMITED | AIVEEN (U) LIMITED | VOXEL-500 | LEVOFLOXACIN | 500MG | MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2015 |
| 1642 | NDA/MAL/HDP/2366 | UNIQUE PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | IFICIPRO INJECTION | CIPROFLOXACIN | 200MG/100ML | UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2005 |
| 1643 | NDA/MAL/HDP/2368 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | DERMIDEX CREAM | MICONAZOLE NITRATE | 2%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1644 | NDA/MAL/HDP/2369 | ARISTO PHARMACEUTICALS | NORVIK ENTERPRISES LIMITED | TRANLOK 500MG INJECTION | TRANEXAMIC ACID | 500MG/5ML | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 01/07/2010 |
| 1645 | NDA/MAL/HDP/2371 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | TOPIZONE CREAM | FUSIDIC ACID + BETAMETHASONE VALERATE | 20MG/G+1MG/G | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2007 |
| 1646 | NDA/MAL/HDP/2375 | GLAXO SMITHLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | CLAVULIN 1G | AMOXICILLIN + CLAVULANIC ACID | 875 MG + 125 MG | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X1.0X7.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1647 | NDA/MAL/HDP/2379 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | PUMPITOR | OMEPRAZOLE | 40MG | PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG | INDONESIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 VIAL CARTON + 1 AMPOULE OF SOLVENT | 01/07/2014 |
| 1648 | NDA/MAL/HDP/2381 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | SIMTRIM-480 TABLETS | CO-TRIMOXAZOLE | 480MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 1649 | NDA/MAL/HDP/2384 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CLARIX 500 | CLARITHROMYCIN | 500MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2007 |

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| 1650 | NDA/MAL/HDP/2385 | COSMOS LIMITED | ASTRA PHARMA (U) LIMITED | COZEPAM 5MG | DIAZEPAM | 5MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2000 |
| 1651 | NDA/MAL/HDP/2387 | DAWA LIMITED | SUPER MEDIC LTD | VERMOUT | MEBENDAZOLE | 100MG/5ML | DAWA LIMITED -BABA DOGO RWARAKA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2010 |
| 1652 | NDA/MAL/HDP/2388 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | DAFRACLAV | AMOXYCILLIN + POTASSIUM CLAVULANATE | 400MG + 57MG | BILIM ILAC SAN. VE. TIC. A.S.-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510 | TURKEY | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1653 | NDA/MAL/HDP /2389 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELOCIN | ERYTHROMYCIN | 250MG | ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 1654 | NDA/MAL/HDP /2390 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | P-ALAXIN | DIHYDROARTEMISININ/ PIPERAQUINE PHOSPHATE | 80MG /640MG | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X80.0 ML BOTTLE,1.0X120.0 ML BOTTLE | 01/07/2008 |
| 1655 | NDA/MAL/HDP /2391 | BIOMATRIX HEALTHCARE PVT LTD | MEDIWORLD PHARMA AFRICA LTD | HEADAID TABLETS | ASPIRIN + CAFFEINE + PARACETAMOL | 300MG + 30MG + 250MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X2.0 TABLET STRIP | 01/07/1997 |

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| 1656 | NDA/MAL/HDP/2394 | MERCK SHARP & DOHME BV. | SURGIPHARM (U) LIMITED | STOCRIN | EFAVIRENZ | 600MG | ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2004 |
| 1657 | NDA/MAL/HDP/2395 | A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FASTUM GEL | KETOPROFEN | 2.5%W/W | A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA SETTE SANTI 3, 50131 FIRENZE-ITALY | ITALY | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE,1.0X30.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE | 01/07/2005 |
| 1658 | NDA/MAL/HDP/2399 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | VOLINI | MULTI INGREDIENT | MULTI INGREDIENT | SUN PHARMACEUTICAL IND. LTD-PLOT NO. B-2, MADKAI INDUSTRIAL ESTATE, PONDA-GOA, INDIA-403404 | INDIA | TOPICAL EXTERNAL OTHER GELS/SOLS | 1.0X1.0X30.0 G TUBE | 01/07/2005 |

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| 1659 | NDA/MAL/HDP/2401 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | ENAT | NATURAL VITAMIN E | 400IU | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280 | THAILAND | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2005 |
| 1660 | NDA/MAL/HDP/2404 | UNICHEM LABORATORIES LIMITEDv | EUROPA HEALTHCARE (U) LTD | LOSAR 50 | LOSARTAN POTASSIUM | 50MG | UNICHEM LABORATORIES LTD---VILLAGE BHATAULI KALA, BADDI HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1661 | NDA/MAL/HDP/2408 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | RENIRON TONIC | MULTI-INGREDIENT | MULTI-INGREDIENT | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1662 | NDA/MAL/HDP/2410 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | DOXYREN | DOXYCYCLINE | 100MG | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2007 |
| 1663 | NDA/MAL/HDP/2411 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | DREZ | POVIDONE IODINE + METRONIDAZOLE | 5%W/W + 1%W/W | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE,1.0X10.0 G TUBE,1.0X100.0 G TUBE,1.0X250.0 G TUBE | 01/07/2010 |
| 1664 | NDA/MAL/HDP/2414 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMCIL | AMPICILLIN | 125MG/5ML | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1998 |

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| 1665 | NDA/MAL/HDP/2415 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | SOLINA TABLETS | DIAZEPAM | 5MG | CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1666 | NDA/MAL/HDP/2423 | MEDLEY PHARMACEUTICALS | MEDVIN PHARMA LIMITED | ATORIN | ATORVASTATIN | 10MG | MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 1667 | NDA/MAL/HDP/2426 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | PROBEX SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X225.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2000 |

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| 1668 | NDA/MAL/HDP /2427 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | CLONEM | CLOTRIMAZOLE | 1%W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1997 |
| 1669 | NDA/MAL/HDP /2428 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | CLOTRI-DENK 1% CREAM | CLOTRIMAZOLE | 1%W/W | C.P.M. CONTRACTPHARMA GMBH & COMPANY KG- FRUHLINGSTR. 7, 83620 FELDKIRCHEN - WESTERHAM | GERMANY | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1998 |
| 1670 | NDA/MAL/HDP /2429 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | CLOTRI-DENK 100 VAGINAL | CLOTRIMAZOLE | 100MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRABE 1,29439 LUCHOW,GERMANY | GERMANY | VAGINAL TABLETS | 1.0X6.0 PESSARY CARTON | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1671 | NDA/MAL/HDP /2431 | ZYDUS LIFESCIENCES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | FORMONIDE 200 | BUDESONIDE + FORMOTEROL FUMARATE | 200MCG/ 6MCG | CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210 | INDIA | LUNG ADMINISTRATION METERED-DOSE INHALER | 1.0X1.0 CANNISTER CARTON | 01/07/2007 |
| 1672 | NDA/MAL/HDP /2432 | CADILA HEALTH CARE LTD | ABACUS PHARMA (AFRICA) LIMITED | FORMONIDE 100 | BUDESONIDE + FORMOTEROL FUMARATE | 100MCG+6MCG | CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210 | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2007 |
| 1673 | NDA/MAL/HDP /2434 | STRIDES PHARMA SCIENCE LIMITED | DELMAW ENTERPRISES LIMITED | SOLCER | OMEPRAZOLE | 40MG | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 01/07/2009 |

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| 1674 | NDA/MAL/HDP/2438 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | HIFENAC | ACECLOFENAC | 100MG | INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1675 | NDA/MAL/HDP/2452 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | DELASED CHEST COUGH SYRUP (NON DROWSY) | GUAIFENESIN + MENTHOL | 100MG/5ML + 1.1MG/5ML | REGAL PHARMACEUTICALS-PLOT 7879/18 BABA DOGO ROAD NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1676 | NDA/MAL/HDP/2458 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | PRISTINEX 2% CREAM | KETOCONAZOLE | 2%W/W | XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 2.0X15.0 G TUBE | 01/07/2006 |

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| 1677 | NDA/MAL/HDP/2461 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | UMERAN SR - 100 | DICLOFENAC | 100MG | UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1678 | NDA/MAL/HDP/2462 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | HISTALIN SYRUP | CHLORPHENIRAMINE MALEATE/PROMETHAZINE/DIPHENHYDRAMINE/EPHEDRINE/AMMONIUM CHLORIDE/SODIUM CITRATE | 1.0MG+ 2.5MG+5.0MG+7.5MG+90.0MG+48.0MG/ 5ML. | REGAL PHARMACEUTICALS LTD..-PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN | 01/07/1997 |
| 1679 | NDA/MAL/HDP/2471 | GLAXOSMITHKLINE LIMITED- | UNITED HEALTHCARE DISTRIBUTORS LTD | OTRIVIN 0.1% NASAL DROPS | XYLOMETAZOLINE | 0.1%W/V | GSK CONSUMER HEALTH SA-GSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND | SWITZERLAND | NASAL SYSTEMIC DROPS | 1.0X10.0 ML BOTTLE | 01/07/2003 |

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| 1680 | NDA/MAL/HDP/2472 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | TRAN-GEL | DICLOFENAC DIETHYLAMMONIUM | 1%W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE,1.0X20.0 G TUBE | 01/07/2011 |
| 1681 | NDA/MAL/HDP/2473 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NUGREL | CLOPIDOGREL | 75MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1682 | NDA/MAL/HDP/2475 | WIN-MEDICURE LTD | SURGIPHARM (U) LIMITED | URGENDOL INJECTION | TRAMADOL HYDROCHLORIDE | 50MG/ML | WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA. | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 ML AMPOULE,1.0X2.0 ML AMPOULE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1683 | NDA/MAL/HDP/2476 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | DERIVA AQUEOUS GEL | ADAPALENE | 0.1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE | 01/07/2003 |
| 1684 | NDA/MAL/HDP/2478 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | DICLOMOL PLUS | PARACETAMOL+DICLOFENAC | 500MG+50MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1685 | NDA/MAL/HDP/2479 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANCEPH-250 CAP | CEPHALEXIN | 250MG | SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1686 | NDA/MAL/HDP/2481 | GALENTIC PHARMA (PVT)LTD | VITACARE LIMITED | NETRACORT | HYDROCORTISONE | 1%W/W | GALENTIC PHARMA PVT LIMITED-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI MUMBAI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE,1.0X20.0 G TUBE | 01/07/2005 |
| 1687 | NDA/MAL/HDP/2489 | VITACARE LIMITED | VITACARE LIMITED | UMETAC-150 | RANITIDINE | 150MG | UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1688 | NDA/MAL/HDP/2492 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | PROFIL 25 | PROMETHAZINE HYDROCHLORIDE | 25MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1689 | NDA/MAL/HDP/2496 | MACLEODS PDHARMACEUTICALS LT | VITACARE LIMITED | ZETIVAS 20 | ATORVASTATIN/EZETIMIBE | 20MG/10MG | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |
| 1690 | NDA/MAL/HDP/2497 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | NEVIMUNE | NEVIRAPINE | 50MG/5ML | CIPLA LTD --PLOT NO 9, 10 & 15, PHARMA ZONE, PHASE II, SECTOR III, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2004 |
| 1691 | NDA/MAL/HDP/2498 | MACLEODS PDHARMACEUTICALS LT | VITACARE LIMITED | ZETIVAS 10 | ATORVASTATIN/EZETIMIBE | 10MG/10MG | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1692 | NDA/MAL/HDP/2500 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | CHLORAMPHENICOL SODIUM SUCCINATE INJECTION BP | CHLORAMPHENICOL SODIUM SUCCINATE | 1G | MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2007 |
| 1693 | NDA/MAL/HDP/2502 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | PROBETA N EYE DROP | BETAMETHASONE + NEOMYCIN | 0.1%W/V+0.5%W/V | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN | PAKISTAN | OPHTHALMIC DROPS | 1.0X7.5 ML VIAL | 01/07/1997 |
| 1694 | NDA/MAL/HDP/2504 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | RESTOCIN | PARACETAMOL + CHLORPHENIRAMINE MALEATE + CAFFEINE + PHENYLEPHRINE HCL | 500MG+ 2MG+ 2MG + 30MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X4.0 TABLET STRIP | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1695 | NDA/MAL/HDP/2506 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | NADOXIN | NADIFLOXACIN | 1%W/W | WOCKHARDT LTD -VILLAGE KUNJHAL P.O BAROTIWALA DIST SOLAN HIMACHAL PRADESH | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE,1.0X20.0 G TUBE | 01/07/2011 |
| 1696 | NDA/MAL/HDP/2507 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EXERMET 1000 | METFORMIN HCL | 1000MG | CIPLA LIMITED ,.,.-VILLAGE UPPER MALPUR, P.O. BHUD, THE. NALAGARH DISTRICT SOLAN HIMACHAL PRADESH PIN 173205 CIPLA LTD ----D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1697 | NDA/MAL/HDP/2509 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | OPELE LOTION | BENZYL BENZOATE | 25%W/V | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL LOTIONS | 1.0X50.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1698 | NDA/MAL/HDP /2510 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | GIRO | ORDNIDAZOLE | 500MG | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0X2.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1699 | NDA/MAL/HDP /2512 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | DICLOFENAC SODIUM INJECTABLE SOLUTION | DICLOFENAC SODIUM | 25MG/ML | WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10. 0X3.0 ML AMPOULE | 01/07/2009 |
| 1700 | NDA/MAL/HDP /2513 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNIPEN DRY SYRUP | PHENOXYMETHYLP ENICILLIN | 125MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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| 1701 | NDA/MAL/HDP/2515 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | SIMFEN 200 TABLETS | IBUPROFEN | 200MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 1702 | NDA/MAL/HDP/2521 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | MOTINORM | DOMPERIDONE | 10MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1703 | NDA/MAL/HDP/2523 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | SULPHUR OINTMENT | SULPHUR | 10%W/W | NEM LABORATORIES PVT LTD --133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X25.0 G TUBE | 01/07/1997 |

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| 1704 | NDA/MAL/HDP /2524 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | PRIMODIL-5 | AMLODIPINE BESYLATE | 5MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI CAUSEWAY ROAD,, KACHIGAM, DAMAN-396 210 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1705 | NDA/MAL/HDP /2525 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DICLO-DENK 100 RETARD | DICLOFENAC SODIUM | 100MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID RETARD TABLETS | 10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/1998 |
| 1706 | NDA/MAL/HDP /2526 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNISTEN COMBI PACK | CLOTRIMAZOLE | 500MG & 1 %W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | VAGINAL COMBINATION PACK TABLETS | 1.0X1.0 PESSARY BLISTER + 1*20G TUBE | 01/07/2009 |

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| 1707 | NDA/MAL/HDP/2528 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LABESTEN | CLOTRIMAZOLE | 1%W/W | LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE,1.0X1.0X20.0 G TUBE | 01/07/1997 |
| 1708 | NDA/MAL/HDP/2529 | B & O PHARM ZAC | TRIDEM PHARMA UGANDA LIMITED | G-CEFTRIA | CEFTRIAXONE | 1G | GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI CHINA NATIONAL MEDICINES, GUORUI PHARMACEUTICAL CO., LTD-CAOYANG EAST ROAD, HUAINAN ECONOMICAL AND TECHNOLOGICAL DEVELOPMENT ZONE, HUAINAN CITY ANHUI PROVINCE | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 10 ML AMPOULE WFI,1.0X1.0X50.0 G VIAL,1.0X1.0 VIAL CARTON | 01/07/2012 |
| 1709 | NDA/MAL/HDP/2545 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | TOBREX | TOBRAMYCIN | 0.3%W/V | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |

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| 1710 | NDA/MAL/HDP/2552 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | CAROFIT | VITAMIN C/ VITAMIN A/ ZINC SULPHATE | 150MG/10MG/75 MG | AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1711 | NDA/MAL/HDP/2553 | GLENMARK PHARMACEUTICAL LTD. | STAR PHARMACEUTICALS LTD | ESOZ-20 | ESOMEPRAZOLE | 20MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X10.0 TABLET STRIP | 01/07/2003 |
| 1712 | NDA/MAL/HDP/2554 | GLENMARK PHARMACEUTICAL LTD. | STAR PHARMACEUTICALS LTD | ESOZ | ESOMEPRAZOLE | 40MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET STRIP,1.0X10.0X10.0 TABLET STRIP | 01/07/2005 |

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| 1713 | NDA/MAL/HDP /2555 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | PHENOBARBITONE TABLETS BP 30MG | PHENOBARBITONE | 30MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER | 01/07/1998 |
| 1714 | NDA/MAL/HDP /2556 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | TRUVADA | EMTRICITABINE/TENOFOVIR | 200MG/300MG | PATHEON INC-ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA TAKEDA GMBH-16515 ORANIENBURG GERMANY | CANADA GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2005 |
| 1715 | NDA/MAL/HDP /2557 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | EPSITRON 25 TABLETS | CAPTOPRIL | 25MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1999 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1716 | NDA/MAL/HDP/2558 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | MYCOREN SUSPENSION | NYSTATIN | 100000 I.U/ML | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL TOPICAL SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2007 |
| 1717 | NDA/MAL/HDP/2559 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | ERYTHROREN | ERYTHROMYCIN STEARATE | 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 1718 | NDA/MAL/HDP/2562 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | TRABILIN-100 | TRAMADOL | 100MG/2ML | MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X5.0X2.0 ML AMPOULE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1719 | NDA/MAL/HDP/2567 | CADILA HEALTH CARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CIPROBID-500 | CIPROFLOXACIN | 500MG | S.KANT HEALTHCARE LIMITED--PLOT NO. 1802-1805,GIDC PHASE II-396195,DIST.VALSAD,GUJARAT,INDIA PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1720 | NDA/MAL/HDP/2568 | GLAXO WELLCOME (KENYA) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZINNAT | CEFUROXIME AXETIL | 500MG | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON | 01/07/1997 |
| 1721 | NDA/MAL/HDP/2576 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENEQUINE TABLETS | CHLOROQUINE PHOSPHATE | 250MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2000 |

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| 1722 | NDA/MAL/HDP/2578 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | MAGNOMINT TABLETS | ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE | 125MG + 250MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER,1.0X50.0X 2.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10 00.0 TABLET CONTAINER | 01/07/1997 |
| 1723 | NDA/MAL/HDP/2580 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | HEDON TABLETS | PARACETAMOL + ASPIRIN + CAFFEINE | 250 MG+ 300 MG + 30 MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA MILAN LABORATORIES (INDIA) PVT LTD - - 63,67,87,35,36, 64, 65 | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X2.0 TABLET STRIP | 01/07/1998 |
| 1724 | NDA/MAL/HDP/2593 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | ATENOLOL DENK 50 | ATENOLOL | 50MG | ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1725 | NDA/MAL/HDP/2594 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FEF | FERROUS SULPHATE + FOLIC ACID | 200MG + 0.4MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 1726 | NDA/MAL/HDP/2595 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | ZEPILEN | CEFAZOLIN | 1000MG | MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 VIAL CARTON | 01/07/2009 |
| 1727 | NDA/MAL/HDP/2597 | E DENK OHG | BENLE CONSULT LIMITED | PARA DENK 250 | PARACETAMOL | 250MG | RUBIEPHARM ARZNEIMITTEL GMHH -BRUDER-GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE BENE-ARZNEIMITTEL GMBH-HERTERICHSTR. 1,81479 MUENCHEN, GERMANY | GERMANY | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1728 | NDA/MAL/HDP/2600 | IND SWIFT LTD | PLANET PHARMACEUTICALS UGANDA LTD | CLARIE-OD | CLARITHROMYCIN( EXTENTED RELEASE) | 500MG | IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X1.0X7.0 TABLET BLISTER | 01/07/2008 |
| 1729 | NDA/MAL/HDP/2601 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | AXETINE 750MG | CEFUROXIME | 750MG | MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 VIAL CARTON | 01/07/2009 |
| 1730 | NDA/MAL/HDP/2602 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | CLAVAM BID | AMOXICILLIN + CLAVULANIC ACID | 200 MG + 28.5 MG/ 5 ML | INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH - 173205 INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1731 | NDA/MAL/HDP/2604 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GROVIT SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | SAKAR HEALTHCARE PVT LTD-SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2000 |
| 1732 | NDA/MAL/HDP/2610 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ATROPINE | ATROPINE | 1MG/ML | NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2009 |
| 1733 | NDA/MAL/HDP/2612 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | RENIRON | MULTI-INGREDIENT | MULTI-INGREDIENT | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 3.0X10.0 CAPSULE BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1734 | NDA/MAL/HDP/2614 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | DIALIN | LOPERAMIDE HCL | 2MG | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/2007 |
| 1735 | NDA/MAL/HDP/2615 | ASTRA ZENECA AB | MACNAUGHTON LIMITED | SYMBICORT TURBUHALER | BUDESONIDE+FORMOTEROL | 160MCG+4.5MCG/DOSE | ASTRAZENECA AB,-GARTUNA & SNACKVIKEN STOCKHOLM | SWEDEN | LUNG ADMINISTRATION METERED-DOSE POWDER INHALER | 1.0X60.0 DOSE CANNISTER,1.0X120.0 DOSE CANNISTER | 01/07/2001 |
| 1736 | NDA/MAL/HDP/2617 | BLUE CROSS LABORATORIES LIMITED | STAR PHARMACEUTICALS LTD | BLUDROX TABLETS DISPERSABLE | CEFADROXIL | 250MG | BLUE CROSS LABORATORIES LIMITED-A-12 MIDC AMBAD-NASHIK-422010 MAHARASHTRA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET STRIP | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1737 | NDA/MAL/HDP /2628 | MICRO LABS LTD | LABOREX UGANDA LIMITED | AZILIDE-500 | AZITHROMYCIN | 500MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 01/07/2004 |
| 1738 | NDA/MAL/HDP /2641 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | AXETINE 250MG | CEFUROXIME AXETIL | 250MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOUS LIMASSOL CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2014 |
| 1739 | NDA/MAL/HDP /2642 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MEDOXANUM | CEFTRIAXONE | 1G | MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 10 ML AMPOULE WFI | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1740 | NDA/MAL/HDP/2645 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANZIDIME 1000 | CEFTAZIDIME | 1000MG | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 ML VIAL | 01/07/2010 |
| 1741 | NDA/MAL/HDP/2647 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | IBUPROFEN DENK 400MG | IBUPROFEN | 400MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1742 | NDA/MAL/HDP/2648 | E DENK OHG | BENLE CONSULT LIMITED | PARA DENK 125 | PARACETAMOL | 125MG | RUBIEPHARM ARZNEIMITTEL GMHH -BRUDER-GRIMM-STRABE 62, 36396, STEINAU AN DER STRABE BENE-ARZNEIMITTEL GMBH-HERTERICHSTR. 1,81479 MUENCHEN, GERMANY | GERMANY | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1743 | NDA/MAL/HDP/2650 | DENK PHARMA | BENLE CONSULT LIMITED | VIT-B-DENK | THIAMINE HCL + PYRIDOXINE HCL | 100MG + 200MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET CARTON,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1744 | NDA/MAL/HDP/2651 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | RINAVIT SYRUP | MULTIVITAMIN | MULTI-INGREDIENT | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1745 | NDA/MAL/HDP/2653 | BLUE CROSS LABORATORIES LTD | STAR PHARMACEUTICALS LTD | SONADERM-GM | CLOBETASOL + MICONAZOLE + GENTAMICIN | 0.05%W/W + 2% W/W+ 0.1%W/W | BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1746 | NDA/MAL/HDP/2654 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | BEBE VIT | VITAMIN A+ VITAMIN D3+VITAMIN E+ VITAMIN C +VITAMIN B1 + VITAMIN B2 | 1500IU+ 400IU+ 5MG+ 40MG+0.5MG+0.6MG | MEDICAL UNION PHARMACEUTICAL CO.- PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | ORAL LIQUID ORDINARY LIQUIDS | 1.0X30.0 ML BOTTLE | 01/07/2006 |
| 1747 | NDA/MAL/HDP/2656 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AMINOPHYLLINE | AMINOPHYLLINE | 100MG | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 1748 | NDA/MAL/HDP/2661 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | FUNGIFEN | CLOTRIMAZOLE | 1%W/W | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1749 | NDA/MAL/HDP /2671 | CIPLA LTD.. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DUOLIN RESPULES | IPRATROPIUM BROMIDE & SALBUTAMOL | 500MG + 2.5 MG /2.5ML | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | LUNG ADMINISTRATION LIQUID FOR INHALATION | 4.0X5.0X2.5 ML VIAL | 01/07/2005 |
| 1750 | NDA/MAL/HDP /2675 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | LIBITUS PLUS SYRUP | TERBUTALINE/ BROMHEXINE/ GUAIPHENESIN | 1.25MG/ 4MG/ 50 MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 1751 | NDA/MAL/HDP /2678 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FORCAN-150 | FLUCONAZOLE | 150MG | CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0 CAPSULE BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1752 | NDA/MAL/HDP /2679 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ALERID SYRUP | CETIRIZINE HYDROCHLORIDE | 5MG/5ML | CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA. | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X30.0 ML BOTTLE | 01/07/2006 |
| 1753 | NDA/MAL/HDP /2680 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMPIREN CAPSULES | AMPICILLIN TRIHYDRATE | 250MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER | 01/07/2007 |
| 1754 | NDA/MAL/HDP /2681 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMOXIREN | AMOXICILLIN TRIHYDRATE | 250MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1755 | NDA/MAL/HDP/2683 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | VITAMIN C | ASCORBIC ACID | 100MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2005 |
| 1756 | NDA/MAL/HDP/2685 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENEDOL(SUSPENSION) | PARACETAMOL | 120MG/5ML | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2007 |
| 1757 | NDA/MAL/HDP/2690 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AMPIMAX-250 | AMPICILLIN | 250MG | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1758 | NDA/MAL/HDP/2691 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AMPIMAX-500 | AMPICILLIN | 500MG | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X500.0 MG VIAL,1.0X100.0 VIAL CARTON | 01/07/2011 |
| 1759 | NDA/MAL/HDP/2695 | FOURTS(INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | IDUMSTRA | PARACETAMOL + IBUPROFEN + CAFFEINE | 325MG + 200MG + 40MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X20.0X10.0 CAPSULE BLISTER | 01/07/2009 |
| 1760 | NDA/MAL/HDP/2696 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | AMPHOTRET | AMPHOTERICIN B | 50MG | BHARAT SERUMS AND VACCINES LTD- PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E ) 412 501 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1761 | NDA/MAL/HDP/2697 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | LUCIN OINTMENT | HYDROCORTISONE | 1%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |
| 1762 | NDA/MAL/HDP/2698 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | AZICIN-500 | AZITHROMYCIN | 500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 01/07/2009 |
| 1763 | NDA/MAL/HDP/2703 | AUROBINDO PHARMA LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KOACT 312.50 | CO-AMOXICLAV (AMOXYCILLIN TRIHYDRATE+POTASSIUM CLAVUNATE) | 250+62.50MG/5ML | AUROBINDO PHARMA LTD, UNIT XII,.-SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1764 | NDA/MAL/HDP/2705 | ASTRAZENECA | MACNAUGHTON LIMITED | PULMICORT NEBULISER | BUDESONIDE | 0.5MG/ML | ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE-151-85,SWEDEN | SWEDEN | LUNG ADMINISTRATION LIQUID FOR INHALATION | 1.0X4.0X5.0X2.0 ML VIAL | 01/07/2011 |
| 1765 | NDA/MAL/HDP/2707 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMCLOXA | CLOXACILLIN | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 100.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,10.0 CAPSULE CONTAINER | 01/07/1997 |
| 1766 | NDA/MAL/HDP/2708 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | HYPER TABLETS | PROPRANOLOL HYDROCHLORIDE | 40MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X2.0X50.0 TABLET BLISTER | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1767 | NDA/MAL/HDP/2710 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AUGMENTIN BD | AMOXICILLIN + CLAVULANIC ACID | 500 MG + 125 MG | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X14.0 TABLET BLISTER | 01/07/1997 |
| 1768 | NDA/MAL/HDP/2712 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | ANAWIN | BUPIVACAINE | 0.025%W/V | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL | 01/07/2014 |
| 1769 | NDA/MAL/HDP/2715 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LAMIVUDINE | LAMIVUDINE | 150MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X60.0 TABLET CONTAINER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1770 | NDA/MAL/HDP/2717 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | OCUMYCIN EYE OINTMENT | CHLORAMPHENICOL | 1%W/W | CENTAUR PHARMA PVT. LTD-PLOT 39-41, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA INDIA | INDIA | OPHTHALMIC OINTMENTS | 1.0X3.5 G TUBE | 01/07/2000 |
| 1771 | NDA/MAL/HDP/2718 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | GYNOMIN | Z | Z | SHAIGAN PHARMACEUTICALS (PVT) LIMITED-14 KM ADYALA RD, RAWALPINDI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/1997 |
| 1772 | NDA/MAL/HDP/2719 | SEDICO PHARMACEUTICAL CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LORASED | LORATADINE | 10MG | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1773 | NDA/MAL/HDP/2720 | SEDICO PHARMACEUTICAL CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION | AMOXICILLIN +FLUCLOXACILLIN | 125MG/5ML+125 MG/5ML | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X80.0 ML BOTTLE | 01/07/2007 |
| 1774 | NDA/MAL/HDP/2721 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | PRIMAFEN TABLET | IBUPROFEN + PARACETAMOL | 400MG + 325MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1775 | NDA/MAL/HDP/2722 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | NO SORES | CHOLINE SALICYLATE/LIDOCAINE | 8.7%W/W+2%W/W | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X10.0 G TUBE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1776 | NDA/MAL/HDP/2725 | ASTRA PHARMA (U) LTD | ASTRA PHARMA (U) LIMITED | STREPTOMYCIN SULPHATE FOR INJECTION | STREPTOMYCIN SULPHATE | 1GM | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X5.0X1.0X10.0 VIAL CARTON | 01/07/2011 |
| 1777 | NDA/MAL/HDP/2726 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | QUININE INJECTION | QUININE DIHYDROCHLORIDE | 600MG/2ML | WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE | 01/07/2008 |
| 1778 | NDA/MAL/HDP/2734 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | AMLODAR-10 | AMLODIPINE BESILATE | 10MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1779 | NDA/MAL/HDP/2737 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | SENEX FORTE | SECNIDAZOLE | 1G | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X2.0 TABLET BLISTER | 07/01/2004 |
| 1780 | NDA/MAL/HDP/2738 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | HEPA-MERZ INFUSION | L-ORNITHINE- L-ASPARTATE | 5G/10ML | WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH | INDIA | PARENTERAL ORDINARY I V VIALS | 1.0X5.0X10.0 ML VIAL | 01/07/2001 |
| 1781 | NDA/MAL/HDP/2739 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | BISPANOL TABLET | HYOSCINE BUTYLBROMIDE | 10MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1782 | NDA/MAL/HDP /2742 | AMANTA HEALTHCARE LTD | PHARMA VILLE LIMITED | STERILIZED WATER FOR INJECTION BP | STERILIZED WATER FOR INJECTION BP | MULTI-INGREDIENT | AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)-PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X10.0X5.0X10.0 ML BOTTLE | 01/07/2016 |
| 1783 | NDA/MAL/HDP /2743 | BEIJING HOLLEY COTEC PHARMA CHINA | SUPER PHARMACEUTICALS LIMITED | DUO-COTECXIN | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 40MG + 320MG | KBN- ZHEJIANG PHARMACEUTICAL CO. LTD-NO. 340 YUNHAI ROAD JIAXING ECONOMIC DEVELOPMENT ZONE, JIAXING CITY, ZHEJIANG PROVINCE | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X9.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER,1.0X30.0X9.0 TABLET BLISTER | 01/07/2005 |
| 1784 | NDA/MAL/HDP /2745 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENFORMIN | METFORMIN HYDROCHLORIDE | 500MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1785 | NDA/MAL/HDP/2746 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | ACYCLOVIR DENK 200 | ACYCLOVIR | 200MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X25.0 TABLET BLISTER | 01/07/2000 |
| 1786 | NDA/MAL/HDP/2753 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | PRASIL | METOCLOPRAMIDE HYDROCHLORIDE | 10MG | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 1787 | NDA/MAL/HDP/2754 | FDC LTD | AIVEEN (U) LIMITED | ZATHRIN 500 | AZITHROMYCIN DIHYDRATE | 500MG | FDC LIMITED -PLOT NO. L121 B PHASE 111A VERNA INDUSTRIAL ESTATE VERNA SALCETE GOA 403 722 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X3.0 TABLET BLISTER,1.0X50.0X 1.0X1.0X3.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1788 | NDA/MAL/HDP/2756 | PFIZER LABORATORIES LTD | LABOREX UGANDA LIMITED | CYTOTEC | MISOPROSTOL | 200MCG | PIRAMAL HEALTHCARE LIMITED-WALTON ROAD MORPETH NORTHUMBERLAND NE 613YA | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2010 |
| 1789 | NDA/MAL/HDP/2760 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | DELASED DRY COUGH SYRUP | DIPHENHYDRAMINE HYDROCHLORIDE+DEXTROMETHORPHAN+SODIUM CITRATE+MENTHOL | 14MG+6.5MG+57MG+2MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1790 | NDA/MAL/HDP/2763 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | CANDISTAT | CLOTRIMAZOLE | 100MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | VAGINAL SUPPOSITORIES | 1.0X2.0X3.0 PESSARY STRIP | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1791 | NDA/MAL/HDP/2773 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | BISPANOL ELIXIR | HYOSCINE-N-BUTYLBROMIDE | 5MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2004 |
| 1792 | NDA/MAL/HDP/2774 | ACINO PHARMA AG - | GOODMAN INTERNATIONAL LTD | BACTIFLOX NEO 500 | CIPROFLOXACIN | 500MG | ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1793 | NDA/MAL/HDP/2776 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | TENSIMIN-100 | ATENOLOL | 100MG | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,14.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1794 | NDA/MAL/HDP/2777 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | CO-DIOVAN 160/12.5MG TABLETS | VALSARTAN + HYDROCHLOROTHIAZIDE | 160MG + 12.5MG | NOVARTIS PHARMA AG-SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER | 01/07/2006 |
| 1795 | NDA/MAL/HDP/2779 | BROOKES PHARMACEUTICAL LABORATORIES L | HARLEYS UGANDA LIMITED | PYODINE SURGICAL SCRUB | POVIDONE IODINE | 7.5%W/V | BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN | PAKISTAN | TOPICAL EXTERNAL LIQUIDS | 1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/2016 |
| 1796 | NDA/MAL/HDP/2781 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | CARVETAS 6.25 | CARVEDILOL | 6.25MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |

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| 1797 | NDA/MAL/HDP/2783 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN SUPPOSITORIES 25MG | DICLOFENAC SODIUM | 25MG | DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE | FRANCE | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X10.0 SUPPOSITORY STRIP | 01/07/2006 |
| 1798 | NDA/MAL/HDP/2787 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOX 125 DT | AMOXICILLIN | 125MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1799 | NDA/MAL/HDP/2788 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | MULTIREN | MULTIINGREDIENT | N/A | RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1800 | NDA/MAL/HDP /2796 | ASTRA PHARMA (UK) LTD | ASTRA PHARMA (U) LIMITED | BENZYLPENICILLIN INJECTION | BENZYLPENICILLIN SODIUM | 1,000,000I.U | CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON | 01/07/2001 |
| 1801 | NDA/MAL/HDP /2797 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | LUMAREN | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X8.0 TABLET BLISTER | 01/07/2010 |
| 1802 | NDA/MAL/HDP /2800 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ACTRAPID FLEXPEN 100 I.U/ML | HUMAN INSULIN | 100 I.U/ML | NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL | DENMARK | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X5.0X3.0 ML PREFILLED PEN,1.0X5.0X1.5 ML PREFILLED PEN | 01/07/1997 |

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| 1803 | NDA/MAL/HDP/2802 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | TASOL | CLOBETASOL | 0.05%W/W | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2005 |
| 1804 | NDA/MAL/HDP/2805 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | NIFELAT 20R TABLETS | NIFEDIPINE | 20MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/1997 |
| 1805 | NDA/MAL/HDP/2807 | GUILIN PHARMACEUTICALS CO.LTD | TRIDEM PHARMA UGANDA LIMITED | ASAQ GPSC | ARTESUNATE + AMODIAQUINE | 100 MG + 270 MG | GUILIN PHARMACEUTICALS CO. LTD-NO 43 QILIDIAN ROAD GUILIN GUANGXI CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0X3.0 TABLET BLISTER,1.0X20.0X 6.0 TABLET BLISTER,1.0X25.0X 3.0 TABLET BLISTER,1.0X25.0X 6.0 TABLET BLISTER | 01/07/2011 |

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| 1806 | NDA/MAL/HDP/2811 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | SULPHUR OINTMENT | SULPHUR PRECIPITATED | 10%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X25.0 G TUBE | 01/07/2001 |
| 1807 | NDA/MAL/HDP/2812 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | CO-ARTESIANE | BETA ARTEMETHER + LUMEFANTRINE | 180 MG/60ML + 1080 MG/60ML | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 01/07/2005 |
| 1808 | NDA/MAL/HDP/2813 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | INTACYCLINE SKIN OINTMENT | TETRACYCLINE HYDROCHLORIDE | 3%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |

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| 1809 | NDA/MAL/HDP /2818 | TRIVENI FORMULATIONS LIMITED | SUPER MEDIC LTD | TRICIP | CIPROFLOXACIN | 500MG | TRIVENI FORMULATION LTD-PLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1810 | NDA/MAL/HDP /2821 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | DIOLIN-M | GLIBENCLAMIDE+ METFORMIN HYDROCHLORIDE TABLETS | 5MG+500MG | LINCOLN PHARMACEUTICAL LIMITED..-LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2011 |
| 1811 | NDA/MAL/HDP /2826 | GLAXO SMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PIRITON SYRUP | CHLORPHENIRAMINE MALEATE | 4MG/10ML | GLAXOSMITHKLINE-LIKONI ROAD IND. AREA, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X2.0 L BOTTLE | 01/07/1997 |

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| 1812 | NDA/MAL/HDP/2835 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | SOLUDINE-M | POVIDONE IODINE / METRONIDAZOLE | 5%W/W / 1%W/W | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE,1.0X125.0 G TUBE | 01/07/2011 |
| 1813 | NDA/MAL/HDP/2837 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | GRAMOFIL TABLETS | NALIDIXIC ACID | 500MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1814 | NDA/MAL/HDP/2838 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | DILCONTIN XL 120 | CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE | 120MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1815 | NDA/MAL/HDP/2848 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | DIPROGENTA OINTMENT | BETAMETHASONE/GENTAMICIN SULPHATE | 0.5MG/G+1.0MG/G | SCHERING-PLOUGH LABONV-INDUSTRIE PARK 30, B-220 HEIST-OP-DEN-BERG, BELGIUM | BELGIUM | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/2001 |
| 1816 | NDA/MAL/HDP/2850 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | DISPERCAM | PIROXICAM | 20MG | MEDICAL UNION PHARMACEUTICAL CO.-PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X3.0X1.0 ML AMPOULE | 01/07/2007 |
| 1817 | NDA/MAL/HDP/2869 | GLAXO SMITHKLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PRIORIX VACCINE | MEASLES + MUMPS + RUBELLA | 103.0CCID50 + 103.7CCID50 + 103.0CCID50 | GLAXO SMITHKLINE BIOLOGICALS S.A-RUE DE L'INSTITUT, 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY DRY VIALS | 1.0X0.5 ML VIAL (1 DOSE) | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1818 | NDA/MAL/HDP/2873 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | HELIGO KIT | TINIDAZOLE/CLARITHROMYCIN/LANSOPRAZOLE | 500MG+250MG+30MG | INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X7.0X6.0 TABLET BLISTER | 01/07/2001 |
| 1819 | NDA/MAL/HDP/2875 | GLAXOSMITHKLINE LIMITED- | UNITED HEALTHCARE DISTRIBUTORS LTD | OTRIVIN 0.05% NASAL DROPS | XYLOMETAZOLINE | 0.05%W/V | GSK CONSUMER HEALTH SA-GSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND | SWITZERLAND | NASAL TOPICAL DROPS | 1.0X10.0 ML BOTTLE | 01/07/2003 |
| 1820 | NDA/MAL/HDP/2880 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CARBIMAZOLE 5 | CARBIMAZOLE | 5MG | REMEDICA LIMITED,-LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1821 | NDA/MAL/HDP/2885 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | FORECOX-TRAC | RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL | 150MG + 75MG+ 400MG + 275MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X6.0 TABLET BLISTER,1.0X24.0X 28.0 TABLET BLISTER | 01/07/2005 |
| 1822 | NDA/MAL/HDP/2891 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | TORVAST 20 | ATORVASTATIN | 20MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1823 | NDA/MAL/HDP/2892 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | NICARDIA-20 TABLETS | NIFEDIPINE | 20MG | UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1824 | NDA/MAL/HDP/2893 | DAWA LIMITED | SUPER MEDIC LTD | STOPACID SUSPENSION | MAGNESIUM TRISILICATE + ALUMINIUM HYDROXIDE | 250MG/5ML + 120MG/5ML | DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2009 |
| 1825 | NDA/MAL/HDP/2894 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MUCOGEL SUSPENSION | DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZAINE | 8G/100ML + 2G/100ML + 0.2 G/100ML | EGYPIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO-10TH OF RAMADAN CITY-FIRST INDUSTRIAL AREA -EGYPT | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X125.0 ML BOTTLE | 01/07/2005 |
| 1826 | NDA/MAL/HDP/2896 | KPI INDUSTRIES(1996) LTED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | MCG CREAM | MICONAZOLE NITRATE BP + CLOBETASOL PROPIONATE BP + GENTAMYCIN SULPHATE | 2.0%W/W + 0.05%W/W + 0.1 %W/W | KPI INDUSTRIES (1996) LTD-PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA | UGANDA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X25.0 G TUBE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1827 | NDA/MAL/HDP/2898 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | TORVAST 10 | ATORVASTATIN | 10MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2006 |
| 1828 | NDA/MAL/HDP/2900 | MICRO LABS LTD | LABOREX UGANDA LIMITED | GRAMOCEF-O-200 | CEFIXIME | 200MG | MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/2005 |
| 1829 | NDA/MAL/HDP/2902 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MEGALIS-20 | TADALAFIL | 20MG | MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X15.0X1.0X4.0 TABLET STRIP | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1830 | NDA/MAL/HDP/2905 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BRONCHOPHANE SYRUP | GUAIPHENESIN+EPHEDRINE HYDROCHLORIDE+DIPHENHYDRAMINE HYDROCHLORIDE+DEXTROMETHORPHAN | 50MG+7.5MG+5MG+4.58MG | EGYPT INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. EIPICO-10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X125.0 ML BOTTLE | 01/07/2007 |
| 1831 | NDA/MAL/HDP/2906 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RIFAMPICIN/ISONIAZID/ETHAMBUTOL | RIFAMPICIN+ISONIAZID+ETHAMBUTOL | 150MG+75MG+275MG | MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 01/07/2012 |
| 1832 | NDA/MAL/HDP/2907 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | LONART DS | ARTEMETHER + LUMEFANTRINE | 80 MG + 480 MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1833 | NDA/MAL/HDP/2908 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | PAINGO MEDICATED CREAM | METHYLSALICYLATE+CAPSICUM OLEORESIN+TURPENTINE OIL | 15%W/W + 1%W/W + 1.47%W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X2.0X15.0 G TUBE | 01/07/2010 |
| 1834 | NDA/MAL/HDP/2910 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | TENVIR EM | TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE | 300MG+200MG | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2009 |
| 1835 | NDA/MAL/HDP/2911 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL LORATADINE | LORATADINE | 10MG | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1836 | NDA/MAL/HDP/2914 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | CHLOROCIDE SUSPENSION | CHLORAMPHENICOL PALMITATE | 125MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1837 | NDA/MAL/HDP/2917 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | CETAMOL TABLETS | PARACETAMOL | 500MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X2.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP,1.0X100.0X10.0 TABLET BLISTER | 01/07/1997 |
| 1838 | NDA/MAL/HDP/2919 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | ODIMONT 5 | MONTELUKAST | 5MG | CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210 | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1839 | NDA/MAL/HDP/2920 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | TRANSLIPO -C CREAM | CLOTRIMAZOLE | 1%W/W | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X20.0 G TUBE,1.0X10.0 G TUBE | 01/07/2001 |
| 1840 | NDA/MAL/HDP/2940 | CENTAUR PHARMACEUTICALS PVT. LTD | GITTOES PHARMACEUTICALS LIMITED | BENZOX 5 GEL | BENZOYL PEROXIDE | 5%W/W | CENTAUR PHARMACEUTICALS LTD-PLOT NO. 39 TIVIN IN | INDIA | TOPICAL EXTERNAL OTHER GELS/SOLS | 1.0X20.0 G TUBE | 01/07/2005 |
| 1841 | NDA/MAL/HDP/2942 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | ARGISSEPT CREAM | CHOLRHEXIDINE GLUCONATE/SILVER SULPHADIAZINE | 0.2%W/W / 1%W/W | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE,1.0X10.0 G TUBE | 01/07/2005 |

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| 1842 | NDA/MAL/HDP/2945 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | ONCET | CETIRIZINE DIHYDROCHLORIDE | 10MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1843 | NDA/MAL/HDP/2946 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TRIMAGO ORAL SUSPENSION | CO-TRIMOXAZOLE | 240MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1998 |
| 1844 | NDA/MAL/HDP/2947 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TRIMAGO TABLETS | CO-TRIMOXAZOLE | 480MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X250.0 BLISTER CARTON | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1845 | NDA/MAL/HDP/2948 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | METFORMIN DENK 850 | METFORMIN HYDROCHLORIDE | 850MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X15.0 TABLET BLISTER | 01/07/2007 |
| 1846 | NDA/MAL/HDP/2950 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | XALATAN | LATANOPROST | 0.005%W/V | PFIZER MANUFACTURING - NV/NA, RIJKSWEG 12 2870, PUURS | BELGIUM | OPHTHALMIC DROPS | 1.0X2.5 ML BOTTLE | 01/07/1998 |
| 1847 | NDA/MAL/HDP/2951 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | LONART FORTE TABLETS | ARTEMETHER + LUMEFANTRINE | 40 MG + 240 MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X2.0X6.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1848 | NDA/MAL/HDP/2956 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | TRANLOK 500MG TABLETS | TRANEXAMIC ACID | 500MG | ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1849 | NDA/MAL/HDP/2957 | MEDIPHARM SALES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MEDITROL | CALCITRIOL | 0.25MCG | MEGA LIFE SCIENCES LIMITED-: PLANT I : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND | THAILAND | ORAL SOLID ORDINARY CAPSULES | 1.0X6.0X5.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2009 |
| 1850 | NDA/MAL/HDP/2959 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | CETAMOL SYRUP | PARACETAMOL | 120MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1851 | NDA/MAL/HDP/2960 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CLAVODAR | AMOXICILLIN/CLAVULANIC ACID | 400MG/57MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY GRANULES | 1.0X70.0 ML BOTTLE | 01/07/2010 |
| 1852 | NDA/MAL/HDP/2963 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | AZIWOK 500 | AZITHROMYCIN | 500MG | WOCKHARDT LIMITED-PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2014 |
| 1853 | NDA/MAL/HDP/2969 | UNIQUE PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | TENSIMIN-50 | ATENOLOL | 50MG | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,14.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1854 | NDA/MAL/HDP/2970 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GLYCOMET 500 | METFORMIN | 500MG | FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2000 |
| 1855 | NDA/MAL/HDP/2971 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | LEFRA-20 TABLETS | LEFLUNOMIDE | 20MG | TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2004 |
| 1856 | NDA/MAL/HDP/2972 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ANTIMIN SYRUP | LORATIDINE | 5MG/ML | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1857 | NDA/MAL/HDP/2979 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | BETADERM N CREAM | BETAMETHASONE VALERATE + NEOMYCIN | 0.1%W/W + 0.5%W/W | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X5.0 G TUBE,1.0X15.0 G TUBE | 01/07/1997 |
| 1858 | NDA/MAL/HDP/2980 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | LONART TABLETS | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X3.0X8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER,1.0X3.0X6.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER,1.0X12.0 TABLET | 01/07/2007 |
| 1859 | NDA/MAL/HDP/2982 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | NEURO-FORTE TABLETS | VITAMIN B1 + VITAMIN B6 + VITAMIN B12 | 200MG + 50MG + 1MG | CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1860 | NDA/MAL/HDP /2983 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FUCOL 200 | FLUCONAZOLE | 200MG | CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA CIPLA LTD KURKUMBH-D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TALUKA-DAUND, PUNE, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X1.0X4.0 CAPSULE BLISTER | 01/07/2004 |
| 1861 | NDA/MAL/HDP /2985 | SANOFI 410 THALES | LABOREX UGANDA LIMITED | EPILIM CHRONO | SODIUM VALPROATE PH. EUR | 500MG | SANOFI WINTHROP INDUSTRIE-1,RUE DE LA VIERGE ,AMBARES ET LAGRAVE 33565,CARBON BLANC CEDEX FRANCE | FRANCE | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |
| 1862 | NDA/MAL/HDP /2990 | MICRO LABS LTD | LABOREX UGANDA LIMITED | PULMOCEF-500 | CEFUROXIME AXETIL USP | 500MG | MICRO LABS LTD--NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X4.0 TABLET BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1863 | NDA/MAL/HDP/2995 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | GALLOP | LOPERAMIDE HYDROCHLORIDE USP | 2MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER | 01/07/2007 |
| 1864 | NDA/MAL/HDP/2997 | MEDLEY PHARMACEUTICALS | MEDVIN PHARMA LIMITED | ACENAC TABLETS | ACECLOFENAC | 100 MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1865 | NDA/MAL/HDP/2998 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | FITIN-5 | LEVOCETIRIZINE DIHYDROCHLORIDE | 5MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI CAUSEWAY ROAD,, KACHIGAM, DAMAN-396 210 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1866 | NDA/MAL/HDP/3002 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | KELVIN | PARACETAMOL | 500MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER,1.0X1000. 0 TABLET CONTAINER | 01/07/2011 |
| 1867 | NDA/MAL/HDP/3003 | GITTOES PHARMACEUTICAL S LIMITED | GITTOES PHARMACEUTICA LS LIMITED | AGOVIR | ACICLOVIR | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000. 0 TABLET CONTAINER,1.0X10 .0 TABLET BLISTER | 01/07/2007 |
| 1868 | NDA/MAL/HDP/3005 | ACINO PHARMA AG - | GOODMAN INTERNATIONAL LTD | OLFEN-100 SR PROLONGED-RELEASE CAPSULES | DICLOFENAC SODIUM | 100MG | ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND | SWITZERLAND | ORAL SOLID RETARD CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1869 | NDA/MAL/HDP/3007 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | TORTAS 5 | TORSEMIDE | 5MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 1870 | NDA/MAL/HDP/3009 | VENUS REMEDIES LIMITED | HARLEYS UGANDA LIMITED | SULBACTOMAX 1.5G | CEFTRIAXONE+SULBACTAM | 1000MG+500MG | VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 ML VIAL | 01/07/2009 |
| 1871 | NDA/MAL/HDP/3012 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | DICLOMOL TABLETS | DICLOFENAC SODIUM | 50MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1872 | NDA/MAL/HDP/3013 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOZOLE | ALBENDAZOLE | 400MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X1.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1873 | NDA/MAL/HDP/3017 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | LIDOCAINE INJECTION | LIDOCAINE HYDROCHLORIDE | 20MG/ML | SANJAR PHARMA LLP HIMATNAGAR-VIJOPUR HIGHWAY, DEDHROTA HIMATNAGAR 383 220, GUJARAT INDIA | CHINA | PARENTERAL ORDINARY VIALS | 1.0X25.0X20.0 ML VIAL | 01/07/2008 |
| 1874 | NDA/MAL/HDP/3019 | MJ BIOPHARM PVT LTD | VITACARE LIMITED | BIOSULIN 30/70 | INSULIN SOLUBLE + INSULIN ISOPHANE | 30 I.U + 70 I.U | MJ BIOPHARM PRT LTD-L-7 MIDC INDUSTRIAL AREA, TALOJA, NARI MUMBAI MAHARASHTRA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1875 | NDA/MAL/HDP/3020 | M.J BIOPHARM PVT LTD | VITACARE LIMITED | BIOSULIN N | INSULIN ISOPHANE | 100 I.U/ML | M.J .BIOPHARM-L7, M.I.D.C INDUSTRIAL AREA TALOJA, NAVI MUMBAI MAHARAHTRA | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/2008 |
| 1876 | NDA/MAL/HDP/3021 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | GLIBENCLAMIDE TABLETS | GLIBENCLAMIDE | 5MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1877 | NDA/MAL/HDP/3023 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOTRAX | LEVAMISOLE HYDROCHLORIDE | 40MG | AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET STRIP,1.0X10.0X1.0X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1878 | NDA/MAL/HDP/3024 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE | LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE | 150MG + 200MG + 300MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD-431136 MAHARASHTRA, INDIA QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2008 |
| 1879 | NDA/MAL/HDP/3029 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOZOLE SUSPENSION | ALBENDAZOLE USP | 200 MG/ 5 ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/2007 |
| 1880 | NDA/MAL/HDP/3030 | MJ BIOPHARM PVT LTD | VITACARE LIMITED | BIOSULIN R | INSULIN SOLUBLE | 100 IU/ML | M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1881 | NDA/MAL/HDP/3031 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMETHASONE | DEXAMETHASONE | 0.5MG | AGOG PHARMA LTD.-NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 1882 | NDA/MAL/HDP/3032 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | XYLO-ACINO 0.05% | XYLOMETAZOLINE | 0.05%W/V | MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN | GERMANY | NASAL TOPICAL SPRAYS WITHOUT GAS | 1.0X10.0 ML BOTTLE | 01/07/2007 |
| 1883 | NDA/MAL/HDP/3035 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFORTE TONIC | FERRIC AMMONIUM CITRATE + FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE + VITAMIN B12 | 50MG + 0.55MG + 2.4MG + 1.2MG + 11MG + 2.5MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1884 | NDA/MAL/HDP/3037 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOVIT SYRUP | VITAMIN A + VITAMIN D3 + VITAMIN B1 + VITAMIN B2 + NIACINAMIDE + VITAMIN B12 + VITAMIN C | 1000I.U + 200I.U + 1.5MG + 1.5MG+ 10MG + 2.5MCG + 40MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1885 | NDA/MAL/HDP/3040 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGODOX | DOXYCYCLINE | 100MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2007 |
| 1886 | NDA/MAL/HDP/3042 | PFIZER LABS LTD | LABOREX UGANDA LIMITED | NEUROTIN | GABAPENTIN | 300MG | PFIZER MANUFACTURING DEUTSCHLAND (PMD) GMBH-PHYSICAL ADDRESS: MOOSWALDALLEE 1D – 79090 FREIBURG | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1887 | NDA/MAL/HDP/3046 | GLAXO SMITHLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | CLAVULIN | AMOXICILLIN + CLAVULANIC ACID | 400 MG + 57 MG | GLAXO WELLCOME PRODUCTION-ZI DE LA PEYENNIERE, 53100, MAYENNE | UNITED KINGDOM | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 01/07/2009 |
| 1888 | NDA/MAL/HDP/3048 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TRIMAGO-DS TABLETS | SULFAMETHOXAZOLE/TRIMETHOPRIM | 800MG/160MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X10.0X10.0 TABLET CONTAINER,1.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 1889 | NDA/MAL/HDP/3051 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | BETROZOLE | DILOXANIDE FUROATE+METRONIDAZOLE BENZOATE+SIMETHICONE | 125MG+160MG+25MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1890 | NDA/MAL/HDP/3057 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | COLD-A-GO CAPSULES | PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + DIPHENHYDRAMINE + CAFFEINE | 400MG + 5MG + 12.5MG + 30MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2007 |
| 1891 | NDA/MAL/HDP/3063 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGODIC-50 | DICLOFENAC SODIUM | 50MG | AGOG PHARMA LTD.-NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1892 | NDA/MAL/HDP/3064 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TIN-TIN TABLETS | TINIDAZOLE | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1893 | NDA/MAL/HDP/3067 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PROMAGO SYRUP | PROMETHAZINE | 5MG/5ML | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2007 |
| 1894 | NDA/MAL/HDP/3068 | REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN | HEALTHCARE LTD. | OPTACHLOR EYE DROPS | CHLORAMPHENICOL | 0.5%W/V | REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM | PAKISTAN | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL | 01/07/1999 |
| 1895 | NDA/MAL/HDP/3069 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMOVE CAPSULES | PIROXICAM | 20MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1896 | NDA/MAL/HDP/3072 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMOL TABLETS(THANE) | PARACETAMOL | 500 MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10 0.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/1998 |
| 1897 | NDA/MAL/HDP/3073 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CARDINOL TABLET | ATENOLOL | 50MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 2.0X14.0 TABLET STRIP | 01/07/1997 |
| 1898 | NDA/MAL/HDP/3076 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO TELVAS 40 | TELMISARTAN | 40MG | ARISTO PHAMACUTLAB PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.2 MANIDIDEEP 462.046 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1899 | NDA/MAL/HDP/3077 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | UNISTEN HC CREAM | CLOTRIMAZOLE + HYDROCORTISONE | 1%W/W + 1%W/W | REGAL PHERMACUTICALS - PLOT 7879/18 OFF BABA RWARAKA NAIROBI KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2008 |
| 1900 | NDA/MAL/HDP/3078 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SINUTAB ALLERGY CONGESTION | PARACETAMOL/ CHLORPHENIRAMINE/ EPHEDRINE | 500MG/ 2MG/ 30MG | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1901 | NDA/MAL/HDP/3083 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO TELVAS 80 | TELMISARTAN | 80MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET STRIP | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1902 | NDA/MAL/HDP/3085 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCOLD TABLETS | PARACETAMOL+PHENYLEPHRINE HCL+CAFFEINE+CHLORPHENIRAMINE HYDROCHLORIDE | 500.MG+5.0MG+30.0MG+2.0MG | AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X25.0X4.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER,1.0X50.0X4.0 TABLET BLISTER | 01/07/2007 |
| 1903 | NDA/MAL/HDP/3090 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CEFODOX | CEFPODOXIME PROXETIL | 100MG/5ML | PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA | JORDAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X50.0 ML BOTTLE | 01/07/2004 |
| 1904 | NDA/MAL/HDP/3092 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | EXFORGE HCT 10MG/160MG/12.5MG | AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE | 10MG + 160MG +12.5MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 01/07/2015 |

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| 1905 | NDA/MAL/HDP/3095 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | AMPHEN SUSPENSION | CHLORAMPHENICOL PALMITATE | 125MG/5ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 1906 | NDA/MAL/HDP/3099 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | ZONA 0.1% CREAM | HYDROCORTISONE 17-BUTYRATE | 0.1%W/W | PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN | JORDAN | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE | 01/07/2007 |
| 1907 | NDA/MAL/HDP/3101 | DAWA LIMITED | SUPER MEDIC LTD | DACOLD SYRUP | PARACETAMOL + PSEUDOEPHEDRINE HCL + CHLORPHENIRAMINE MALEATE | 120MG/5ML+10MG/5ML+2MG/5ML | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1908 | NDA/MAL/HDP/3104 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | NYSTALEB ORAL SUSPENSION | NYSTATIN | 100000IU/ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2007 |
| 1909 | NDA/MAL/HDP/3108 | IPCA LABORATOIES LTD | MEDVIN PHARMA LIMITED | ZERODOL | ACECLOFENAC | 100MG | IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA IPCA LABORATORIES LTD, PLOT NO. T-139-PLOT NO. T-139, MIDC, INDUSTRIAL ESTATE, TARAPUR, BOISOR, DIST-PALGHAR, THANE 401506, MAHARASHTRA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |
| 1910 | NDA/MAL/HDP/3111 | GLAXOSMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CALPOL | PARACETAMOL | 120MG/5ML | GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1911 | NDA/MAL/HDP/3116 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | KLOXY | CLOXACILLIN | 125MG/5ML | LABORATORY & ALLIED LTD.--PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1912 | NDA/MAL/HDP/3117 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | HYDROCORTISONE SODIUM SUCCINATE | HYDROCORTISONE SODIUM SUCCINATE | 100MG | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-#14, II PHASE PIA, BANGALORE 560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X100.0 MG VIAL,1.0X50.0X100.0 MG VIAL | 01/07/2010 |
| 1913 | NDA/MAL/HDP/3118 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LUMARTEM | ARTEMETHER /LUMEFANTRINE | 20MG /120MG | QUALITY CHEMICAL INDUSTRIES LIMITED. -PLOT NO. 1-7 LUZIRA INDUSTRIAL PARK, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X24.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X18.0 TABLET | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1914 | NDA/MAL/HDP /3122 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GROVIT CHEWABLE TABLETS | MULTI-INGREDIENT | MULTI-INGREDIENT | REMIDEX PHARMA PVT LTD-B-249+ 250 II STAGE PEENYA INDUSTRIAL ESTATE BANGLORE 560058. | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2002 |
| 1915 | NDA/MAL/HDP /3123 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | RECTOL 250 SUPPOSITORY | PARACETAMOL BP | 250 MG | BLISS GVS PHARMA LIMITED-PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA | INDIA | RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES | 1.0X1.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 1916 | NDA/MAL/HDP /3125 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | AMLODAR 5 | AMLODIPINE BESILATE | 5MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1917 | NDA/MAL/HDP/3134 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | TOFF PLUS | PARACETAMOL+CHLORPHENIRAMINE MALEATE+ DEXTROMETHORPHAN + PHENYLEPHRINE | 500 MG + 2 MG + 15 MG + 10 MG | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2004 |
| 1918 | NDA/MAL/HDP/3136 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | TENOFOVIR DISOPROXIL FUMARATE | TENOFOVIR DISOPROXIL FUMARATE | 300MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2007 |
| 1919 | NDA/MAL/HDP/3139 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | OMEDAR | OMEPRAZOLE | 20MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1920 | NDA/MAL/HDP /3141 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | AMLOPRESS-5 | AMLODIPINE BESYLATE | 5MG | CIPLA LTD-CIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 1921 | NDA/MAL/HDP /3144 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICA L INDUSTRIES 1996 LIMITED | ULSEC | OMEPRAZOLE | 20MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE STRIP | 01/07/2007 |
| 1922 | NDA/MAL/HDP /3145 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | AMOXICAP | AMOXYCILLIN | 500MG | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1923 | NDA/MAL/HDP/3146 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | ZOKAST | MONTELUKAST SODIUM | 10MG | UNICHEM LABORATORIES LTD-UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD ,.,-PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 1924 | NDA/MAL/HDP/3147 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO TELVAS-H 40/12.5 | TELMISARTAN/HYDROCHLOROTHIAZIDE | 40MG/12.5MG | ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,3.0X10.0 TABLET BLISTER | 01/07/2009 |
| 1925 | NDA/MAL/HDP/3156 | PFIZER LABORATORIES (PTY) | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN DAYTIME FLU | PSEUDOEPHEDRINE HCL + IBUPROFEN | 30MG + 200MG | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1926 | NDA/MAL/HDP /3158 | MJ BIOPHARM PVT LTD | VITACARE LIMITED | GLIBEX-5 | GLIBENCLAMIDE | 5MG | M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2012 |
| 1927 | NDA/MAL/HDP /3159 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | LARTEM FORTE | ARTEMETHER + LUMEFANTRINE | 80MG + 480MG | SKANT HEALTH CARE LTD - 1802-1805 GIDC PHASE III VAPI GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2015 |
| 1928 | NDA/MAL/HDP /3163 | NORVATIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN SUPPOSITORIES 50MG | DICLOFENAC SODIUM | 50MG | DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE | FRANCE | RECTAL SYSTEMIC ADULT SUPPOSITORIES | 1.0X1.0X10.0 SUPPOSITORY STRIP | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1929 | NDA/MAL/HDP/3166 | BETA HEALTHCARE INTERNATIONAL LIMITED | BETA HEALTHCARE UGANDA LIMITED | SEPTRIN | TRIMETHOPRIM + SULPHAMETHOXAZOLE | 40MG/5ML + 200MG/5ML | GLAXO WELLCOME EGYPT CO. S.A.E-CAIRO | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1930 | NDA/MAL/HDP/3167 | MJ BIOPHARM PVT LTD | KIMSY MEDS LTD | MONAN-0.5G | MEROPENEM | 0.5G | M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X0.5 G VIAL | 01/07/2010 |
| 1931 | NDA/MAL/HDP/3169 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | RANOPHAGE OD | METFORMIN HCL | 1000MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED - INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1932 | NDA/MAL/HDP/3175 | M.J.BIOPHARM PVT LTD | VITACARE LIMITED | SPACOVIN | DROTAVERINE | 40MG | M.J. BIOPHARM PVT. LTD-L-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2012 |
| 1933 | NDA/MAL/HDP/3176 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | DOXYRONE-100 | DOXYCYCLINE HYDROCHLORIDE | 100 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2005 |
| 1934 | NDA/MAL/HDP/3177 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | BETADERM CREAM | BETAMETHASONE VALERATE | 0.1%W/W | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1935 | NDA/MAL/HDP/3178 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | BENDURIC TABLETS | BENDROFLUMETHIAZIDE | 5MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2005 |
| 1936 | NDA/MAL/HDP/3179 | GOOD DAY PHARMACY LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | SULFUR OINTMENT | SULPHUR | 10%W/W | KREMOINT PHARMA PVT LTD--B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X25.0 G TUBE | 01/07/2013 |
| 1937 | NDA/MAL/HDP/3184 | M.J BOPHARM PUT LTD | KIMSY MEDS LTD | MONAN | MEROPENEM | 1G | M.J BIOPHARM PUT LTD -L-7 MIDC INDUSTRIOL DIST GAIDED TOLOJA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1938 | NDA/MAL/HDP /3191 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ERECTO -100 | SILDENAFIL CITRATE | 100 MG | CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2007 |
| 1939 | NDA/MAL/HDP /3192 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ANZAVIR-R | ATAZANAVIR + RITONAVIR | 300 MG + 100 MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2013 |
| 1940 | NDA/MAL/HDP /3193 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ERECTO- 50 | SILDENAFIL CITRATE | 50MG | CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1941 | NDA/MAL/HDP/3196 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | MOTINORM | DOMPERIDONE | 10MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X30.0 ML BOTTLE | 01/07/2000 |
| 1942 | NDA/MAL/HDP/3197 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | TRIAM-DENK 40 INJECTION | TRIAMCINOLONE ACETONIDE | 40 MG/ML | FISIOPHARMA S.R.L.-NUCLEOO INDUSTRIALE, 84020, PALOMONTE (SA) - ITALY DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY ITALY | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2004 |
| 1943 | NDA/MAL/HDP/3199 | MERCK SHARP & DOHME BV. | SURGIPHARM (U) LIMITED | ISENTRESS | RALTEGRAVIR | 400MG | ZHEIJIANG HUAHAI PHARMACEUTICAL CO LTD - ZHEIJIANG HUAHAI PHARMACEUTICAL CO LTD XUNQIAE LINHAI ZHIJIANG | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1944 | NDA/MAL/HDP/3200 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LETRAX | LEVAMISOLE HYDROCHLORIDE | 40MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X200.0 TABLET CONTAINER,1.0X25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER | 01/07/1997 |
| 1945 | NDA/MAL/HDP/3202 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | PRESARTAN-50 | LOSARTAN | 50MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 1946 | NDA/MAL/HDP/3204 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | RELCER GEL | ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE + LIQUORICE | 365MG/5ML + 80MG/5ML + 100MG/5ML + 400MG/5ML | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X180.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1947 | NDA/MAL/HDP /3206 | HEALTHCARE LTD. | HEALTHCARE LTD. | POSTINOR 2 | LEVONORGESTREL | 0.75MG | GEDEON RICHTER PLC-1103 BUDAPEST GYOMROI UT 19-21 | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X2.0 TABLET BLISTER | 01/07/2010 |
| 1948 | NDA/MAL/HDP /3207 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | DILCONTIN XL 90 | CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE | 90MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2010 |
| 1949 | NDA/MAL/HDP /3212 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CLOPRESS 75MG | CLOPIDOGREL BISULPHATE | 75MG | CIPLA LIMITED ,.,.-VILLAGE UPPER MALPUR, P.O. BHUD, THE. NALAGARH DISTRICT SOLAN HIMACHAL PRADESH PIN 173205 CIPLA LTD--PLOT NO L-139,VERNA IND ESTATE, VERNA GOA-403 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X3.0X1 0.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1950 | NDA/MAL/HDP /3214 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | INDICONTIN | INDAPAMIDE | 1.5MG | MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 1951 | NDA/MAL/HDP /3215 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | SEROCORT 125 | SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE | 25MCG + 125MCG | CIPLA LTD-CIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2009 |
| 1952 | NDA/MAL/HDP /3219 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPHENOL ORAL SUSPENSION | CHLORAMPHENICOL | 125MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1953 | NDA/MAL/HDP/3220 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | PYLO KIT | LANSOPRAZOLE+TINIDAZOLE+CLARITHROMYCIN | 30MG+500MG+250 MG | CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS) | 01/07/2005 |
| 1954 | NDA/MAL/HDP/3224 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM FLUFED ELIXIR | MULTI-INGREDIENT | MULTI-INGREDIENT | TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH- | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X60.0 ML BOTTLE | 01/07/1997 |
| 1955 | NDA/MAL/HDP/3225 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | DIFLAME | DICLOFENAC DIETHYLAMINE + LINSEED OIL + METHYL SALICYLATE MENTHOL | N/A | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1956 | NDA/MAL/HDP/3229 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | CIFLO | CIPRFLOXACIN | 500MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER | 01/07/2003 |
| 1957 | NDA/MAL/HDP/3231 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | FLUCOMOL | PARACETAMOL/PHENYLEPHRINE HCL/DEXTROMETHORPHAN HBR/CHLORPHENIRAMINE MALEATE | 500MG/10MG/15MG/2MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1.0X10.0 CAPSULE BLISTER | 01/07/2008 |
| 1958 | NDA/MAL/HDP/3232 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | L-TRIM | SULFAMETHOXAZOLE + TRIMETHOPRIM | 400MG + 80MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1959 | NDA/MAL/HDP/3233 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | WHITFIELD'S OINTMENT BP | BENZOIC ACID + SALICYLIC ACID | 0.06G+0.03G | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE | 01/07/1997 |
| 1960 | NDA/MAL/HDP/3237 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | KONAZOL CREAM | KETOCONAZOLE | 2% W/W | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2008 |
| 1961 | NDA/MAL/HDP/3241 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | CLOTRILIN | CLOTRIMAZOLE | 1%W/W | LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE,1.0X15.0 G TUBE | 01/07/2008 |

# NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - MARCH 2023

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1962 | NDA/MAL/HDP/3243 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RAPITUS | LEVODROPROPIZINE | 30MG/5ML | MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2016 |
| 1963 | NDA/MAL/HDP/3244 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | UMICILLIN | AMPICILLIN | 250MG | UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2015 |
| 1964 | NDA/MAL/HDP/3245 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NYSTATIN ORAL DROPS | NYSTATIN | 100,000 I.U/ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | ORAL TOPICAL DROPS | 1.0X30.0 ML BOTTLE | 01/07/2013 |

# NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - MARCH 2023

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1965 | NDA/MAL/HDP/3246 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | COMPOUND MAGNESIUM TRISILICATE | MAGNESIUM TRISILICATE | 370MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2000 |
| 1966 | NDA/MAL/HDP/3252 | GALENTIC PHARMA LTD | VITACARE LIMITED | PYLOOCAIN | BETAMETHASONE + PHENYLEPHRINE + LIDOCAINE | O.5 MG/G + 1 MG/G + 25 MG/G | GALENTIC PHARMA( INDIA ) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X30.0 G TUBE | 01/07/2005 |
| 1967 | NDA/MAL/HDP/3255 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | SATISFIL-50 | SILDENAFIL CITRATE | 50MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1968 | NDA/MAL/HDP /3259 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | TIGBODERM | BETAMETHASONE + CHLOROCRESOL + GENTAMICIN + CLIOQUINOL + TOLNAFTATE | 0.05% W/W + 0.1% W/W + 0.1% W/W + 1% W/W + 1% W/W | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 1969 | NDA/MAL/HDP /3261 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ | TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ | 300MG+200MG+600MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA MYLAN LABORATORIES LIMITED - PLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2008 |
| 1970 | NDA/MAL/HDP /3262 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENEGEL | MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE | 250MG + 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1971 | NDA/MAL/HDP/3263 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | TRIMEX MUCOLYTIC SYRUP | SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN | 2MG/5ML + 4MG/5ML + 100MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2009 |
| 1972 | NDA/MAL/HDP/3265 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AMOXICILLIN | AMOXICILLIN TRIHYDRATE | 250MG | CSPC ZHONGNUO PHARMACEUTICALS (SHIJIAZHUANG) CO. LTD-SHIJIAZHUANG CITY M/S SCOTT-EDIL PHARMACIA LTD -56 EPIP, PHASE-I, JHARMAJRI, BADDI, DISTT. SOLAN (H.P) INDIA | CHINA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER | 01/07/2010 |
| 1973 | NDA/MAL/HDP/3266 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | SALIMIA LINIMENT | METHYL SALICYLATE+TURPENTINE OIL | 5ML+25ML | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL LIQUIDS | 1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1974 | NDA/MAL/HDP/3270 | ASTRA PHARMA (UK) LTD | ASTRA PHARMA (U) LIMITED | FORTIFIED PROCAINE PENICILLIN | FORTIFIED PROCAINE PENICILLIN | 4000000 IU | CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON | 01/07/2001 |
| 1975 | NDA/MAL/HDP/3273 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | BETASOL CREAM | BETAMETHASONE VALERATE | 0.1%W/W | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/1997 |
| 1976 | NDA/MAL/HDP/3275 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | MEFLIN-500 | MEFENAMIC ACID | 500MG | LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1977 | NDA/MAL/HDP/3276 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | ROSUVAS 10 | ROSUVASTATIN | 10MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)- VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 01/07/2014 |
| 1978 | NDA/MAL/HDP/3279 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | HAEMOFORTE SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA BAROQUE PHARMACEUTICALS PVT LTD --S.NO.192/2 & S.NO.192/2 &3 SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/1997 |
| 1979 | NDA/MAL/HDP/3282 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | KOFF-GO | PHENYLEPHRINE HCL + CHLORPHENIRAMINE MALEATE + DEXTROMETHORPHAN | 5MG/5ML + 2MG/5ML + 10MG/5ML | TORQUE PHARMACEUTICALS (P) LTD-P.O.DAPPAR VILLISS | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1980 | NDA/MAL/HDP/3284 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | CHALEATE | CHLORPHENIRAMINE MALEATE | 4MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 1981 | NDA/MAL/HDP/3285 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AMOXIL FORTE 250MG/5ML | AMOXYCILLIN | 250MG/5ML | GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE | FRANCE | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 1982 | NDA/MAL/HDP/3286 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LOMAC-20 | OMEPRAZOLE | 20 MG | CIPLA LTD --PLOT NO 9, 10 & 15, PHARMA ZONE, PHASE II, SECTOR III, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1983 | NDA/MAL/HDP/3288 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | DELASED CHESTY COUGHS SYRUP | DIPHENHYDRAMINE HCL BP+AMMONIUM CHLORIDE BP+SODIUM CITRATE BP+MENTHOL BP | 14MG+135MG+57MG+1.1MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |
| 1984 | NDA/MAL/HDP/3289 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | CANDID DUSTING POWDER | CLOTRIMAZOLE | 1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL DUSTING POWDERS | 1.0X30.0 G BOTTLE,1.0X100.0 G BOTTLE | 01/07/1999 |
| 1985 | NDA/MAL/HDP/3291 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | FINTOP | BUTENAFINE HCL | 1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1986 | NDA/MAL/HDP/3292 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | DELASED PAEDIATRIC SYRUP | DIPHENHYDRAMINE HYDROCHLORIDE+SODIUM CITRATE+MENTHOL | 7MG+28.5MG+0.55MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |
| 1987 | NDA/MAL/HDP/3294 | WIN-MEDICARE LTD | SURGIPHARM (U) LIMITED | URGENDOL CAPSULES | TRAMADOL HYDROCHLORIDE | 50 MG | WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2004 |
| 1988 | NDA/MAL/HDP/3295 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | GLEVATE | CLOBETASOL | 0.05%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1989 | NDA/MAL/HDP/3296 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | LOPINAVIR / RITONAVIR | LOPINAVIR / RITONAVIR | 100MG / 25MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET CONTAINER,1.0X60.0 TABLET CONTAINER | 01/07/2011 |
| 1990 | NDA/MAL/HDP/3297 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | NEPIN-SR-20 | NIFEDIPINE | 20MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 1991 | NDA/MAL/HDP/3300 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | MUCOSOL PEDIATRIC SYRUP | CARBOCISTEINE | 125 MG/5 ML | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1992 | NDA/MAL/HDP/3302 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | AMOXICILLIN ORAL SUSPENSION | AMOXICILLIN | 125MG/5ML | OKASA PVT LTD-346 KUNDAIM INDUSTRIAL ESTATE GOA, 403115 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2009 |
| 1993 | NDA/MAL/HDP/3309 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | CLORIFORT VAGINAL TABLETS | CLOTRIMAZOLE | 100MG | UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA. | INDIA | VAGINAL TABLETS | 1.0X6.0 PESSARY STRIP | 01/07/2002 |
| 1994 | NDA/MAL/HDP/3312 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | TIDOMET FORTE | CO-CARELDOPA | 25MG/250MG | TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1995 | NDA/MAL/HDP/3314 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | SILVEREX | SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE | 10MG/G+10MG/G | SUN PHARMACEUTICALS IND. LTD-B-2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA-403404, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X250.0 G TUBE,1.0X25.0 G TUBE,1.0X10.0 G TUBE | 01/07/2004 |
| 1996 | NDA/MAL/HDP/3315 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ERO-250 TABLETS | ERYTHROMYCIN STEARATE | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2003 |
| 1997 | NDA/MAL/HDP/3316 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMOX | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 1998 | NDA/MAL/HDP/3318 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENETRIM TABLETS | CO-TRIMOXAZOLE | 480MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2000 |
| 1999 | NDA/MAL/HDP/3319 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | FERROTONE CAPSULES | FERROUS FUMERATE+FOLIC ACID+VITAMIN B12 | 162MG +0.75MG +7.5MCG | MEGA LIFESCIENCES LTD.-384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN | THAILAND | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X10.0 CAPSULE BLISTER | 01/07/2005 |
| 2000 | NDA/MAL/HDP/3321 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | DERMOLIN-GM | CLOBETASOL+GENTAMICIN+MICONAZOLE | 0.05%W/W+0.1%W/W+2%W/W | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2001 | NDA/MAL/HDP/3328 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | BENZYLPENICILLIN INJECTION | BENZYLPENICILLIN | 1 MU | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X1.0 MU VIAL,1.0X10.0X1.0 MU VIAL | 01/07/2001 |
| 2002 | NDA/MAL/HDP/3331 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | BETOPTIC | BETAXOLOL | O.5%W/V | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML VIAL | 01/07/1997 |
| 2003 | NDA/MAL/HDP/3333 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | NOVACLAV-625 | AMOXICILLIN + CLAVULANATE POTASSIUM | 500 MG + 125 MG | MEDISPRAY LABORATORIES PVT LTD,UNIT II-368-348 KUNDAIM INDUSTRIAL ESTATE,KUNDAIM GOA - 403115,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X5.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2004 | NDA/MAL/HDP/3334 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MYCLAV 375 | AMOXICILLIN + CLAVULANIC ACID | 250 MG + 125 MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET STRIP,1.0X10.0X6.0 TABLET STRIP | 01/07/2005 |
| 2005 | NDA/MAL/HDP/3341 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | AZILIN-250 | AZITHROMYCIN | 250MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X6.0 TABLET BLISTER | 01/07/2008 |
| 2006 | NDA/MAL/HDP/3343 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | MEDIVEN-CREAM | BETAMETHASONE VALERATE | 0.1%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2007 | NDA/MAL/HDP/3346 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | ZEDEX | BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DEXTROMETHORPHAN | 8MG+100MG+5MG+10MG | WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2008 | NDA/MAL/HDP/3347 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNIPEN TABLETS | PHENOXYMETHYLPENICILLIN | 250MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2009 | NDA/MAL/HDP/3348 | VENUS REMEDIES LTD | HARLEYS UGANDA LIMITED | PIMCEF | CEFEPIME USP | 1G | VENUS REMEDIES LTD.-UNIT 11 HOLL TOP INDUSTRIAL ESTATE JHARMAJRI | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 ML VIAL | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2010 | NDA/MAL/HDP/3354 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | MEDIVEN OINTMENT | BETAMETHASONE VALERATE | 0.1%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2011 | NDA/MAL/HDP/3357 | CENTAUR PHAMACUITICALS | GITTOES PHARMACEUTICALS LIMITED | ESOREST 20 | ESOMEPRAZOLE | 20MG | CENTAUR PHARMACEUTICALS PVT L.T.D.-CENTAUR HOUSE NEAR | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2012 | NDA/MAL/HDP/3359 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | ARTI | ARTEMETHER | 80MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X6.0X1.0 ML AMPOULE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2013 | NDA/MAL/HDP/3364 | CENTAUR PHAMACUITICALS | GITTOES PHARMACEUTICALS LIMITED | ESOREST 40 | ESOMEPRAZOLE | 40MG | CENTAUR PHARMACEUTICALS PVT L.T.D.-CENTAUR HOUSE NEAR | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2014 | NDA/MAL/HDP/3367 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMOL SUSPENSION | PARACETAMOL | 125 MG/5ML | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2000 |
| 2015 | NDA/MAL/HDP/3368 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | VIAGRA 50MG | SILDENAFIL | 50MG | PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE | FRANCE | ORAL SOLID ORDINARY TABLETS | 1.0X12.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2016 | NDA/MAL/HDP/3369 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | AZILIN-500 | AZITHROMYCIN | 500MG | LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X3.0 TABLET BLISTER | 01/07/2008 |
| 2017 | NDA/MAL/HDP/3370 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | DERMOREN 500 | GRISEOFULVIN | 500MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2018 | NDA/MAL/HDP/3372 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | MUCOLEX | AMBROXOL HYDROCHLORIDE + SALBUTAMOL SULPHATE + GUAIFENESIN + MENTHOL | 30 MG/5ML + 1 MG/5ML + 50 MG/5ML + 0.5 MG/5ML | S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2019 | NDA/MAL/HDP/3373 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MYCLAV 625 | AMOXILLICIN/CLAVULANATE | 500MG/125MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET STRIP,1.0X10.0X6.0 TABLET STRIP | 01/07/2005 |
| 2020 | NDA/MAL/HDP/3374 | COSMOS LIMITED | ASTRA PHARMA (U) LIMITED | ZITHROX 250MG | AZITHROMYCIN | 250MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 01/07/2008 |
| 2021 | NDA/MAL/HDP/3377 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AMILINE | AMITRIPTYLINE | 25 MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | NDA/MAL/HDP/3378 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CHLOZINE TABLETS | CHLORPROMAZINE | 100MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 2023 | NDA/MAL/HDP/3379 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIFASI | HUMAN CHORIONIC GONADOTROPIN | 5000I.U | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X2.0 AMPOULE CARTON | 01/07/2011 |
| 2024 | NDA/MAL/HDP/3382 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFEN SUSPENSION | IBUPROFEN | 100MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2010 |

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| 2025 | NDA/MAL/HDP/3383 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ZEPIN-200 | CARBAMAZEPINE | 200 MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2026 | NDA/MAL/HDP/3384 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PROXIMEXA 250MG | CEFUROXIME AXETIL | 250MG | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2027 | NDA/MAL/HDP/3385 | BLUE CROSS LABORATORIES LTD | STAR PHARMACEUTICALS LTD | MEFTAL-P-SUSPENSION | MEFENAMIC ACID | 100MG/5ML | BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2028 | NDA/MAL/HDP/3387 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PROXIMEXA 500MG | CEFUROXIME AXETIL | 500MG | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2029 | NDA/MAL/HDP/3389 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | CLARINASE REPE TABS | LORATADINE + PSEUDOEPHEDRINE | 5MG + 120MG | SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM | BELGIUM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2009 |
| 2030 | NDA/MAL/HDP/3390 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ALUGEL | ALUMINIUM HYDROXIDEL / MAGNESIUM TRISLICATE | 120MG/250MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X5.0 ML JERRYCAN | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2031 | NDA/MAL/HDP/3391 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CEZIN TABLET | CETIRIZINE | 10MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X5.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER | 01/07/2012 |
| 2032 | NDA/MAL/HDP/3393 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AUGMENTIN 375MG | AMOXICILLIN + CLAVULANIC ACID | 250 MG + 125 MG | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 2.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2033 | NDA/MAL/HDP/3399 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | LDNIL 10 | ROSUVASTATIN | 10MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2034 | NDA/MAL/HDP/3400 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | OLFEN GEL | DICLOFENAC SODIUM | 1%W/W | SOFARIMEX INDUSTRIA QUIMIRA E FARMACEUTICA SA-AV. DAS INDUSTRIAS - ALTO DO COLARIDE, 2735-213 AGUALVA CACEM | PORTUGAL | TOPICAL EXTERNAL GELS AND SOLS | 1.0X50.0 G TUBE,1.0X20.0 G TUBE | 01/07/1997 |
| 2035 | NDA/MAL/HDP/3405 | GLAXO SMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PANADOL BABY AND INFANT 120MG/5ML | PARACETAMOL | 120MG/5ML | GLAXOSMITHKLINE LIMITED-LIKONI ROAD, INDUSTRIAL AREA, P.O. BOX 78392-00507, VIWANDANI, NAIROBI | FRANCE | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2008 |
| 2036 | NDA/MAL/HDP/3406 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | MICRONEMA | SODIUM CITRATE + SODIUM LAURYL SULPHATE + GLYCERIN | 450MG/10ML+75 MG/10ML+ 90%V/V | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI, PAKISTAN | PAKISTAN | RECTAL SYSTEMIC ENEMA LIQUIDS | 1.0X10.0 ML BOTTLE,1.0X20.0 ML BOTTLE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2037 | NDA/MAL/HDP/3409 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | CLARITYNE | LORATADINE | 10MG | BAYER BITTERFELD GMBH-ORTSTEIL GREPPIN SALEGASTER CHAUSSEE 1, 06803 BITTERFELD, WOLFEN - GERMANY | NULL | ORAL SOLID ORDINARY TABLETS | 3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2000 |
| 2038 | NDA/MAL/HDP/3411 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABNAL NASAL DROPS | SODIUM CHLORIDE | 0.9%W/V | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | NASAL SYSTEMIC DROPS | 1.0X10.0 ML VIAL | 01/07/2011 |
| 2039 | NDA/MAL/HDP/3414 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | EXFORGE 10MG/160MG | AMLODIPINE + VALSARTAN | 10 MG + 160 MG | NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFAUSERTRASSE NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2040 | NDA/MAL/HDP/3415 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDID V-1 | CLOTRIMAZOLE | 500MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | VAGINAL TABLETS | 1.0X1.0 PESSARY STRIP | 01/07/2004 |
| 2041 | NDA/MAL/HDP/3426 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | RUBEM CREAM | METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALICYLATE | 1%W/W+0.1%W/W+5%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X25.0 G TUBE | 01/07/1997 |
| 2042 | NDA/MAL/HDP/3429 | XEPA-SOUL PATTINSON | DELMAW ENTERPRISES LIMITED | EZEDE | LORATADINE | 10MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250<br>MALEKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2006 |

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| 2043 | NDA/MAL/HDP/3433 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | CO-DIOVAN 80/12.5 | VALSARTAN + HYDROCHLOROTHIAZIDE | 80 MG +12.5 MG | NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2006 |
| 2044 | NDA/MAL/HDP/3437 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | REMYCIN 100 CAPSULES | DOXYCYCLINE HYDROCHLORIDE | 100MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 2045 | NDA/MAL/HDP/3439 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENECHLOR CAPSULE | CHLORAMPHENICOL | 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,10.0X10.0 CAPSULE BLISTER | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2046 | NDA/MAL/HDP/3440 | ELI-LILLY EXPORT SA | LABOREX UGANDA LIMITED | HUMALOG | INSULIN LISPRO | 100IU | LILLY FRANCE SA-FRANCE | FRANCE | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/2000 |
| 2047 | NDA/MAL/HDP/3444 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | CORVADIL 10 | AMLODIPINE BESILATE | 10MG | UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2010 |
| 2048 | NDA/MAL/HDP/3449 | VENUS REMEDIES LTD | HARLEYS UGANDA LIMITED | IMMUNOX | CEFTRIAXONE SODIUM | 1000MG | VENUS REMEDIES LIMITED ,.-HILL TOP,INDUSTRIAL ESTATE,JHARMAJRI, EPIP,PHASE 1,(EXTN.) ,BHATOLI KALAN,BADDI - H.P.INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1000.0 MG VIAL,1.0X10.0X1.0 X10.0 ML VIAL | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2049 | NDA/MAL/HDP/3450 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | TRAMADEX 50 | TRAMADOL | 50MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2009 |
| 2050 | NDA/MAL/HDP/3451 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPHENOL CAPSULES (THANE0 | CHLORAMPHENICOL | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER | 01/07/1998 |
| 2051 | NDA/MAL/HDP/3458 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNIXIL 250MG | AMOXYCILLIN TRIHYDRATE | 250MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2052 | NDA/MAL/HDP/3459 | AMOUN PHARMACEUTICALS COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ENEMAX | HYPERTONIC SOLUTION OF SODIUM PHOSPHATES | 6GM AND 16GM/100ML | AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT | EGYPT | RECTAL SYSTEMIC ENEMA LIQUIDS | 1.0X120.0 ML BOTTLE | 01/07/1997 |
| 2053 | NDA/MAL/HDP/3460 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | MALANIL ADULT TABLETS | ATOVAQUONE + PROGUANIL HCL | 250MG + 100MG | GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS | SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 01/07/2007 |
| 2054 | NDA/MAL/HDP/3461 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ZIDOVUDINE | ZIDOVUDINE | 300MG | MYLAN LABORATORIES LTD .- F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2055 | NDA/MAL/HDP/3464 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TARTAR CONTROL LISTERINE ANTISEPTIC | ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL | 18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML | JOHNSON&JOHNSON PTY LTD..-241 MAIN ROAD RETREAT 794 | SOUTH AFRICA | ORAL LIQUID ORDINARY OTHER LIQUIDS | 1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2007 |
| 2056 | NDA/MAL/HDP/3465 | MONDI-MUNDI PHARMA PVT LIMITED | SURGIPHARM (U) LIMITED | FECONTIN-Z | FERROUS GLYCINE SULPHATE+ZINC SULPHATE+FOLIC ACID | 100MG+61.8MG+0.5MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2057 | NDA/MAL/HDP/3466 | DAWA LIMITED | SUPER MEDIC LTD | DAWASEC | SECNIDAZOLE | 1G | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2058 | NDA/MAL/HDP /3467 | VENUS REMEDIES LTD | HARLEYS UGANDA LIMITED | RONEM | MEROPENEM TRIHYDRATE | 1000MG | VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1000.0 MG VIAL | 01/07/2008 |
| 2059 | NDA/MAL/HDP /3473 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | TRIXONE | CEFTRIAXONE | 1G | P.R & INJECT CARE PARENTERALS PVT LTD-PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI-396195,GUJARAT,INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL | 01/07/2016 |
| 2060 | NDA/MAL/HDP /3474 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMCLOREN DRY SYRUP | AMPICILLIN + CLOXACILLIN | 125MG+125MG/5 ML | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2061 | NDA/MAL/HDP/3475 | VENUS REMIDIES LTD | HARLEYS UGANDA LIMITED | RONEM | MEROPENEM | 500MG | VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X500.0 MG VIAL | 01/07/2010 |
| 2062 | NDA/MAL/HDP/3476 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | PARAFIL | PARACETAMOL | 500MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2063 | NDA/MAL/HDP/3478 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | DICLOREN | DICLOFENAC SODIUM BP | 50MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2064 | NDA/MAL/HDP/3483 | JOHNSON&JOHNSON PTY LTD. 241 | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SINUTAB 3-WAY | IBUPROFEN + PSEUDOEPHEDRINE HCL | 200MG + 30MG | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2065 | NDA/MAL/HDP/3485 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | ERGOMETRINE | ERGOMETRINE MALEATE | 0.5MG/ML | CIRON DRUGS AND PHARMACEUTICALS PRIVATE LTD-N-118 MIDC TARAPUM BOISAR DIST THANE 401506 MAHARASHTRA, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X100.0X1.0 ML AMPOULE | 01/07/2007 |
| 2066 | NDA/MAL/HDP/3490 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | LAXOLAC SYRUP | LACTULOSE | 67G/100ML | MEDICAL UNION PHARMACEUTICALS LTD-ABU SULTAN, ISMAILLIA, EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2067 | NDA/MAL/HDP/3492 | ACINO PHARMA AG - | GOODMAN INTERNATIONAL LTD | OLFEN-50 GASTRO-RESISTANT TABLETS | DICLOFENAC SODIUM | 50MG | ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2068 | NDA/MAL/HDP/3494 | FERRER INTERNATIONAL, S.A. | LABOREX UGANDA LIMITED | GAMALATE B6 SOLUTION | MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6 | 2G + 2G + 1G +1G | FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | ORAL LIQUID ORDINARY LIQUIDS | 1.0X80.0 ML BOTTLE | 01/07/2015 |
| 2069 | NDA/MAL/HDP/3497 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | LIVOLIN FORTE | MULTI-INGREDIENT | MULTI-INGREDIENT | MEGA LIFE SCIENCES LIMITED-: PLANT I : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND | THAILAND | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2070 | NDA/MAL/HDP/3500 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | GIZLAN 300 | IRBESARTAN | 300MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2071 | NDA/MAL/HDP/3502 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HYDROCORTISONE SODIUM SUCCINATE | HYDROCORTISONE SODIUM SUCCINATE | 100MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI | 01/07/2010 |
| 2072 | NDA/MAL/HDP/3504 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BIFRIL | ZOFENOPRIL | 30MG | A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.I-VIA CAMPO DI PILE 67100 L'AQUILA | ITALY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X7.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2073 | NDA/MAL/HDP/3506 | ABBVIE (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ULTANE | SEVOFLURANE | 100%W/W | ABBVIE S.R.L.-S.R. 148 PONTINA KM 52, SNC - CAMPOVERDE DI APRILIA 04011 APRILIA (LT) ITALY | ITALY | NASAL SYSTEMIC UNIT DOSE LIQUIDS | 1.0X250.0 ML BOTTLE | 01/07/2011 |
| 2074 | NDA/MAL/HDP/3507 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOX 250 | AMOXICILLIN | 250MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2011 |
| 2075 | NDA/MAL/HDP/3512 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | LAMISIL 250MG | TERBINAFINE | 250MG | NORVATIS PHARMA PRODUKTIONS GMBH -79644 WEHR/BADEN-GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X14.0 TABLET CARTON | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2076 | NDA/MAL/HDP /3515 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN 40/240 | ARTEMETHER + LUMEFANTRINE | 40 MG + 40 MG | AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X30.0X1.0X6.0 TABLET BLISTER | 01/07/2007 |
| 2077 | NDA/MAL/HDP /3516 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | BENZHEXOL TABLETS BP 5MG | TRIHEXYPHENIDYL HYDROCHLORIDE | 5MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET BLISTER | 01/07/1998 |
| 2078 | NDA/MAL/HDP /3517 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | TOTO ZINC | ZINC SULPHATE | 20MG | MEDICAMEN BIOTECH LTD-SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 2079 | NDA/MAL/HDP/3519 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | TENOFOVIR DISOPROXIL FUMARATE | TENOFOVIR DISOPROXIL FUMARATE | 300MG | STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2010 |
| 2080 | NDA/MAL/HDP/3520 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | DREZ POWDER | POVIDONE IODINE + METRONIDAZOLE | 1%W/W + 5%W/W | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | TOPICAL EXTERNAL POWDERS | 1.0X100.0 G BOTTLE,1.0X10.0 G BOTTLE,1.0X40.0 G CONTAINER | 01/07/2010 |
| 2081 | NDA/MAL/HDP/3522 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CLOXACILLIN SODIUM FOR INJECTION | CLOXACILLIN SODIUM | 500MG | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY VIALS | 1.0X10.0X500.0 MG VIAL | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2082 | NDA/MAL/HDP/3525 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCLLIN | AMPICILLIN TRIHYDRATE | 250MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/1998 |
| 2083 | NDA/MAL/HDP/3527 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | LEVOTOP-500 | LEVOFLOXACIN | 500MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2084 | NDA/MAL/HDP/3533 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | LEVOZIN | LEVOCETIRIZINE | 5MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2085 | NDA/MAL/HDP/3535 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | ADIFLAM-50 | DICLOFENAC SODIUM GASTRO-RESISTANT TABLETS BP | 50MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2086 | NDA/MAL/HDP/3542 | BETA HEALTH CARE INTERNATIONAL LTD | BETA HEALTHCARE UGANDA LIMITED | MARA MOJA | ASPIRIN + PARACETAMOL + CAFFEINE | 400MG + 200MG + 50MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X2.0 TABLET STRIP,1.0X110.0X2.0 TABLET STRIP | 01/07/2005 |
| 2087 | NDA/MAL/HDP/3545 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDID MOUTH PAINT | CLOTRIMAZOLE | 1%W/W | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL TOPICAL LIQUIDS | 1.0X15.0 ML BOTTLE | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2088 | NDA/MAL/HDP/3546 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENETRIM D.S | SULPHAMETHOXAZOLE + TRIMETHOPRIM | 800MG + 160MG | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2013 |
| 2089 | NDA/MAL/HDP/3547 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | CORBIS-10 | BISOPROLOL | 10 MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2008 |
| 2090 | NDA/MAL/HDP/3548 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BECORT 200 | BECLOMETASONE | 200MCG/DOSE | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | LUNG ADMINISTRATION METERED-DOSE INHALER | 1.0X200.0 METERED DOSE CANNISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2091 | NDA/MAL/HDP/3549 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | TRIMEX PAEDIATRIC COUGH EXPECTORANT | CHLORPHENIRAMINE MALEATE+PSEUDOEPHEDRINE HCL+GUAIPHENISIN+MENTHOL | 1.0MG+15.0MG+50.0MG+0.5MG / 5ML | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2007 |
| 2092 | NDA/MAL/HDP/3551 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ZAHA-500MG | AZITHROMYCIN | 500MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER,1.0X10.0X1.0X3.0 TABLET BLISTER | 01/07/2009 |
| 2093 | NDA/MAL/HDP/3553 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FALCIMON 25/67.5 B/L | ARTESUNATE+AMODIAQUINE | 25MG+67.5MG | CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER | 01/07/2014 |

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| 2094 | NDA/MAL/HDP/3556 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | GRISACTIN-500 TABLETS | GRISEOFULVIN TABLETS | 500MG | REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2095 | NDA/MAL/HDP/3558 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | SEROCORT 250 | SALMETEROL+ FLUTICASONE PROPIONATE | 25MCG + 250MCG | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2009 |
| 2096 | NDA/MAL/HDP/3561 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCILLIN ORAL SUSPENSION | AMPICILLIN TRIHYDRATE | 125MG/5ML | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2097 | NDA/MAL/HDP/3566 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | ARTESUN | ARTESUNATE | 60 MG | GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*5% NAHCO3 + 5 ML NACL INJECTION | 01/07/2008 |
| 2098 | NDA/MAL/HDP/3571 | CADILA PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | CADIPHEN EXPECTORANT | CHLORPHENIRAMINE/GUAIFENESIN/AMMONIUM CHLORIDE | 2MG//80MG/100 MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2099 | NDA/MAL/HDP/3574 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | METOZ 2.5 TABLET | METOLAZONE TABLETS USP | 2.5MG | CENTAUR PHARMA PVT.LIMITED-PLANT I-PLOT3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAPUSA GOA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2100 | NDA/MAL/HDP/3575 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CEFIX 400 CAPSULES | CEFIXIME | 400MG | PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X5.0 CAPSULE BLISTER | 01/07/2007 |
| 2101 | NDA/MAL/HDP/3577 | ASTRA PHARMA (U) LTD | ASTRA PHARMA (U) LIMITED | METOCLOPRAMIDE | METOCLOPRAMIDE | 5MG/ML | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2009 |
| 2102 | NDA/MAL/HDP/3578 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | CINNARON 25 | CINNARIZINE | 25MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2103 | NDA/MAL/HDP/3580 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | FEXOFEN-120 | FEXOFENADINE HYDROCHLORIDE | 120MG | ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA N0 11 MANDIDEEP | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X6.0 TABLET BLISTER | 01/07/2008 |
| 2104 | NDA/MAL/HDP/3581 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | METOZ 5 | METOLAZONE | 5MG | CENTAUR PHARMA PVT.LTD-PLANT I-PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAPUSA GOA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2105 | NDA/MAL/HDP/3582 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | SULPHADIMIDINE | SULPHADIMIDINE | 500MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2106 | NDA/MAL/HDP/3588 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | FEXOFEN-180 | FEXOFENADINE | 180MG | ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA N0 11 MANDIDEEP | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X6.0 TABLET BLISTER | 01/07/2008 |
| 2107 | NDA/MAL/HDP/3590 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | ALFOXAN 500 FC TABLETS | MEFENAMIC ACID | 500MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2004 |
| 2108 | NDA/MAL/HDP/3591 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | ARTESIANE 80MG/ML | ARTEMETHER | 80MG/ML | ANFARM HELLAS S.A.-61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI VIOTIAS - GREECE | GREECE | PARENTERAL ORDINARY I M AMPOULES | 1.0X5.0X1.0 ML AMPOULE | 01/07/1998 |

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| 2109 | NDA/MAL/HDP/3592 | FOURRTS (INDIA) LABORATORIES PUT LTD | SUPER MEDIC LTD | MEGATRIM DS | CO-TRIMOXAZOLE BP | 960 MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X1000. 0 TABLET CONTAINER | 01/07/2008 |
| 2110 | NDA/MAL/HDP/3593 | AUROBINDO PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DROX 500 | CEFADROXIL | 500MG | AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI- R7-AUROBINDO PHARMA LIMITED, FORMULATIONS UNIT-VI SY.NO.329/39 & 329/47 CHITKUL(V) PATANCHERU MANDAL, SANGA REDDY DISTTELANGANA502307 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER,1.0X10.0X 10.0 CAPSULE BLISTER | 01/07/2007 |
| 2111 | NDA/MAL/HDP/3594 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | STERILE QUININE DIHYDROCHLORIDE | QUININE DIHYDROCHLORIDE | 300MG/ML | CIRON DRUGS AND PHARMACEUTICALS PVT LIMITED-N-118, N119, N113, MIDC TARAPUR BOISAR DIST THANE 401506, INIDA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X100.0X2.0 ML AMPOULE | 01/07/2007 |

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| 2112 | NDA/MAL/HDP /3597 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | ARTESIANE 20 PAEDIATRIC | ARTEMETHER | 20MG/ML | ANFARM HELLAS S.A.-61ST KM. NATIONAL ROAD, ATHENS-LAMIA, 320 09 SCHIMATARI VIOTIAS - GREECE | GREECE | PARENTERAL ORDINARY I M AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2001 |
| 2113 | NDA/MAL/HDP /3598 | WIN-MEDICURE LTD | SURGIPHARM (U) LIMITED | MYOSPAZ | PARACETAMOL + CHLORZOXAZONE | 500MG + 250MG | WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2114 | NDA/MAL/HDP /3600 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | P-ALAXIN TABLETS | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 40MG + 320MG | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X9.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X15.0 TABLET BLISTER | 01/07/2008 |

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| 2115 | NDA/MAL/HDP /3601 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | HYDROKANT | HYDROCORTISONE ACETATE | 1%W/W | SKANT HEALTH CARE LTD - 1802-1805 GIDC PHASE III VAPI GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2009 |
| 2116 | NDA/MAL/HDP /3603 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | VUMTREX SYRUP | LEVAMISOLE | 40MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X30.0 ML BOTTLE | 01/07/2003 |
| 2117 | NDA/MAL/HDP /3604 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | AC-FENAC | ACECLOFENAC | 100MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2118 | NDA/MAL/HDP /3605 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | STOMACID | CPD MAGNESIUM TRISILICATE | MULTIINGRIDIENT | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X25.0X4.0 TABLET BLISTER | 01/07/1997 |
| 2119 | NDA/MAL/HDP /3607 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | LINOPRIL | LISINOPRIL DIHYDRATE | 20MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X14.0X2.0 TABLET BLISTER | 01/07/2004 |
| 2120 | NDA/MAL/HDP /3608 | SHAIGAN PHARMACEUTICALS (PVT) LTD | HARLEYS UGANDA LIMITED | MESAN | NICLOSAMIDE | 500MG | SHAIGAN PHARMACEUTICALS (PVT) LIMITED-14 KM ADYALA RD, RAWALPINDI, PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/1997 |

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| 2121 | NDA/MAL/HDP/3610 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | PROMETHAZINE TABLETS BP 25MG | PROMETHAZINE HYDROCHLORIDE | 25MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER | 01/07/1998 |
| 2122 | NDA/MAL/HDP/3611 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | COLDRIL SYRUP | PARACETAMOL + CHLORPHENIRAMINE + PSEUDOEPHEDRINE | 120MG+1MG+10MG | BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA ROAD INDUSTRIAL AREA, P.O.BOX 42569-00100 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2000 |
| 2123 | NDA/MAL/HDP/3612 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | LOSARTAS-H 12.5 | LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |

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| 2124 | NDA/MAL/HDP /3613 | HETERO LABS LTD | AIVEEN (U) LIMITED | ZIDOVUDINE ORAL SOLUTION | ZIDOVUDINE | 50MG/5ML | HETERO LABS LTD UNIT III-22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH , | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X240.0 ML BOTTLE | 01/07/2016 |
| 2125 | NDA/MAL/HDP /3614 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | ERYTHROREN SUSPENSION | ERYTHROMYCIN STEARATE | 125MG/5ML | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2008 |
| 2126 | NDA/MAL/HDP /3618 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | CLOXACILLIN SODIUM | CLOXACILLIN SODIUM | 500MG | CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0 VIAL CARTON | 01/07/2011 |

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| 2127 | NDA/MAL/HDP/3619 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | CAPTOPRIL DENK -25 | CAPTOPRIL | 25MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2000 |
| 2128 | NDA/MAL/HDP/3620 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | HALOXEN 10 TABLETS | HALOPERIDOL BP | 10MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER | 01/07/2004 |
| 2129 | NDA/MAL/HDP/3622 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PROXIMEXA | CEFUROXIME AXETIL | 125MG/5ML | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X50.0 ML BOTTLE | 01/07/2008 |

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| 2130 | NDA/MAL/HDP/3626 | ZYDUS LIFESCIENCES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ORIPHEX CAPSULES | CEPHALEXIN | 250MG | SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA. SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 2131 | NDA/MAL/HDP/3628 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | CELEMIN 5S | AMINO ACIDS/SORBITOL | 5%W/V+5%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION BAGS | 1.0X500.0 ML BOTTLE | 01/07/2001 |
| 2132 | NDA/MAL/HDP/3630 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | UNICONTIN 600 | THEOPHYLLINE | 600MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2133 | NDA/MAL/HDP/3631 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | ENA-DENK 10 | ENALAPRIL MALEATE | 10MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2134 | NDA/MAL/HDP/3634 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPLUS | PARACETAMOL+DEXTROMETHORPHAN HCL+ CHLORPHENIRAMINE+PHENYLEPHRINE HCL | 500MG+15MG+2MG+10MG | AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2008 |
| 2135 | NDA/MAL/HDP/3635 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | CIROGAN | PROMETHAZINE HYDROCHLORIDE | 25MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2011 |

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| 2136 | NDA/MAL/HDP/3637 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | TINODERM | MULTI-INGREDIENT | MULTI-INGREDIENT | NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X18.0 G TUBE | 01/07/1997 |
| 2137 | NDA/MAL/HDP/3639 | GLAXO SMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | PANADOL ADVANCE | PARACETAMOL | 500MG | GLAXOSMITHKLINE DUNGARAVAN LTD-KNOCKBRACK DUNGARVAN CO. WATERFORD | IRELAND | ORAL SOLID ORDINARY TABLETS | 1.0X11.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X2.0X1 0.0 TABLET BLISTER | 01/07/2010 |
| 2138 | NDA/MAL/HDP/3641 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | TRD-CONTIN 100 | TRAMADOL HYDROCHLORIDE | 100MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2139 | NDA/MAL/HDP/3642 | IND-SWIFT | PLANET PHARMACEUTICALS UGANDA LTD | CLARIE 250 | CLARITHROMYCIN | 250MG | IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X2.0X7.0 TABLET BLISTER | 01/07/2007 |
| 2140 | NDA/MAL/HDP/3645 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | NEUROBEX | THIAMINE + RIBOFLAVIN + PYRIDOXINE + CYANOCOBALAMIN+ FOLIC ACID | 250MG + 15MG + 200MG + 250MG + 500MCG | TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2141 | NDA/MAL/HDP/3647 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | NYSTAGO ORAL SUSPENSION | NYSTATIN | 100000 IU | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL TOPICAL SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2142 | NDA/MAL/HDP /3648 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | UNICONTIN 400 | THEOPHYLLINE | 400MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2143 | NDA/MAL/HDP /3649 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | LAMISIL | TERBINAFINE | 125MG | NOVARTIS BARBERA -SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/1997 |
| 2144 | NDA/MAL/HDP /3651 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | ORIPHEX SYRUP | CEPHALEXIN | 125MG/5ML | SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA. SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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| 2145 | NDA/MAL/HDP/3653 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN | ARTEMETHER + LUMEFANTRINE | 80 MG + 480 MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO),30.0X1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),30.0X1.0X6.0 TABLET BLISTER (WITHOUT AMFM | 01/07/2008 |
| 2146 | NDA/MAL/HDP/3655 | FOURRTS (INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | QUADRAJEL GEL | CHLORHEXIDINE+ METRONIDAZOLE+ LIDOCAINE | 5%W/W+1.61%W/W+2.13%W/W | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X15.0 G TUBE | 01/07/2008 |
| 2147 | NDA/MAL/HDP/3657 | DAWA LIMITED | SUPER MEDIC LTD | DAWASTIN | NYSTATIN | 100000IU/ML | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2148 | NDA/MAL/HDP/3664 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | AZZY | AZITHROMYCIN | 500MG | TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2011 |
| 2149 | NDA/MAL/HDP/3666 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | STROM 50 | TRAMADOL HYDROCHLORIDE | 50MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2008 |
| 2150 | NDA/MAL/HDP/3668 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AUGMENTIN BD | AMOXICILLIN + CLAVULANIC ACID | 200 MG/ 5 ML + 28.5 MG/ 5 ML | GLAXO WELLCOME PRODUCTION-ZI DE LA PEYENNIERE, 53100, MAYENNE | FRANCE | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE,1.0X140.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2151 | NDA/MAL/HDP/3670 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | TETRAREN CAPSULES | TETRACYCLINE HYDROCHLORIDE | 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2000 |
| 2152 | NDA/MAL/HDP/3671 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CLAVULIN TABLETS | AMOXICILLIN + CLAVULANIC ACID | 500 MG + 125 MG | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X14.0 TABLET STRIP,10.0X10.0 TABLET STRIP,1.0X20.0 TABLET STRIP | 01/07/2003 |
| 2153 | NDA/MAL/HDP/3672 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | NITROCONTIN 6.4 | NITROGLYCERIN | 6.4MG | MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE | INDIA | ORAL SOLID ORDINARY SUBLINGUAL TABLETS | 1.0X25.0 TABLET CONTAINER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2154 | NDA/MAL/HDP/3673 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | PROMETHAZINE INJECTABLE SOLUTION | PROMETHAZINE HCL | 25MG/ML | WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE | 01/07/2010 |
| 2155 | NDA/MAL/HDP/3674 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | INTAMINE SYRUP | PROMETHAZINE HYDROCHLORIDE | 5MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN | 01/07/1997 |
| 2156 | NDA/MAL/HDP/3677 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | IBUREN | IBUPROFEN | 200MG | RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2157 | NDA/MAL/HDP /3678 | FOURRTS LABORATORIES LTD | DELMAW ENTERPRISES LIMITED | REDINPLUS | IRON PENTACARBONYL + ZINC SULPHATE MONOHYDRATE + FOLIC ACID + SODIUM SELENITE + LYSINE HYDROCHLORIDE + HISTIDINE HYDROCHLORIDE + CHOLINE BITARTRATE | 100MG + 30MG + 7.5MG + 0.11MG + 26MG + 4.4MG + 52MG | FOURRTS (INDIA) LABS PVT LTD .-VANDALUR ROAD. KELAMBAKK AM-603103 TAMIL, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X30.0 CAPSULE BLISTER | 01/07/2008 |
| 2158 | NDA/MAL/HDP /3681 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENEDOL | PARACETAMOL | 500MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2000 |
| 2159 | NDA/MAL/HDP /3683 | FOURTS(INDIA) LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | COLD TABS FORTINSA | PARACETAMOL + PHENYLEPHRINE +CHLORPHENIRAMINE + CAFFEINE | 500MG + 5MG + 2MG + 30MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X25.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2160 | NDA/MAL/HDP/3686 | ACINO PHARMA AG - | GOODMAN INTERNATIONAL LTD | NEURORUBINE ™-FORTE 20 FILM-COATED TABLETS | MULTIVITAMIN | MULTINGREDIENT | ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER | 01/07/1997 |
| 2161 | NDA/MAL/HDP/3687 | DAWA LIMITED | SUPER MEDIC LTD | DAWA-PROM | PROMETHAZINE HCL | 5MG/5ML | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE | 01/07/2010 |
| 2162 | NDA/MAL/HDP/3688 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | NEUTRAFLUX MINT FLAVOUR | ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE | 200MG +250MG + 250MG + 250MG + 125MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2163 | NDA/MAL/HDP/3694 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | LORIDIN RAPITAB | LORATADINE | 10MG | CADILANHEALTH CARE LTD ,,;-KUNDAIN INDUSTRIAL ESTATE PONDA GOA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2002 |
| 2164 | NDA/MAL/HDP/3698 | CADILA HEALTHCARE PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | HIPEN SYRUP | AMOXICILLIN | 125MG/5ML | SPARSH BIO-TECH LTD -PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2165 | NDA/MAL/HDP/3699 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SINOPRIL 5MG TABLETS | LISINOPRIL | 5MG | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2166 | NDA/MAL/HDP/3702 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ATORFIT-20 | ATORVASTATIN | 20MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2167 | NDA/MAL/HDP/3703 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | SONATEC | CETYLPYRIDINIUM CHLORIDE | 0.05%W/V | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL TOPICAL LIQUIDS | 1.0X250.0 ML BOTTLE | 01/07/2014 |
| 2168 | NDA/MAL/HDP/3705 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SORAL 20MG CAPSULES | TENOXICAM | 20MG | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER,1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2005 |

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| 2169 | NDA/MAL/HDP/3707 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | OBETAS-120 | ORLISTAT | 120MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2010 |
| 2170 | NDA/MAL/HDP/3709 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | NIGHT & DAY -N | PARACETAMOL/ DIPHENHYDRAMINE CHLORIDE + PARACETAMOL/ PSEUDOEPHEDRINE | 500MG/ 25MG +600MG/ 90MG | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2171 | NDA/MAL/HDP/3710 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LACILLIN | AMPICILLIN | 250MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2172 | NDA/MAL/HDP /3711 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | POLY-MXB | POLYMYXIN B | 500,000 UNITS | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X5.0 ML VIAL | 01/07/2013 |
| 2173 | NDA/MAL/HDP /3712 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AMLOZAAR | LOSARTAN POTASSIUM / AMLODIPINE | 50MG + 5MG | MICRO LABS LTD-92,SIPCOT INDUSTRIAL COMPLEX,HOSUR-635-126(T.N)INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2174 | NDA/MAL/HDP /3714 | BAYER EAST AFRICA LTD | SURGIPHARM (U) LIMITED | ADALAT LA | NIFEDIPINE | 30MG | BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY | GERMANY | ORAL SOLID RETARD FILM-COATED TABLETS | 2.0X14.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2175 | NDA/MAL/HDP/3717 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CEFTRIAXONE SODIUM | CEFTRIAXONE SODIUM | 1G | CSPC ZHONGNUO PHARMACEUTICALS LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL | 01/07/2011 |
| 2176 | NDA/MAL/HDP/3723 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | LACILLIN | AMPICILLIN | 125MG/5ML | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 07/07/1997 |
| 2177 | NDA/MAL/HDP/3724 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | EPIGAB | PREGABALIN | 150MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0X14.0 CAPSULE BLISTER | 01/07/2015 |

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| 2178 | NDA/MAL/HDP/3725 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | NEW TUXIRIL | DEXTROMETHORPHAN HBR + PHENYLEPHRINE HCL + MENTHOL | 10MG/ML + 5MG/10ML + 5MG/10ML | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 2179 | NDA/MAL/HDP/3728 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DICLO-DENK 50 | DICLOFENAC SODIUM | 50MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER + 1 * 10 SAMPLE | 01/07/1998 |
| 2180 | NDA/MAL/HDP/3729 | MEDLEY PHARMACEUTICALS | MEDVIN PHARMA LIMITED | DECIFEN-SR | DICLOFENAC SODIUM | 100MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID RETARD ENTERIC-COATED TABLETS | 1.0X10.0X20.0 TABLET STRIP,1.0X3.0X10.0 TABLET STRIP | 01/07/2008 |

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| 2181 | NDA/MAL/HDP /3730 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | AVELOX | MOXIFLOXACIN HYDROCHLORIDE | 400MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 2.0X5.0 TABLET BLISTER,1.0X5.0 TABLET BLISTER | 01/07/2001 |
| 2182 | NDA/MAL/HDP /3732 | REGAL PHARMACEUTICAL S LTD | REGAL PHARMA (U) LTD | ALBASOL TABLETS 200MG | ALBENDAZOLE | 200MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0 TABLET STRIP | 01/07/2003 |
| 2183 | NDA/MAL/HDP /3734 | XEPA-SOUL PATTINSON | DELMAW ENTERPRISES LIMITED | ZARICORT CREAM | MICONAZOLE + HYDROCORTISONE | 2%W/W + 1%W/W | XEPA SAUL PATTINSON MALAYSIA-1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1998 |

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| 2184 | NDA/MAL/HDP/3736 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | RECTOL 125 SUPPOSITORY | PARACETAMOL | 125MG | BLISS GVS PHARMA LIMITED-PLOT NO. 10/11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 2185 | NDA/MAL/HDP/3737 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | ECOFLOX 500 TABLETS | CIPROFLOXACIN HYDROCHLORIDE | 500MG | MEDLEY PHARMACEUTICALS LTD..-PLOT NO. 18 & 19, SURVEY NO.378/7&8, 379/2&3,ZARI CAUSEWAY ROAD, KACHIGAM,DAMAN (U.T) 396210-INDIA MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2186 | NDA/MAL/HDP/3738 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | AMPICILLIN SODIUM | AMPICILLIN SODIUM | 500MG | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-#14, II PHASE PIA, BANGALORE 560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL,1.0X50.0X500.0 MG VIAL | 01/07/2010 |

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| 2187 | NDA/MAL/HDP/3741 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | ACTIZINE | CETIRIZINE HYDROCHLORIDE | 10MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X15.0X10.0 TABLET BLISTER | 01/07/2006 |
| 2188 | NDA/MAL/HDP/3745 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | WINDERM CREAM | BECLOMETHASONE+MICONAZOLE+NEOMYCIN | 0.025%W/W + 2%W/W + 0.5%W/W | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 01/07/2008 |
| 2189 | NDA/MAL/HDP/3746 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | BENDRO | BENDROFLUMETHIAZIDE | 5MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2190 | NDA/MAL/HDP /3747 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | ALZOL TABLETS | ALBENDAZOLE | 200MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 30.0X2.0 TABLET BLISTER | 01/07/2002 |
| 2191 | NDA/MAL/HDP /3752 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | PAINOTAB | PARACETAMOL + CAFFEINE | 650MG + 30MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2003 |
| 2192 | NDA/MAL/HDP /3753 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | MYFORTIC 180 | MYCOPHENOLATE SODIUM | 180MG | NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-OEFLINGER STR. 4479664 WEHR GERMANY | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X12.0X10.0 TABLET BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2193 | NDA/MAL/HDP/3754 | CENTAUR PHARMACEUTICALS PRIVATE LIMITED | GITTOES PHARMACEUTICALS LIMITED | SINAREST PD NASAL DROPS | OXYMETAZOLINE HYDROCHLORIDE | 0.025%W/V | CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | NASAL TOPICAL DROPS | 1.0X10.0 ML BOTTLE | 01/07/2006 |
| 2194 | NDA/MAL/HDP/3757 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNITRIM SUSPENSION | CO-TRIMOXAZOLE | 240MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |
| 2195 | NDA/MAL/HDP/3760 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | COMPOUND MAGNESIUM TRISILICATE | MAGNESIUM TRISILICATE | 370MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2196 | NDA/MAL/HDP /3761 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | RIFACOS-300 | RIFAMPICIN | 300 MG | COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000. 0 CAPSULE CONTAINER | 01/07/1997 |
| 2197 | NDA/MAL/HDP /3763 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | NORVASC | AMLODIPINE | 5MG | PFIZER PHARMACEUTICAL LLC -ROAD 689 KM 1.9 VEGA BAJA PUERTO RICO 00693 | USA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/1997 |
| 2198 | NDA/MAL/HDP /3765 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ALPRIM | CO-TRIMOXAZOLE | 480MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2199 | NDA/MAL/HDP/3766 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | BUKOL TABLETS | HYOSCINE N-BUTYLBROMIDE | 10MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2200 | NDA/MAL/HDP/3767 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | AMPOXIN 500 | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER | 01/07/1999 |
| 2201 | NDA/MAL/HDP/3768 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | NIMOTOP 30MG | NIMODIPINE | 30MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2202 | NDA/MAL/HDP/3770 | AMOUN PHARMACEUTICALS COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | XITHRONE | AZITHROMYCIN | 500 MG | AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT | EGYPT | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 01/07/2005 |
| 2203 | NDA/MAL/HDP/3771 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BRONQUIDIAZINA C.R | TRIMETHOPRIM/SULFAMETHOXAZOLE/BROMHEXINE/SODIUM BENZOATE/TOLU BALSAM | 80MG/400MG/4MG/250MG/325MG | FAES FARMA, S.A -MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA | SPAIN | ORAL LIQUID ORDINARY LIQUIDS | 1.0X150.0 ML BOTTLE | 01/07/2014 |
| 2204 | NDA/MAL/HDP/3772 | ELI-LILLY (SUISSE) SA | LABOREX UGANDA LIMITED | HUMULIN N NPH | HUMAN INSULIN ISOPHANE | 100IU | LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,-INDIANA 46285 USA | EGYPT | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 01/07/2005 |

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| 2205 | NDA/MAL/HDP/3773 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOBUTOL-4 | SALBUTAMOL SULPHATE | 4 MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2206 | NDA/MAL/HDP/3778 | AMOUN PHARMACEUTICALS COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | XITHRONE | AZITHROMYCIN | 200MG/5ML | AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X15.0 ML BOTTLE | 01/07/2004 |
| 2207 | NDA/MAL/HDP/3781 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ALZENTAL | ALBENDAZOLE | 20MG/ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X20.0 ML BOTTLE | 01/07/2014 |

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| 2208 | NDA/MAL/HDP/3782 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LAE-PEN V | PHENOXYMETHYLPENICILLIN | 250MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2209 | NDA/MAL/HDP/3784 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | CIPIUM | CHLORPHENIRAMINE | 2MG/5ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2011 |
| 2210 | NDA/MAL/HDP/3787 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPENIV | PHENOXYMETHYLPENICILLIN | 125MG/5ML | SPARSH BIO-TECH PVT. LTD .-PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2004 |

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| 2211 | NDA/MAL/HDP /3789 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | LEVITRA | VARDENAFIL HCL | 5MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2005 |
| 2212 | NDA/MAL/HDP /3790 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFLOX-P | PEFLOXACIN | 400MG | AGOG PHARMA-PLOT 33 SECTOR THE VASAI-TULUKA CO-OP ESTATE LTD INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2213 | NDA/MAL/HDP /3794 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMET-200 | METRONIDAZOLE | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2005 |

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| 2214 | NDA/MAL/HDP/3797 | ELDA INTERNATIONAL DMCC | REDDYS PHARMA LIMITED | PROVIVE 1% | PROPOFOL | 10MG/ML | BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITED-CHACHARWADI - VASANA, AHMEDABAD, IN 382213 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X50.0 ML VIAL,1.0X20.0 ML VIAL | 01/07/2002 |
| 2215 | NDA/MAL/HDP/3798 | AMOUN PHARMACEUTICAL COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | NEUROTON TABLET | MULTI-INGREDIENT | N/A | AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT | EGYPT | ORAL SOLID ORDINARY COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2004 |
| 2216 | NDA/MAL/HDP/3801 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | FUNGISTIN ORAL SUSPENSION | NYSTATIN | 100000 IU/ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2002 |

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| 2217 | NDA/MAL/HDP /3802 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | LEVITRA 10MG | VARDENAFIL MONOHYDROCHL ORIDE TRIHYDRATE | 10 MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2005 |
| 2218 | NDA/MAL/HDP /3803 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | DICLODYNE SUPPOSITORY | DICLOFENAC SODIUM | 100MG | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | RECTAL SYSTEMIC ADULT SUPPOSITORIES | 1.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 2219 | NDA/MAL/HDP /3804 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | NEURORUBINE IM | VITAMIN B1+VITAMIN B6+VITAMIN B12 | 100MG+100MG+1 MG | HAUPT PHARMA WULFING GMBH.-BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE MERCKLE GMBH (A MEMBER OF RATIOPHARM GROUP)-LUDWIG MERCKLE STR. 3, 89143 BLAUBEUREN WEILER | SWITZERLAND | PARENTERAL ORDINARY I M AMPOULES | 1.0X5.0X3.0 ML AMPOULE | 01/07/1997 |

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| 2220 | NDA/MAL/HDP/3807 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ARTEMETHER INJECTION | ARTEMETHER | 80MG/ML | NINGBO DAHONGYING PHARMACEUTICALS-N0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | CHINA | PARENTERAL ORDINARY I M AMPOULES | 1.0X6.0X1.0 ML AMPOULE | 01/07/2008 |
| 2221 | NDA/MAL/HDP/3808 | NORVATIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN SUPPOSITORIES 12.5MG | DICLOFENAC SODIUM | 12.5MG | DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE | FRANCE | RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY STRIP | 01/07/2006 |
| 2222 | NDA/MAL/HDP/3809 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | COLDRID DAY & NIGHT | PARACETAMOL+CHLORPHENIRAMINE MALEATE+PHENYLEPRINE HYDROCHLORIDE + CAFFEINE | 500MG+2MG+5MG+15MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET STRIP | 01/07/2006 |

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| 2223 | NDA/MAL/HDP/3812 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | B-TONE | PHENOBARBITONE | 30MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2224 | NDA/MAL/HDP/3813 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | ACTIPAR | PIPERAZINE CITRATE | 500MG/5ML | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X30.0 ML BOTTLE | 01/07/1997 |
| 2225 | NDA/MAL/HDP/3814 | MARTINDALE PHARMACEUTICALS LTD | LABOREX UGANDA LIMITED | PETHIDINE INJECTION | PETHIDINE | 50MG/1ML | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/1997 |

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| 2226 | NDA/MAL/HDP/3827 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ATORFIT-10 | ATORVASTATIN | 10MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2227 | NDA/MAL/HDP/3829 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | BETACOOL | DRIED ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIMETHICANE | 300MG / 25MG / 50MG / 25MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X50.0 TABLET STRIP | 01/07/2006 |
| 2228 | NDA/MAL/HDP/3831 | ABBVIE (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | ALUVIA | LOPINAVIR+RITONAVIR | 200MG+50MG | ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY. | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X120.0 TABLET CONTAINER | 01/07/2007 |

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| 2229 | NDA/MAL/HDP/3833 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | LABSTATIN VAGINAL TABLETS | NYSTATIN | 100.000 I.U | LABORATORY & ALLIED LTD.-PLOT 209/10349 OFF MOMBASA RD NAIROBI | KENYA | VAGINAL TABLETS | 1.0X15.0 PESSARY STRIP | 01/07/2000 |
| 2230 | NDA/MAL/HDP/3835 | GLAXOSMITHKLINE LTD | BETA HEALTHCARE UGANDA LIMITED | HEDEX CAPLETS | PARACETAMOL+ASPIRIN+CAFFEINE ANHYDROUS | 200MG+400MG+50MG | SMITHKLINE BEECHAM (NAIROBI)-NAIROBI, KENYA BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA DINLAS PHARMA EPZ LIMITED-PLOT NO. LR 7149/121, MOMBASA ROAD, SYOKIMAU | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK | 01/07/1997 |
| 2231 | NDA/MAL/HDP/3837 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | NITROFURANTOIN | NITROFURANTOIN | 100MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |

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| 2232 | NDA/MAL/HDP/3839 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | FLURID | ACETAMINOPHEN + PHENIRAMINE MALEATE | 500 MG + 10.5 MG | KAMPALA PHARMACEUTICALS INDUSTIES-PLOT M 444B STRETCHER NTINDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X4.0 TABLET BLISTER | 01/07/2006 |
| 2233 | NDA/MAL/HDP/3840 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | TORACTIN TABLETS | CYPROHEPTADINE | 4MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 2.0X50.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2000 |
| 2234 | NDA/MAL/HDP/3841 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | MEGATRIM TABLETS | CO-TRIMOXAZOLE | 480MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 2235 | NDA/MAL/HDP /3844 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | VOLTAREN RETARD | DICLOFENAC SODIUM | 100MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1-80052, TORRE ANNUNCIATA (NA) ITALY | SWITZERLAND | ORAL SOLID RETARD TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/1997 |
| 2236 | NDA/MAL/HDP /3845 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICA L INDUSTRIES 1996 LIMITED | CARDIPAC | AMLODIPINE | 5MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2237 | NDA/MAL/HDP /3846 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | LEVITRA | VARDENAFIL HCL | 20 MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2238 | NDA/MAL/HDP/3850 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ANGIZAAR-H | LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2239 | NDA/MAL/HDP/3853 | MISSION PHARMA A/S | JOINT MEDICAL STORE (UPMB - UCMB) | ZINC SULPHATE TABLET USP | ZINC SULPHATE | 20MG | MEDICAMEN BIOTECH LTD-SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2240 | NDA/MAL/HDP/3854 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | LOSARTAS 50 TABLETS | LOSARTAN POTASSIUM | 50MG | INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2241 | NDA/MAL/HDP/3859 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | IFIMOL | PARACETAMOL | 10MG/ML | UNIQUE PHARMACEUTICAL LABORATORIES--PLOT NO. 4 PASE IV, GIDC PANOLI -394 116<br>GUJARAT INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 2242 | NDA/MAL/HDP/3860 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOLAC | LACTULOSE | 3.35MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/2009 |
| 2243 | NDA/MAL/HDP/3862 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | LAMITOR 100 | LAMOTRIGINE | 100MG | TORRENT PHAMACEUTICALS LTD-TORRENT PHAMACEUTICALS LTD INDRAD 382721 DIST MEHSANA INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2244 | NDA/MAL/HDP /3866 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | RL | COMPOUND SODIUM LACTATE INFUSION BP | 0.6/ 0.25 /0.04 / 0.027 % W/V | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/2010 |
| 2245 | NDA/MAL/HDP /3867 | ROYAL GROUP | ABACUS PHARMA (AFRICA) LIMITED | BETADERM OINTMENT | BETAMETHASONE VALERATE | 0.1%W/W | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X5.0 G TUBE | 01/07/1997 |
| 2246 | NDA/MAL/HDP /3871 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | DOVERIN 40 | DROTAVERINE HYDROCHLORIDE | 40MG | INTAS PHARMACEUTICALS LIMITED-PLOT NO. 457 / 458 SARKHEJ-BAVLA HIGHWAY, MATODA - 382 210, TALUKA - SANAND, DISTRICT - AHMEDABAD, STATE - | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2247 | NDA/MAL/HDP/3872 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | ZYNCET SYRUP | CETIRIZINE HYDROCHLORIDE | 5MG/5ML | THE MADRAS PHARMACEUTICALS-137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 01/07/2006 |
| 2248 | NDA/MAL/HDP/3874 | AJANTA PHARMA LTD 31-0 | ABACUS PHARMA (AFRICA) LIMITED | RIDMAL 40/320 | DIHYDROARTEMISININ + PIPERAQUINE | 40MG + 320MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X8.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER | 01/07/2010 |
| 2249 | NDA/MAL/HDP/3875 | PHAMA INTERNATIONAL CO | OMAB UGANDA LIMITED | OPTIMAL(0.05% GEL | TRETINOIN USP | 0.25MG/1G | PHARMA INTERNATIONAL COMPANY .-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN | JORDAN | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2250 | NDA/MAL/HDP/3881 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | MOXACIL | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2009 |
| 2251 | NDA/MAL/HDP/3882 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | PEDIVIT FORTE CAPSULES | MULTIINGREDIENT | N/A | J.B. CHEMICALS AND PHARMACEUTICALS LTD-J.B. CHEMICALS & PHARMACEUTICALS LTD, 215/216, GIDC, PANOLI, GUJARAT | INDIA | ORAL SOLID ORDINARY CAPSULES | 3.0X7.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 2252 | NDA/MAL/HDP/3883 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | MYFORTIC 360 | MYCOPHENOLATE SODIUM | 360MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS PHARMA PRODUKTIONS GMBH-OEFLINGER STR.4479664 WEHR GERMANY | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X12.0X10.0 TABLET BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2253 | NDA/MAL/HDP/3886 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | DELOR | CLOBETASOL PROPIONATE | 0.5 MG/G | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | TOPICAL EXTERNAL CREAMS | 1.0X25.0 G TUBE | 01/07/2004 |
| 2254 | NDA/MAL/HDP/3887 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | LYRICA 150MG | PREGABALIN | 150 MG | PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2007 |
| 2255 | NDA/MAL/HDP/3888 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | PYRIREN | PYRIDOXINE HYDROCHLORIDE | 25MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2256 | NDA/MAL/HDP/3889 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | LYRICA 75MG | PREGABALIN | 75 MG | PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2007 |
| 2257 | NDA/MAL/HDP/3891 | PHARMATHEN S.A | GOODMAN INTERNATIONAL LTD | LADININ | CIPROFLOXACIN | 500MG | PHARMATHEN S.A--6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE | GREECE | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2258 | NDA/MAL/HDP/3892 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | TETRAX | LEVAMISOLE HYDROCHLORIDE | 40MG/5ML | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X15.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2259 | NDA/MAL/HDP/3893 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | EPINEPHRINE INJECTION USP | EPINEPHRINE HCL | 1MG/ML | NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2008 |
| 2260 | NDA/MAL/HDP/3896 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | VALCONTIN 500 | SODIUM VALPROATE (CONTROLLED RELEASE) | 500MG | MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2261 | NDA/MAL/HDP/3897 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CLAVODAR | AMOXICILLIN/CLAVULANIC ACID | 875MG/125MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2262 | NDA/MAL/HDP /3899 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | FEDATE SYRUP | SODIUM FEREDETATE + PYRIDOXINE + CYANOCOBALAMIN + FOLIC ACID | 216.87MG + 1.5MG + 7.5MCG + 1.5MG | AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2013 |
| 2263 | NDA/MAL/HDP /3906 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | LEROLE | PANTOPRAZOLE | 40MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL 1*10ML 0.9%NACL AMPOULE | 01/07/2011 |
| 2264 | NDA/MAL/HDP /3913 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | VALCONTIN | SODIUM VALPROATE | 200 MG | MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2012 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2265 | NDA/MAL/HDP/3914 | GLAXOSMITHKLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | AUGMENTIN | AMOXICILLIN + CLAVULANATE POTASSIUM | 875 MG + 125 MG | SMITHKLINE BEECHAM PHARMACEUTICALS,-CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X1.0X7.0 TABLET BLISTER | 01/07/2010 |
| 2266 | NDA/MAL/HDP/3922 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | DIAZI | DIAZEPAM | 5MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2011 |
| 2267 | NDA/MAL/HDP/3924 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | FLUFED | PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPOLIDINE HYDROCHLORIDE | 300MG+36MG+1.5 MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2268 | NDA/MAL/HDP/3926 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | MIFUPEN TABLETS | ACETYLSALICYLIC ACID + CAFFEINE | 350MG + 30MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET STRIP | 01/07/1997 |
| 2269 | NDA/MAL/HDP/3927 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL CEPHALEXIN 125 | CEPHALEXIN MONOHYDRATE | 125MG/5ML | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2008 |
| 2270 | NDA/MAL/HDP/3928 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | MALAREN | SULPHADOXINE + PYRIMETHAMINE | 500MG/25MG | RENE INDUSTRIES LTD .-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X3.0 TABLET BLISTER | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2271 | NDA/MAL/HDP/3931 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | COARTEM 80/480 | ARTEMETHER + LUMEFANTRINE | 80MG +480MG | NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESI IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2014 |
| 2272 | NDA/MAL/HDP/3932 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIRAX TABLETS | CLIDINIUM BROMIDE + CHLORDIAZEPOXIDE | 2.5MG + 5MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2008 |
| 2273 | NDA/MAL/HDP/3933 | TORRENT PHARAMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | TOZAAR-50 | LOSARTAN POTASSIUM | 50MG | TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721 | INDIA | ORAL SOLID ORDINARY TABLETS | 5.0X10.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2274 | NDA/MAL/HDP/3938 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | ADRENALINE INJECTION | ADRENALINE | 1MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X100.0X1.0 ML AMPOULE | 01/07/2013 |
| 2275 | NDA/MAL/HDP/3945 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | CEFONE | CEFTRIAXONE | 1G | SWISS PARENTERALS LTD, UNIT- II-PLOT NO. 402,412-414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2011 |
| 2276 | NDA/MAL/HDP/3947 | INTAS PHARMACUITICALS LTD | NORVIK ENTERPRISES LIMITED | RABTAS-20 | RABEPRAZOLE SODIUM | 20 MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2277 | NDA/MAL/HDP/3948 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | TAXIM-O | CEFIXIME | 50MG/5ML | ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2009 |
| 2278 | NDA/MAL/HDP/3949 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | MAGNOMINT SUSPENSION | COMPOUND MAGNESIUM TRISILICATE | N/A | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2279 | NDA/MAL/HDP/3950 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | STROM | TRAMADOL HYDROCHLORIDE | 50MG/ML | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2280 | NDA/MAL/HDP /3951 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMCLOX | AMPICILLIN + CLOXACILLIN | 125MG/5ML + 125MG/5ML | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2004 |
| 2281 | NDA/MAL/HDP /3954 | WOCKHARDT LTD | STAR PHARMACEUTICALS LTD | POWERCEF 1GM INJECTION | CEFTRIAXONE SODIUM | 1GM | ZEISS PHARMACEUTICALS PVT. LIMITED-PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA WOCKHARDT LIMITED-B-15/2 MIDC, WALUJ, AURANGABAD 431136, MAHARASHTRA STATE, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL + 1*10ML AMPOULE OF WFI | 01/07/2001 |
| 2282 | NDA/MAL/HDP /3960 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | IBUPAR | PARACETAMOL/IBUPROFEN | 325/400MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2283 | NDA/MAL/HDP/3963 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | COARTEM DISPERSIBLE TABLETS | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | NOVARTIS URUNLERI TURKEY-YENISEHIR MAHALLESI, IHLARA VADISI SOKAK, NO. 2, TR 34912, PENDIK, INSTANBUL, TURKEY. | UNITED STATES | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X6.0 TABLET BLISTER,1.0X30.0X 6.0 TABLET BLISTER,1.0X1.0X6. 0 TABLET BLISTER,2.0X1.0X2 4.0 TABLET BLISTER,2.0X1.0X1 8.0 TABLET BLISTER,1.0X36.0X 6.0 TABLET | 01/07/2009 |
| 2284 | NDA/MAL/HDP/3965 | EMCURE PHARMACEUTICAL S LTD | HARLEYS UGANDA LIMITED | OROFER SYRUP | IRON(II) HYDROXIDE POLYMALTOSE COMPLEX | 50MG/5ML | EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X150.0 ML BOTTLE | 01/07/2004 |
| 2285 | NDA/MAL/HDP/3966 | DAWA LIMITED | SUPER MEDIC LTD | ASCORBIC ACID TABLETS | ASCORBIC ACID | 100 MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER,10.0X1 0.0 TABLET BLISTER | 01/07/2008 |

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| 2286 | NDA/MAL/HDP/3967 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCLOX-125 | CLOXACILLIN | 125MG/5ML | MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI). | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 2287 | NDA/MAL/HDP/3969 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FAWAR FRUIT EFFERVESCENT GRANULES | SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID | 2.8G + 1.33G + 0.82G | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES | 1.0X6.5 G SACHET | 01/07/2002 |
| 2288 | NDA/MAL/HDP/3970 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | LECOTRIM | CO-TRIMOXAZOLE | 480MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2289 | NDA/MAL/HDP /3971 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | VIRIAXONE-SL | CEFTRIAXONE + SULBACTAM | 1G+500MG | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 10 ML AMPOULE WFI | 01/07/2013 |
| 2290 | NDA/MAL/HDP /3983 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | EXTRADOL | PARACETAMOL/CAFFEINE TABLETS | 500MG/65MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X 2.0 TABLET BLISTER | 01/07/2008 |
| 2291 | NDA/MAL/HDP /3985 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMYCIN SUSPENSION | ERYTHROMYCIN ESTOLATE | 125MG/5ML | AGOG PHARMA-PLOT 33 SECTOR THE VASAI-TULUKA CO-OP ESTATE LTD INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2008 |

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| 2292 | NDA/MAL/HDP/3987 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | ROHISOL SYRUP | LEVAMISOLE HYDROCHLORIDE | 40MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE | 01/07/1997 |
| 2293 | NDA/MAL/HDP/3990 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNIXIL SYRUP | AMOXYCILLIN TRIHYDRATE | 125MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2294 | NDA/MAL/HDP/3991 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFULVIN | GRISEOFULVIN TABLETS | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2295 | NDA/MAL/HDP/3993 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | NEM SCAB | MULTI-INGREDIENT | MULTI-INGREDIENT | NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2296 | NDA/MAL/HDP/3996 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOTOIN TABLETS | NITROFURANTOIN BP | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2297 | NDA/MAL/HDP/3998 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOKOFF SYRUP | TERBUTALINE SULPHATE +GUAIFENESIN+BROMHEXINE HYDROCHLORIDE +LEVOMENTHOL | 1.25MG/5ML+50MG//5ML+4MG/5ML +2.5MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2298 | NDA/MAL/HDP/4000 | AMOUN PHARMACEUTICAL COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APIDONE SYRUP | CHLORPHENARIMINE MALEATE/DEXAMETHASONE | 2MG/5ML + 0.5MG/5ML | AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE,EL OBOUR CITY, CAIRO, EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X125.0 ML BOTTLE | 01/07/2008 |
| 2299 | NDA/MAL/HDP/4001 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCOLD PLUS SYRUP | PARACETAMOL+PHENYLEPHRINE+CHLORPHENIRAMINE+SODIUM CITRATE | 125MG/5ML+2.5MG/5ML+1MG/5ML+60MG /5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2008 |
| 2300 | NDA/MAL/HDP/4002 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCID | ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE | 250MG/5ML+ 250MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X170.0 ML BOTTLE | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2301 | NDA/MAL/HDP/4004 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | ANTHEL | ALBENDAZOLE | 400MG | LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 01/07/2005 |
| 2302 | NDA/MAL/HDP/4010 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | PYRI | PYRIDOXINE HYDROCHLORIDE | 25MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2303 | NDA/MAL/HDP/4012 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | MESPORIN 2000 | CEFTRIAXONE | 2000MG | LABESFAL LABORATORIOS ALMIRO, S.A ,.--ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS | PORTUGAL | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X50.0 ML VIAL | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2304 | NDA/MAL/HDP/4016 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | COMPOUND SODIUM LACATE INTRAVENOUS INFUSION | MULTI-INGREDIENT | MULTI-INGREDIENT | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2007 |
| 2305 | NDA/MAL/HDP/4019 | SEDICO PHARMACEUTICAL CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FLUCAMOX 1G | AMOXICILLIN + FLUCLOXACILLIN | 500 MG + 500 MG | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X1.0 G VIAL | 01/07/2007 |
| 2306 | NDA/MAL/HDP/4023 | CENTAUR PHARMACEUTICALS PVT. LTD | GITTOES PHARMACEUTICALS LIMITED | SINAREST LINCTUS | CHLORPHENAMINE MALEATE+DEXTROMETHORPHAN HYDROBROMIDE+MENTHOL | (4MG +10MG +3MG)/10ML | CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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| 2307 | NDA/MAL/HDP/4024 | SEDICO PHARMACEUTICAL CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SEDALAC SYRUP | LACTULOSE | 3.350G/5ML | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2007 |
| 2308 | NDA/MAL/HDP/4030 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | XBETA- N | BETAMETHASONE + NEOMYCIN | 0.1%W/V +0.5%W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/2011 |
| 2309 | NDA/MAL/HDP/4033 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN PAEDIATRIC SYRUP | DIPHENHYDRAMINE HYDROCHLORIDE | 7MG/5ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 01/07/2007 |

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| 2310 | NDA/MAL/HDP /4035 | BAYER SCHERING PHARMA | SURGIPHARM (U) LIMITED | YASMIN | DROSPIRENONE + ETHINYLESTRADIOL | 3MG+0.3MG | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X21.0 TABLET BLISTER | 01/07/2010 |
| 2311 | NDA/MAL/HDP /4038 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | PREDSONE-5 | PREDNISOLONE | 5MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2012 |
| 2312 | NDA/MAL/HDP /4042 | SWISS PARENTERALS PVT. LTD. | SHREEJI CARE LIMITED | S-CHLOR | CHLORAMPHENICOL | 1G | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2313 | NDA/MAL/HDP /4055 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | BAYER ASPIRIN CARDIO | ACETYLSALICYLIC ACID | 100MG | BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY | GERMANY | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2006 |
| 2314 | NDA/MAL/HDP /4057 | MICRO LABS | MALIX PHARMA (U) LIMITED | LAMPY | AMPICILLIN | 250MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE BLISTER,1.0X10.0X 10.0 CAPSULE BLISTER,1.0X100.0 X10.0 CAPSULE BLISTER | 01/07/2011 |
| 2315 | NDA/MAL/HDP /4060 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | TOBRADEX | TOBRAMYCIN/DEX AMETHASONE | 0.3%W/V+ 0.1%W/V | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2316 | NDA/MAL/HDP/4062 | GLAXO SMITHLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | KIVEXA | ABACAVIR SULFATE + LAMIVUDINE | 600 MG + 300 MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE, SG12 ODJ | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X30.0 TABLET CONTAINER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2006 |
| 2317 | NDA/MAL/HDP/4063 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | AVOCOMB TABLET | LAMIVUDINE/ZIDOVUDINE | 150MG/300MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)-VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X60.0 TABLET CONTAINER | 01/07/2003 |
| 2318 | NDA/MAL/HDP/4064 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | TERAFINE | TERBINAFINE | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 01/07/2010 |

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| 2319 | NDA/MAL/HDP/4066 | UNIVERSAL CORPORATION LTD | DELMAW ENTERPRISES LIMITED | UNIBROL | AMINOSIDINE | 125MG/ML | UNIVERSAL CORPORATION LTD-KIKUYU NAIROBI KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE | 01/07/2011 |
| 2320 | NDA/MAL/HDP/4074 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | UMICORT-100 | HYDROCORTISONE SODIUM SUCCINATE | 100MG | UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X100.0 MG VIAL | 01/07/2001 |
| 2321 | NDA/MAL/HDP/4075 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | CHERICOF COUGH FORMULAR | CHLORPHENIRAMINE/DEXTROMETHORPHAN HBR/PHENYLEPHRINE HCL | 2MG/10MG/5MG | RANBAXY LABORATORIES LTD AT: THE MADRAS PHARMACEUTICALS-137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2322 | NDA/MAL/HDP /4078 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | EPIGAB | PREGABALIN | 75MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X14.0 CAPSULE BLISTER | 01/07/2013 |
| 2323 | NDA/MAL/HDP /4079 | PHARMA INTL CO.. | OMAB UGANDA LIMITED | NERVAMINE | MECOBALAMIN | 500MCG | PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2009 |
| 2324 | NDA/MAL/HDP /4086 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | KELVIN SUSPENSION | PARACETAMOL | 120MG/5ML | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2325 | NDA/MAL/HDP /4092 | PRISMA PHARMACEUTICALS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FLORANORM | SACCHAROMYCES BOULARDII | 250MG | BHARAT BIOTECH INTERNATIONAL LTD-TURKPALLY SHAMEX 500 078 MYDERAHAD INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X2.0X250.0 MG SACHET,1.0X10.0X 250.0 MG SACHET | 01/07/2010 |
| 2326 | NDA/MAL/HDP /4093 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | BECLOMIN OINTMENT | BECLOMETHASONE+MICONAZOLE+NEOMYCIN | 0.025%W/W + 2%W/W + 0.5%W/W | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2007 |
| 2327 | NDA/MAL/HDP /4094 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | EFAVIRENZ | EFAVIRENZ | 200MG | STRIDES PHARMA SCIENCE LIMITED (STRIDES SHASUN)-KRS GARDENS, PLOT 36/7 SURAGAJKKANAHALLI, INDLAWADI CROSS, ANKAL TALUK, BANGALORE SOUTH - 562106, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X90.0 TABLET CONTAINER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2328 | NDA/MAL/HDP/4095 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | IBUT-200 | IBUPROFEN | 200MG | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2329 | NDA/MAL/HDP/4097 | GLAXOSMITHKLINE LTD UK | UNITED HEALTHCARE DISTRIBUTORS LTD | DERMOVATE | CLOBETASOL PROPIONATE | 0.05%W/W | GLAXOSMITHKLINE HARMIRE -GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM | UNITED KINGDOM | TOPICAL EXTERNAL CREAMS | 1.0X25.0 G TUBE,1.0X30.0 G TUBE | 01/07/1997 |
| 2330 | NDA/MAL/HDP/4098 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | EFAVIRENZ TABLETS | EFAVIRENZ | 600MG | STRIDES SHASUN LTD-N0. 36/7, SURAGAJAKKHANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BANGALORE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2007 |

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| 2331 | NDA/MAL/HDP/4099 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | GLEVO I.V | LEVOFLOXACIN | 500MG/100ML | AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 2332 | NDA/MAL/HDP/4100 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | NORETHISTERONE | NORETHISTERONE | 5MG | REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2333 | NDA/MAL/HDP/4101 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | AMLOTRUST 5 | AMLODIPINE | 5MG | CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |

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| 2334 | NDA/MAL/HDP/4103 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | POLIO SABIN - ONE AND THREE [ORAL] | LIVE ATTENUATED POLIOMYELITIS VIRUS VACCINE OF THE SABIN STRAINS TYPE 1 +TYPE 2 | $10^{6}CCID_{50}+10^{5}.^{8}CCID_{50}$ | GLAXO SMITHKLINE BIOLOGICALS S.A-RUE DE L'INSTITUT, 89 B-1330 RIXENSART | BELGIUM | ORAL LIQUID ORDINARY DROPS | 1.0X100.0X2.0 ML VIAL (20 DOSES) | 01/07/2016 |
| 2335 | NDA/MAL/HDP/4104 | DAWA LIMITED | SUPER MEDIC LTD | DAWA-PROM | PROMETHAZINE HCL | 25MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2336 | NDA/MAL/HDP/4112 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | ERYTHRONE TABLETS 250MG | ERYTHROMYCIN | 250MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2005 |

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| 2337 | NDA/MAL/HDP/4113 | MICRO LABS LTD | LABOREX UGANDA LIMITED | EROSTIN 10 | EBASTINE | 10 MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2338 | NDA/MAL/HDP/4114 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | RINALIN SYRUP | CHLORPHENIRAMINE MALEATE | 2MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/1997 |
| 2339 | NDA/MAL/HDP/4115 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | PREDILONE | PREDNISOLONE | 5.0 MG | REGAL PHARMACEUICALS LTD-PLOT NO 7879 OFF BABA DOGO ROAD KUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2007 |

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| 2340 | NDA/MAL/HDP/4118 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | OCUREST-AH | PHENYLEPHRINE HYDROCHLORIDE+NAPHAZOLINE HYDROCHLORIDE+CHLORPHRENIRAMINE MALEATE+MENTHOL+CAMPHOR | 0.12%+0.05%+0.1%+0.005%+0.01% | CENTAUR PHARMACEUTICALS PRIVATE LIMITED-PLOT NO.3,TIVIM INDUSTRIAL ESTATE KARASWADA MUPUSA-GOA 403 526 INDIA | INDIA | OPHTHALMIC DROPS | 1.0X10.0 ML VIAL | 01/07/2005 |
| 2341 | NDA/MAL/HDP/4119 | MEDIPAK LIMITED | HEALTHCARE LTD. | MEDITIM | TIMOLOL MALEATE | 0.5% W/V | MEDIPAK LIMITED-132/1 INDUSTRIAL AREA KOTLAKHPAT LAHORE | PAKISTAN | OPHTHALMIC LIQUIDS | 1.0X5.0 ML VIAL | 01/07/2007 |
| 2342 | NDA/MAL/HDP/4127 | SANOFI 410 THALES | LABOREX UGANDA LIMITED | EPILIM | SODIUM VALPROATE | 200MG/5ML | UNITHER LIQUID MANUFACTURING INDUSTRIE -COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770 | FRANCE | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE,1.0X300.0 ML BOTTLE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2343 | NDA/MAL/HDP /4128 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | VITAREN SYRUP | VITAMIN A + VITAMIN B2 + VITAMIN B1 + VITAMIN B6 + VITAMIN C + VITAMIN E + VITAMIN B3 | 1500IU/5ML + 1MG/5ML + 1MG/5ML + 0.5MG/5ML + 20MG/5ML + 100 IU/5ML + 10MG/5ML | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 01/07/2008 |
| 2344 | NDA/MAL/HDP /4138 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYCLOX CAPSULES | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER | 01/07/1997 |
| 2345 | NDA/MAL/HDP /4141 | SANOFI 410 THALES | LABOREX UGANDA LIMITED | EPILIM 200 | SODIUM VALPROATE | 200MG | FISONS LTD (ALSO KNOWN AS SANOFI-AVENTIS)-RIELL, SPAIN | SPAIN | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2001 |

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| 2346 | NDA/MAL/HDP/4143 | MODI NUNDIPHARMA PVT LTD | SURGIPHARM (U) LIMITED | TAM CONTIN 0.4 | TAMSULOSIN HYDROCHLORIDE | 0.4MG | MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2013 |
| 2347 | NDA/MAL/HDP/4146 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMPICLOX | AMPICILLIN + CLOXACILLIN | 250 MG + 250 MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2011 |
| 2348 | NDA/MAL/HDP/4147 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | NIFEDI-DENK 20 RETARD | NIFEDIPINE | 20MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2000 |

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| 2349 | NDA/MAL/HDP /4148 | COSMOS LIMITED | ASTRA PHARMA (U) LIMITED | AMITRIPTYLINE TABLETS | AMITRIPTYLINE | 25MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 2350 | NDA/MAL/HDP /4150 | TORRENT PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | ANGIOPRIL-25 | CAPTOPRIL | 25MG | TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2351 | NDA/MAL/HDP /4165 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | ZEFONE INJECTION | CEFTRIAXONE SODIUM | 1G | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT ZEISS PHARMACEUTICALS PVT LTD- | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2001 |

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| 2352 | NDA/MAL/HDP/4169 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCOZYD-200 | FLUCONAZOLE | 200MG | CADILA HEALTH CARE LTD-SARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDAD 382210, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0X7.0 CAPSULE BLISTER,1.0X5.0X4.0 CAPSULE BLISTER | 01/07/2008 |
| 2353 | NDA/MAL/HDP/4171 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | TOREX | MULTIINGREDIENT | N/A | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2354 | NDA/MAL/HDP/4172 | RENE INDUSTRIES | RENE INDUSTRIES LIMITED | KOF OFF EXPECTORANT | MULTI-INGREDIENT | MULTI-INGREDIENT | RENE INDUSTRIES-PLOT 680 KAMULI KIREKA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X110.0 ML BOTTLE | 01/07/2005 |

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| 2355 | NDA/MAL/HDP/4173 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | NASONEX | MOMETASONE FUROATE MONOHYDRATE | 0.05%W/V | SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM | BELGIUM | NASAL SYSTEMIC METERED-DOSE LIQUIDS | 1.0X1.0X120.0 METERED DOSE CANNISTER | 01/07/2009 |
| 2356 | NDA/MAL/HDP/4175 | AUROBINDO PHARMA LTD UNIT VII | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KOACT 156.25 | AMOXYCILLIN TRIHYDRATE+POTASSIUM CLAVUNALATE | 156.25MG/5ML | AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE) | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2007 |
| 2357 | NDA/MAL/HDP/4180 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | OSMOWIN | LACTULOSE | 10G/15ML | G.S PHAMBUTOR PVT LTD-G.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/2015 |

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| 2358 | NDA/MAL/HDP/4182 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | SINAREST-FORTE | MULTI INGREDIENT | MULTI INGREDIENT | CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X4.0 TABLET STRIP | 01/07/2007 |
| 2359 | NDA/MAL/HDP/4187 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | NORIGYNON | ESTRADIOL VALERATE +NORETHINDRONE ENANTHATE | 5 MG+50 MG / ML | BAYER PHARMA A.G-MULLERSTRASSE 178, 13353 BERLIN, GERMANY | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 ML AMPOULE | 01/07/1997 |
| 2360 | NDA/MAL/HDP/4188 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOPRAZ | PRAZIQUANTEL | 600MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X4.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER | 01/07/2013 |

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| 2361 | NDA/MAL/HDP /4241 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AMPICILLIN SODIUM FOR INJECTION BP | AMPICILLIN SODIUM | 500MG | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL | 01/07/2011 |
| 2362 | NDA/MAL/HDP /4275 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | AVASTIN 100MG/4ML | BEVACIZUMAB | 100 MG/ 4ML | F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY | SWITZERLAND | PARENTERAL ORDINARY VIALS | 1.0X4.0 ML VIAL | 01/07/2016 |
| 2363 | NDA/MAL/HDP /4276 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | FALCI CARE | ARTESUNATE | 60MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 5 ML NACL + 1 ML SODIUM BICARBONATE | 01/07/2013 |

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| 2364 | NDA/MAL/HDP/4277 | NABIQASIM INDUSTRIES (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | VIVIRON PLUS SYRUP | FERRIC AMMONIUM CITRATE +FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE | 50MG + 0.5MG + 2.2MG + 1.3MG +11MG | NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN. | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2014 |
| 2365 | NDA/MAL/HDP/4279 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROTIM | TIMOLOL MALEATE | 0.5% W/V | AUROLAB-NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2016 |
| 2366 | NDA/MAL/HDP/4280 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ABACAVIR SULFATE+LAMIVUDINE | ABACAVIR SULFATE + LAMIVUDINE | 600 MG + 300 MG | MYLAN LABORATORIES LTD ,-PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775, DIST DHAR – MADHYA PRADESH MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2013 |

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| 2367 | NDA/MAL/HDP /4284 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | AVASTIN 400MG/4ML | BEVACIZUMAB | 400MG/4ML | F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY | SWITZERLAND | PARENTERAL ORDINARY VIALS | 1.0X16.0 ML VIAL | 01/07/2016 |
| 2368 | NDA/MAL/HDP /4287 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANAXONE 1000 | CEFTRIAXONE | 1000MG | SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL,1.0X50.0X10.0 ML VIAL | 01/07/2010 |
| 2369 | NDA/MAL/HDP /4292 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | HERCEPTIN 150MG | TRASTUZUMAB | 150MG | ROCHE DIAGNOSTICS GMBH MANNHEIM--SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY. | SWITZERLAND | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2016 |

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| 2370 | NDA/MAL/HDP /4303 | PFIZER LABORATORIES (PTY) | LABOREX UGANDA LIMITED | SAYANA PRESS | MEDROXYPROGESTERONE ACETATE | 104MG/0.65ML | PFIZER MANUFACTURING - NV/NA, RIJKSWEG 12 2870, PUURS | BELGIUM | PARENTERAL ORDINARY I M PRE-FILLED SYRINGES | 1.0X200.0X0.65 ML PRE- FILLED SYRINGE | 01/07/2010 |
| 2371 | NDA/MAL/HDP /4307 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | MIKACIN | AMIKACIN SULPHATE | 500MG/2ML | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | PARENTERAL ORDINARY VIALS | 1.0X5.0X8.0X2.0 ML VIAL,1.0X1.0X2.0 ML VIAL | 01/07/2009 |
| 2372 | NDA/MAL/HDP /4309 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | LAMIVUDINE + ZIDOVUDINE | LAMIVUDINE + ZIDOVUDINE | 150MG + 300MG | HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2010 |

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| 2373 | NDA/MAL/HDP /4312 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GONAL-F | FOLLITROPIN ALFA | 75IU/IE | MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND | SWITZERLAND | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI | 01/07/2016 |
| 2374 | NDA/MAL/HDP /4315 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | DESLORA-DENK 5 | DESLORATIDINE | 5MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2375 | NDA/MAL/HDP /4317 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | COLOSAR-DENK 50/12.5 | LOSARTAN + HYDROCHLOROTHIAZIDE | 50MG + 12.5MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2376 | NDA/MAL/HDP/4318 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | AKUGABALIN | PREGABALIN | 75 MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 07/01/2016 |
| 2377 | NDA/MAL/HDP/4320 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | HYOSCINE BUTYL BROMIDE | HYOSCINE BUTYL BROMIDE | 10MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2005 |
| 2378 | NDA/MAL/HDP/4325 | AJANTA PHARMA LTD 31-0 | ABACUS PHARMA (AFRICA) LIMITED | ACTINAC 100 | ACECLOFENAC | 100MG | AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X2.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2379 | NDA/MAL/HDP/4329 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-CPM | CHLORPHENIRAMINE MALEATE | 2MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2010 |
| 2380 | NDA/MAL/HDP/4330 | SPARSH BIO-TECH PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCLOXACILLIN CAPSULES | FLUCLOXACILLIN | 250MG | SPARSH BIO-TECH PVT. LTD.--PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE STRIP | 01/07/2016 |
| 2381 | NDA/MAL/HDP/4331 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | STEDNAC | ACECLOFENAC | 100MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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| 2382 | NDA/MAL/HDP/4334 | DENK PHARM GMBH&CO.KG | BENLE CONSULT LIMITED | LOSAR-DENK 50 | LOSARTAN | 50MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2011 |
| 2383 | NDA/MAL/HDP/4335 | DAWA LIMITED | SUPER MEDIC LTD | CURAMOL SUSPENSION | PARACETAMOL | 120MG/5ML | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2009 |
| 2384 | NDA/MAL/HDP/4339 | GLAXOSMITHKLINE LIMITED | UNITED HEALTHCARE DISTRIBUTORS LTD | SERETIDE 125 EVOHALER | SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE | 25MCG/125MCG | GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX | FRANCE | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X120.0 METERED DOSE CANNISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2385 | NDA/MAL/HDP/4340 | ASTRA PHARMA (U) LTD | ASTRA PHARMA (U) LIMITED | VITAMIN B COMPLEX | VITAMIN B1 + VITAMIN B2 + SODIUM NICOTINAMIDE + VITAMIN B6 + D-PANTHENOL SODIUM | 10MG + 1.37MG + 15MG + 1MG + 0.5MG | WUHAN FUXING BIOLOGICAL PHARMACEUTICAL COMPANY LIMITED-NO. 9 FUXING ROAD HANCHUAN ECONOMIC DEVELOPMENT DISTRICT, HUBEI PROVINCE - CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2008 |
| 2386 | NDA/MAL/HDP/4348 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | MEDICLOAMP SYRUP | CLOXACILLIN+AMPICILLIN | 250MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2387 | NDA/MAL/HDP/4350 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | OLFEN-75 | DICLOFENAC SODIUM | 75MG/2ML | MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN HAUPT PHARMA WULFING GMBH.-BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X2.0 ML AMPOULE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2388 | NDA/MAL/HDP/4352 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REQUIN SYRUP | QUININE HYDROCHLORIDE | 100MG/5ML | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2001 |
| 2389 | NDA/MAL/HDP/4356 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | FRESHEN | BISACODYL | 5 MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X12.0 TABLET BLISTER | 01/07/2016 |
| 2390 | NDA/MAL/HDP/4358 | A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LIOTON | HEPARIN SODIUM | 1000I.U/G | A. MENARINI MANUFACTURING LOGICTICS AND SERVICES-VIA 3 SETTE SANTI FLORENCE 50131 ITALY | ITALY | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE,1.0X15.0 G TUBE | 01/07/2016 |

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| 2391 | NDA/MAL/HDP/4361 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | TAXIM-O | CEFIXIME | 200MG | ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2392 | NDA/MAL/HDP/4362 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LEVOMAC 750 | LEVOFLOXACIN HEMIHYDRATE | 750MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2393 | NDA/MAL/HDP/4365 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ACTINAC PLUS | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | AJANTA PHARMA LIMITED-B-4/5/6,MIDC AREA, PAITHAN,431 148 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2394 | NDA/MAL/HDP/4366 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | CLOXISPA | CLOXACILLIN | 250MG | SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2004 |
| 2395 | NDA/MAL/HDP/4367 | ASTRA ZENECA | MACNAUGHTON LIMITED | ATACAND 8MG | CANDESARTAN | 8MG | ASTRA ZENECA AB, SODERTALJE-GARTUNAYEGEN, SODERTALJE | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2010 |
| 2396 | NDA/MAL/HDP/4375 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | ZITHROMAX | AZITHROMYCIN DIHYDRATE | 200MG/5ML | HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE PFIZER LABORATORIES (PTY) LTD;--SOUTH AFRICA | ITALY | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE | 01/07/1997 |

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| 2397 | NDA/MAL/HDP /4379 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | SINURHON | MULTI-INGREDIENT | 5MG/ 2MG/ 500MG / 30MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X12.0X40.0 TABLET BLISTER,1.0X1.0X6.0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER | 01/07/2010 |
| 2398 | NDA/MAL/HDP /4380 | GLAXO WELLCOME (KENYA) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ZINNAT SUSPENSION | CEFUROXIME AXETIL- | 125MG/5ML | GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED | UNITED KINGDOM | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE | 01/07/1998 |
| 2399 | NDA/MAL/HDP /4388 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | TAZOBAK | PIPERACILLIN SODIUM + TAZOBACTAM SODIUM | 4.0G + 0.5G | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X4.5 G VIAL | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2400 | NDA/MAL/HDP /4390 | AUROLAB | SWASTIK PHARMACEUTICA L LTD | AUROCOL | CHLORAMPHENIC OL | 0.5%W/V | AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA | INDIA | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE | 01/07/2016 |
| 2401 | NDA/MAL/HDP /4392 | IND SWIFT LTD | PLANET PHARMACEUTICA LS UGANDA LTD | CAPLOR | CLOPIDOGREL | 75MG | IND SWIFT LTD-GBU JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2402 | NDA/MAL/HDP /4394 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | NS | SODIUM CHLORIDE | 0.9% W/V | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE | 01/07/2010 |

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| 2403 | NDA/MAL/HDP /4396 | MYLAN LABORATORIES LIMITED (OTL) | KIMSY MEDS LTD | ABACAVIR SULPHATE | ABACAVIR SULFATE | 300MG | MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2007 |
| 2404 | NDA/MAL/HDP /4399 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | GEFIL | COMPOUND MAGNESIUM TRISILICATE | ALUMINIUM HYDROXIDE & MAGNESIUM TRISILICATE 132 & | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2005 |
| 2405 | NDA/MAL/HDP /4400 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | ORAL REHYDRATION SALT (DTS) | ORAL REHYDRATION SALT | N/A | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X100.0X20.6 G SACHET,1.0X100.0 X10.3 G SACHET | 01/07/1997 |

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| 2406 | NDA/MAL/HDP/4401 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPICEPHIN | CEFTRIAXONE DISODIUM | 2G | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X2.0 G VIAL + 2*5 ML OF WFI GLASS AMPOULES | 01/07/2014 |
| 2407 | NDA/MAL/HDP/4402 | VIRBAC RSA (PTY) LTD | METRO PHARMACEUTICALS LIMITED | CLOTRILIN | CLOTRIMAZOLE | 100MG | LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR,GUJARAT, INDIA | INDIA | VAGINAL TABLETS | 1.0X6.0 TABLET STRIP | 01/07/2014 |
| 2408 | NDA/MAL/HDP/4404 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | FOLIGRAF | RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE | 75I.U/ VIAL | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2409 | NDA/MAL/HDP /4406 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | SATISFIL -100 | SILDENAFIL | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2011 |
| 2410 | NDA/MAL/HDP /4407 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | SUXAMETHONIUM CHLORIDE-FRESENIUS | SUXAMETHONIUM CHLORIDE | 100MG/2ML | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD V-6 GIBAUD…ROAD KORSTEN, PORT ELIZABETH, SOUTH AFRICA. | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2016 |
| 2411 | NDA/MAL/HDP /4408 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | UNISTEN CREAM | CLOTRIMAZOLE | 1%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1997 |

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| 2412 | NDA/MAL/HDP/4411 | ASTRAZENECA AG | MACNAUGHTON LIMITED | ATACAND PLUS | CANDESARTAN + HYDROCHLOROTHIAZIDE | 16 MG + 12.5 MG | ASTRA ZENECA AB, SODERTALJE-GARTUNAYEGEN, SODERTALJE | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2010 |
| 2413 | NDA/MAL/HDP/4413 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPICEPHIN | CEFTRIAXONE | 1G | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL (+ 1 GLASS AMPOULE OF 10ML WFI) | 01/07/2011 |
| 2414 | NDA/MAL/HDP/4415 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | CATAFLAM 5OMG TABLETS | DICLOFENAC POTASSIUM | 50MG | NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY NOVARTIS--URUNLERI INSTABUL TURKEY | ITALY | ORAL SOLID ORDINARY COATED TABLETS | 10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2415 | NDA/MAL/HDP /4417 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPICEPHIN | CEFTRIAXONE SODIUM | 500MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES | 01/07/2014 |
| 2416 | NDA/MAL/HDP /4418 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | VALORAN | CEFOTAXIME | 1000MG | MEDOCHEMIC LTD-1-10 ASTRONAFTON & CONSTANTINOPOLEOS 3505 LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 VIAL CARTON | 01/07/2009 |
| 2417 | NDA/MAL/HDP /4419 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIGONAL 75 | HUMAN MENOPAUSAL GONADOTROPHIN | 75IU/5ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NACL | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2418 | NDA/MAL/HDP /4425 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REQUIN FC | QUININE | 300MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 2419 | NDA/MAL/HDP /4480 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | KIPEL 5 | MONTELUKAST | 5MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2420 | NDA/MAL/HDP /4483 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | WORMOL SUSPENSION | MEBENDAZOLE | 100MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE,1.0X100.0 L BOTTLE | 01/07/1997 |

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| 2421 | NDA/MAL/HDP/4519 | ARISTO PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | S-AMLOSAFE 5 | AMLODIPINE BESILATE | 5MG | ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA N0 11 MANDIDEEP | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2422 | NDA/MAL/HDP/4522 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | S-AMLOSAFE 2.5 | AMLODIPINE BESILATE | 2.5 MG | ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA N0 11 MANDIDEEP | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2423 | NDA/MAL/HDP/4523 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | BIGOMET SR 500 | METFORMIN HYDROCHLORIDE | 500MG | ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2424 | NDA/MAL/HDP/4524 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCOZAL 150 | FLUCONAZOLE | 150MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0 CAPSULE BLISTER | 01/07/2008 |
| 2425 | NDA/MAL/HDP/4526 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AZ-500 | AZITHROMYCIN | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2011 |
| 2426 | NDA/MAL/HDP/4528 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | PIOSAFE MF 15/500 | PIOGLITAZONE + METFORMIN | 15 MG + 500 MG | ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2427 | NDA/MAL/HDP/4530 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | TREDOL 100 | ATENOLOL | 100MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2428 | NDA/MAL/HDP/4531 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | TREDOL 50 | ATENOLOL | 50MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2429 | NDA/MAL/HDP/4532 | DELOBORIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | VIRUCID 400 | ACICLOVIR | 400 MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2430 | NDA/MAL/HDP /4534 | DELOBORIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | LORYTEC 10 | LORATADINE | 10MG | DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2431 | NDA/MAL/HDP /4536 | SEDICO PHARMACEUTICAL CO. | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FLUCAMOX | FLUCLOXACILLIN + AMOXICILLIN | 250MG+250MG | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0X4.0 CAPSULE STRIP | 01/07/2004 |
| 2432 | NDA/MAL/HDP /4540 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | VIPROLOX 500 | CIPROFLOXACIN | 500MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2433 | NDA/MAL/HDP/4542 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | CLERON 500 | CLARITHROMYCIN | 500MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 01/07/2008 |
| 2434 | NDA/MAL/HDP/4544 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | SALBUT TABLET 4MG | SALBUTAMOL | 4MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER | 01/07/2000 |
| 2435 | NDA/MAL/HDP/4545 | CACHET PHAMACUITICALS PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | CACH-ART 20/120 | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X8.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2436 | NDA/MAL/HDP/4546 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | CHLORAMPHENICOL INJECTION IG | CHLORAMPHENICOL SODIUM SUCCINATE | 1G | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-#14, II PHASE PIA, BANGALORE 560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X100.0X1.0 G VIAL,1.0X50.0X1.0 G VIAL | 01/07/1998 |
| 2437 | NDA/MAL/HDP/4553 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | ARTESUN | ARTESUNATE | 30MG | GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE | 01/07/2011 |
| 2438 | NDA/MAL/HDP/4556 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CLAVAM 375 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 250MG + 125MG | INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH - 173205 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2439 | NDA/MAL/HDP/4559 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | PREGASAFE 75 | PREGABALIN | 75MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 2440 | NDA/MAL/HDP/4561 | TORRENT PHARMACEUTICALS LTD | KARURI PHARMACEUTICALS LTD. | LORVAS SR | INDAPAMIDE | 1.5MG | TORRENT PHARMACEUTICALS LTD. - AHMEDABAD-MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET CONTAINER | 01/07/2009 |
| 2441 | NDA/MAL/HDP/4568 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CLAVAM 625 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 500MG + 125MG | INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH - 173205 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2442 | NDA/MAL/HDP /4575 | FDC LTD | AIVEEN (U) LIMITED | PYRICORT EYE/EAR DROPS | DEXAMETHASONE +GENTAMICIN | 0.1%+0.3%W/V | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2013 |
| 2443 | NDA/MAL/HDP /4581 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CLAVAM 1000 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 875MG + 125MG | INDCHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL PRADESH - 173205 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET STRIP | 01/07/2005 |
| 2444 | NDA/MAL/HDP /4588 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | FLUCAN 200 | FLUCONAZOLE | 200MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2445 | NDA/MAL/HDP /4591 | S KAGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | SILVER KANT | SILVER SULPHADIAZINE USP | 1%W/W | S.KANT HEALTHCARE LTD-1802-18-5 GIDC PHASE III, VAPI-396195,GUJARAT INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2009 |
| 2446 | NDA/MAL/HDP /4592 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | PENTALINK 40 | PANTOPRAZOLE | 40MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2447 | NDA/MAL/HDP /4593 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | ERYTHROKANT-250 | ERYTHROMYCIN STEARATE | 250MG | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2448 | NDA/MAL/HDP/4594 | CADILA HEALTH CARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TINIBA-500 TABLETS | TINIDAZOLE | 500MG | CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA. . | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X60.0X4.0 TABLET BLISTER,1.0X25.0X 4.0 TABLET BLISTER,1.0X5.0X5. 0X4.0 TABLET BLISTER | 01/07/1997 |
| 2449 | NDA/MAL/HDP/4595 | LINCOLN PHARMACEUTICAL S LTD | METRO PHARMACEUTICA LS LIMITED | VAST-20 | ATORVASTATIN | 20MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1 0.0 TABLET BLISTER | 01/07/2010 |
| 2450 | NDA/MAL/HDP/4598 | GITTOES PHARMACEUTICAL S LIMITED | GITTOES PHARMACEUTICA LS LIMITED | AZ-250 | AZITHROMYCIN | 250MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2451 | NDA/MAL/HDP/4602 | ELI-LILLY (SUISSE) SA | LABOREX UGANDA LIMITED | HUMALOG MIX 50 | INSULIN LISPRO | 100 .IU(50 I.U+50 I.U) | LILLY FRANCE SA-FRANCE | FRANCE | PARENTERAL ORDINARY S C VIALS | 1.0X3.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/2000 |
| 2452 | NDA/MAL/HDP/4603 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | HALOXEN - 5 | HALOPERIDOL | 5MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2453 | NDA/MAL/HDP/4605 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGODRYL SYRUP | BROMHEXINE HCL+DEXTROMETHORPHAN HBR+AMMONIUM CHLORIDE+MENTHOL | 4MG/5ML+5MG/5ML+50MG/5ML+2.5MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE | 01/07/2009 |

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| 2454 | NDA/MAL/HDP/4606 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | ROVAS 10 | ROSUVASTATIN | 10MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2455 | NDA/MAL/HDP/4609 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYCORT | HYDROCORTISONE | 1%W/W | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2456 | NDA/MAL/HDP/4611 | DAFRA PHARMA LTD | MULTIPHAR UGANDA LIMITED | DAFRACLAV | AMOXYCILLIN + POTASSIUM CLAVULANATE | 200MG + 28MG | BILIM ILAC SAN. VE. TIC. A.S.-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC, MH. 5. SK. NO. 6, KAPAKLI - TEKIRDAG 59510 | TURKEY | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2457 | NDA/MAL/HDP /4614 | GALENTIC PHARMA LTD | VITACARE LIMITED | COMPOUND BENZOIC ACID OINTMENT | BENZOIC ACID + SALICYLIC ACID | 6 %W/W + 3 %W/W | GALENTIC PHARMA( INDIA ) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X25.0 G TUBE,1.0X500.0 G TUBE | 01/07/2006 |
| 2458 | NDA/MAL/HDP /4615 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | TASIGNA 150 | NILOTONIB HYDROCHLORIDE MONOHYDRATE | 150MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. | SWITZERLAND | ORAL SOLID ORDINARY CAPSULES | 1.0X7.0X4.0 CAPSULE BLISTER | 01/07/2014 |
| 2459 | NDA/MAL/HDP /4619 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CHLORAMPHENICOL SODIUM SUCCINATE | CHLORAMPHENICOL SODIUM SUCCINATE | 1G | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | CHINA | PARENTERAL ORDINARY VIALS | 1.0X50.0X1.0 G VIAL | 01/07/2009 |

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| 2460 | NDA/MAL/HDP /4620 | GLAXO SMITH KLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | MALANIL PAEDIATRIC TABLET | ATOVAQUONE + PROGUANIL | 62.5 MG + 25.0 MG | GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS | SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 01/07/2007 |
| 2461 | NDA/MAL/HDP /4622 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | CLOXAREN | CLOXACILLIN | 250MG | RENE INDUSTRIES-PLOT 680 KAMULI KIREKA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER | 01/07/2007 |
| 2462 | NDA/MAL/HDP /4623 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | LOPERAREN | LOPERAMIDE HYDROCHLORIDE | 2MG | RENE INDUSTRIAL LTD-RENE INDUSTRIES LTD, PLOT 680, KAMULI-KIREKA KAMPALA UGANDA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2007 |

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| 2463 | NDA/MAL/HDP /4626 | ACINO PHARMA AG - | GOODMAN INTERNATIONAL LTD | GASEC-20 | OMEPRAZOLE | 20MG | ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X14.0 CAPSULE BOTTLE | 01/07/2005 |
| 2464 | NDA/MAL/HDP /4627 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | HYCORUM CREAM | HYDROCORTISONE | 1%W/W | LABORATORY AND ALLIED LTD-PLOT 209/10349-MOMBASA ROAD NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2465 | NDA/MAL/HDP /4634 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | LOSAR-DENK 100 | LOSARTAN | 100MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2011 |

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| 2466 | NDA/MAL/HDP/4636 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | ZOLARAM 0.5 | ALPRAZOLAM | 0.5MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2467 | NDA/MAL/HDP/4641 | YURIA PHARM LTD-UKRAINE | PHARMA VILLE LIMITED | RHEOSORBILACT | SORBITOL + SODIUM LACTATE + NACL + CALCIUM CHLORIDE + MAGNESIUM CHLORIDE | 6G +1.9G +0.6G + 0.01G +0.03G +0.02 | YURIA-PHARM LLC MANUFACTURING SITE NO. 1-108, KOBZARSKA STREET, CHERKASY, 18030 | UKRAINE | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X200.0 ML BOTTLE,1.0X400.0 ML BOTTLE | 01/07/2013 |
| 2468 | NDA/MAL/HDP/4650 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | DUOTRAV | TRAVOPROST + TIMOLOL MALEATE | 40MG/ML + 5MG/ML | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X1.0X2.5 ML VIAL | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2469 | NDA/MAL/HDP/4652 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | SII TETANUS TOXOID VACCINE | TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE | ≥ 5 LF (≥ 40 IU) ON ≤ 1.25 MG OF ALUMINIUM PHOSPHATE | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0 ML AMPOULE (1 DOSE AMPOULE),1.0X10.0 ML VIAL (20 DOSE VIAL) | 01/07/1997 |
| 2470 | NDA/MAL/HDP/4657 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | VOLAR 300MG | GABAPENTIN | 300MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2013 |
| 2471 | NDA/MAL/HDP/4658 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | MEROSAN 0.5 | MEROPENEM | 0.5G | PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA | INDONESIA | PARENTERAL ORDINARY DRY VIALS | 1.0X0.5 G VIAL | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2472 | NDA/MAL/HDP /4660 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | RISDONE 2MG | RISPERIDONE | 2MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2473 | NDA/MAL/HDP /4666 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | ANTIPLEX | CLOPIDOGREL BISULFATE | 30MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2474 | NDA/MAL/HDP /4669 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | DICLOGESIC 100MG SUPPOSITORIES | DICLOFENAC SODIUM. | 100MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | TOPICAL EXTERNAL ADULT SUPPOSITORIES | 1.0X5.0 SUPPOSITORY STRIP | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2475 | NDA/MAL/HDP/4670 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOX 500 | AMOXICILLIN | 500MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 2476 | NDA/MAL/HDP/4675 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | DICLOGESIC RETARD 100 | DICLOFENAC SODIUM | 100MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X6.0 CAPSULE BLISTER | 01/07/2013 |
| 2477 | NDA/MAL/HDP/4677 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | ZOCEF | CEFUROXIME | 125MG/5ML | ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML BOTTLE,1.0X70.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2478 | NDA/MAL/HDP/4678 | : ALKEM LABORATORIES LIMITEDv | ABACUS PHARMA (AFRICA) LIMITED | ZOCEF-500 | CEFUROXIME AXETIL | 500MG | ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2479 | NDA/MAL/HDP/4680 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANCEPH DS | CEPHALEXIN | 125MG/5ML | SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 2480 | NDA/MAL/HDP/4690 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYPEN | PHENOXYMETHYL PENICILLIN | 250MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2481 | NDA/MAL/HDP /4693 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELYVATE | BETAMETHASONE VALERATE | 1%W/W | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2482 | NDA/MAL/HDP /4694 | MERCK SHARP & DOHME INTAPHARMA | SURGIPHARM (U) LIMITED | ROTATEQ | ROTAVIRUS LIVE REASSORTANT VIRUS G1+G2+G3+G4 &P1 | 2.2M IU+2.8M IU+2.2M IU+2.0M IU | MERK & CO. INC-SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA | UNITED STATES | ORAL LIQUID ORDINARY EMULSIONS | 1.0X10.0 ML BOTTLE | 01/07/2011 |
| 2483 | NDA/MAL/HDP /4697 | PT SAMBE FARMA | MEDVIN PHARMA LIMITED | SANBE CLANEKSI | AMOXICILLIN + CLAVULANIC ACID | 1000 MG + 200 MG | PT SANBE FARMA-JI LEUIGAJAH NO. 162 CIMINDI, INDONESIA | INDONESIA | PARENTERAL ORDINARY VIALS | 1.0X6.0 VIAL CARTON | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2484 | NDA/MAL/HDP/4701 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | MEBRONE 100 TABLETS | MEBENDAZOLE | 100MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2485 | NDA/MAL/HDP/4702 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABTOL 20%W/V | MANNITOL | 200MG/ML | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, P MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2011 |
| 2486 | NDA/MAL/HDP/4703 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABGYL | METRONIDAZOLE | 500MG | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, P MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2487 | NDA/MAL/HDP /4704 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | DICLOGESIC 12.5 | DICLOFENAC SODIUM | 12.5MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY BLISTER | 01/07/2012 |
| 2488 | NDA/MAL/HDP /4705 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | DICLOGESIC-50 | DICLOFENAC | 50MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY BLISTER | 01/07/2012 |
| 2489 | NDA/MAL/HDP /4706 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | DICLOMOL GEL | DICLOFENAC DIETHYLAMINE | 1.16%W/W | G,S PHARMBUTOR PVT LTD - B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G CONTAINER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2490 | NDA/MAL/HDP /4707 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | DICLOMOL INJECTION | DICLOFENAC SODIUM | 25MG/ML | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X3.0 ML AMPOULE | 01/07/1998 |
| 2491 | NDA/MAL/HDP /4710 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | MEDOPRESS TABLETS 250MG | METHYLDOPA | 250MG | COSMOS LIMITED..-RANGWE ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 2492 | NDA/MAL/HDP /4712 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | MEFINAL-500 | MEFENAMIC ACID | 500MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2493 | NDA/MAL/HDP/4715 | BLUE CROSS LABARATORIES LIMITED | STAR PHARMACEUTICALS LTD | MEFTAL FORTE | MEFENAMIC ACID + PARACETAMOL | 500MG + 450MG | BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X2.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2494 | NDA/MAL/HDP/4717 | BLUE CROSS LABARATORIES LIMITED | STAR PHARMACEUTICALS LTD | MEFTAL-SPAS | MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE | 250MG + 10MG | BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X3.0X10.0 TABLET BLISTER,1.0X10.0X3.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2495 | NDA/MAL/HDP/4718 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | ACNOTIN 20 | ISOTRETINOIN | 20MG | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280 | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2496 | NDA/MAL/HDP/4719 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | ACNOTIN 10 | ISOTRETINOIN | 10MG | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280 | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2011 |
| 2497 | NDA/MAL/HDP/4721 | PT SAMBE FARMA | MEDVIN PHARMA LIMITED | MEGABAL | MECOBALAMIN | 5000MCG | PT SANBE FARMA,UNIT 1-JI INDUSTRI NO.9 LEUWIGAJAH CIMINDI CIMAHI WEST JAVA,INDONESIA | INDONESIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/2011 |
| 2498 | NDA/MAL/HDP/4723 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | MEGYL SUSPENSION | METRONIDAZOLE BENZOATE | 200MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2499 | NDA/MAL/HDP/4725 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | MEGYL TABLET | METRONIDAZOLE | 200MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2500 | NDA/MAL/HDP/4726 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | ADB MIN MULTIPOWER | MULTI-INGREDIENT | MULTI-INGREDIENT | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X300.0 ML BOTTLE | 01/07/1997 |
| 2501 | NDA/MAL/HDP/4731 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | MENAFRIVAC | MENINGOCOCCAL A CONJUGATE VACCINE | 10MCG/ 0.5ML + 10-33MCG/0.5ML | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X10.0 DOSE VIAL + 1*5ML AMPOULE OF DILUENT | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2502 | NDA/MAL/HDP /4738 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | CILOXAN | CIPROFLOXACIN | 0.3%W/V | ALCON PHARMACEUTICALS LIMITED-ALCON COUVREUR NV B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |
| 2503 | NDA/MAL/HDP /4743 | DAFRA PHARMA N.V/S.A | MULTIPHAR UGANDA LIMITED | MERONIA 1000 | MEROPENEM | 1000MG | DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS | GREECE | PARENTERAL ORDINARY VIALS | 1.0X1000.0 MG VIAL | 01/07/2013 |
| 2504 | NDA/MAL/HDP /4744 | DAFRA PHARMA N.V/S.A | MULTIPHAR UGANDA LIMITED | MERONIA 500 | MEROPENEM | 500MG | DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS | GREECE | PARENTERAL ORDINARY DRY VIALS | 1.0X500.0 MG VIAL | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2505 | NDA/MAL/HDP/4745 | ALKEM LABORATORIES LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PIPZO | PIPERACILLIN + TAZOBACTAM | 4.5G | ALKEM LABS LTD.-VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X4.5 G VIAL + STERILIZED WATER FOR INJECTION | 01/07/2014 |
| 2506 | NDA/MAL/HDP/4747 | RIVA PHARMA FREE ZONE | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ZITHRORIV | AZITHROMYCIN | 200MG/5ML | RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT | EGYPT | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X22.5 ML BOTTLE | 01/07/2011 |
| 2507 | NDA/MAL/HDP/4748 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | ACICONE-S CHEWABLE TABLET | MAGALDRATE+SIMETHICONE | 720MG+25MG | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X5.0X4.0 TABLET BLISTER | 01/07/2006 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2508 | NDA/MAL/HDP /4749 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | MEROSAN | MEROPENEM | 1G | PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA | INDONESIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2012 |
| 2509 | NDA/MAL/HDP /4751 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FEROL | FERROUS SULPHATE | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2510 | NDA/MAL/HDP /4757 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | METFORMIN-DENK 500 | METFORMIN | 500MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2511 | NDA/MAL/HDP /4758 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | METFORMIN DENK 1000 | METFORMIN | 1000MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X15.0 TABLET BLISTER | 01/07/2011 |
| 2512 | NDA/MAL/HDP /4759 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CIPRODAR | CIPROFLOXACIN | 500MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2513 | NDA/MAL/HDP /4766 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOBEN SUSPENSION | MEBENDAZOLE | 100MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2514 | NDA/MAL/HDP /4767 | MEDIPAK LIMITED | HEALTHCARE LTD. | CIPROFENA | CIPROFLAXACIN HYDROCHLORIDE | 0.3%W/V | MEDIPAK LIMITED-132/1 INDUSTRIAL AREA KOTLAKHPAT LAHORE | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X5.0 ML VIAL | 01/07/2006 |
| 2515 | NDA/MAL/HDP /4769 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOBEX | MEBENDAZOLE | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER | 01/07/2009 |
| 2516 | NDA/MAL/HDP /4784 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | D50 | GLUCOSE INTRAVENOUS INFUSION | 50%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2517 | NDA/MAL/HDP /4785 | JASSEN-CILAG (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | DAKTACORT | MICONAZOLE NITRATE+HYDROCORTISONE | 2%W/W+1%W/W | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE | SOUTH AFRICA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2518 | NDA/MAL/HDP /4787 | JASSEN-CILAG (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | DAKTARIN | MICONAZOLE NITRATE | 20MG/G | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE | SOUTH AFRICA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1997 |
| 2519 | NDA/MAL/HDP /4788 | JASSEN-CILAG (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | DAKTARIN ORAL GEL | MICONAZOLE NITRATE | 20MG/G | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE | SOUTH AFRICA | ORAL TOPICAL GELS AND SOLS | 1.0X40.0 G TUBE | 01/07/1997 |

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| 2520 | NDA/MAL/HDP /4789 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | DALACIN C | CLINDAMYCIN HYDROCHLORIDE | 300MG | FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE | FRANCE | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0 CAPSULE CARTON,1.0X2.0X8 .0 CAPSULE STRIP | 01/07/1997 |
| 2521 | NDA/MAL/HDP /4790 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | DALACIN C | CLINDAMYCIN HYDROCHLORIDE | 150MG | FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE | BELGIUM | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X8.0 CAPSULE STRIP,1.0X100.0 CAPSULE CARTON | 01/07/1997 |
| 2522 | NDA/MAL/HDP /4792 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | DALACIN C | CLINDAMYCIN PHOSPHATE | 150MG/ML | PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM | BELGIUM | PARENTERAL ORDINARY VIALS | 1.0X4.0 ML VIAL,1.0X2.0 ML VIAL | 01/07/1997 |

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| 2523 | NDA/MAL/HDP /4794 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | DALADOL | DICLOFENAC SODIUM + PARACETAMOL | 50MG+500MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2012 |
| 2524 | NDA/MAL/HDP /4795 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | DAROXIME | CEFUROXIME | 500MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BOTTLE | 01/07/2010 |
| 2525 | NDA/MAL/HDP /4796 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | DARROWS SOLUTION (HALF STRENGTH) | POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE | 0.13%+0.20%+0.30 % | ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2011 |

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| 2526 | NDA/MAL/HDP/4800 | DAWA LIMITED | SUPER MEDIC LTD | DAWAVITE SYRUP | MULTI-INGREDIENT | MULTI-INGREDIENT | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2009 |
| 2527 | NDA/MAL/HDP/4801 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | DAZEL KIT | FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE | 150MG + 1G + 1G | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 01/07/2009 |
| 2528 | NDA/MAL/HDP/4804 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CLAVODAR | AMOXICILLIN + CLAVULANIC | 200MG + 28MG /5ML | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 01/07/2012 |

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| 2529 | NDA/MAL/HDP/4806 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFER | FERROUS SULPHATE+FOLIC ACID | 200MG + 0.25MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2530 | NDA/MAL/HDP/4807 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOFORMIN | METFORMIN | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 2531 | NDA/MAL/HDP/4809 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCORT SKIN CREAM | HYDROCORTISONE | 0.1%W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |

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| 2532 | NDA/MAL/HDP /4811 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOGYL | METRONIDAZOLE | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER | 01/07/2009 |
| 2533 | NDA/MAL/HDP /4812 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOMETROL SUSPENSION | METRONIDAZOLE BENZOATE | 125MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2001 |
| 2534 | NDA/MAL/HDP /4815 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | FERROLIC-LF | FERROUS SULPHATE +FOLIC ACID | 200MG+0.4MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER | 01/07/2014 |

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| 2535 | NDA/MAL/HDP/4818 | LABORATORY AND ALLIED LTD | HARLEYS UGANDA LIMITED | FERROUS SULPHATE | FERROUS SULPHATE | 200MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2536 | NDA/MAL/HDP/4819 | FDC LIMITED | AIVEEN (U) LIMITED | ORAL REHYDRATION SALT | ORAL REHYDRATION SALT | 21.8G | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | ORAL LIQUID ORDINARY UNIT DOSE POWDERS | 1.0X21.8 G SACHET | 01/07/2000 |
| 2537 | NDA/MAL/HDP/4821 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | METPURE-XL 50 | METOPROLOL | 50MG | EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI-BRAHMANA JAMMU ,181133 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2538 | NDA/MAL/HDP/4823 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | METRIS INFUSION | METRONIDAZOLE | 5MG/ML | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2539 | NDA/MAL/HDP/4826 | UNIQUE PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | METROGYL DENTA GEL | METRONIDAZOLE + CHLORHEXIDINE | 1%W/W + 0.25%W/W | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2004 |
| 2540 | NDA/MAL/HDP/4828 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | METROGYL GEL | METRONIDAZOLE | 1%W/W | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH | INDIA | TOPICAL EXTERNAL EMULSION GELS | 1.0X30.0 G TUBE (ALUMINIUM TUBE),1.0X30.0 G TUBE (LAMINATED TUBE) | 01/07/2001 |

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| 2541 | NDA/MAL/HDP/4830 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | METROGYL INJECTION | METRONIDAZOLE | 5MG/ML | UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--304-308 GIDC INDUSTRIAL | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2542 | NDA/MAL/HDP/4832 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | METROGYL SUSPENSION | METRONIDAZOLE | 200MG/5ML | UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA. J.B. CHEMICALS AND PHARMACEUTICALS LTD .-128/1, GIDC, ANKLESHWAR 393 002, GUJARAT | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2543 | NDA/MAL/HDP/4836 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | METRON | METRONIDAZOLE | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2009 |

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| 2544 | NDA/MAL/HDP/4839 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | ANOMEX | ZINC OXIDE+LIDOCAINE+HYDROCORTISONE+ALLANTOIN | 5%W/W+3%W/W+0.25%W/W+0.5%W/W | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X5.0 SUPPOSITORY BLISTER,1.0X2.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 2545 | NDA/MAL/HDP/4851 | SHAIGAN PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | CLOZOX V | CLOTRIMAZOLE | 100MG | SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN | PAKISTAN | VAGINAL TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 07/10/2004 |
| 2546 | NDA/MAL/HDP/4854 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | METROREN FC | METRONIDAZOLE | 200MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2014 |

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| 2547 | NDA/MAL/HDP/4855 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | ASCORIL EXPECTORANT | SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN + MENTHOL | (2MG + 4MG + 100MG + 1MG)/10ML | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2000 |
| 2548 | NDA/MAL/HDP/4856 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | METROREN | METRONIDAZOLE | 200MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2001 |
| 2549 | NDA/MAL/HDP/4858 | RENE INDUSTRIES | RENE INDUSTRIES LIMITED | METROREN SUSPENSION | METRONIDAZOLE BENZOATE | 200MG/5ML | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2001 |

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| 2550 | NDA/MAL/HDP/4863 | MEDICAL UNION PHARMACUITICALS | KARURI PHARMACEUTICALS LTD. | MICONAZ ORAL GEL | MICONAZOLE | 2%W/W | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | ORAL TOPICAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2003 |
| 2551 | NDA/MAL/HDP/4865 | MEDICAL UNION PHARMACUITICALS | KARURI PHARMACEUTICALS LTD. | MICONAZ CREAM | MICONAZOLE NITRATE | 2%W/W | MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT | EGYPT | VAGINAL CREAMS | 1.0X20.0 G TUBE | 01/07/2003 |
| 2552 | NDA/MAL/HDP/4867 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | MICONA ORAL GEL | MICONAZOLE | 20MG | CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526 | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X40.0 G TUBE,1.0X20.0 G TUBE | 01/07/2003 |

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| 2553 | NDA/MAL/HDP/4872 | DAWA LIMITED | SUPER MEDIC LTD | MICLOCIN CREAM | MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICN | 2%W/W+0.5%W/W+0.1W/W | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |
| 2554 | NDA/MAL/HDP/4875 | PHARM ACCESS AFRICA LTD | MARIE STOPES UGANDA LIMITED | MISOCLEAR | MISOPROSTOL | 200MCG | ACME FORMULATION PVT LTD,-ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2555 | NDA/MAL/HDP/4880 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | MISOPROST 200 | MISOPROSTOL | 200MCG | CIPLA LTD .-CIPLA GOA UNIT 8 L-147 TO L-147/1 L-147-3 TO L-138 VERNA INDUSTRIAL ESTATE VERNA GOA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER,1.0X7.0X4.0 TABLET BLISTER,1.0X15.0X4.0 TABLET BLISTER | 01/07/2014 |

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| 2556 | NDA/MAL/HDP /4887 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCOZAL | FLUCONAZOLE | 200MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 2557 | NDA/MAL/HDP /4889 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCOZAL | FLUCONAZOLE | 50MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X14.0 CAPSULE BLISTER | 01/07/1999 |
| 2558 | NDA/MAL/HDP /4890 | DELORBIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCOZAL | FLUCONAZOLE | 100MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/1997 |

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| 2559 | NDA/MAL/HDP/4891 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | ASPEC TABLET | ASPIRIN+PARACETAMOL+CAFFEINE ANHYDROUS | 150MG+250MG+300MG | REGAL PHARMACEUTICALS LTD-OFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER | 01/07/1997 |
| 2560 | NDA/MAL/HDP/4895 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CLOMIFERT | CLOMIPHENE | 50MG | DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2561 | NDA/MAL/HDP/4903 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CMT-TABLETS | MAGNESIUM TRISILICATE+DRIED ALUMINIUM HYDROXIDE+PEPPERMINT OIL | 250MG+120MG+0.003ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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| 2562 | NDA/MAL/HDP /4904 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MIXTARD 30 | INSULIN HUMAN | 100 I.U/ML | NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE | DENMARK FRANCE | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/1997 |
| 2563 | NDA/MAL/HDP /4905 | XEPA-SOUL PATTINSON | DELMAW ENTERPRISES LIMITED | AVORAX CREAM | ACYCLOVIR | 5%W/W | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X5.0 G TUBE | 01/07/1997 |
| 2564 | NDA/MAL/HDP /4906 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | AVORAX TABLETS | ACYCLOVIR | 200MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X5.0 TABLET STRIP | 01/07/1997 |

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| 2565 | NDA/MAL/HDP/4907 | XEPA-SOUL PATTINSON | DELMAW ENTERPRISES LIMITED | AVORAX TABLETS | ACYCLOVIR | 400MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250<br>MALEKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X5.0 TABLET STRIP | 01/07/1997 |
| 2566 | NDA/MAL/HDP/4908 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MIXTARD 30 PENFILL | BIPHASIC ISOPHANE INSULIN (HUMAN) | 100 I.U/ML | NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL | DENMARK | PARENTERAL ORDINARY CARTRIDGES | 1.0X1.5 ML FLEXPEN,1.0X5.0X3.0 ML FLEXPEN | 01/07/1997 |
| 2567 | NDA/MAL/HDP/4910 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | FLUZOL | FLUCONAZOLE | 200MG | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2011 |

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| 2568 | NDA/MAL/HDP/4911 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | MOFILET-500 | MYCOPHENOLATE MOFETIL | 500MG | EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI-BRAHMANA JAMMU ,181133 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2569 | NDA/MAL/HDP/4915 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | FOGYL-S TABLETS | METRONIDAZOLE | 200MG | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2570 | NDA/MAL/HDP/4916 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | NEOPROFANE 200 TABLETS | IBUPROFEN | 200MG | FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2001 |

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| 2571 | NDA/MAL/HDP /4917 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL EVILINE FORTE SUSPENSION | MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIMETHICONE | 400MG/5ML+400 MG/5ML+40MG/5 ML | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL--382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | MALAYSIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X120.0 ML BOTTLE | 01/07/2010 |
| 2572 | NDA/MAL/HDP /4918 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | FOGYL SUSPENSION | METRONIDAZOLE BENZOATE | 200MG/5ML | FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2573 | NDA/MAL/HDP /4919 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL FUSIDIC ACID- B CREAM | FUSIDIC ACID+BETAMETHASONE 17 VALERATE | 2%,W/W,+0.1% W/W | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2008 |

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| 2574 | NDA/MAL/HDP/4920 | LEBEN LABORATORIES LTD | MALIX PHARMA (U) LIMITED | FOLIBEN | FOLIC ACID | 5MG | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | NULL | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X20.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2575 | NDA/MAL/HDP/4922 | KOPRAN LIMITED | TATA UGANDA LIMITED | CIPROQUIN-500 | CIPROFLOXACIN | 500MG | KOPRAN LIMITED-VILLAGE-SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER | 01/07/1999 |
| 2576 | NDA/MAL/HDP/4926 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | FOLIC ACID | FOLIC ACID | 5MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2577 | NDA/MAL/HDP/4927 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | AZOPT | BRINZOLAMIDE | 10MG/ML | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC SUSPENSIONS | 1.0X5.0 ML BOTTLE | 01/07/2009 |
| 2578 | NDA/MAL/HDP/4928 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | FOLIC ACID TABLETS | FOLIC ACID | 5MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP | 01/07/1997 |
| 2579 | NDA/MAL/HDP/4929 | MARTINDALE AND AURUM PHARMACEUTICAL | LABOREX UGANDA LIMITED | MORPHINE INJECTION | MORPHINE | 15MG/ML | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/1997 |

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| 2580 | NDA/MAL/HDP/4932 | MARTINDALE AND AURUM PHARMACEUTICAL | LABOREX UGANDA LIMITED | MORPHINE INJECTION | MORPHINE | 10MG/ML | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/1997 |
| 2581 | NDA/MAL/HDP/4933 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | AZUDOX | DOXYCYCLINE HYDROCHLORIDE | 100MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X100.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |
| 2582 | NDA/MAL/HDP/4934 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | FOLIFRED | FOLIC ACID | 5MG | FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2583 | NDA/MAL/HDP /4936 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | COMBIFEN | IBUPROFEN + PARACETAMOL | 400MG + 500MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2584 | NDA/MAL/HDP /4937 | JASSEN-CILAG (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | MOTILIUM | DOMPERIDONE | 10MG | JANSSEN-CILAG-DOMAINE DE MAIGREMONT, 27100 VAL DE REUIL - FRANCE | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0 TABLET BLISTER, 1.0X30.0 TABLET BLISTER | 01/07/1997 |
| 2585 | NDA/MAL/HDP /4939 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | FOLIREN | FOLIC ACID | 5MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2586 | NDA/MAL/HDP/4940 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FOLON | FOLIC ACID | 5MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 2587 | NDA/MAL/HDP/4943 | ASTRAZENECA | MACNAUGHTON LIMITED | NOLVADEX | TAMOXIFEN | 20MG | ASTRAZENECA UK LIMITED - ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2588 | NDA/MAL/HDP/4944 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | BENA EXPECTORANT | DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE | 14MG + 135MG + 57.5MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA | MALAYSIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X120.0 ML BOTTLE | 01/07/1997 |

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| 2589 | NDA/MAL/HDP /4946 | ESAPHARM SRL | BYAMAKA PHARMACEUTICAL COMPANY LTD | MOVATE | CLOBETASOL | 0.05%W/W | ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY | ITALY | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/1999 |
| 2590 | NDA/MAL/HDP /4949 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN DRY COUGH DM | DEXTROMETHORPHAN HYDROBROMIDE | 15MG/ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2591 | NDA/MAL/HDP /4951 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN ORIGINAL | DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE | 12.5 MG/5ML + 125 MG/5ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X2.5 L BOTTLE | 01/07/1997 |

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| 2592 | NDA/MAL/HDP/4952 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN WITH CODEINE | DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + CODEINE PHOSPHATE | 12.5MG/5ML +125MG/5ML +10MG/5ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 01/07/1997 |
| 2593 | NDA/MAL/HDP/4953 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | NAT-B | MULTI-INGREDIENT | MULTI-INGREDIENT | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280 | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2009 |
| 2594 | NDA/MAL/HDP/4956 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | CONTRAPAQUE 350 | IOHEXOL | 350MG | UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0 ML VIAL | 01/07/2010 |

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| 2595 | NDA/MAL/HDP /4957 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | MUMFER | IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID | 100MG + 500MCG | GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2004 |
| 2596 | NDA/MAL/HDP /4958 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BENZOSED | MIDAZOLAM | 1MG/ML | TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X5.0 ML VIAL | 01/07/2011 |
| 2597 | NDA/MAL/HDP /4959 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | CONTUS PAEDIATRIC LINCTUS | CHLORPHENIRAMINE / PHENYLEPHRINE / DEXTROMETHORPHAN | 1MG/ 5MG/ 10MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X50.0 ML BOTTLE | 01/07/2011 |

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| 2598 | NDA/MAL/HDP/4962 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | BETAD | BETAMETHASONE DIPROPRIONATE | 0.05%W/W | S.KANT HEALTHCARE LTD-PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE,1.0X1.0X15.0 G TUBE | 01/07/2010 |
| 2599 | NDA/MAL/HDP/4964 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | CONTUS PLUS PAEDIATRIC SUSPENSION | CHLORPHENAMINE+PHENYLEPHRINE +PARACETAMOL | IMG+5MG+160MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X50.0 ML BOTTLE | 01/07/2011 |
| 2600 | NDA/MAL/HDP/4965 | BETA HEALTHCARE INTERNATIONAL LTD | BETA HEALTHCARE UGANDA LIMITED | BETAFEN SYRUP | IBUPROFEN | 100MG/5ML | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2001 |

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| 2601 | NDA/MAL/HDP/4966 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | CONTUS-650 | CHLORPHENIRAMINE + PHENYLEPHRINE + PARACETAMOL | 2MG + 5MG + 650MG | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X 1.0X6.0 TABLET BLISTER | 01/07/2010 |
| 2602 | NDA/MAL/HDP/4968 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FRUSEMIDE INJECTION | FUROSEMIDE | 10MG/ML | NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2008 |
| 2603 | NDA/MAL/HDP/4969 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | BENZATHINE PENICILLIN | BENZATHINE PENICILLIN | 2.4 M.U | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X2.4 MU VIAL | 01/07/2001 |

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| 2604 | NDA/MAL/HDP/4971 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | FRUSEMIDE TABLETS | FUROSEMIDE | 40MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2605 | NDA/MAL/HDP/4972 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | COOLMINT LISTERINE | MENTHOL + ALCOHOL 95% | 0.02% + 4.58ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X250.0 ML CONTAINER,1.0X500.0 ML CONTAINER | 01/07/2001 |
| 2606 | NDA/MAL/HDP/4973 | MERCK | UNITED HEALTHCARE DISTRIBUTORS LTD | PERGOVERIS | FOLLITROPIN ALFA/LUTROPIN ALFA | 150 I.U/75 I.U | MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND | SWITZERLAND | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2607 | NDA/MAL/HDP /4974 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | FRUSEMIDE TABLETS BP 40MG | FUROSEMIDE | 40MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 2608 | NDA/MAL/HDP /4975 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | FRUSINA TABLETS | FUROSEMIDE | 40MG | FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2609 | NDA/MAL/HDP /4976 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | PERGLIM 2 | GLIMEPIRIDE | 2MG | INVENTIA HEALTHCARE PVT. LTD .-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2610 | NDA/MAL/HDP /4979 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | FUROSEMIDE | FUROSEMIDE | 10MG/ML | CIRON DRUGS AND PHARMACEUTICALS PVT LTD-N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2010 |
| 2611 | NDA/MAL/HDP /4982 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | COSMAG TABLETS | MAGNESIUM TRISILICATE | 370MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 2612 | NDA/MAL/HDP /4983 | PT SAMBE FARMA | MEDVIN PHARMA LIMITED | PELASTIN | IMIPENEM + CILASTATIN | 500MG + 500MG | PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA | INDONESIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2011 |

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| 2613 | NDA/MAL/HDP/4999 | UNIQUE PHARMACEUTICAL LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | PAMIDOL*370 | IOPAMIDOL | 755.3MG/ML | UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0 ML VIAL,1.0X1.0X100.0 ML VIAL | 01/07/2010 |
| 2614 | NDA/MAL/HDP/5001 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | GENTAMICIN INJECTION | GENTAMYCIN | 80MG/2ML | WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE | 01/07/2007 |
| 2615 | NDA/MAL/HDP/5002 | ELI-LILLY EXPORT SA | LABOREX UGANDA LIMITED | HUMALOG MIX 25 | INSULIN LISPRO + INSULIN LISPRO PROTAMINE | 25I.U+75I.U | LILLY FRANCE SA-FRANCE | FRANCE | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 01/07/2000 |

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| 2616 | NDA/MAL/HDP/5004 | GLAXOSMITHKLINE LIMITED LIKONI | BETA HEALTHCARE UGANDA LIMITED | COFTA TABLETS | MULTI-INGREDIENT | N/A | GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY LOZENGES | 1.0X100.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X150.0 TABLET CARTON | 01/07/1997 |
| 2617 | NDA/MAL/HDP/5005 | MACK BROWN PHARMACEUTICALS PVT LIMITED | SHURIK LTD | COLD GO | PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE+CHLORPHENIRAMINE MALEATE+CAFFEINE | 325MG+10MG+2MG+30MG | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X4.0 TABLET BLISTER | 01/07/2010 |
| 2618 | NDA/MAL/HDP/5007 | DELOBORIS PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | VIRUCID | ACYCLOVIR | 200MG | DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X25.0 TABLET CONTAINER | 01/07/1997 |

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| 2619 | NDA/MAL/HDP/5008 | UNIMED INDIA | ASTRA PHARMA (U) LIMITED | COLDAFEX | MULTI-INGREDIENT | MULTI-INGREDIENT | UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2005 |
| 2620 | NDA/MAL/HDP/5010 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | ZARIN CREAM | MICONAZOLE NITRATE | 2%W/W | XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2621 | NDA/MAL/HDP/5011 | UNIMED INDIA | ASTRA PHARMA (U) LIMITED | COLDAFEX TABLETS | MULTI-INGREDIENT | MULTI-INGREDIENT | UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X4.0 TABLET STRIP,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2622 | NDA/MAL/HDP/5014 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | VERMOREX SUSPENSION | MEBENDAZOLE | 100MG/5ML | J.B CHEMICALS & PHARMACEUTICALS LTD-128/1 GIDC ANKLESHWAR 393 022 GUJARAT INDIA UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/1998 |
| 2623 | NDA/MAL/HDP/5015 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | COLDCAP CAPSULES | PHENYLEPHRINE HYDROCHLORIDE+ CHLORPHENIRAMINE | 5MG+4MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X8.0X12.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 2624 | NDA/MAL/HDP/5017 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA (U) LTD | COLDCAP SYRUP | PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HYDROCHLORIDE | 120MG/5ML + 2MG/5ML + 10MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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| 2625 | NDA/MAL/HDP/5018 | GLAXO WELLCOME (KENYA) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | VENTOLIN | SALBUTAMOL | 100MCG | GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE NO.2 23, RUE LAVOISIER 27000 EVREUX,FRANCE. | FRANCE | LUNG ADMINISTRATION METERED-DOSE INHALER | 1.0X200.0 METERED DOSE CANNISTER | 01/07/1997 |
| 2626 | NDA/MAL/HDP/5019 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | COLOSPASMIN FORTE | MEBEVERINE | 135MG | EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)-EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O) | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X20.0 TABLET BLISTER | 01/07/2011 |
| 2627 | NDA/MAL/HDP/5021 | BAYER SCHERING PHARMA FRANCE | SURGIPHARM (U) LIMITED | COMBINATION 3 | ETHINYL ESTRADIOL+ LEVONORGESTREL +FERROUS FUMARATE | 0.03MG+0.15MG+ 75MG | BAYER PHARMA AG -13353 BERLIN GERMANY BAYER WEIMAR GMBH UND CO. KG,-WEIMAR DEBEREINERSTRASSE 20, 99427 WEIMAR GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X100.0X28.0 TABLET BLISTER | 01/07/2011 |

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| 2628 | NDA/MAL/HDP/5028 | THE MENTHOLATUM COMPANY LTD TWY | HARLEYS UGANDA LIMITED | DEEP HEAT SPRAY | MULTI-INGREDIENT | MULTI-INGREDIENT | COLEP LAUPHEIM GMBH & CO KG-FOCKESTRASSE 12, 88471, LAUPHEIM | GERMANY | TOPICAL EXTERNAL PRESSURISED AEROSOLS | 1.0X150.0 ML CANNISTER | 01/07/1997 |
| 2629 | NDA/MAL/HDP/5030 | PFIZER LAB LTD | LABOREX UGANDA LIMITED | SOLU-MEDROL | METHYLPREDNISOLONE HEMISUCCINATE | 125MG/2ML | PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM | BELGIUM | PARENTERAL ORDINARY DRY VIALS | 1.0X2.0 ML VIAL,1.0X8.0 ML VIAL | 01/07/1997 |
| 2630 | NDA/MAL/HDP/5031 | THE MENTHOLATUM COMPANY LTD | HARLEYS UGANDA LIMITED | DEEP HEAT RUB | MULTI-INGREDIENT | MULTI-INGREDIENT | THE MENTHOLATUM COMPANY LTD, TWYFORD,-1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND | UNITED KINGDOM | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X35.0 G TUBE,1.0X67.0 G TUBE,1.0X100.0 G TUBE | 01/07/1997 |

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| 2631 | NDA/MAL/HDP/5032 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | DELASED DRY COUGH SYRUP (NON DROWSY) | DEXTROMETHORPHAN | 7.5MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2004 |
| 2632 | NDA/MAL/HDP/5033 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | SUPER MEDIC LTD | MEBFIL TABLETS | MEBENDAZOLE | 100MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2633 | NDA/MAL/HDP/5035 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | MEBENDAZOLE | MEBENDAZOLE | 100MG/5ML | MEDICAMEN BIOTECH LTD - - SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2014 |

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| 2634 | NDA/MAL/HDP/5038 | UNICHEM LABORATORIES LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | M-CAM TABLETS | MELOXICAM | 15MG | UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X5.0X10.0 TABLET BLISTER | 01/07/2002 |
| 2635 | NDA/MAL/HDP/5040 | PFIZER LABORATORIES (PTY) LTD BELGIUM | LABOREX UGANDA LIMITED | DEPO-MEDROL | METHYLPREDNISOLONE ACETATE | 40MG/ML | PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM | BELGIUM | PARENTERAL ORDINARY VIALS | 1.0X1.0 ML VIAL,1.0X2.0 ML VIAL,1.0X5.0 ML VIAL | 01/07/1997 |
| 2636 | NDA/MAL/HDP/5041 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | MAXITROL | DEXAMETHASONE/NEOMYCIN/POLYMYXIN B | 0.1%W/W +0.1%W/W+6000 I.U | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC OINTMENTS | 1.0X3.5 G TUBE | 01/07/1997 |

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| 2637 | NDA/MAL/HDP/5042 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | COSATRIM DS TABLETS | CO-TRIMOXAZOLE | 960MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER | 01/07/1998 |
| 2638 | NDA/MAL/HDP/5043 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | MAXITROL | DEXAMETHASONE/NEOMYCIN/POLYMYXIN B | 0.1%W/W+3500I.U/ML+6000I.U/ML | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |
| 2639 | NDA/MAL/HDP/5044 | PFIZER LABORATORIES (PTY) LTD BELGIUM | LABOREX UGANDA LIMITED | DEPO-PROVERA | MEDROXYPROGESTERONE ACETATE | 150MG/ML | PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM | BELGIUM | PARENTERAL ORDINARY I M VIALS | 1.0X3.5 ML VIAL,1.0X1.0 ML VIAL | 01/07/1997 |

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| 2640 | NDA/MAL/HDP/5046 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | GIZLAN PLUS 150/12.5 | IRBESARTAN+HYDROCHLOROTHIAZIDE | 150MG+12.5MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 2641 | NDA/MAL/HDP/5049 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | GIZLAN PLUS 300/12.5 | IRBESARTAN/HYDROCHLOROTHIAZIDE | 300MG/12.5MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2013 |
| 2642 | NDA/MAL/HDP/5050 | NORVATIS PHARMA AG-SWITZERLAND | LABOREX UGANDA LIMITED | MAXIDEX | DEXAMETHASONE | 0.1%W/V | ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM | BELGIUM | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |

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| 2643 | NDA/MAL/HDP/5051 | CADILA HEALTHCARE LIMITED SARKHEJ | ABACUS PHARMA (AFRICA) LIMITED | DERIHALER | SALBUTAMOL | 100CMG/DOSE | CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210 | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X200.0 METERED DOSE CANNISTER | 01/07/2005 |
| 2644 | NDA/MAL/HDP/5055 | GLAXOSMITHKLINE LTD UK | UNITED HEALTHCARE DISTRIBUTORS LTD | DERMOVATE | CLOBETASOL PROPIONATE | 0.05%W/W | GLAXOSMITHKLINE HARMIRE -GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM | UNITED KINGDOM | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE,1.0X25.0 G TUBE | 01/07/1997 |
| 2645 | NDA/MAL/HDP/5068 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | DEXAMETHASONE SODIUM PHOSPHATE | DEXAMETHASONE SODIUM PHOSPHATE | 8MG/2ML | NINGBO DAHONGYING PHARMACEUTICAL CO LTD.-NO. 3986, HI-TECH PARK MINZHU ROAD, NINGBO CITY, ZHEJIANG LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2010 |

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| 2646 | NDA/MAL/HDP/5073 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | DEXONA EYE/EAR DROP | DEXAMATHASONE SODIUM PHOSPHATE+NEOMYCIN SULPHATE | 0.35%W/V+0.1%W/V | AHLCON PARENTERALS (INDIA) LTD-SP-917-918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE,1.0X2.5 ML BOTTLE | 01/07/1997 |
| 2647 | NDA/MAL/HDP/5074 | CADILA HEALTH CARE LTD | ABACUS PHARMA (AFRICA) LIMITED | DEXONA INJECTION | DEXAMETHASONE DISODIUM PHOSPHATE | 4MG/ML | SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI | INDIA | PARENTERAL ORDINARY VIALS | 1.0X6.0X2.0 ML VIAL,16.0X6.0X2.0 ML VIAL | 01/07/1997 |
| 2648 | NDA/MAL/HDP/5075 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | DEXONA TABLETS | DEXAMETHASONE | 0.5MG | CADILA HEALTHCARE LIMITED SARKHEJ-SARKHEJ-BAVLA N.H NO.8A, N.H NO.8A, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP | 01/07/1997 |

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| 2649 | NDA/MAL/HDP/5076 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | DEXTRACIN EYE DROPS | DEXAMETHASONE + NEOMYCIN | 0.1MG + 0.5MG | XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA | MALAYSIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/1997 |
| 2650 | NDA/MAL/HDP/5078 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | GLANDIN E2 VAGINAL | DINOPROSTONE | 3MG | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | VAGINAL TABLETS | 1.0X1.0 TABLET STRIP | 01/07/2006 |
| 2651 | NDA/MAL/HDP/5086 | FOURTS(INDIA) LABORATORIES PVT LTD | AIVEEN (U) LIMITED | GLIFIL M FORT | GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE | 5MG+500MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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| 2652 | NDA/MAL/HDP/5087 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DIABEN TABLETS | GLIBENCLAMIDE | 5MG | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/1998 |
| 2653 | NDA/MAL/HDP/5092 | MICRO LABS LTD 92 SIPCOT | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DIAPRIDE | GLIMEPIRIDE | 2MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2654 | NDA/MAL/HDP/5093 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | LIPODAR 10 | ATORVASTATIN | 10MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2655 | NDA/MAL/HDP /5095 | MICRO LABS LTD | LABOREX UGANDA LIMITED | DIAPRIDE PLUS | GLIMEPIRIDE + METFORMIN | 1MG + 500MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2656 | NDA/MAL/HDP /5096 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | SCABION | CROTAMITON + SULPHUR | 10 G + 2G/100G | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X60.0 ML BOTTLE | 01/07/2003 |
| 2657 | NDA/MAL/HDP /5099 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | GLUCOMET | METFORMIN | 500MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X4.0X14.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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| 2658 | NDA/MAL/HDP/5102 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOPHAGE 500MG | METFORMIN | 500MG | MERCK SANTÉ-2, RUE DU PRESSOIR VERT F 45400, SEMOY NKUNZI PHARMACEUTICALS (PTY) LTD.-259 DAVIDSON ROAD CNR PEDDIE STREET, WADEVILLE EST. 1 GERMISTON 1422 | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X6.0X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER | 01/07/2010 |
| 2659 | NDA/MAL/HDP/5103 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOPHAGE 1000MG | METFORMIN | 1000MG | NKUNZI PHARMACEUTICALS (PTY) LTD --259 DAVIDSON ROAD, WADEVILLE, EXT 1, GERMINSTON, SOUTH AFRICA | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X15.0 TABLET BLISTER | 01/07/2010 |
| 2660 | NDA/MAL/HDP/5104 | NOVO NORDISK PHARMA GULF FZ-LC | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | LEVEMIR FLEXPEN | INSULIN DETEMIR | 100 I.U/ML | NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - | DENMARK | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X5.0X3.0 ML PREFILLED PEN | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2661 | NDA/MAL/HDP/5106 | ESAPHARM SRL | BYAMAKA PHARMACEUTICAL COMPANY LTD | LEMONVATE CREAM | CLOBETASOL PROPIONATE | 0.05%W/W | ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY | ITALY | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/2003 |
| 2662 | NDA/MAL/HDP/5107 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | INDOREN CAPSULES | INDOMETHACIN | 25MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/2000 |
| 2663 | NDA/MAL/HDP/5109 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | LEBASMA ORAL SOLUTION | SALBUTAMOL | 2MG/5ML | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2664 | NDA/MAL/HDP/5112 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | DICLOMOL SR TABLETS | DICLOFENAC SODIUM | 100MG | WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA | INDIA | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1998 |
| 2665 | NDA/MAL/HDP/5115 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | INDOS-25 | INDOMETHACIN | 25MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1000.0 CAPSULE CONTAINER,20.0X5.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2000 |
| 2666 | NDA/MAL/HDP/5117 | VENUS REMEDIES LIMITED | HARLEYS UGANDA LIMITED | LASTINEM | IMIPENEM + CILASTATIN | 500MG + 500MG | VENUS REMMEDIES-UNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2667 | NDA/MAL/HDP/5119 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | DELMAW ENTERPRISES LIMITED | KONTRAC 200 | MISOPROSTOL | 200MCG | FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X2.0 TABLET STRIP,1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2668 | NDA/MAL/HDP/5120 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | GLYFORMIN 500 TABLETS | METFORMIN | 500MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER | 01/07/1999 |
| 2669 | NDA/MAL/HDP/5121 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | DICLORAN GEL | DICLOFENAC DIETHYLAMMONIUM | 1%W/W | UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116 | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X50.0 G TUBE,1.0X20.0 G TUBE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2670 | NDA/MAL/HDP/5122 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | KOFAREST SYRUP | SALBUTAMOL SULPHATE/AMBROXOL SULPHATE/GUAFENESIN/MENTHOL | 2MG+30MG+100MG+5MG/10ML | CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2007 |
| 2671 | NDA/MAL/HDP/5124 | GLAXOSMITHKLINE LTD BELGIUM | UNITED HEALTHCARE DISTRIBUTORS LTD | INFANRIX-HEXA | DIPHTHERIA TOXOID+TETANUS TOXOID+PERTUSSIS TOXOID(PT)+FILAMENTOUS HAEMAGGLUTININ (FHA)+PERTACTIN(69KDA OMP)+HBSAG PURIFIED,INACTIVATED POLIO VIRUS | MIN 30 I.U+MIN 40 I.U+25MG+25MG+8MG+10MG,40DU+8DU+32DU+10MG | GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY COMBINATION PACK VIALS | 1.0X1.0 PACK CARTON (DTPA-HBV-IPV IN PREFILLED SYRINGE + 2 NEEDLES+FREEZE DRIED HIB IN A VIAL) | 01/07/2013 |
| 2672 | NDA/MAL/HDP/5125 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | GLYGESIC FORTE RHUMETIC CREAM | MULTI INGREDIENT | N/A | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1998 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2673 | NDA/MAL/HDP/5126 | UNIVERSAL CORPORATION LTD | DELMAW ENTERPRISES LIMITED | KNAC-75 | DICLOFENAC | 75MG | UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2674 | NDA/MAL/HDP/5128 | MERCK (PTY) LTD | ABACUS PHARMA (AFRICA) LIMITED | GOFEN 400 CLEARCAP | IBUPROFEN | 400MG | MEGA LIFESCIENCES LTD.-384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN | THAILAND | ORAL SOLID ORDINARY CAPSULES | 6.0X1.0X10.0 CAPSULE BLISTER | 01/07/2009 |
| 2675 | NDA/MAL/HDP/5129 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | KLEEN ENEMA | DISODIUM BISPHOSPHATE/ SODIUM PHOSPHATE | 19.2G+7.2G/ 120ML | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | RECTAL SYSTEMIC ENEMA LIQUIDS | 1.0X135.0 ML BOTTLE | 01/07/2006 |

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| 2676 | NDA/MAL/HDP/5130 | UNIQUE PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | DICLORAN MS GEL | DICLOFENAC+METHYL SALICYLATE+MENTHOL | 1%W/W+10%W/W+5%W/W | UNIQUE PHARMACEUTICALS LABS ( A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116 | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2005 |
| 2677 | NDA/MAL/HDP/5131 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | INSULATARD | ISOPHANE INSULIN (HUMAN) | 100 I.U/ML | NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE | DENMARK | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/1997 |
| 2678 | NDA/MAL/HDP/5133 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GONAL-F PEN 900IU/1.5ML(66MCG/1.5ML) | FOLLITROPIN ALFA | 66MCG/1.5ML | MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI | SWITZERLAND | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X1.0 CARTRIDGE PREFILLED PEN + 20 NEEDLES FOR INJECTION,1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION. | 01/07/2015 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2679 | NDA/MAL/HDP/5134 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | GOODMORNING COUGH TABLETS | MULTIINGREDIENT | N/A | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CARTON | 01/07/1997 |
| 2680 | NDA/MAL/HDP/5135 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | KETOZ | KETOCONAZOLE | 2%W/W | SK ANT HEALTHCARE LTD-1802-1805 GIDC PHASE III, VAPI-396195 GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/2010 |
| 2681 | NDA/MAL/HDP/5136 | BETA HEALTHCARE INTERNATIONAL LTD | BETA HEALTHCARE UGANDA LIMITED | GOODMORNING LUNG TONIC | MULTIINGREDIENT | N/A | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE | 01/07/1997 |

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| 2682 | NDA/MAL/HDP /5139 | NOVO NORDISK | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | INSULATARD HM PENFILL | ISOPHANE INSULIN (HUMAN) | 100I.U/ML | NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCTION SAS-45 AVENUE D'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL | DENMARK | PARENTERAL ORDINARY CARTRIDGES | 1.0X5.0X3.0 ML PREFILLED PEN,1.0X5.0X1.5 ML PREFILLED PEN | 01/07/1997 |
| 2683 | NDA/MAL/HDP /5140 | PFIZER LABORATORIES PTY LTD | LABOREX UGANDA LIMITED | DIFLUCAN | FLUCONAZOLE | 200MG | FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE | FRANCE | ORAL SOLID ORDINARY CAPSULES | 1.0X7.0 CAPSULE BLISTER | 01/07/1997 |
| 2684 | NDA/MAL/HDP /5141 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | KETOMAC SHAMPOO | KETOCONAZOLE | 2%W/V | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | TOPICAL EXTERNAL LIQUID SOAPS/WASHES | 75.0 ML BOTTLE | 01/07/2003 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2685 | NDA/MAL/HDP/5142 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | INTAMINE CREAM | MEPYRAMINE MALEATE | 2%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X25.0 G TUBE,1.0X400.0 G TUBE | 01/07/1997 |
| 2686 | NDA/MAL/HDP/5143 | ASTRA ZENECA | MACNAUGHTON LIMITED | BETALOC ZOK - 25MG | METOPROLOL | 25MG | ASTRA ZENECA AB-GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 01/07/2011 |
| 2687 | NDA/MAL/HDP/5146 | ASTRA ZENECA | MACNAUGHTON LIMITED | BETALOC ZOK - 100MG | METOPROLOL | 100MG | ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN) | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2688 | NDA/MAL/HDP/5147 | ASTRA ZENECA | MACNAUGHTON LIMITED | BETALOC ZOK - 50MG | METOPROLOL | 50MG | ASTRA ZENECA AB-GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2011 |
| 2689 | NDA/MAL/HDP/5150 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | KETO PLUS SHAMPOO | KETOCONAZOLE/ZINC PYRITHIONE | 1%W/V+2%W/V | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | TOPICAL EXTERNAL LIQUID SOAPS/WASHES | 1.0X60.0 ML BOTTLE | 01/07/2003 |
| 2690 | NDA/MAL/HDP/5154 | BETA HEALTHCARE UGANDA LIMITED | BETA HEALTHCARE UGANDA LIMITED | BETASIL PAEDIATRIC SYRUP | IPECACUANHA TINCTURE | 0.5ML | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X50.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |

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| 2691 | NDA/MAL/HDP /5155 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | BETAVEL | MULTI-INGREDIENT | N/A | NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/1997 |
| 2692 | NDA/MAL/HDP /5157 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | BETAVEL N | BETAMETHASONE +NEOMYCIN SULPHATE | 1MG+5MG | NEM LABORATORIES PVT LTD 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X3.0 G TUBE,1.0X15.0 G TUBE | 01/07/1997 |
| 2693 | NDA/MAL/HDP /5161 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | GRISEOSIM-500 | GRISEOFULVIN | 500MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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| 2694 | NDA/MAL/HDP/5164 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | BROMSAL EXPECTORANT | SALBUTAMOL SULPHATE+BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+MENTHOL | 1MG+2MG+50MG+0.5MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2010 |
| 2695 | NDA/MAL/HDP/5165 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | GRISEOFULVIN 500 TABLETS | GRISEOFULVIN | 500MG | REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER | 01/07/2003 |
| 2696 | NDA/MAL/HDP/5166 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | KETAMINE HYDROCHLORIDE | KETAMINE HYDROCHLORIDE | 50MG/ML | UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 01/07/2004 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2697 | NDA/MAL/HDP/5167 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | BRUSTAN TABLETS | IBUPROFEN + PARACETAMOL | 400MG + 325MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED - INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER | 01/07/1998 |
| 2698 | NDA/MAL/HDP/5169 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | GVGYL SUPPOSITORY | METRONIDAZOLE BP | 500MG | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY BLISTER | 01/07/2007 |
| 2699 | NDA/MAL/HDP/5170 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | CANDITRAL CAPSULE | ITRACONAZOLE | 100MG | GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0 CAPSULE STRIP | 01/07/2000 |

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| 2700 | NDA/MAL/HDP/5171 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | KETAMAX-50 | KETAMINE | 50MG/ML | TROIKAA PHARMACUETICALS LIMITED-C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 01/07/2011 |
| 2701 | NDA/MAL/HDP/5175 | JASSEN-CILAG (PTY) LTD | MEDICAL ACCESS (UGANDA) LIMITED | GYNO-DAKTARIN | MICONAZOLE NITRATE | 20MG/G | SPECPHARM HOLDINGS-15TH ROAD HALFWAY HOUSE | SOUTH AFRICA | VAGINAL CREAMS | 1.0X40.0 G TUBE | 01/07/1997 |
| 2702 | NDA/MAL/HDP/5176 | BAYER AG | SURGIPHARM (U) LIMITED | CANESTEN | CLOTRIMAZOLE | 100MG | BAYER AG -D-51368 LEVERKUSEN GERMANY | GERMANY | VAGINAL TABLETS | 1.0X6.0 TABLET STRIP | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2703 | NDA/MAL/HDP/5177 | YURIA PHARM LTD | PHARMA VILLE LIMITED | ISONIAZID | ISONIAZID | 100MG/5ML | YURIA-PHARM LLC MANUFACTURING SITE NO. 1-108, KOBZARSKA STREET, CHERKASY, 18030 | UKRAINE | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2013 |
| 2704 | NDA/MAL/HDP/5179 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CEFIX 200MG CAPSULES | CEFIXIME TRIHYDRATE | 200MG | PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X8.0 CAPSULE BLISTER | 01/07/2007 |
| 2705 | NDA/MAL/HDP/5180 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | ISORYN DROPS ( PAEDRIATRIC) | EPHEDRINE HYDROCHLORIDE | 5MG/ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | NASAL TOPICAL DROPS | 1.0X15.0 ML BOTTLE | 01/07/1997 |

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| 2706 | NDA/MAL/HDP/5182 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | ISORYN DROPS (ADULT) | EPHEDRINE HYDROCHLORIDE | 10MG/ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | NASAL TOPICAL DROPS | 1.0X15.0 ML BOTTLE | 01/07/1997 |
| 2707 | NDA/MAL/HDP/5183 | PHARCO B PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | GYNOZOL VAGINAL CAPSULES | MICONAZOLE NITRATE | 400MG | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | VAGINAL SUPPOSITORIES | 1.0X3.0 CAPSULE BLISTER | 01/07/2000 |
| 2708 | NDA/MAL/HDP/5184 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | GYNOZOL VAGINAL CREAM | MICONAZOLE NITRATE | 2%W/W | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | VAGINAL CREAMS | 1.0X40.0 G TUBE | 01/07/2000 |

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| 2709 | NDA/MAL/HDP/5186 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ISOTROY 250 | ISOFLURANE | 250ML | TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA | INDIA | OTHER SYSTEMIC LIQUID INHALATIONS | 1.0X250.0 ML BOTTLE | 01/07/2014 |
| 2710 | NDA/MAL/HDP/5187 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | HEALIT SKIN OINTMENT | BACITRACIN+POLYMYXIN B SO4+NEOMYCIN+LIDOCAINE | 500UNITS+5000UNITS+3.5MG+40MG/G | ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI, PAKISTAN | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X10.0 G TUBE | 01/07/2007 |
| 2711 | NDA/MAL/HDP/5188 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | ITRAZ CAPSULES | ITRACONAZOLE | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X5.0 CAPSULE BLISTER,1.0X6.0X10.0 CAPSULE BLISTER | 01/07/2009 |

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| 2712 | NDA/MAL/HDP/5189 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | HEMOZEBEX | FERROUS SULPHATE+FOLIC ACID+PYRIDOXINE HCL+CYANOCOBALAMIN+ZINC SULPHATE | 300MG+1000MCG+1.5MG+7.5MG+61.8MG | TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2713 | NDA/MAL/HDP/5200 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | HYDRALAZINE TABLETS B.P 25MG. | HYDRALAZINE HYDROCHLORIDE | 25MG | COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1998 |
| 2714 | NDA/MAL/HDP/5201 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM BENDAZOLE | MEBENDAZOLE | 100MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2715 | NDA/MAL/HDP/5205 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM-VENT | SALBUTAMOL | 4MG | KAMPALA PHARMACEUTICALS INDUSTIES-PLOT NO M44B STRETCHER ROAD INTINDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET JAR,1.0X500.0 TABLET JAR,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2716 | NDA/MAL/HDP/5207 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | DIGOXIN TABLETS | DIGOXIN | 0.25MG | NEM LABORATORIES PVT. LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2013 |
| 2717 | NDA/MAL/HDP/5211 | SK AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | DINAC GEL | DICLOFENAC | 1%W/W | S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2009 |

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| 2718 | NDA/MAL/HDP/5215 | J.B CHEMICALS & PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | METROGYL TABLETS | METRONIDAZOLE | 200MG | J.B. CHEMICALS AND PHARMACEUTICALS LTD .-128/1, GIDC, ANKLESHWAR 393 002, GUJARAT GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X20.0X5.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X5.0X2.0X10.0 TABLET BLISTER | 01/07/2001 |
| 2719 | NDA/MAL/HDP/5221 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | DICLOFENAC SODIUM | DICLOFENAC SODIUM | 75MG/3ML | NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X3.0 ML AMPOULE,1.0X10.0X3.0 ML AMPOULE | 01/07/2006 |
| 2720 | NDA/MAL/HDP/5222 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | EMTRICITABINE +TENOFOVIR DF | EMTRICITABINE/TENOFOVIR | 200MG/300MG | MYLAN LABORATORIES LTD ,-PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775, DIST DHAR – MADHYA PRADESH MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 07/07/2008 |

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| 2721 | NDA/MAL/HDP/5224 | AUROBINDO PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | EMTRICITABINE+TENOFOVIR DISOPROXIL FUMERATE | EMTRICITABINE/TENOFOVIR DISOPROXIL FUMERATE | 200MG/300MG | AUROBINDO PHARMA LTD UNIT III-AUROBINDO PHARMA LTD UNIT III SURVEY NO. 313 BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2009 |
| 2722 | NDA/MAL/HDP/5226 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | EMTRICITABINE+TENOFOVIR DISOPROXIL FUMERATE | EMTRICITABINE+TENOFOVIR DISOPROXIL FUMERATE | 200MG/300MG | HETERO DRUGS LTD-UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055 HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2013 |
| 2723 | NDA/MAL/HDP/5228 | CENTAUR PHARMACEUTICALS PVT LTD | GITTOES PHARMACEUTICALS LIMITED | DICLOGENTA | DICLOFENAC SODIUM+GENTAMICIN SULPHATE | 1MG/ML+3MG/ML | CENTAUR PHARMACEUTICALS PVT LTD --PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2009 |

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| 2724 | NDA/MAL/HDP /5231 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | ENAPRIL 10 | ENALAPRIL MALEATE | 10MG | INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2725 | NDA/MAL/HDP /5232 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | ENAPRIL-5 | ENALAPRIL MALEATE | 5MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 2726 | NDA/MAL/HDP /5233 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | ENVAS 10 MG TABLETS | ENALAPRIL | 10MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2727 | NDA/MAL/HDP/5234 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | ENVAS 5MG TABLETS | ENALAPRIL MALEATE | 5MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2728 | NDA/MAL/HDP/5235 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | DICLORAN DELAYED-RELEASE TABLETS | DICLOFENAC SODIUM | 50MG | UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID RETARD ENTERIC-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,5.0X2.0X10.0 TABLET BLISTER | 01/07/1997 |
| 2729 | NDA/MAL/HDP/5243 | IND SWIFT LTD | PLANET PHARMACEUTICALS UGANDA LTD | EZO 20 | ESOMEPRAZOLE MAGNESIUM | 20MG | IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI | INDIA | ORAL SOLID RETARD TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2013 |

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| 2730 | NDA/MAL/HDP/5245 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | FABUTAS-40 | FEBUXOSTAT | 40MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2731 | NDA/MAL/HDP/5248 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM-AMPI | AMPICILLIN | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER | 01/07/1997 |
| 2732 | NDA/MAL/HDP/5249 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | ENCIFER | IRON SUCROSE | 100MG/5ML | SAMRUDH PHARMACEUTICALS PVT LTD-J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506 | INDIA | PARENTERAL ORDINARY INFUSION AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 01/07/2013 |

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| 2733 | NDA/MAL/HDP/5250 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | FARCOLIN SYRUP | SALBUTAMOL + AMMONIUM CHLORIDE | 2MG/5ML +100MG/5ML | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/1998 |
| 2734 | NDA/MAL/HDP/5251 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | DIFLUCAN | FLUCONAZOLE | 150MG | PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE | FRANCE | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0 CAPSULE BLISTER | 01/07/1997 |
| 2735 | NDA/MAL/HDP/5255 | GLAXOSMITHKLINE LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ENO LEMONFRUIT SALT | MULTI-INGREDIENT | MULTI-INGREDIENT | GLAXO SMITH KLINE LTD-LIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA GLAXOSMITHLINE-CAPE TOWN, S.A | SOUTH AFRICA | ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES | 1.0X8.0X4.5 G SACHET,1.0X10.0X4.5 G SACHET,1.0X48.0X4.5 G SACHET,1.0X4.0X4.5 G SACHET,1.0X24.0X4.5 G SACHET | 01/07/1997 |

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| 2736 | NDA/MAL/HDP/5256 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | DIPROFOS INJECTION | BETAMETHASONE DISODIUM PHOSPHATE + BETAMETHASONE DIPROPIONATE | 2MG + 5MG/ML | SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG | BELGIUM | PARENTERAL ORDINARY AMPOULES | 1.0X2.0 ML AMPOULE | 01/07/2001 |
| 2737 | NDA/MAL/HDP/5259 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CARDINOL TABLET | ATENOLOL | 100MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 2.0X14.0 TABLET STRIP | 01/07/1997 |
| 2738 | NDA/MAL/HDP/5260 | KAMPALA PHARMACEUTICAL INDUSTRIES LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | ERYMYCIN | ERYTHROMYCIN ESTOLATE | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED --STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 2739 | NDA/MAL/HDP/5263 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | DIPROSALIC OINTMENT | BETAMETHASONE + SALICYLIC ACID | 0.5 %W/W + 0.3 %W/W | SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG | BELGIUM | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 MG TUBE | 01/07/2001 |
| 2740 | NDA/MAL/HDP/5269 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | DIVAA OD 500 | DIVALPROEX | 500MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2741 | NDA/MAL/HDP/5271 | REGAL PHARMA U LIMITED | REGAL PHARMA (U) LTD | ERYTHYL SYRUP | ERYTHROMYCIN ETHYL SUCCINATE | 125MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |

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| 2742 | NDA/MAL/HDP/5272 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | DIX | DIGOXIN | 0.25MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2011 |
| 2743 | NDA/MAL/HDP/5279 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DOSIN | DOXAZOCIN | 2MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2744 | NDA/MAL/HDP/5281 | AUROBINDO PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | EFAVIRENZ+EMTRICITABINE+TENOFOVIR DISOPROXIL | EFAVIRENZ + EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE | 600MG +200MG + 300MG | AUROBINDO PHARMA LTD UNIT VII-SEZ SURVEY NO. 411/P,425/P, 434/P, 435/P AND 458/P PLOT NO S1 ( PART) SPECIAL ECONOMIC ZONE GREEN INDUSTRIAL PARK POLEPALLY VILLAGRE ANDHRA PRADESH 509302 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2015 |

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| 2745 | NDA/MAL/HDP/5282 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | DORFEN | ACECLOFENAC | 100MG | TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2746 | NDA/MAL/HDP/5283 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | IBUMEX GEL | IBUPROFEN | 5%W/W | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | TOPICAL EXTERNAL EMULSION GELS | 1.0X25.0 G TUBE | 01/07/2001 |
| 2747 | NDA/MAL/HDP/5287 | AUROBINDO PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMERATE | EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMERATE | 600MG + 300MG + 300MG | AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), - SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2748 | NDA/MAL/HDP/5288 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | IBUMEX SUSPENSION | IBUPROFEN | 100MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 100.0 ML BOTTLE,60.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2749 | NDA/MAL/HDP/5290 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | ELOCOM CREAM | MOMETASONE FUROATE | 0.1%W/W | SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM | BELGIUM | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2000 |
| 2750 | NDA/MAL/HDP/5291 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | IBUMEX TABLET | IBUPROFEN | 200MG | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2751 | NDA/MAL/HDP/5292 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | DOMI 10 | DOMPERIDONE | 10MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2011 |
| 2752 | NDA/MAL/HDP/5294 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | ELOCOM OINTMENT | MOMETASONE FUROATE | 0.1%W/W | SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM | BELGIUM | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2000 |
| 2753 | NDA/MAL/HDP/5295 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | DOXY | DOXYCYCLINE | 100MG | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X280.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2000 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2754 | NDA/MAL/HDP/5297 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELOGYL | METRONIDAZOLE | 200MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2755 | NDA/MAL/HDP/5298 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | ELOGYL | METRONIDAZOLE | 200MG/5ML | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2756 | NDA/MAL/HDP/5299 | PHARMA INTERNATIONAL.CO | OMAB UGANDA LIMITED | KENAZOLE | KETOCONAZOLE | 20MG/ML | PHARMA INTERNATIONAL COMPANY ,.-AL-QASTAL INDUSTRIAL AREA/AMMAN | JORDAN | TOPICAL EXTERNAL LIQUID SOAPS/WASHES | 1.0X100.0 ML BOTTLE | 01/07/2014 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2757 | NDA/MAL/HDP/5300 | CADILA PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | DOLAC | KETOROLAC TROMETHAMINE | 30MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2015 |
| 2758 | NDA/MAL/HDP/5302 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | IBUGO-COMBI | IBUPROFEN + PARACETAMOL + CAFFEINE | 200MG + 325MG + 30MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2014 |
| 2759 | NDA/MAL/HDP/5305 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | IBUGO - 200 | IBUPROFEN | 200MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2760 | NDA/MAL/HDP/5307 | USV PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | DUOTROL | GLYBURIDE + METFORMIN HYDROCHLORIDE | 5MG + 500MG | FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2761 | NDA/MAL/HDP/5311 | ABBOTT HEALTHCARE PRODUCTS B.V. | HARLEYS UGANDA LIMITED | DUPHASTON TABLETS | DYDROGESTERONE | 10MG | ABBOTT BIOLOGICALS B.V - ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST | NETHERLANDS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X20.0 TABLET BLISTER | 01/07/2001 |
| 2762 | NDA/MAL/HDP/5312 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | DOXYCYCLINE | DOXYCYCLINE | 100MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2763 | NDA/MAL/HDP/5316 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | DYNAPAR | DICLOFENAC SODIUM + PARACETAMOL | 50MG + 500MG | TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2764 | NDA/MAL/HDP/5317 | MACK BROWN | SHURIK LTD | DR MAC'S COUGH FORMULA | TERBUTALINE SULPHATE+BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+MENTHOL | 2.5MG+8.0MG+100MG+5MG | TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2003 |
| 2765 | NDA/MAL/HDP/5318 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | DYNAPAR AQ (1ML) | DICLOFENAC SODIUM | 75MG/ML | TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X1.0 ML AMPOULE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2766 | NDA/MAL/HDP/5320 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | INDOL | INDOMETHACIN | 25MG | LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER | 01/07/2010 |
| 2767 | NDA/MAL/HDP/5321 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | IBUGESIC COLD & SINUS | IBUPROFEN/PSEUDOEPHEDRINE | 200MG/30MG | DAR AL DAWA-NA'UR PLANT AMMAN | JORDAN | ORAL SOLID ORDINARY GELATIN-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2012 |
| 2768 | NDA/MAL/HDP/5323 | STEDMAN PHARMACEUTICALS LTD | VEERAM HEALTHCARE (U) LIMITED | DREZ | IODINATED POVIDONE + METRONIDAZOLE | 1.0% W/V + 5.0% W/V | STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR | INDIA | TOPICAL EXTERNAL LIQUIDS | 1.0X60.0 ML CONTAINER,1.0X30.0 ML CONTAINER,1.0X100.0 ML CONTAINER,1.0X500.0 ML CONTAINER | 01/07/2010 |

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| 2769 | NDA/MAL/HDP/5324 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | AIVEEN (U) LIMITED | IBUFIL 400 | IBUPROFEN | 400MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1998 |
| 2770 | NDA/MAL/HDP/5326 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | ECODAX G CREAM | ECONAZOLE NITRATE + GENTAMYCIN + BECLAMETASONE | 1%+0.1%+0.025% | UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE,1.0X100.0 G TUBE | 01/07/1997 |
| 2771 | NDA/MAL/HDP/5327 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | AIVEEN (U) LIMITED | IBUFIL 200 | IBUPROFEN | 200MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 2772 | NDA/MAL/HDP/5329 | ELYS CHEMICAL INDUSTRIES LTD | ELYS CHEMICALS INDUSTRIES UGANDA LTD | IBUFEN TABLETS | IBUPROFEN | 200MG | ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 CAPSULE CONTAINER | 01/07/1997 |
| 2773 | NDA/MAL/HDP/5330 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | DREZ-V | MICONAZOLE + METRONIDAZOLE | 2.0%W/W + 1.0%W/W | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2011 |
| 2774 | NDA/MAL/HDP/5333 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | IBUFEN | IBUPROFEN | 200MG | KPI ( KAMPALA PHARMACEUTICAL INDUSTIRES LTD-PLOT M444 B STRETCHER ROAD NTINDA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X100.0X10.0 TABLET BLISTER,500.0 TABLET CONTAINER,1000.0 TABLET CONTAINER,250.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/1997 |

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| 2775 | NDA/MAL/HDP/5338 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | HYDROSIL TABLETS | ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE+SIMETHICONE | 200MG+200MG+20MG | XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X20.0 TABLET BLISTER | 01/07/1997 |
| 2776 | NDA/MAL/HDP/5340 | SEARLE PAKISTAN LIMITED | HEALTHCARE LTD. | HYDRYLLIN SYRUP | DIPHENHYDRAMINE HCL/DEXTROMETHORPHAN HBR | 5MG/6.25MG | THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/1997 |
| 2777 | NDA/MAL/HDP/5341 | LABORATORY&ALLIED LTD | HARLEYS UGANDA LIMITED | HYDOPA | METHYLDOPA | 250MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |

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| 2778 | NDA/MAL/HDP/5346 | PHARMA INTERNATIONAL CO | OMAB UGANDA LIMITED | CEFUTIL 500 | CEFUROXIME AXETIL | 500MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET CONTAINER | 01/07/2014 |
| 2779 | NDA/MAL/HDP/5347 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | CEFUTIL 250 | CEFUROXIME AXETIL | 250MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2780 | NDA/MAL/HDP/5348 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | CELEPID 20 | INTRAVENOUS FAT EMULSION | 20%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/2005 |

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| 2781 | NDA/MAL/HDP/5350 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | CEPHADAR FORTE | CEPHALEXIN | 250MG/5ML | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2010 |
| 2782 | NDA/MAL/HDP/5352 | GLENMARK PHARMACUTICALS LTD | STAR PHARMACEUTICALS LTD | MUMFER | IRON(111) POLYMALTOSE COMPLEX | 50MG/5ML | GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X150.0 ML BOTTLE | 01/07/2005 |
| 2783 | NDA/MAL/HDP/5356 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | BURNNEM | MULTI-INGREDIENT | N/A | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/1997 |

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| 2784 | NDA/MAL/HDP/5358 | CADILA HEALTHCARE LTD | ABACUS PHARMA (AFRICA) LIMITED | CADISTIN EXPECTORANT | CHLORPHENIRAMINE MALEATE + GUAIFENESIN + AMMONIUM CHLORIDE + SODIUM CITRATE + LEVOMENTHOL + TERPIN HYDRATE + TOLU BALSAM + VASAKA SYRUP | (2MG + 80MG + 100MG + 44MG + 0.8MG + 4MG + 6MG + 0.133ML)/5ML | SAKAR HEALTHCARE PVT LTD-SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/1997 |
| 2785 | NDA/MAL/HDP/5361 | MACK BROWN PHARMECEUTICALS PVT LTD | SHURIK LTD | CALFIC | MULTI-INGREDIENT | N/A | TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 2786 | NDA/MAL/HDP/5362 | ASTRA ZENECA | MACNAUGHTON LIMITED | CASODEX 150MG | BICALUTAMIDE | 150MG | ASTRAZENECA MACCLESFIELD-CHESHIRE | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 2.0X14.0 TABLET STRIP | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2787 | NDA/MAL/HDP /5363 | ASTRA ZENECA | MACNAUGHTON LIMITED | CASODEX 50MG | BICALUTAMIDE | 50MG | ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, BULK CORDEN PHARMA GMBH-OTT HAHN STRASSE ,68723 GERMANY | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/1997 |
| 2788 | NDA/MAL/HDP /5368 | PHARMA INTERNATIONAL COMPANY | OMAB UGANDA LIMITED | CEFIX 100MG/5ML DRY SUSPENSION | CEFIXIME | 100MG/5ML | PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA | JORDAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE | 01/07/2007 |
| 2789 | NDA/MAL/HDP /5370 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | HYOSCINE BUTYLBROMIDE | HYOSCINE N-BUTYLBROMIDE | 10 MG | COSMOS LIMITED -RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA | KENYA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X1000.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2010 |

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| 2790 | NDA/MAL/HDP/5377 | JOHNSON&JOHNSON PTY LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN FOUR FLU LIQUID | DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE | 25MG/20ML + 1G/20ML + 45MG/20ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2001 |
| 2791 | NDA/MAL/HDP/5379 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ZOLANAS-30 | LANSOPRAZOLE | 30MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2008 |
| 2792 | NDA/MAL/HDP/5380 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | CIROZEP | DIAZEPAM | 5MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA. | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 01/07/2013 |

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| 2793 | NDA/MAL/HDP /5381 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | ADIFLAM GEL | DICLOFENAC DIETHYLAMINE | 1.16%W/W | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2008 |
| 2794 | NDA/MAL/HDP /5386 | WIN-MEDICARE LTD | SURGIPHARM (U) LIMITED | UDIHEP TABLETS | URSODEOXYCHOLIC ACID | 150MG | WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2001 |
| 2795 | NDA/MAL/HDP /5388 | IPCA LABORATOIES LTD | MEDVIN PHARMA LIMITED | LARINATE-60 | ARTESUNATE | 60MG | IPCA LABORATORIES LTD,-SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*5 ML SODIUM CHLORIDE INJECTION + 1*1 ML AMPOULE OF SODIUM BICARBONATE INJECTION | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2796 | NDA/MAL/HDP/5389 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LUMARTEM | ARTEMETHER + LUMEFANTRINE | 20MG + 120 MG | CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775 CIPLA LTD., PATALGANGA UNIT I & UNIT II-PLOT NO. A-33(UNIT-I), A-42( UNIT-II), MIDC PATALGANGA, 410220 DISTRICT RAIGAD, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X24.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X30.0X12.0 TABLET | 01/07/2016 |
| 2797 | NDA/MAL/HDP/5391 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | NITROFURANTOIN | NITROFURANTOIN | 100MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 01/07/2008 |
| 2798 | NDA/MAL/HDP/5392 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | AMLO-DENK 10 | AMLODIPINE MESILATE MONOHYDRATE | 10MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2799 | NDA/MAL/HDP/5393 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | AMLO-DENK 5 | AMLODIPINE MESILATE MONOHYDRATE | 5MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2800 | NDA/MAL/HDP/5394 | FOURTS(INDIA) LABORATORIES PVT LTD | SUPER MEDIC LTD | FINAZOL | ALBENDAZOLE | 400MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/2007 |
| 2801 | NDA/MAL/HDP/5395 | MICRO LABS LTD | LABOREX UGANDA LIMITED | OFLOX | OFLOXACIN | 200MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2802 | NDA/MAL/HDP/5400 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ALBEN SUSPENSION | ALBENDAZOLE | 400MG/10ML | PANACEA BIOTEC LTD-MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X10.0 ML BOTTLE | 01/07/1999 |
| 2803 | NDA/MAL/HDP/5401 | PIRAMAL HEALTHCARE LTD | TATA UGANDA LIMITED | HALOTHANE | HALOTHANE | 250ML | PIRAMAL ENTERPRISES LTD -- DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH | INDIA | OTHER SYSTEMIC LIQUID INHALATIONS | 1.0X250.0 ML BOTTLE | 01/07/2005 |
| 2804 | NDA/MAL/HDP/5404 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | HIFENAC P | ACECLOFENAC + PARACETAMOL | 100 MG + 500 MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2805 | NDA/MAL/HDP/5406 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | HIFENAC SR | ACECLOFENAC | 200 MG | INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2806 | NDA/MAL/HDP/5409 | LINCOLN P'CALS LTD | METRO PHARMACEUTICALS LIMITED | MINTO GEL | ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE | 150 MG + 150 MG + 25 MG | LINCOLN PARENTERAL LTD .-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X180.0 ML BOTTLE | 01/07/2012 |
| 2807 | NDA/MAL/HDP/5410 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | UNICTAM 1500 | AMPICILLIN + SULBACTAM | 1000 MG + 500 MG | MEDICAL UNION PHARMACEUTICALS LTD - -ABU SULTAN, CR 13363 ISMAILLIA, EGYPT | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2808 | NDA/MAL/HDP /5414 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | XYLO-ACINO 0.1% | XYLOMETAZOLINE | 0.1 % W/V | MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN | GERMANY | NASAL TOPICAL DROPS | 1.0X1.0X10.0 ML BOTTLE | 01/07/2007 |
| 2809 | NDA/MAL/HDP /5415 | CENTAUR PHARMACEUTICALS PVT. LTD | GITTOES PHARMACEUTICALS LIMITED | SINAREST | OXYMETAZOLINE | 0.05%W/V | CENTAUR PHARMACEUTICALS PVT LTD - -PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA | INDIA | NASAL TOPICAL DROPS | 1.0X10.0 ML BOTTLE | 01/07/2009 |
| 2810 | NDA/MAL/HDP /5416 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | CIPROX | CIPROFLOXACIN | 0.2%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2811 | NDA/MAL/HDP/5417 | PHARMA INTERNATIONAL.CO | OMAB UGANDA LIMITED | CIPROPHARM | CIPROFLOXACIN | 500MG | PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2007 |
| 2812 | NDA/MAL/HDP/5418 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | PAEDIATRIC CO-TRIMOXAZOLE | CO-TRIMOXAZOLE | 240MG/5ML | MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2005 |
| 2813 | NDA/MAL/HDP/5419 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-CPM | CHLORPHENIRAMINE | 4MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER | 01/07/2005 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2814 | NDA/MAL/HDP/5423 | HETERO LABS LTD | AIVEEN (U) LIMITED | EFAVIRENZ+LAMIVUDINE+TENOFOVIR | EFAVIRENZ+LAMIVUDINE+TENOFOVIR | 600MG/300MG/300MG | HETERO DRUGS LTD-UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055 HETERO LABS LTD. UNIT (V) .-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET JAR,1.0X100.0 TABLET JAR | 01/07/2013 |
| 2815 | NDA/MAL/HDP/5425 | ROYAL GROUP | HARLEYS UGANDA LIMITED | PARACETAMOL | PARACETAMOL | 500MG | HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-INDIA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2014 |
| 2816 | NDA/MAL/HDP/5428 | FOURRTS(INDIA) LABORATORIES PVT.LIMITED | SUPER MEDIC LTD | CIPFIL 500 | CIPROFLOXACIN | 500MG | FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2817 | NDA/MAL/HDP/5429 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CIPRO-500 | CIPROFLOXACIN | 500MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON | 01/07/2006 |
| 2818 | NDA/MAL/HDP/5435 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | PIC | PARACETAMOL+IBUPROFEN+CAFFEINE | 500MG+200MG+30MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X25.0X4.0 TABLET STRIP | 01/07/2015 |
| 2819 | NDA/MAL/HDP/5439 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENIRON SYRUP | VITAMIN B6 + FERROUS GLUCONATE + VITAMIN B1 + VITAMIN C + VITAMIN B2 | 2MG/5ML + 200MG/5ML + 2MG/5ML + 20MG/5ML + 2MG/5ML | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2820 | NDA/MAL/HDP/5441 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL NASATAB TABLETS | PARACETAMOL+CHLORPHENIRAMINE+PSEUDOEPHEDRINE | 500MG+4MG+60MG | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 2821 | NDA/MAL/HDP/5442 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | CHLORAMPHENICOL OPHTHALMIC OINTMENT USP 1% | CHLORAMPHENICOL | 1%W/W | NEM LABORATORIES PVT LTD 133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA | INDIA | OPHTHALMIC OINTMENTS | 1.0X20.0X3.5 G TUBE | 01/07/2013 |
| 2822 | NDA/MAL/HDP/5444 | MSD (PTY) LIMITED SA | SURGIPHARM (U) LIMITED | AERIUS TABLETS | DESLORATIDINE | 5MG | MSD (PTY) LTD- LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA SCHERING PLOUGH LABO NV-INDUSTRIE PARK 30, ZONE A, 2220, HEIST OP-DEN-BERG | CANADA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X15.0 TABLET BLISTER | 01/07/2001 |

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| 2823 | NDA/MAL/HDP/5447 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | DICLOFENAC | DICLOFENAC SODIUM | 50MG | TRIVENI FORMULATION LTD-PLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CARTON,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2012 |
| 2824 | NDA/MAL/HDP/5449 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | CLOFENAC 50 | DICLOFENAC SODIUM | 50MG | HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 2825 | NDA/MAL/HDP/5454 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | MOXILEB | AMOXICILLIN | 125MG/5ML | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY POWDERS | 1.0X100.0 ML BOTTLE | 01/07/2010 |

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| 2826 | NDA/MAL/HDP/5457 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FALCIMON 100/270 B/L | ARTESUNATE+AMODIAQUINE | 100MG+270MG | CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER | 01/07/2014 |
| 2827 | NDA/MAL/HDP/5458 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FALCIMON 50/135 B/L | ARTESUNATE+AMODIAQUINE | 50MG+135MG | CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER | 01/07/2014 |
| 2828 | NDA/MAL/HDP/5460 | GUILIN PHARMACEUTICALS CO.LTD | TRIDEM PHARMA UGANDA LIMITED | ASAQ GPSC | ARTESUNATE+AMODIAQUINE | 50MG+135MG | GUILIN PHARMACEUTICALS CO. LTD-NO 43 QILIDIAN ROAD GUILIN GUANGXI CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0X20.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER | 01/07/2011 |

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| 2829 | NDA/MAL/HDP/5464 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CO-METHER | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X4.0 TABLET BLISTER,1.0X3.0X8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,2.0X6.0 TABLET BLISTER,4.0X6.0 TABLET BLISTER,1.0X1.0X24.0 TABLET | 01/07/2007 |
| 2830 | NDA/MAL/HDP/5467 | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMSIDAR | SULFADOXINE/PYRIMETHAMINE | 525MG | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 2831 | NDA/MAL/HDP/5469 | BAYER PHARMA AG | SURGIPHARM (U) LIMITED | NIMOTOP | NIMODIPINE | 0.2MG/ML | SOLUPHARM GMBH - INDUSTRIESTRASSE 3, 34212 MELSUNGEN BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | PARENTERAL ORDINARY I V VIALS | 1.0X50.0 ML VIAL | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2832 | NDA/MAL/HDP/5471 | MICRO LABS LTD | LABOREX UGANDA LIMITED | AVAS 40 | ATORVASTATIN | 40MG | MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2013 |
| 2833 | NDA/MAL/HDP/5472 | CLARIS OTSUKA LIMITED | REDDYS PHARMA LIMITED | NS | SODIUM CHLORIDE | 0.9%W/V | OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X100.0 ML BAG | 01/07/2007 |
| 2834 | NDA/MAL/HDP/5473 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TROYPOFOL | PROPOFOL | 1%W/V | TROIKAA PHARMACEUTICALS LTD .-C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X20.0 ML VIAL | 01/07/2012 |

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| 2835 | NDA/MAL/HDP/5474 | PHARMA INTERNATIONAL.CO | OMAB UGANDA LIMITED | CEFODOX | CEFPODOXIME PROXETIL | 200MG | PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 01/07/2005 |
| 2836 | NDA/MAL/HDP/5476 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | MESPORIN 1000MG I.V | CEFTRIAXONE | 1000MG | LABESFAL LABORATORIES-ALMIRO S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157, SANTIAGO DE BESTERIROS PORTUGAL | PORTUGAL | PARENTERAL ORDINARY DRY VIALS | 1.0X1000.0 MG VIAL + 10 ML WFI | 01/07/2002 |
| 2837 | NDA/MAL/HDP/5478 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BECORT 50 | BECLOMETHASONE DIPROPIONATE | 50MCG/ACTUATION | CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA | INDIA | LUNG ADMINISTRATION METERED-DOSE INHALER | 1.0X1.0X200.0 METERED DOSE CANNISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2838 | NDA/MAL/HDP/5479 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | RANFERON 12 CAPSULES | MULTI-INGREDIENT | MULTI-INGREDIENT | SUN PHARMACEUTICAL INDUSTRIES LIMITED,-INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X30.0 CAPSULE BLISTER | 01/07/1997 |
| 2839 | NDA/MAL/HDP/5482 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-LIN | SALBUTAMOL | 2MG/5ML | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2010 |
| 2840 | NDA/MAL/HDP/5483 | GUILIN PHARMACEUTICALS CO.LTD | TRIDEM PHARMA UGANDA LIMITED | ASAQ GPSC | ARTESUNATE + AMODIAQUINE | 25 MG + 67.5 MG | GUILIN PHARMACEUTICALS CO. LTD-NO 43 QILIDIAN ROAD GUILIN GUANGXI CHINA | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0X20.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER | 01/07/2011 |

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| 2841 | NDA/MAL/HDP/5486 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | FOSEAL 400 | SEVELAMER HCL | 400MG | EMCURE PHARMACEUTICALS LIMITED-PLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER | 01/07/2009 |
| 2842 | NDA/MAL/HDP/5489 | UNICHEM LABORATORIES LTD | EUROPA HEALTHCARE (U) LTD | CORBIS-5 | BISOPROLOL | 5MG | UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 01/07/2008 |
| 2843 | NDA/MAL/HDP/5495 | AGOG PHARMA LTD | GITTOES PHARMACEUTICALS LIMITED | AGOCAL TABLETS | CALCIUM LACTATE | 300MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2844 | NDA/MAL/HDP/5496 | ASTRAZENECA AG | MACNAUGHTON LIMITED | ATACAND 16MG | CANDESARTAN CILEXETIL | 16MG | ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN) | SWEDEN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2010 |
| 2845 | NDA/MAL/HDP/5497 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | EXPEN | BENZYLPENICILLIN | 1MU | SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X1.0 MU VIAL,1.0X10.0X1.0 MU VIAL,1.0X100.0X1.0 MU VIAL | 01/07/2011 |
| 2846 | NDA/MAL/HDP/5591 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | SWISSCILLIN | AMPICILLIN | 500MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X500.0 MG VIAL | 01/07/2011 |

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| 2847 | NDA/MAL/HDP/5619 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | RABELOC 20 | RABEPRAZOLE SODIUM | 20MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X1.0X10.0 TABLET STRIP | 01/07/2006 |
| 2848 | NDA/MAL/HDP/5639 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | FEROMAX | IRON SUCROSE | 20MG/ML | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E. | UNITED ARAB EMIRATES | PARENTERAL ORDINARY INFUSION AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 01/07/2014 |
| 2849 | NDA/MAL/HDP/5644 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | FORTIFIED PROCAINE PENICILLIN | FORTIFIED PROCAINE PENICILLIN | 4 MEGA UNITS | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407 | CHINA | PARENTERAL ORDINARY VIALS | 1.0X4.0 MU VIAL | 01/07/2001 |

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| 2850 | NDA/MAL/HDP/5648 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | CLOXACILLIN SODIUM | CLOXACILLIN SODIUM | 500MG | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-#14, II PHASE PIA, BANGALORE 560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL | 01/07/2010 |
| 2851 | NDA/MAL/HDP/6032 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | MET XL 100 | METOPROLOL SUCCINATE | 100MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 2852 | NDA/MAL/HDP/6034 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOXIN -250 DT | AMOXICILLIN TRIHYDRATE | 250 MG | MILAN LABS PVT LTD-63-67 JAWAHAR CO.OP. INDUSTRIAL ESTATE KAMOTHE,NAVI MUMBAI | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 2853 | NDA/MAL/HDP/6036 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | OFLOTECH-O | OFLOXACIN + ORNIDAZOLE | 200MG + 500MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 27/03/2019 |
| 2854 | NDA/MAL/HDP/6037 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AVIT | VITAMIN A | 200,000 IU | OLIVE HEALTHCARE-197/2, ATHIYAWAD DABHEL VILLAGE DAMAN 396210 (U.T) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X30.0 CAPSULE BLISTER,1.0X10.0X 10.0 CAPSULE BLISTER,1.0X1000. 0 CAPSULE JAR | 01/07/2017 |
| 2855 | NDA/MAL/HDP/6040 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | U-TRYP | ULINASTATIN | 100,000 I.U | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2856 | NDA/MAL/HDP/6041 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | CANDIZOL | CLOTRIMAZOLE | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | VAGINAL TABLETS | 1.0X6.0 PESSARY STRIP | 01/07/2017 |
| 2857 | NDA/MAL/HDP/6047 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | HERTRAZ 150 | TRASTUZUMAB (R-DNA ORIGIN) | 150MG | BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099 | INDIA | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X150.0 MG VIAL ,1X10ML VIAL OF WFI | 01/07/2017 |
| 2858 | NDA/MAL/HDP/6050 | MICRO LABS LTD | LABOREX UGANDA LIMITED | ITACARE | ITRACONAZOLE | 100MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2859 | NDA/MAL/HDP/6053 | SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | GLIMEPIRIDE | GLIMEPIRIDE | 4MG | LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKOW-INDUSTRIAL ESTATES | POLAND | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2860 | NDA/MAL/HDP/6054 | SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | GLIMEPIRIDE | GLIMEPIRIDE | 1MG | LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKOW-INDUSTRIAL ESTATES | POLAND | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2012 |
| 2861 | NDA/MAL/HDP/6057 | BROOKES PHARMACEUTICAL LABORATORIES L | HARLEYS UGANDA LIMITED | CORAM 5MG | AMLODIPINE BESYLATE | 5MG | BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2862 | NDA/MAL/HDP /6058 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | FENTANYL FRESENIUS 100MCG/2ML | FENTANYL | 100MCG/2ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2017 |
| 2863 | NDA/MAL/HDP /6059 | RESONANT PHARMACEUTICALS PVT LTD | SHREEJI CARE LIMITED | NEUROZONE | MECOBALAMIN + PREGABALIN | 750MCG + 75MG | ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 2864 | NDA/MAL/HDP /6061 | CIPLA LTD.. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | NASEHALER | MOMETASONE FUROATE | 50MCG /SPRAY | CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775 | INDIA | NASAL TOPICAL SPRAYS WITHOUT GAS | 1.0X140.0 METERED DOSE BOTTLE | 01/07/2017 |

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| 2865 | NDA/MAL/HDP/6065 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | PROXYREN | PIROXICAM | 20MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 2866 | NDA/MAL/HDP/6067 | RENE PHARMACY(R) LTD.. | RENE PHARMACY LTD | DIAZEPAM | DIAZEPAM | 5MG | NEM LABORATORIES PVT LTD 133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2867 | NDA/MAL/HDP/6070 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | VAZKOR | AMLODIPINE BESILATE | 10MG | DEVA HOLDING A.S-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 2868 | NDA/MAL/HDP/6071 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | VAZKOR | AMLODIPINE BESILATE | 5MG | DEVA HOLDING A.S-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2869 | NDA/MAL/HDP/6073 | EVA PHARMA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MILGA | BENFOTIAMINE + PYRIDOXINE + CYANOCOBALAMIN | 40MG + 60MG + 20MCG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2870 | NDA/MAL/HDP/6075 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OLOHISTINE | OLOPATADINE HYDROCHLORIDE | 1MG/ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2017 |

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| 2871 | NDA/MAL/HDP/6076 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | FALCI CARE | ARTESUNATE | 30MG | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X30.0 MG VIAL + 1*5 ML OF 0.9%W/V NACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE | 01/07/2017 |
| 2872 | NDA/MAL/HDP/6078 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TIMOLOL MALEATE | TIMOLOL MALEATE | 5MG/ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2017 |
| 2873 | NDA/MAL/HDP/6079 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | ALLERGEX | CHLORPHENIRAMINE MALEATE | 4MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 2874 | NDA/MAL/HDP/6080 | EXPHAR SA | SURGIPHARM (U) LIMITED | FEBRILEX JUNIOR | PARACETAMOL+CHLORPHENIRAMINE MALEATE | 125MG+1MG/5ML | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X150.0 ML BOTTLE | 01/07/2017 |
| 2875 | NDA/MAL/HDP/6081 | EXPHAR SA | SURGIPHARM (U) LIMITED | ANTALGEX T | PARACETAMOL/TRAMADOL HYDROCHLORIDE | 325MG/37.5MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 2876 | NDA/MAL/HDP/6082 | EXPHAR SA | SURGIPHARM (U) LIMITED | CROMSOL | SODIUM CROMOGLYCATE | 2%W/V | AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345 | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2017 |

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| 2877 | NDA/MAL/HDP/6086 | UNOSOURCE PHARMA LTD | MEDVIN PHARMA LIMITED | ACEWEL-P | ACECLOFENAC+PARACETAMOL | 100MG+500MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2017 |
| 2878 | NDA/MAL/HDP/6092 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPOTCLAV 1000 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 875 MG + 125 MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2879 | NDA/MAL/HDP/6093 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPOTCLAV 625 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 500 MG + 125 MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 2880 | NDA/MAL/HDP/6094 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPOTCLAV 375 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 250 MG + 125 MG | SPARSH BIO-TECH PVT. LTD-PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR-361 006, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2881 | NDA/MAL/HDP/6095 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | DIPGEN | BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE | 0.64 MG/G + 1 MG/G | S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE,1.0X15.0 G TUBE | |
| 2882 | NDA/MAL/HDP/6099 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | HARIPIL-60 | ARTESUNATE | 60MG | PSYCHOTROPICS INDIA LTD - PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*5 ML OF 0.9% W/V NACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE | 01/07/2017 |

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| 2883 | NDA/MAL/HDP/6101 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | TELPRESS-H 40/12.5 | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2884 | NDA/MAL/HDP/6102 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | TELPRESS 80 | TELMISARTAN | 80MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2885 | NDA/MAL/HDP/6103 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | OZACE MD 5 | OLANZAPINE | 5MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2886 | NDA/MAL/HDP /6114 | FDC LTD | AIVEEN (U) LIMITED | ZOXAN | CIPROFLOXACIN | 0.3% W/V | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 01/07/2005 |
| 2887 | NDA/MAL/HDP /6116 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | ZOLEDRO-DENK 4MG/5ML | ZOLEDRONIC ACID | 4MG/5ML | HAMELN PHARMACEUTICALS GMBH-LANGES FELD 13 31789 HAMELN | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X5.0 ML VIAL | 01/07/2017 |
| 2888 | NDA/MAL/HDP /6117 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | GRAN-DENK | GRANISETRON HYDROCHLORIDE | 1MG/ML | SIEGFRIED HAMELN GMBH-LANGES FELD 13,31789 HAMELN | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X5.0 ML AMPOULE | 01/07/2017 |

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| 2889 | NDA/MAL/HDP /6118 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | L-TRIM DS | SULPHAMETHOXAZOLE + TRIMETHOPRIM | 800MG + 160MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2890 | NDA/MAL/HDP /6120 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | KMINE | KETAMINE HYDROCHLORIDE | 50MG/ML | NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA NEPAL | NEPAL | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 01/07/2017 |
| 2891 | NDA/MAL/HDP /6121 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LTD | DEXIREN | DEXKETOPROFEN TROMETAMOL | 25MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 2892 | NDA/MAL/HDP/6126 | MEDICAL UNION PHARMACEUTICALS | KARURI PHARMACEUTICALS LTD. | DERMOTRACIN | NEOMYCIN SULPHATE + BACITRACIN | 165,000 IU + 12,500 IU | MEDICAL UNION PHARMACEUTICAL CO.-PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | TOPICAL EXTERNAL PRESSURISED AEROSOLS | 1.0X150.0 ML CANNISTER | 01/07/2016 |
| 2893 | NDA/MAL/HDP/6127 | JANSSEN-CILAG INTERNATIONAL NV | MEDICAL ACCESS (UGANDA) LIMITED | INTELENCE | ETRAVIRINE | 25MG | JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA | ITALY | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET BOTTLE | 01/07/2016 |
| 2894 | NDA/MAL/HDP/6129 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | TRIUMEQ | DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE | 50MG + 600MG + 300MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK<br>GLAXOSMITHKLINE PHARMACEUTICALS SA-GRUNWALDZKA 189 STREET, 60-322 POZNANA | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 01/07/2016 |

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| 2895 | NDA/MAL/HDP/6132 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | KETOVID | KETOCONAZOLE | 2%W/W | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | TOPICAL EXTERNAL LIQUID SOAPS/WASHES | 1.0X120.0 ML BOTTLE | 01/07/2016 |
| 2896 | NDA/MAL/HDP/6133 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | RILIF-100 | ACECLOFENAC | 100MG | UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2897 | NDA/MAL/HDP/6134 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ZAMADOL P | TRAMADOL HYDROCHLORIDE+ ACETAMINOPHEN | 37.5MG+325MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 2898 | NDA/MAL/HDP/6135 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | TRIXONE-S | CEFTRIAXONE SODIUM+SULBACTAM | 1000MG+500MG | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA ZEISS PHARMA LIMITED-IGC,SIDCO, PHASE II, SAMBA, JAMMU - 184121,(J&K) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 ML VIAL | 01/07/2016 |
| 2899 | NDA/MAL/HDP/6137 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | LUPRODEX | LEUPROLIDE ACETATE | 3.75MG | BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA | INDIA | PARENTERAL ORDINARY S C VIALS | 1.0X1.0 ML VIAL + 1*2ML GLASS AMPOULE OF DILUENT (EACH ML CONTAINS 50MG OF D-MANNITOL AND WFI TO Q.S) + 1 DISPOSABLE SYRINGE, 2 NEEDLES AND 2 ALCOHOL SWABS | 01/07/2016 |
| 2900 | NDA/MAL/HDP/6141 | UNOSOURCE PHARMA LTD | MEDVIN PHARMA LIMITED | ACEWEL | ACECLOFENAC | 100MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2901 | NDA/MAL/HDP/6142 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOCARB | ACTIVATED CHARCOAL | 0.25GM | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET BOTTLE,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2016 |
| 2902 | NDA/MAL/HDP/6143 | IESUS GROUP | SHREEJI PHARMACEUTICALS LIMITED | CONTRACTUBEX | EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLANTOIN | 10G+5000 I.U+1G/100G | MARCYRL PHARMACEUTICAL INDUSTRIES.-EL OBOUR CITY CAIRO | EGYPT | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2016 |
| 2903 | NDA/MAL/HDP/6144 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | NIKO | PARACETAMOL | 500MG | NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA | NEPAL | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2904 | NDA/MAL/HDP/6149 | AMANTA HEALTHCARE LTD | PHARMA VILLE LIMITED | SODIUM CHLORIDE INFUSION | SODIUM CHLORIDE | 0.9%W/V | AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)-PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2016 |
| 2905 | NDA/MAL/HDP/6158 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | DESEFIN | CEFTRIAXONE SODIUM | 1G | DEVA HOLDING A.S-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG | TURKEY | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2016 |
| 2906 | NDA/MAL/HDP/6159 | NORVATIS ACCESS | SURGIPHARM (U) LIMITED | AMLODIPINE | AMLODIPINE | 10MG | LEK PHARMACEUTICALS .D.D VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA | SLOVENIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2907 | NDA/MAL/HDP /6166 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | GMICIN | GENTAMICIN SULPHATE | 0.3%W/V | NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA | NEPAL | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE | 01/07/2016 |
| 2908 | NDA/MAL/HDP /6167 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | AKUROSE | IRON SUCROSE | 20MG/ML | AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403 | INDIA | PARENTERAL ORDINARY INFUSION AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 07/01/2016 |
| 2909 | NDA/MAL/HDP /6169 | JANSSEN-CILAG INTERNATIONAL NV | MEDICAL ACCESS (UGANDA) LIMITED | INTELENCE | ETRAVIRINE | 100MG | JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA | ITALY | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET BOTTLE | 01/07/2016 |

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| 2910 | NDA/MAL/HDP/6171 | ROTEXMEDICA GMBH ARZNEIMITTELWERK | GITTOES PHARMACEUTICALS LIMITED | SUXAMETHONIUM CHLORIDE | SUXAMETHONIUM CHLORIDE | 50MG/ML | ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU | GERMANY | PARENTERAL ORDINARY DRY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2016 |
| 2911 | NDA/MAL/HDP/6173 | CIPLA LTD.. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | MONTAIR 5 | MONTELUKAST SODIUM | 5MG | CIPLA LTD ----L139 TO L-146 VERNA INDUSTRIAL ESTATE VERNA SALCETTE GOA 403 722 | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2912 | NDA/MAL/HDP/6174 | PANPHARMA GMBH | GITTOES PHARMACEUTICALS LIMITED | FLUPHENAZINE DECANOATE INJECTION USP 25MG/ML | FLUPHENAZINE DECANOATE | 25MG/ML | PANPHARMA GMBH-BUNSENSTRASSE 4, 22946 TRITTAU | GERMANY | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2016 |

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| 2913 | NDA/MAL/HDP/6179 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | ON.SETRON-DENK 4MG ODT | ONDANSENTRON | 4MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2016 |
| 2914 | NDA/MAL/HDP/6181 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | AZINOWEL-500 | AZITHROMYCIN | 500MG | AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2016 |
| 2915 | NDA/MAL/HDP/6184 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ATOXIA 60MG | ETORICOXIB | 60MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 2916 | NDA/MAL/HDP /6185 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | DOLOFORTE DENK | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 37.5MG + 325MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2917 | NDA/MAL/HDP /6186 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ATOXIA 90MG F.C. TABLETS | ETORICOXIB | 90MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2918 | NDA/MAL/HDP /6188 | DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD | GAMA PHARMACEUTICALS (U) LIMITED | GIZLAN 150 | IRBESARTAN | 150MG | DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 2919 | NDA/MAL/HDP/6189 | UNEED GLOBAL GROUP LIMITED | ABACUS PHARMA (AFRICA) LIMITED | WORMEE-4 | ALBENDAZOLE | 400MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2016 |
| 2920 | NDA/MAL/HDP/6190 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | D-LYTE | ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSIUM CHLORIDE,ANHYDROUS GLUCOSE+SODIUM CHLORIDE+TRISODIUM CITRATE+POTASSI | 2.7MG+0.52MG+0.58MG+0.30MG PER 200ML SACHET,6.75MG+1.30MG+1.45MG+0.75MG PER 500ML SACHET,13.5MG+2.60MG+2.90MG+1.50MG PER 1000ML SACHET | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X500.0 ML SACHET,1.0X1000.0 ML SACHET,1.0X200.0 ML SACHET | 01/07/2015 |
| 2921 | NDA/MAL/HDP/6191 | AMOUN PHARMACEUTICALS COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | KAPRON AMPOULE | TRANEXAMIC ACID | 500MG/5ML | AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X6.0X5.0 ML AMPOULE | 01/07/2016 |

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| 2922 | NDA/MAL/HDP /6194 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | FENTANYL FRESENIUS 500MCG/10ML | FENTANYL CITRATE | 500MCG/10ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X10.0 ML AMPOULE | 01/07/2016 |
| 2923 | NDA/MAL/HDP /6195 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | MORPHINE SULPHATE FRESENIUS | MORPHINE SULPHATE | 10MG/ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2016 |
| 2924 | NDA/MAL/HDP /6196 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | MORPHINE SULPHATE FRESENIUS | MORPHINE SULPHATE | 15MG/ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2016 |

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| 2925 | NDA/MAL/HDP/6197 | ALLY PHARMA OPTIONS PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | NYSTATIN | NYSTATIN | 100,000 IU | MEDICAMEN BIOTECH LTD .-SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA | INDIA | VAGINAL TABLETS | 1.0X14.0 PESSARY STRIP | 01/07/2016 |
| 2926 | NDA/MAL/HDP/6201 | SPARSH BIO-TECH PVT.LTD. | ABACUS PHARMA (AFRICA) LIMITED | SPAMOXIFLOX | AMOXICILLIN TRIHYDRATE + FLUCLOXACILLIN SODIUM | 250MG + 250MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE STRIP | 01/07/2016 |
| 2927 | NDA/MAL/HDP/6203 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DEROX-5 | AMLODIPINE BESILATE | 5MG | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2016 |

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| 2928 | NDA/MAL/HDP/6204 | AMANTA HEALTHCARE LTD | PHARMA VILLE LIMITED | GLUCOSE 5% I.V | GLUCOSE | 5%W/V | AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)-PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2016 |
| 2929 | NDA/MAL/HDP/6207 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | GO!GEL | DICLOFENAC DIETHYLAMINE+METHYL SALICYLATE | 1.16%W/W + 10%W/W | S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2016 |
| 2930 | NDA/MAL/HDP/6211 | EXPHAR SA | SURGIPHARM (U) LIMITED | CLOFAINS | PARACETAMOL/DICLOFENAC SODIUM | 500MG/50MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 2931 | NDA/MAL/HDP/6217 | INDIAN IMMUNOLOGICALS LTD | TATA UGANDA LIMITED | ELOVAC -B | HEPATITIS B (RDNA) | 20MCG/ML | HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD)- RAKSHAPURAM GACHIBOWLI POST HYDERABAD 500032 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0X1.0 ML VIAL (1 DOSE VIAL) | 01/07/2016 |
| 2932 | NDA/MAL/HDP/6218 | ASTRA ZENECA | MACNAUGHTON LIMITED | FORXIGA | DAPAGLIFLOZIN | 10MG | ASTRAZENECA PHARMACEUTICALS LP-4601 HIGHWAY 62 EAST, MOUNT VERNON, IN 47620-1500 - UNITED STATES OF AMERICA | UNITED STATES | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2016 |
| 2933 | NDA/MAL/HDP/6220 | SHOSAAN ASIC PACIFIC | RENE PHARMACY LTD | METHYLDOPA | METHYLDOPA | 250MG | NEM LABORATORIES PVT LTD PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2934 | NDA/MAL/HDP/6223 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROPROST- RT | LATANOPROST | 0.005%W/V | AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA | INDIA | OPHTHALMIC DROPS | 1.0X2.5 ML BOTTLE | 01/07/2016 |
| 2935 | NDA/MAL/HDP/6227 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ISONIAZID | ISONIAZID | 300MG | MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13<br>MIDC, WALUJ INDUSTRIAL AREA,<br>AURANGABAD. – 431136,<br>MAHARASHTRA STATE,<br>INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2016 |
| 2936 | NDA/MAL/HDP/6229 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | CO-FLUAMPICIL CAPSULES BP 500MG | FLUCLOXACILLIN SODIUM + AMPICILLIN TRIHYDRATE | 250MG +250MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0 CAPSULE STRIP | 01/07/2016 |

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| 2937 | NDA/MAL/HDP/6230 | CACHET PHAMACUITICALS PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | EMITINO | ONDANSENTRON | 4MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2938 | NDA/MAL/HDP/6231 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP DISPERSIBLE | DIHYDROARTEMISININ/PIPERAQUINE | 20MG/160MG | GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X35.0 TABLET BLISTER | 01/07/2016 |
| 2939 | NDA/MAL/HDP/6232 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | H-CURE | LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE | 30MG + 250MG + 500MG | FREDUN PHARMACEUTICALS LTD-VEOOR PALGHAR ( E ) 401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X7.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2CAPSULES OF LANSOPRAZOLE + 2 TABLETS OF CLARITHROMYCIN + 2 TABLETS OF TINIDAZOLE) | 01/07/2016 |

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| 2940 | NDA/MAL/HDP/6234 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP DISPERSIBLE | DIHYDROARTEMESININE/ PIPERAQUINE PHOSPHATE | 40MG/320MG | GUILIN PHARMACEUTICAL CO.,LTD-NO 43 QILIDIAN ROAD GUILIN 541002, GUANGXI | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X25.0 TABLET BLISTER | 01/07/2016 |
| 2941 | NDA/MAL/HDP/6235 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ANGINET 160MG | VALSARTAN | 160MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2942 | NDA/MAL/HDP/6237 | HETERO LABS LTD | AIVEEN (U) LIMITED | LOPINAVIR/RITONAVIR | LOPINAVIR/ RITONAVIR | 100MG/25MG | HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X120.0 TABLET BOTTLE,1.0X60.0 TABLET CONTAINER | 01/07/2016 |

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| 2943 | NDA/MAL/HDP/6238 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILONG -AM | NEBIVOLOL HYDROCHLORIDE + AMLODIPINE BESILATE | 5MG + 5MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2944 | NDA/MAL/HDP/6239 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | GSUNATE | ARTESUNATE | 60MG | BLISS GVS PHARMA LTD-PLOT 73 -76 SILVER INDUSTRIAL ESTATE BHIMPORE DAMAN 396 210 (UT) EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*5 ML AMPOULE OF 0.9%W/V NACL + 1*1 ML OF 5%W/V SODIUM BICARBONATE | 01/07/2016 |
| 2945 | NDA/MAL/HDP/6242 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP | DIHYDROARTEMESININ/PIPERAQUINE PHOSPHATE | 80MG/640MG | GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X25.0 TABLET BLISTER | 01/07/2016 |

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| 2946 | NDA/MAL/HDP/6243 | ABBVIE (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | SURVANTA | BERACTANT | 100MG/4ML | ABBVIE NORTH CHICAGO FACILITY-1401 SHERDAN ROAD NORTH CHICAGO FACILITY ILLINOIS 60064 - 4000 | UNITED STATES | TOPICAL EXTERNAL INSTILLATION VIALS | 1.0X4.0 ML VIAL,1.0X8.0 ML VIAL | 01/07/2016 |
| 2947 | NDA/MAL/HDP/6244 | CACHET PHAMACUITICALS PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | CABALIN | PREGABALIN | 75MG | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X12.0 CAPSULE BLISTER | 01/07/2016 |
| 2948 | NDA/MAL/HDP/6245 | BIOLOGICAL E. LTD | ABACUS PHARMA (AFRICA) LIMITED | COSCOPIN LINCTUS | NOSCAPINE + CHLORPHENIRAMINE MALEATE + SODIUM CITRATE + AMMONIUM CHLORIDE | 7MG+2 MG+ 3.25 MG+28 MG/5 ML. | BIOLOGICAL E. LTD -PLOT NO.31 & 32 PHARMA CITY SELAQUI INDUSTRIAL AREA SELAQUI DEHRADUN-248 197 UTTARAKHAND,INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2949 | NDA/MAL/HDP/6246 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | LUTHER | ARTEMETHER | 80MG/ML | CIRON DRUGS AND PHARMACEUTICALS PVT. LTD-N-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X6.0X1.0 ML AMPOULE | 01/07/2016 |
| 2950 | NDA/MAL/HDP/6247 | MILAN LABORATORIES LTD (INDIA) PVT LTD | GITTOES PHARMACEUTICALS LIMITED | MILOXY 250-DT | AMOXICILLIN TRIHYDRATE | 250MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2951 | NDA/MAL/HDP/6249 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL METRONIDAZOLE -200 TABLETS | METRONIDAZOLE | 200MG | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2952 | NDA/MAL/HDP /6256 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | AZIMAX- 250 | AZITHROMYCIN DIHYDRATE | 250MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 01/07/2016 |
| 2953 | NDA/MAL/HDP /6257 | JANSSEN-CILAG INTERNATIONAL NV | MEDICAL ACCESS (UGANDA) LIMITED | EDURANT | RILPIVIRINE | 25MG | JANSSEN CILAG S.P.A-VIA C.JANSSEN, BORGO | ITALY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2016 |
| 2954 | NDA/MAL/HDP /6264 | ACINO PHARMA AG | GOODMAN INTERNATIONAL LTD | PARACONICA 1000 MG IV | PARACETAMOL | 10MG/ML | S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO-POTENZA (PZ) ITALY | ITALY | PARENTERAL ORDINARY I V VIALS | 1.0X100.0 ML VIAL | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2955 | NDA/MAL/HDP/6267 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | TRAMADOL DENK 50 | TRAMADOL HYDROCHLORIDE | 50MG | LOSAN PHARMA GMBH-OTTO-HAHN-STR 13 79395 NEUENBURG | GERMANY | ORAL SOLID ORDINARY EFFERVESCENT TABLETS | 1.0X10.0 TABLET BOTTLE | 01/07/2016 |
| 2956 | NDA/MAL/HDP/6270 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | FEBUMAC 80 | FEBUXOSTAT | 80MG | MACLEODS PHARMACEUTICALS LTD - - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 2957 | NDA/MAL/HDP/6281 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | HOMAGON | CHLORPHENAMINE MALEATE + CAFFEINE ANHYDROUS + PSEUDOEPHEDRINE HYDROCHLORIDE + PARACETAMOL | 4MG + 30MG + 30MG + 400MG | LABORATORY AND ALLIED LTD-PLOT 209/10349-MOMBASA ROAD NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER | 07/11/2018 |

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| 2958 | NDA/MAL/HDP/6282 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MEBUX-40 | FEBUXOSTAT | 40MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 07/11/2018 |
| 2959 | NDA/MAL/HDP/6283 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MEBUX-80 | FEBUXOSTAT | 80 MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 07/11/2018 |
| 2960 | NDA/MAL/HDP/6285 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN 493ML - 550KCAL | MULTI-INGREDIENT | MULTI-INGREDIENT | FRESENIUS KABI AUSTRIA GMBH --HAFNERSTRASSEM 36,A-8055 GRAZ, AUSTRIA FRESENIUS KABI AB-RAPSGATAN 7 SE-751 74 UPPSALA SWEDEN | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X493.0 ML BAG (1*[250ML AMINO ACID SOLUTION WITH ELECTROLYTES + 149ML GLUCOSE 42% SOLUTION + 94ML LIPID EMULSION], MULTI-CHAMBER PLASTIC BAGS | 07/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2961 | NDA/MAL/HDP/6286 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED - | SURGIPHARM (U) LIMITED | SMOFKABIVEN PERIPHERAL, EMULSION FOR INFUSION, 1206ML - 800KCAL | MULTI-INGREDIENT | MULTI-INGREDIENT | FRESENIUS KABI AUSTRIA GMBH --HAFNERSTRASSEM 36,A-8055 GRAZ, AUSTRIA FRESENIUS KABI AB-RAPSGATAN 7 SE-751 74 UPPSALA SWEDEN | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1206.0 ML BAG (1*[656ML GLUCOSE 13% SOLUTION + 380ML AMINO ACID SOLUTION WITH ELECTROLYTES + 170ML LIPID EMULSION], MULTI-CHAMBER PLASTIC BAG) | 27/11/2018 |
| 2962 | NDA/MAL/HDP/6292 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VENAXAN 250 MG | LEVOFLOXACIN HEMIHYDRATE | 250MG | SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT. | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 27/11/2018 |
| 2963 | NDA/MAL/HDP/6293 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | NEUROGAB 150 | PREGABALIN | 150MG | "MACLEODS PHARMACEUTICALS LTD,--BLOCK N2, VILLAGE THEDA, POST OFFICE LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH – 174101 INDIA." | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 27/11/2018 |

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| 2964 | NDA/MAL/HDP/6294 | BAYER EAST AFRICA LTD | SURGIPHARM (U) LIMITED | NEXAVAR | SORAFENIB TOSYLATE | 200MG | BAYER PHARMA AG -51368 LEVERKUSEN GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X28.0 TABLET BLISTER | 07/11/2018 |
| 2965 | NDA/MAL/HDP/6300 | GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD | TRIDEM PHARMA UGANDA LIMITED | AMOXICILLIN | AMOXICILLIN | 250MG | SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA | CHINA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X2.0X10.0 CAPSULE BLISTER | 31/01/2018 |
| 2966 | NDA/MAL/HDP/6302 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | PLENOX | OFLOXACIN | 200MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |

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| 2967 | NDA/MAL/HDP/6304 | UNOSOURCE PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | UNOSURE 72 | LEVONORGESTREL | 1.5MG | AKUMS DRUGS & PHARMACEUTICALS LTD .- PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0 TABLET BLISTER | 27/03/2019 |
| 2968 | NDA/MAL/HDP/6305 | YELURI FORMULATIONS PVT LTD | QUALITY CHEMICALS LTD | ELMOX-CV 375 | AMOXICILLIN TRIHYDRATE +CLAVULANATE POTASSIUM | 250MG+125MG | YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X5.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 01/07/2018 |
| 2969 | NDA/MAL/HDP/6314 | YELURI FORMULATIONS PVT LTD | QUALITY CHEMICALS LTD | ELMOX-CV 625 | AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM | 500MG+125MG | YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X5.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 30/05/2018 |

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| 2970 | NDA/MAL/HDP /6317 | YELURI FORMULATIONS PVT LTD | QUALITY CHEMICALS LTD | ELMOX-CV 1000 | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 875MG + 125MG | YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X5.0 TABLET BLISTER,1.0X3.0X5.0 TABLET BLISTER | 01/07/2018 |
| 2971 | NDA/MAL/HDP /6325 | LEBEN LABORATORIES PVT. LTD. | MALIX PHARMA (U) LIMITED | PZQ TABLET | PRAZIQUANTEL | 600MG | LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X4.0 TABLET BLISTER,4.0X10.0 TABLET BLISTER | 29/11/2017 |
| 2972 | NDA/MAL/HDP /6327 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENESTEN-V | CLOTRIMAZOLE | 100MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X6.0 PESSARY BLISTER | 27/11/2018 |

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| 2973 | NDA/MAL/HDP/6332 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | AMOXIREN DT 250 | AMOXICILLIN TRIHYDRATE | 250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/11/2018 |
| 2974 | NDA/MAL/HDP/6334 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | ENDOPROST 250MCG/1ML | CARBOPROST TROMETHAMINE | 250MCG/ML | BHARAT SERUM AND VACCINES LIMITED-PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (EAST) INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X1.0 ML VIAL | 27/03/2019 |
| 2975 | NDA/MAL/HDP/6338 | BIOTON S.A. | BHL HEALTHCARE LIMITED | GENSULIN M30 (30/70) | INSULIN HUMAN OF RECOMBINANT DNA ORIGIN (30% SOLUBLE INSULIN + 70% ISOPHANE INSULIN) | 100 IU/ML | BIOTON S.A-MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI | POLAND | PARENTERAL ORDINARY S C VIALS | 1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 27/03/2019 |

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| 2976 | NDA/MAL/HDP/6339 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OXY-POL | OXYTETRACYCLINE HCL + POLYMYXIN B SULPHATE | 5MG+10000IU/G | EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O -- 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT | EGYPT | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 30/05/2018 |
| 2977 | NDA/MAL/HDP/6340 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | AXYLIN CAPSULES | AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM | 250MG +250 MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 31/01/2018 |
| 2978 | NDA/MAL/HDP/6341 | MACLEODS PHARMACEUTICALS LTDS LTD | VITACARE LIMITED | ROSUMAC 20 | ROSUVASTATIN CALCIUM | 20MG | MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2979 | NDA/MAL/HDP /6342 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIFENAC EYE DROPS | DICLOFENAC SODIUM SALT | 1MG/ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT | EGYPT | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 30/05/2018 |
| 2980 | NDA/MAL/HDP /6343 | BIOTON S.A. | BHL HEALTHCARE LIMITED | GENSULIN N | ISOPHANE HUMAN HUMAN OF RECOMBINANT DNA ORIGIN | 100 IU/ML | BIOTON S.A-MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI | POLAND | PARENTERAL ORDINARY S C VIALS | 1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 27/03/2019 |
| 2981 | NDA/MAL/HDP /6344 | S KAGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | LACTEASE | LACTULOSE SOLUTION | 66.7% W/W | S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 26/09/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2982 | NDA/MAL/HDP /6345 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MAGNABIOTIC 600MG VAIL | AMOXYCILLIN SODIUM/ CLAVULANATE POTASSIUM | 500MG/100MG | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 25/07/2018 |
| 2983 | NDA/MAL/HDP /6346 | BIOTON S.A. | BHL HEALTHCARE LIMITED | GENSULIN R | SOLUBLE HUMAN INSULIN OF RECOMBINANT DNA ORIGIN | 100 IU/ML | BIOTON S.A-MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI | POLAND | PARENTERAL ORDINARY S C VIALS | 1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE | 27/03/2019 |
| 2984 | NDA/MAL/HDP /6348 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP | SODIUM LACTATE SOLUTION +SODIUM CHLORIDE + CALCIUM CHLORIDE + POTASSIUM CHLORIDE | 0.533 GM +0.600 GM + 0.027G+ 0.040 GM/100ML | ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2985 | NDA/MAL/HDP/6349 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | GSUNATE -120 | ARTESUNATE | 120MG | BLISS INDASI LIFESCINCES PRIVATE LIMITED - -PLOT 73-76 SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN 396 210, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1*10ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*2ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE | 26/09/2018 |
| 2986 | NDA/MAL/HDP/6350 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | INVEL | METRONIDAZOLE + MICONAZOLE NITRATE | 500MG + 100MG | BLISS GVS PHARMA LIMITED-10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR,MAHARASHTRA 401404,INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X7.0 SUPPOSITORY STRIP | 27/03/2019 |
| 2987 | NDA/MAL/HDP/6353 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | DOLUTEGRAVIR /LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE TABLETS 50MG/300MG/300MG | DOLUTEGRAVIR+LAMIVUDINE+TENOFOVIR DISOPROXIL FUMARATE TABLETS | 50MG+300MG+300MG | LAURUS LABS LIMITED, (UNIT-2) - -PLOT NO:19, 20 & 21,WESTERN SECTOR, APSEZ, ATCHUTAPURAM MANDAL, VISAKHAPATNAM-DISTRICT-531011, ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X1.0X90.0 TABLET BOTTLE | 07/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2988 | NDA/MAL/HDP /6354 | EXPHAR SA. | SURGIPHARM (U) LIMITED | TIMOSOL ® | TIMOLOL MALEATE | O.5%W/V | AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345 | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2017 |
| 2989 | NDA/MAL/HDP /6361 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | NYSKA-P | NYSTATIN | 1,00,000 I.U/ML | S.KANT HEALTHCARE LTD-PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2018 |
| 2990 | NDA/MAL/HDP /6365 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | EASY PILL | LEVONORGESTREL | 1.5MG | CORONA REMEDIES PVT LTD-CORONA HOUSE, C MONDEAL BUSINESS PARK, NR. GURUDWARA GOVINDDHAM LANE, SG HIGHWAY, THALTEJ, AHMEDABAD 380059, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2991 | NDA/MAL/HDP /6369 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVXIM SUSPENSION | CEFIXIME TRIHYDRATE | 100MG/5ML | ASSOCIATED BIOTECH-VILLAGE : KISHANPURA, GURU MAJRA, BADDI, DISTT. SOLAN, INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 31/01/2018 |
| 2992 | NDA/MAL/HDP /6374 | MICRO LABS | MALIX PHARMA (U) LIMITED | PREDLEB-5 DT | PREDNISOLONE | 5MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 28/03/2018 |
| 2993 | NDA/MAL/HDP /6375 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ETHAMBUTOL DISPERSIBLE TABLETS 100 MG | ETHAMBUTOL HYDROCHLORIDE | 100MG | MACLEODS PHARMACEUTICALS LTD ,-PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET STRIP | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2994 | NDA/MAL/HDP/6380 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MAGNABIOTIC 1200MG VIAL | AMOXICILLIN + CLAVULANIC ACID | 1000MG+120MG | SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT | EGYPT | PARENTERAL ORDINARY DRY VIALS | 1.0X1.2 G VIAL | 25/07/2018 |
| 2995 | NDA/MAL/HDP/6381 | MANKIND PHARM LTD | TATA UGANDA LIMITED | SERTAKIND | SERTACONAZOLE NITRATE | 2.0%W/W | CURETECH SKINCARE-PLOT NO. 33 & 34, PHASE IV, BHATOLI KALAN, BADDI DISTT. SOLAN (HP) 173205 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X10.0 G TUBE,1.0X20.0 G TUBE | 27/03/2019 |
| 2996 | NDA/MAL/HDP/6383 | EXPHAR SA. | SURGIPHARM (U) LIMITED | EXXIB | CELECOXIB | 200MG | GRACURE PHARMACEUTICALS LIMITED E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN-301019 DIST. ALWAR, RAJASTHAN, INDI | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 2997 | NDA/MAL/HDP/6385 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | AMOXIKID-250 | AMOXICILLIN | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA | UGANDA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X10.0 TABLET STRIP | 25/07/2018 |
| 2998 | NDA/MAL/HDP/6386 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | JUSDEE 60K GRANULES | COLECALCIFEROL | 60000 IU | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X8.0X1.0 G SACHET | 30/05/2018 |
| 2999 | NDA/MAL/HDP/6389 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | METRONIDAZOLE BP | METRONIDAZOLE | 0.5%W/V | ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3000 | NDA/MAL/HDP/6390 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ROSUMAC 10 | ROSUVASTATIN CALCIUM | 10MG | MACLEODS PHARMACEUTICALS LTD ,.-PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 06/02/2019 |
| 3001 | NDA/MAL/HDP/6392 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MET XL 50 | METOPROLOL SUCCINATE | 50 MG | AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3002 | NDA/MAL/HDP/6394 | ADWIA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DANSET | ONDANSETRON HYDROCHLORIDE | 8MG | ADWIA -1ST INDUSTRIAL ZONE, A1, 10TH OF RAMADAN CITY | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X3.0X4.0 ML AMPOULE,1.0X1.0X4.0 ML AMPOULE | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3003 | NDA/MAL/HDP /6395 | EXPHAR SA. | SURGIPHARM (U) LIMITED | FLOXSOL ® | NORFLOXACIN | 0.3%W/V | AHLCON PARENTERALS (INDIA) LIMITED-SP-917-918, PHASE 111, BHIWADI - 301019, ALWAR, RAJASTHAN INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML VIAL | 28/05/2019 |
| 3004 | NDA/MAL/HDP /6396 | NVS KENYA LTD | SURGIPHARM (U) LIMITED | LETROZOLE 2.5 | LETROZOLE | 2.5MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3005 | NDA/MAL/HDP /6400 | MERIDIAN ENTERPRISES PRIVATE LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | FENSUPP-100 | DICLOFENAC SODIUM | 100MG | MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA | INDIA | RECTAL SYSTEMIC ADULT SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY STRIP | 01/07/2017 |

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| 3006 | NDA/MAL/HDP/6401 | MERIDIAN ENTERPRISES PRIVATE LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | SUPPOL 250 SUPPOSITORIES | ACETAMINOPHEN | 250MG | MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE,NAVSARI 396424 GUJARAT,INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X5.0 SUPPOSITORY STRIP | 01/07/2017 |
| 3007 | NDA/MAL/HDP/6404 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | STEDNAC GEL | ACECLOFENAC + LINSEED OIL + METHYL SALICYLATE | 1.5%W/W + 3.0W/W +10.0%W/W | STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X50.0 G TUBE,1.0X100.0 G TUBE | 01/07/2017 |
| 3008 | NDA/MAL/HDP/6406 | LINCOLN PARENTERAL LIMITED | METRO PHARMACEUTICALS LIMITED | LIDOCAINE INJECTION BP 2% | LIDOCAINE HYDROCHLORIDE | 2% W/V | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | PARENTERAL ORDINARY VIALS | 1.0X25.0X30.0 ML VIAL | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3009 | NDA/MAL/HDP/6407 | ZIM LABORATORIES LTD | REDDYS PHARMA LIMITED | ZIMCOX 200 | CELECOXIB | 200 MG | ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA, | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 29/11/2017 |
| 3010 | NDA/MAL/HDP/6408 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DECOZAL | XYLOMETAZOLINE HCL | 0.1%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | NASAL TOPICAL METERED DOSE AEROSOLS | 1.0X10.0 ML BOTTLE | 28/05/2019 |
| 3011 | NDA/MAL/HDP/6412 | PHARCO PHARMACEUTICALS LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BUCCAZOLE ORAL GEL | MICONAZOLE | 2%W/W | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL TOPICAL GELS AND SOLS | 1.0X20.0 G TUBE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3012 | NDA/MAL/HDP /6414 | CIPLA LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | IMATIB 100 | IMATINIB MESYLATE | 100MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 28/05/2019 |
| 3013 | NDA/MAL/HDP /6415 | CIPLA LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | IMATIB 400 | IMATINIB MESYLATE | 400MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 28/05/2019 |
| 3014 | NDA/MAL/HDP /6419 | CRATUS PHARMA PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | CLINICEF CV | CEFIXIME + POTASSIUM CLAVULANATE | 200MG + 125MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD --UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 26/09/2018 |

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| 3015 | NDA/MAL/HDP/6424 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | ASCORIL LS | LEVOSALBUTAMOL SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIFENESIN | 1 MG + 30 MG + 100 MG | GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205 | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 27/03/2019 |
| 3016 | NDA/MAL/HDP/6426 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | SODIUM CHLORIDE INTRAVENOUS INFUSION BP | SODIUM CHLORIDE | 0.9%W/V | ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2017 |
| 3017 | NDA/MAL/HDP/6430 | IPCA LABORATOIES LTD | MEDVIN PHARMA LIMITED | LUMERAX DT 20/120 | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | IPCA LABORATORIES LIMITED .-PLOT 225/1, VILLAGE ATHAL, DANDRA AND NAGAR HAVELI UNION TERRITORY, SILVASSA-396 230 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X30.0X1.0X6.0 TABLET BLISTER,1.0X30.0X 1.0X12.0 TABLET BLISTER | 27/03/2019 |

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| 3018 | NDA/MAL/HDP/6431 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRUMOX 125 | AMOXICILLIN TRIHYDRATE | 125MG/5ML | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3019 | NDA/MAL/HDP/6432 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | UMBI-GEL | CHLORHEXIDINE GLUCONATE | 4 % W/W | KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTD-STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | TOPICAL EXTERNAL CREAMS | 1.0X50.0X1.0X5.0 G TUBE | 27/03/2019 |
| 3020 | NDA/MAL/HDP/6433 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | FICYC CREAM | ACICLOVIR | 5%W/W | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3021 | NDA/MAL/HDP/6435 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | FIMABUTE 200 | CEFIXIME TRIHYDRATE | 200MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3022 | NDA/MAL/HDP/6437 | MERIDIAN ENTERPRISES PRIVATE LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | PILORECT | HYDROCORTISONE ACETATE +LIDOCAINE +ZINC OXIDE +ALLANTOIN | 0.25%W/W+3%W/W+5%W/W+0.5% W/W | MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI GUJARAT,INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X6.0 SUPPOSITORY STRIP | 29/11/2017 |
| 3023 | NDA/MAL/HDP/6438 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAMADOL PLUS | PARACETAMOL + CAFFEINE | 500 MG + 65 MG | KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTD-STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3024 | NDA/MAL/HDP/6439 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LIZOMAC 600 | LINEZOLID | 600MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X6.0X10.0 TABLET STRIP,1.0X10.0X10.0 TABLET STRIP | 01/07/2017 |
| 3025 | NDA/MAL/HDP/6440 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | CEFIWEL 400 | CEFIXIME TRIHYDRATE | 400MG | MALIK LIFESCIENCES PRIVATE LIMITED-PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/03/2018 |
| 3026 | NDA/MAL/HDP/6442 | ZIM LABORATORIES LTD | REDDYS PHARMA LIMITED | AZITO SUSPENSION | AZITHROMYCIN DIHYDRATE | 200 MG/5ML | ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA, | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3027 | NDA/MAL/HDP /6443 | MICRO LABS | MALIX PHARMA (U) LIMITED | SINURHON SUSPENSION | CHLORPHENIRAMINE + PHENYLEPHRINE + PARACETAMOL | 1MG + 5MG + 125MG | LEBEN LABORATORIES PVT LTD .-L-14 PHASE III MIDC AKOLA 444 104 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 27/03/2019 |
| 3028 | NDA/MAL/HDP /6447 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | AZIBRU 500 | AZITHROMYCIN DIHYDRATE | 500MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0 TABLET BLISTER | 01/07/2017 |
| 3029 | NDA/MAL/HDP /6448 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIZOLONE-DEPOT 40 MG/ 1 ML VIAL | METHYLPREDNISOLONE ACETATE | 40 MG/ ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X1.0X1.0 ML VIAL | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3030 | NDA/MAL/HDP /6452 | SANDOZ GMBH . | SURGIPHARM (U) LIMITED | AMLODIPINE 5MG TABLETS | AMLODIPINE | 5MG | LEK PHARMACEUTICALS DD-VEROVSKOVA 57, SI-1526 LJUBLJANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3031 | NDA/MAL/HDP /6453 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | ALLMYCIN | ERYTHROMYCIN STEARATE | 125 MG/5 ML | LINCOLN PHARMACEUTICALS LTD .,.-10,12,13, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ-382721 TA: KALOL, DIST. GHANDINAGAR, GUJARAT | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE WITH 10ML PLASTIC DOSING CAP | 27/03/2019 |
| 3032 | NDA/MAL/HDP /6454 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MAGRILAN 20MG | FLUOXETINE HYDROCHLORIDE | 20MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 29/01/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3033 | NDA/MAL/HDP/6455 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | FICYC TABLETS | ACYCLOVIR | 200MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3034 | NDA/MAL/HDP/6456 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | GLUCOSE INTRAVENOUS INFUSION BP (5% W/V) | GLUCOSE ANHYDROUS | 5%W/V | ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 01/07/2017 |
| 3035 | NDA/MAL/HDP/6458 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | VAXATO | RIVAROXABAN | 10 MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |

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| 3036 | NDA/MAL/HDP/6459 | MACLEODS PHARMACEUTICALS LTDS LTD | VITACARE LIMITED | MACSUNATE AQ FORTE | ARTESUNATE + AMODIAQUINE | 100MG + 270MG | MACLEODS PHARMACEUTICALS LTD ,.- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X 3.0 TABLET BLISTER,1.0X25.0X 6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER | 27/03/2019 |
| 3037 | NDA/MAL/HDP/6460 | MANKIND PHARM LTD | TATA UGANDA LIMITED | NUROKIND-OD | MECOBALAMIN | 1500MCG/ML | MANKIND PHARMA LTD.- VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X4.0X1.0 ML AMPOULE | 27/03/2019 |
| 3038 | NDA/MAL/HDP/6462 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | AMOXYN-500 | AMOXICILLIN TRIHYDRATE | 500MG | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 26/09/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3039 | NDA/MAL/HDP/6465 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | NEUROGAB 75 | PREGABALIN | 75MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 3040 | NDA/MAL/HDP/6466 | S KAGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | NYSTATIN ORAL TABLETS USP 500,000 I.U. | NYSTATIN | 500,000IU | S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3041 | NDA/MAL/HDP/6468 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CIROLAZINE | HYDRALAZINE HYDROCHLORIDE | 20MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE,1.0X5.0 X1.0 ML AMPOULE | 30/05/2018 |

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| 3042 | NDA/MAL/HDP/6469 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | JUSPRIN 81 E/C TABLETS | ASPIRIN | 81MG | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X2.0X20.0 TABLET BLISTER | 01/07/2017 |
| 3043 | NDA/MAL/HDP/6472 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MOXICLAV 375 | AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID | 250MG + 125MG | MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X2.0X10.0 CAPSULE STRIP | 29/01/2019 |
| 3044 | NDA/MAL/HDP/6476 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPIZOLONE-DEPOT | METHYLPREDNISOLONE | 80MG/2ML | EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT | EGYPT | PARENTERAL RETARD VIALS | 1.0X1.0X2.0 ML VIAL | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3045 | NDA/MAL/HDP/6477 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MEDOFULVIN | GRISEOFULVIN | 500 MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 27/03/2019 |
| 3046 | NDA/MAL/HDP/6481 | GULF PHARMACEUTICAL INDUSTRIES(JULP HAR). | OMASI MED LIMITED | MOXAL PLUS CHEWABLE TABLETS | DRIED ALUMINIUM HYDROXIDE GEL+MAGNESIUM HYDROXIDE+SIMET HICONE | 200MG+200MG+2 5MG | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3047 | NDA/MAL/HDP/6482 | MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | EUTHROX 75MCG | LEVOTHYROXINE SODIUM | 75 MCG | MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X25.0 TABLET BLISTER | 27/03/2019 |

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| 3048 | NDA/MAL/HDP/6485 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | CEFUZIME 750 | CEFUROXIME SODIUM | 750MG | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E. | UNITED ARAB EMIRATES | PARENTERAL ORDINARY DRY VIALS | 1.0X750.0 MG VIAL | 31/01/2018 |
| 3049 | NDA/MAL/HDP/6489 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | ASCORIL-SF | SALBUTAMOL+BROMHEXINE HYDROCHLORIDE+GUAIFENESIN | 2MG+4MG+100MG/10ML | GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3050 | NDA/MAL/HDP/6491 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | PREGATAS ME 75 | PREGABALIN +MECOBALAMIN | 75MG+750MCG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3051 | NDA/MAL/HDP /6492 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | LIDOCAINE INJECTION BP 2%W/V | LIDOCAINE HYDROCHLORIDE | 2%W/V | UMEDICA LABORATORIES PVT, VAPI - -PLOT 221, GIDC II, VAPI-396195, VALSAD GUJARAT INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0X20.0 ML VIAL | 28/03/2018 |
| 3052 | NDA/MAL/HDP /6495 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | MACROLYN® 500 MG FILM COATED TABLETS | AZITHROMYCIN DIHYDRATE | 500MG | DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 29/11/2017 |
| 3053 | NDA/MAL/HDP /6498 | MICRO LABS LIMITED | PHARMA VILLE LIMITED | AMOXICILLIN DISPERSIBLE TABLETS 250 MG | AMOXICILLIN TRIHYDRATE | 250MG | MICRO LABS LIMITED PLOT - NO. 16, VEERASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BANGALORE – 560 100. KARNATAKA, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET STRIP | 25/07/2018 |

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| 3054 | NDA/MAL/HDP/6499 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | TACROZ FORTE | TACROLIMUS USP | 0.1%W/W | GLENMARK PHARMACEUTICALS LTD .- PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X10.0 G TUBE | 28/05/2019 |
| 3055 | NDA/MAL/HDP/6500 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | DERIVA C GEL | ADAPLENE BP + CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN | 1MG + 10MG | GLENMARK PHARMACEUTICALS LTD .- PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE | 28/05/2019 |
| 3056 | NDA/MAL/HDP/6501 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AARTROGYL 200 TABLET | METRONIDAZOLE | 200MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3057 | NDA/MAL/HDP/6502 | M/S HETERO LABS LIMITED | AIVEEN (U) LIMITED | ALOVIR 400 | ACYCLOVIR | 400MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET BOTTLE,1.0X10.0X8.0 TABLET BLISTER | 29/05/2019 |
| 3058 | NDA/MAL/HDP/6507 | IPCA LABORATORIES LTD | MEDVIN PHARMA LIMITED | ZITRAM P | ACETAMINOPHEN + TRAMADOL HYDROCHLORIDE | 325MG + 37.5MG | IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3059 | NDA/MAL/HDP/6510 | GLENMARK PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | TACROZ | TACROLIMUS USP | 0.03%W/W | GLENMARK PHARMACEUTICALS LTD .-PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X10.0 G TUBE | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3060 | NDA/MAL/HDP/6511 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ABIDONE | POVIDONE IODINE | 5%W/W | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE | 28/05/2019 |
| 3061 | NDA/MAL/HDP/6513 | MACARTHYS LABORATORIES | LABOREX UGANDA LIMITED | GLYCOPYRRONIUM BROMIDE 200 MICROGRAMS PER ML SOLUTION FOR INJECTION | GLYCOPYRRONIUM BROMIDE | 200MCG/ML | MACARTHYS LABORATORIES LIMITED T\A MARTINDALE PHARMA-BAMPTON ROAD, ROMFORD, ESSEX RM3 8UG, | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0 ML AMPOULE | 28/05/2019 |
| 3062 | NDA/MAL/HDP/6514 | EXPHAR SA. | SURGIPHARM (U) LIMITED | FEBRILEX | PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENAMINE MALEATE | 500MG + 5M + 2MG | MILAN LABORATORIES (INDIA) PVT LTD,-63,67,87,35,36, 64, 65 JAWAHAR CO-OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET STRIP | 28/05/2019 |

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| 3063 | NDA/MAL/HDP/6517 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | FERROTONE LIQUIZ | FERROUS FUMARATE + FOLIC ACID + CYANOCOBALAMIN | 100MG + 0.5MG + 5MCG | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X120.0 ML BOTTLE,1.0X180.0 ML BOTTLE | 29/05/2019 |
| 3064 | NDA/MAL/HDP/6520 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | VOMIKIND-MD 8 | ONDASENTRON | 8MG | MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3065 | NDA/MAL/HDP/6521 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | KIPEL 4 | MONTELUKAST | 4MG | MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/03/2019 |

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| 3066 | NDA/MAL/HDP/6522 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EPNONE 25 | EPLERENONE | 25MG | MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3067 | NDA/MAL/HDP/6523 | EXPHAR SA. | SURGIPHARM (U) LIMITED | FLEXDOL | IBUPROFEN+METHOCARBAMOL | 200MG+500MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3068 | NDA/MAL/HDP/6524 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | RAMGIC | TRAMADOL HYDROCHLORIDE | 50MG/ML | MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X5.0X2.0 ML AMPOULE | 27/03/2019 |

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| 3069 | NDA/MAL/HDP /6527 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PULMOFIRST 62.5 | BOSENTAN MONOHYDRATE | 62.5MG | MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3070 | NDA/MAL/HDP /6528 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PULMOFIRST 125 | BOSENTAN MONOHYDRATE | 125MG | MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3071 | NDA/MAL/HDP /6530 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | NECIPRO | CIPROFLOXACIN HYDROCHLORIDE | 0.3%W/V | NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA, | NEPAL | OPHTHALMIC LIQUIDS | 1.0X1.0X10.0 ML VIAL | 28/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3072 | NDA/MAL/HDP /6532 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | BUNASE 200 | BUDESONIDE | 200MCG / ACTUATION | OXALIS LABS--VILLAGE THEDA,P.O.LODHIMAJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA | INDIA | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X1.0 CANNISTER CARTON | 28/03/2018 |
| 3073 | NDA/MAL/HDP /6533 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | NIKODIN | PARACETAMOL + CODEINE PHOSPHATE | 500MG + 10MG | NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA, | NEPAL | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 28/03/2019 |
| 3074 | NDA/MAL/HDP /6535 | OCTOBER PHARMA S.A.E | ABACUS PHARMA (AFRICA) LIMITED | SARCOZIDE | CANDERSATAN + HYDROCHLOROZIDE | 16MG + 12.5MG | OCTOBER PHARMA-PLOT NO. 190, 1ST INDUSTRIAL ZONE-6 OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 28/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3075 | NDA/MAL/HDP /6536 | PHARMATHEN INVESTMENTS GROUP LTD | GOODMAN INTERNATIONAL LTD | OZAPEX 5MG | OLANZAPINE | 5MG | PHARMATHEN S.A-6, DERVENAKION STR. 15351 PALLINI ATHENS | GREECE | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 28/03/2019 |
| 3076 | NDA/MAL/HDP /6537 | EXPHAR SA | SURGIPHARM (U) LIMITED | CARBOSOL | CARMELLOSE SODIUM | 0.5%W/V | AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345 | INDIA | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE | 31/01/2018 |
| 3077 | NDA/MAL/HDP /6538 | PHARMATHEN INVESTMENTS GROUP LTD | GOODMAN INTERNATIONAL LTD | OZAPEX 10MG | OLANZAPINE | 10MG | PHARMATHEN S.A-6, DERVENAKION STR. 15351 PALLINI ATHENS | GREECE | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X4.0X7.0 TABLET BLISTER | 28/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3078 | NDA/MAL/HDP /6543 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CIFF-O | OFLOXACIN + CEFIXIME | 200MG + 200MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/03/2019 |
| 3079 | NDA/MAL/HDP /6544 | GULF PHARMACEUTICAL INDUSTRIES(JULP HAR). | OMASI MED LIMITED | ORAMAX 150MG | FLUCONAZOLE | 150MG | GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E | UNITED ARAB EMIRATES | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X1.0 CAPSULE BLISTER | 28/03/2018 |
| 3080 | NDA/MAL/HDP /6545 | RAPTAKOS, BRETT & CO. LTD. | EUROPA HEALTHCARE (U) LTD | ZYTEE RB | CHOLINE SALICYLATE + BENZALKONIUM CHLORIDE | 9%W/W + 0.02% W/V | RAPTAKOS BRETT & CO.LTD-1ST POKHRAN ROAD,THANE 400 606 | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X10.0 ML TUBE | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3081 | NDA/MAL/HDP/6546 | RAPTAKOS, BRETT & CO. LTD. | EUROPA HEALTHCARE (U) LTD | NEOPEPTINE | ALPHA AMYLASE + PAPAIN | 100MG + 50MG /5ML | RAPTAKOS BRETT & CO.LTD-1ST POKHRAN ROAD,THANE 400 606 | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X60.0 ML BOTTLE | 27/03/2019 |
| 3082 | NDA/MAL/HDP/6547 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | AMYDRAMINE PAEDIATRIC SYRUP | DIPHENHYDRAMINE HYDROCHLORIDE+SODIUM CITRATE+MENTHOL | 7MG+28.5MG+0.55 MG/5 ML | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2017 |
| 3083 | NDA/MAL/HDP/6550 | REDDYS PHARMA LIMITED | REDDYS PHARMA LIMITED | REDCEPHIN | CEFTRIAXONE | 1 G | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3084 | NDA/MAL/HDP/6551 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | NUROFEN FOR CHILDREN SUGAR FREE | IBUPROFEN | 100MG/5ML | ABBOTT -DAMSON LANE,HULL, HUB HU8 7DS | UNITED KINGDOM | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE | 27/03/2019 |
| 3085 | NDA/MAL/HDP/6552 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | NUROFEN | IBUPROFEN + LYSINE | 342MG | ABBOTT -DAMSON LANE,HULL, HUB HU8 7DS | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 27/03/2019 |
| 3086 | NDA/MAL/HDP/6553 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENSOL SOLUTION | CHLORHEXIDINE GLUCONATE + ISOPROPYL ALCOHOL | 0.5% W/W + 70% W/W | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | TOPICAL EXTERNAL LIQUIDS | 1.0X5.0 L CONTAINER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3087 | NDA/MAL/HDP/6554 | CRATUS PHARMA PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | RESPIQUIN-750 | LEVOFLOXACIN | 750MG | SAI MIRRA INNOPHARM PVT LIMITED -288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098 | INDIA | ORAL SOLID ORDINARY TABLETS | 2.0X1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3088 | NDA/MAL/HDP/6556 | SAVA HEALTHCARE LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BECLOGEN CREAM | CLOTRIMAZOLE USP, BECLOMETASONE DIPROPIONATE BP, GENTAMICIN SULPHATE BP | 1%W/W, 0.025%W/W, 0.1%W/W | SAVA HEALTHCARE LIMITED.- PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 27/03/2019 |
| 3089 | NDA/MAL/HDP/6557 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | COMBIART-DT | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | STRIDES SHASUN LIMITED- NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3090 | NDA/MAL/HDP /6559 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | BIOCOBAL 500MCG | MECOBALAMIN | 500MCG / ML | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 27/03/2019 |
| 3091 | NDA/MAL/HDP /6561 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | RISEK | OMEPRAZOLE | 20MG | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | ORAL SOLID ORDINARY CAPSULES | 1.0X14.0 CAPSULE BOTTLE | 31/01/2018 |
| 3092 | NDA/MAL/HDP /6563 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ANATAX ® 16MG | BETAHISTINE DIHYDROCHLORIDE | 16MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY-JORDAN - NUZHAT SAHAB | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3093 | NDA/MAL/HDP/6564 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ANATAX ® 24MG | BETAHISTINE DIHYDROCHLORIDE | 24MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY-JORDAN - NUZHAT SAHAB | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3094 | NDA/MAL/HDP/6565 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | IBUPROFEN | IBUPROFEN | 200MG | TRIVENI FORMULATIONS LTD-PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3095 | NDA/MAL/HDP/6568 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | PINNADIP 50 TABLET | DICLOFENAC | 50MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3096 | NDA/MAL/HDP/6569 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | MARDAGRA 50 | SILDENAFIL CITRATE | 50MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 27/03/2019 |
| 3097 | NDA/MAL/HDP/6577 | UNOSOURCE PHARMA LTD | MEDVIN PHARMA LIMITED | CEFIWEL-200 | CEFIXIME | 200MG | MALIK LIFESCIENCES PRIVATE LIMITED-PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3098 | NDA/MAL/HDP/6578 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ACINET DRY SYRUP 228.5MG/5ML | AMOXYCILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 200MG + 28.5MG PER 5ML | INDCHEMIE HEALTH SPECIALITIES PVT. LTD-VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 27/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3099 | NDA/MAL/HDP/6581 | CADILA HEALTHCARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ZYDALIS 20 | TADALAFIL | 20 MG | CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA. . | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 27/08/2019 |
| 3100 | NDA/MAL/HDP/6584 | ZIFAM PINNACLE LTD | DELMAW ENTERPRISES LIMITED | ZIFLODIP 5 | AMLODIPINE BESYLATE | 5 MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3101 | NDA/MAL/HDP/6585 | ZIFAM PINNACLE PTY. LTD. | DELMAW ENTERPRISES LIMITED | ZIFLODIP 10 | AMLODIPINE BESYLATE | 10 MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 27/08/2019 |

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| 3102 | NDA/MAL/HDP/6587 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SEDALAM | MIDAZOLAM | 1MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X10.0X5.0 ML VIAL | 28/05/2019 |
| 3103 | NDA/MAL/HDP/6588 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SEDALAM | MIDAZOLAM | 5MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X3.0 ML VIAL | 28/05/2019 |
| 3104 | NDA/MAL/HDP/6589 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | VANBACT | VANCOMYCIN HYDROCHLORIDE | 500MG | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 28/05/2019 |

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| 3105 | NDA/MAL/HDP/6590 | PHARMACTIV FZCO | JEET PHARMACEUTICALS LIMITED | LOPROT | OMEPRAZOLE SODIUM | 40MG | NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 28/05/2019 |
| 3106 | NDA/MAL/HDP/6593 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | TRANSIC | TRANEXAMIC ACID | 500MG | SURGE LABS (PVT) LTD-10TH KM FAISALABAD ROAD, BIKHI DISTRICT SHEIKHUPURA | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0 ML AMPOULE | 28/05/2019 |
| 3107 | NDA/MAL/HDP/6595 | RAVIAN LIFE SCIENCE PVT. LTD | ROYAL PHARMA 2011 LIMITED | MOLURAV | LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM | 5MG + 10MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT NO.34,SECTOR-8A,IIE,HARIDWAR-249403, UTTARKHAND | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3108 | NDA/MAL/HDP/6598 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | BREATHEZY-L (10/5) | MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORIDE | 10MG + 5MG | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/01/2019 |
| 3109 | NDA/MAL/HDP/6600 | EXPHAR SA. | SURGIPHARM (U) LIMITED | PROSTALEN | ALFUZOSIN HYDROCHLORIDE | 10MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3110 | NDA/MAL/HDP/6602 | EXPHAR SA. | SURGIPHARM (U) LIMITED | CARDIURINE | CAPTOPRIL + HYDROCHLOROTHIAZIDE | 50MG + 25MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |

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| 3111 | NDA/MAL/HDP/6607 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RANI | RANITIDINE HYDROCHLORIDE | 150MG | PHARCO PHARMACEUTICALS-KM 31, ALEX, CAIRO DESERT AMRIYA, ALEXANDRA | EGYPT | ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES | 1.0X6.0X5.4 G SACHET | 28/05/2019 |
| 3112 | NDA/MAL/HDP/6608 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CIPROCIN 0.3% | CIPROFLOXACIN HYDROCHLORIDE | 0.3%W/W | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO.(EIPICO)-10TH RAMADHAN CITY INDUSTRIAL AREA-B1 , P. O. BOX 149 TENTH, EGYPT | EGYPT | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 28/05/2019 |
| 3113 | NDA/MAL/HDP/6610 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | VOMIKIND | ONDANSENTRON HYDROCHLORIDE | 2MG/ML | MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X4.0X2.0 ML AMPOULE,1.0X4.0 X4.0 ML AMPOULE | 01/07/2014 |

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| 3114 | NDA/MAL/HDP/6611 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | MARDAGRA 100 | SILDENAFIL CITRATE | 100MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 29/05/2019 |
| 3115 | NDA/MAL/HDP/6612 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | APRAZOLE PLUS-20 | OMEPRAZOLE + SODIUM BICARBONATE | 20MG/6G + 1680MG/6G | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY POWDERS | 1.0X20.0X6.0 G SACHET | 01/07/2008 |
| 3116 | NDA/MAL/HDP/6613 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | OLMAT-40 | OLMESARTAN MEDOXOMIL | 40MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3117 | NDA/MAL/HDP/6614 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | AXETINE | CEFUROXIME SODIUM | 1.5MG | MEDOCHEMIC LTD-1-10 ASTRONAFTON & CONSTANTINOPOLEOS 3505 LIMASSOL | CYPRUS | PARENTERAL ORDINARY VIALS | 1.0X10.0 VIAL CARTON | 01/07/2008 |
| 3118 | NDA/MAL/HDP/6616 | SHIN POONG PHARMACEUTICALS CO.LTD | AAFIYA (A) LIMITED | PYRAMAX | PYRONARIDINE TETRAPHOSPHATE + ARTESUNATE | 180MG + 60MG | SHIN POONG PHARM. CO., LTD-70, SANDAN-RO, 19 BEON-GIL, DANWON-GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA | SOUTH KOREA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X9.0 TABLET BLISTER | 01/07/2016 |
| 3119 | NDA/MAL/HDP/6617 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | APFLU | CHLOROPHENERAMINE + PARACETAMOL + VITAMIN C | 0.5MG + 120MG + 50MG | AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3120 | NDA/MAL/HDP/6619 | ESAPHARM SRL | BYAMAKA PHARMACEUTICAL COMPANY LTD | ORANVATE | CLOBETASOL PROPIONATE | 0.05G/100G | ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY | ITALY | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 01/07/2016 |
| 3121 | NDA/MAL/HDP/6620 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILET 5MG | NEBIVOLOL HYDROCHLORIDE | 5MG | BERLIN-CHEMIE AG-BERLIN-CHEMIE AG GLIENICKER WEG 125 D-12489 BERLIN | GERMANY | ORAL SOLID ORDINARY TABLETS | 1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER | 01/07/2016 |
| 3122 | NDA/MAL/HDP/6621 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | BAROLE 20 | RABEPRAZOLE | 20MG | INVENTIA HEALTHCARE PVT. LTD .-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3123 | NDA/MAL/HDP/6622 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | CEFIWEL-100 DT | CEFIXIME TRIHYDRATE | 100MG | MALIK LIFESCIENCES PRIVATE LIMITED-PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667 | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3124 | NDA/MAL/HDP/6625 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILET PLUS 5/12.5 | NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROTHIAZIDE | 5MG + 12.5MG | BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, -) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFER WEG 83 D-12347 BERLIN GERMANY BERLIN-CHEMIE AG/MENARINI,-GLIENICKER WEG 125, D-12489 BERLIN GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER (FREE MEDICAL SAMPLE) | 01/07/2016 |
| 3125 | NDA/MAL/HDP/6627 | RECKITT BENCKISER HEALTHCARE INTERNATIONAL | GITTOES PHARMACEUTICALS LIMITED | STREPSILS HONEY & LEMON | MULTI-INGREDIENT | MULTI-INGREDIENT | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND | THAILAND | ORAL SOLID ORDINARY LOZENGES | 1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,50.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER | 01/07/1997 |

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| 3126 | NDA/MAL/HDP/6628 | RECKITT BENCKISER HEALTHCARE INTERNATIONAL | GITTOES PHARMACEUTICALS LIMITED | STREPSILS ORIGINAL | MULTI-INGREDIENT | MULTI-INGREDIENT | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-RECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND | THAILAND | ORAL SOLID ORDINARY LOZENGES | 1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,100.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER | 01/07/1997 |
| 3127 | NDA/MAL/HDP/6629 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILET PLUS 5/25 | NEBIVOLOL+HYDROCHLOROTHIAZIDE | 5MG+25MG | BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION)-TEMPELHOFER WEG 83 D-12347 BERLIN GERMANY BERLIN-CHEMIE AG/MENARINI-GLIENICKER WEG 125, D-12489 BERLIN GERMANY(BATCH RELEASE) | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER | 01/07/2016 |
| 3128 | NDA/MAL/HDP/6631 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOBURN | SILVER SULFADIAZINE | 1%W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE,1.0X500.0 G JAR | 01/07/2016 |

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| 3129 | NDA/MAL/HDP/6632 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | CIPROFLOXACIN | CIPROFLOXACIN | 500MG | UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2006 |
| 3130 | NDA/MAL/HDP/6633 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | COLDRIL | PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HCL | 500MG + 30MG + 2MG | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0X1.0X2.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 3131 | NDA/MAL/HDP/6636 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | COSAMIDE 100 | LACOSAMIDE | 100MG | MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3132 | NDA/MAL/HDP /6638 | MSN LABORATORIES PRIVATE LIMITED | GOOD DAY PHARMACY LIMITED | COSAMIDE 50 | LACOSAMIDE | 50MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3133 | NDA/MAL/HDP /6640 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SAFETELMI H ( 40/ 12.5) | TELMISARTAN + HYDROCHLOROTHI AZIDE | 40MG + 12.5MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3134 | NDA/MAL/HDP /6641 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | CEFTRISONE- S 1.5G | CEFTRIAXONE SODIUM + SULBACTAM SODIUM | 1.0G + 0.5G | AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.5 G VIAL + 10ML WFI AMPOULE | 01/07/2016 |

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| 3135 | NDA/MAL/HDP /6645 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SAFETELMI H ( 80/ 12.5) | TELMISARTAN + HYDROCHLOROTHI AZIDE | 80MG + 12.5MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3136 | NDA/MAL/HDP /6648 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | DEXAMETHASO NE INJECTION | DEXAMETHASONE SODIUM PHOSPHATE | 4MG/ML | UMEDICA LABORATORIES PVT. LTD-PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0X2.0 ML VIAL | 01/07/2016 |
| 3137 | NDA/MAL/HDP /6650 | INDUS LIFE SCIENCES PVT LIMITED | NORVIK ENTERPRISES LIMITED | INTRIAX-S-1 | CEFTRIAXONE SODIUM+SULBACT AM SODIUM | 1G+0.5G | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3138 | NDA/MAL/HDP /6652 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LAMIVUDINE +TENOFOVIR DISOPROXIL FUMARATE | LAMIVUDINE+TENOFOVIR DISOPROXIL FUMARATE | 300MG+300MG | CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2016 |
| 3139 | NDA/MAL/HDP /6654 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | LIVOLUK FIBRE | LACTULOSE + ISPAGHULA HUSK | 10G + 3.5G/ 15G | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X90.0 G CONTAINER | 01/07/2016 |
| 3140 | NDA/MAL/HDP /6658 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | NEBIEM 10 | NEBIVOLOL | 10MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3141 | NDA/MAL/HDP/6662 | SAKAR HEALTHCARE PVT LTD | ROYAL PHARMA 2011 LIMITED | DIAPAM | DIAZEPAM | 5MG/ML | SAKAR HEALTHCARE PVT LIMITED-PLOT 10/13 SARKHEJ-BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X2.0 ML AMPOULE | 01/07/2013 |
| 3142 | NDA/MAL/HDP/6663 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | SITCOM | EUPHORBIA PROSTATA DRY EXTRACT | 10MG/G | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/2013 |
| 3143 | NDA/MAL/HDP/6664 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMOX 125 KID | AMOXICILLIN TRIHYDRATE | 125MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3144 | NDA/MAL/HDP/6665 | REGAL PHARMACEUICALS LTD | REGAL PHARMA (U) LTD | SALBUMOL SYRUP | SALBUTAMOL | 2MG/5ML | REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/1997 |
| 3145 | NDA/MAL/HDP/6666 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | NEBIEM 5 | NEBIVOLOL HYDROCHLORIDE | 5MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3146 | NDA/MAL/HDP/6667 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPAMOX 250 DT | AMOXICILLIN TRIHYDRATE | 250MG | SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA. | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2016 |

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| 3147 | NDA/MAL/HDP/6669 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | SUPER WELGRA-100 | SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE | 100MG + 60MG | AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2016 |
| 3148 | NDA/MAL/HDP/6670 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | METROSIM-200 | METRONIDAZOLE | 200MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/1997 |
| 3149 | NDA/MAL/HDP/6674 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | UMERAN-75 | DICLOFENAC SODIUM | 75MG/3ML | UMEDICA LABORATORIES PVT. LTD-PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT | INDIA | PARENTERAL ORDINARY I M AMPOULES | 1.0X1.0X10.0X3.0 ML AMPOULE | 01/07/2016 |

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| 3150 | NDA/MAL/HDP/6675 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | UNOSEMIDE -10 | FUROSEMIDE | 10MG/ML | AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403 | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2016 |
| 3151 | NDA/MAL/HDP/6679 | BLUE CROSS LABORATORIES LIMITED | STAR PHARMACEUTICALS LTD | WOMIBAN TABLETS | ALBENDAZOLE | 400MG | BLUE CROSS LABORATORIES LTD-A-12, M.I.D.C AMBAD NASHIK-422010 BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722 | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0 TABLET STRIP | 01/07/1997 |
| 3152 | NDA/MAL/HDP/6681 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | WELQUINE | LEVOFLOXACIN | 0.5%W/V | AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, HARIDWAR, UTTARAKHAND | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2016 |

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| 3153 | NDA/MAL/HDP/6685 | NEON LABARATORIES LTD. | NORVIK ENTERPRISES LIMITED | EVACEF | CEFOTAXIME | 1 G | NEON LABORATORIES LTD-PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2014 |
| 3154 | NDA/MAL/HDP/6686 | DAWA LIMITED | SUPER MEDIC LTD | DAWASOLONE | PREDNISOLONE | 5MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |
| 3155 | NDA/MAL/HDP/6691 | SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | BINOZYT 200 MG/ 5 ML | AZITHROMYCIN MONOHYDRATE | 200MG/5ML | SANDOZ SRL LTD-LIVEZENI STREET 7A540472 TARGU MURES ROMANIA | ROMANIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X15.0 ML BOTTLE | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3156 | NDA/MAL/HDP /6692 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | ASUNRA 100 | DEFERASIROX | 100MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X5.0X6.0 TABLET BLISTER | 01/07/2016 |
| 3157 | NDA/MAL/HDP /6693 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | CERTICAN1 | EVEROLIMUS | 1MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3158 | NDA/MAL/HDP /6694 | NOVARTIS PHARMA SERVICES INC. | SURGIPHARM (U) LIMITED | CERTICAN 0.5 | EVEROLIMUS | 0.5MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 3159 | NDA/MAL/HDP/6699 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ATVIN-20 | ATORVASTATIN | 20MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/05/2019 |
| 3160 | NDA/MAL/HDP/6700 | CACHET PHAMACUITICALS PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | ARTIMED | DICLOFENAC SODIUM | 50MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 3161 | NDA/MAL/HDP/6705 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACHEWORM | MEBENDAZOLE | 100MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2010 |

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| 3162 | NDA/MAL/HDP/6706 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACH-E-WORM | MEBENDAZOLE | 100MG/5ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 01/07/2009 |
| 3163 | NDA/MAL/HDP/6709 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACHPAR | PARACETAMOL | 500MG | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2012 |
| 3164 | NDA/MAL/HDP/6711 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACHPAR | PARACETAMOL | 125MG/5ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2009 |

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| 3165 | NDA/MAL/HDP/6712 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACID-O | OMEPRAZOLE | 20MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/2011 |
| 3166 | NDA/MAL/HDP/6713 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CAMET | METOCLOPRAMIDE HYDROCHLORIDE | 10MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2009 |
| 3167 | NDA/MAL/HDP/6714 | SEARLE PAKISTAN LIMITED | HEALTHCARE LTD. | HYDRYLLIN SYRUP | AMINOPHYLLINE+ AMMONIUM HCL+ DIPHENHYDRAMINE HCL | 32MG +300MG+8MG | THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3168 | NDA/MAL/HDP/6715 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CAZITHRO | AZITHROMYCIN | 200MG/5ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X15.0 ML BOTTLE | 01/07/2009 |
| 3169 | NDA/MAL/HDP/6717 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CAZITHRO | AZITHROMYCIN | 500MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 01/07/2011 |
| 3170 | NDA/MAL/HDP/6722 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | CILZEC 40 | TELMISARTAN | 40MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/05/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3171 | NDA/MAL/HDP /6724 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | CILZEC 80 | TELMISARTAN | 80MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3172 | NDA/MAL/HDP /6728 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | CIPROCOS-500 TABLETS | CIPROFLOXACIN | 500MG | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER | 01/07/2000 |
| 3173 | NDA/MAL/HDP /6729 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | COSCOF 'C' LINCTUS | MULTI-INGREDIENT | MULTI-INGREDIENT | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3174 | NDA/MAL/HDP /6732 | COSMOS LTD | ASTRA PHARMA (U) LIMITED | COSCOF EXPECTORANT ORIGINAL | MULTI-INGREDIENT | MULTI-INGREDIENT | COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 01/07/2010 |
| 3175 | NDA/MAL/HDP /6734 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EASCOF | BROMHEXIDINE HCL + SALBUTAMOL SULPHATE + GUAIPHENESIN | 24MG/100ML + 42MG/100ML + 1G/ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2009 |
| 3176 | NDA/MAL/HDP /6736 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | SANDOSTATIN | OCTREOTIDE ACETATE | 0.05MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X1.0 ML AMPOULE | 01/07/2016 |

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| 3177 | NDA/MAL/HDP/6750 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | NYTIN | NYSTATIN | 500,000IU | KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER | 01/07/2005 |
| 3178 | NDA/MAL/HDP/6752 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | VITACEE | ASCORBIC ACID | 100MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10 .0X10.0 TABLET BLISTER | 01/07/2000 |
| 3179 | NDA/MAL/HDP/6754 | INDIAN IMMUNOLOGICALS LIMITED | TATA UGANDA LIMITED | ABHAYRAB | RABIES ANTIGEN DERIVED FROM RABIES VIRUS(L.PASTEUR 2061/VERO STRAIN) | >2.5 I.U PER VIAL | HUMAN BIOLOGICALS INSTITUTE ( A DIVISION OF INDIAN IMMUNOLOGICALS LTD) .-KOZHIPANNAI PUDUMUND P.O DR. BASAVAIAH NAGAR UDHAGAMANDALAM PIN: 643007 TAMIL NADU | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X2.5 I.U VIAL 1*0.5ML DILUENT(0.9%W/V SODIUM CHLORIDE INJ. B.P) - 1 DOSE VIAL | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3180 | NDA/MAL/HDP/6758 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | ADCO-NAPAMOL | PARACETAMOL | 500MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3181 | NDA/MAL/HDP/6759 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | BETAPYN | PARACETAMOL+CODEINE PHOSPHATE+DOXYLAMINE+CAFFEINE | 450 MG+10 MG+5 MG+50 MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 2.0X9.0 TABLET BLISTER,6.0X9.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER | 01/07/2017 |
| 3182 | NDA/MAL/HDP/6763 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | COMPRAL HEADACHE TABLETS | PARACETAMOL+ASPIRIN+CAFFEINE ANHYDROUS | 100MG+400MG+130MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X48.0X2.0 TABLET STRIP | 01/07/2005 |

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| 3183 | NDA/MAL/HDP/6765 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | IBUCACH 200 | IBUPROFEN | 200MG | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2010 |
| 3184 | NDA/MAL/HDP/6767 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | MEDI-KEEL A | BENZOCAINE+CETYLPYRIDINIUM CHLORIDE | 12MG+1.5MG | UNIQUE PHARMACEUTICALS LABORATORIES-SURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA | INDIA | ORAL SOLID ORDINARY LOZENGES | 1.0X2.0X8.0 LOZENGE BLISTER | 01/07/2016 |
| 3185 | NDA/MAL/HDP/6769 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | MEDI-KEEL A HONEY & LEMON | BENZOCAINE+CETYLPYRIDINIUM CHLORIDE | 12MG+1.5MG | UNIQUE PHARMACEUTICALS LABORATORIES-SURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA | INDIA | ORAL SOLID ORDINARY LOZENGES | 1.0X2.0X8.0 LOZENGE BLISTER | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3186 | NDA/MAL/HDP/6771 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIFLUVID | FLUCONAZOLE | 150MG | HOVID BERHAD,-LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK | MALAYSIA | ORAL SOLID ORDINARY CAPSULES | 1.0X4.0 CAPSULE BLISTER | 01/07/2016 |
| 3187 | NDA/MAL/HDP/6772 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | PIOSAFE 30 | PIOGLITAZONE HCL | 30MG | ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2007 |
| 3188 | NDA/MAL/HDP/6776 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | M-FORLIN 500 | METFORMIN | 500MG | LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3189 | NDA/MAL/HDP/6778 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | AXCEL IBUPROFEN | IBUPROFEN | 100MG/5ML | KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL--382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | MALAYSIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2016 |
| 3190 | NDA/MAL/HDP/6781 | IND SWIFT LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | NETAZOX-500 | NITAZOXANIDE | 500MG | IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X6.0 TABLET BLISTER | 01/07/2007 |
| 3191 | NDA/MAL/HDP/6785 | IND SWIFT LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | NETAZOX DT | NITAZOXANIDE | 200MG | IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0X1.0X6.0 TABLET BLISTER | 01/07/2008 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3192 | NDA/MAL/HDP/6787 | IND SWIFT LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | NETAZOX | NITAZOXANIDE | 100MG/5ML | IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE | 01/07/2008 |
| 3193 | NDA/MAL/HDP/6790 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | LIMZER | OMEPRAZOLE + DOMPERIDONE | 20MG + 30MG | INVENTIA HEALTHCARE PVT. LTD-FI – FI /1 ADDITIONAL AMBERNATH, M.I.D.C. AMBERNATH (EAST) – 421 506, DIST. THANE, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE STRIP | 01/07/2016 |
| 3194 | NDA/MAL/HDP/6791 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | CIMETIDINE | CIMETIDINE | 200MG | UMEDICA LABORATORIES PVT. LTD-PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP | 01/07/2005 |

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| 3195 | NDA/MAL/HDP/6794 | HETERO LABS LTD | AIVEEN (U) LIMITED | ZOLID | LINEZOLID | 600MG | HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOBNAGAR DISTRICT). PIN 509301 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2017 |
| 3196 | NDA/MAL/HDP/6795 | PHARAONIA PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CRONOMESONE OINTMENT | BETAMETHASONE VALERATE | 1%W/W | PHARAONIA PHARMACEUTICALS-NEW BORG EL ARAB CITY-ALEXANDRIA | EGYPT | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2016 |
| 3197 | NDA/MAL/HDP/6797 | MARTINDALE PHARMACEUTICALS LTD | LABOREX UGANDA LIMITED | PETHIDINE INJECTION | PETHIDINE | 100MG/2ML | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/1997 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3198 | NDA/MAL/HDP/6798 | UMEDICA LABORATORIES PVT LTD | VITACARE LIMITED | PRAZIQUANTEL TABLETS USP 600MG | PRAZIQUANTEL | 600MG | UMEDICA LABORATORIES PVT. LTD-PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X8.0 TABLET BOTTLE | 01/07/2017 |
| 3199 | NDA/MAL/HDP/6808 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | GLYGEN-500 | METFORMIN HYDROCHLORIDE | 500MG | LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3200 | NDA/MAL/HDP/6810 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CERVARIX | HUMAN PAPILLOMA VIRUS VACCINE (RDNA) | TYPE 16 L1 PROTEIN + TYPE 18 L1 PROTEIN + 3-0-DESACYL-4'MONOPHOSPHORYL LIPID A(MPL) | GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE I'INSTITUT 89 B-1330 RIXENSART | BELGIUM | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X10.0X0.5 ML VIAL,1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE) + A 25 GAUGE NEEDLE | 01/07/2007 |

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| 3201 | NDA/MAL/HDP/6812 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | NOFLOX | NORFLOXACIN | 0.3%W/V | ABACUS PARENTERAL DRUGS LIMITED-PLOT 114, BLOCK 191 | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE | 01/07/2016 |
| 3202 | NDA/MAL/HDP/6815 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABCROM EYE DROPS | SODIUM CROMOGLYCATE | 2%W/V | ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE | 01/07/2016 |
| 3203 | NDA/MAL/HDP/6817 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | LETROZOLE DENK 2.5 | LETROZOLE | 2.5MG | HAUPT PHARMA MÜNSTER GMBH-SCHLEEBRÜGGENKAMP 15 48159 MÜNSTER GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 3204 | NDA/MAL/HDP/6820 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABBORI EAR DROPS | BORIC ACID | 1.83%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | OTIC DROPS | 1.0X10.0 ML BOTTLE | 01/07/2017 |
| 3205 | NDA/MAL/HDP/6821 | LABOREX UGANDA LIMITED | LABOREX UGANDA LIMITED | MAGNESIUM SULPHATE INJECTION | MAGNESIUM SULPHATE | 50%W/V | MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X10.0 ML AMPOULE | 01/07/2016 |
| 3206 | NDA/MAL/HDP/6823 | LABOREX UGANDA LIMITED | LABOREX UGANDA LIMITED | EPHEDRINE HYDROCHLORIDE | EPHEDRINE HYDROCHLORIDE | 30MG/ML | MARTINDALE PHARMACEUTICALS .- ROMFORD ESSEX RM3 8UG UK | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 01/07/2016 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3207 | NDA/MAL/HDP/6833 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | ON.SENTRON-DENK 8MG ODT | ONDANSETRON | 8MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X6.0 TABLET BLISTER | 01/07/2016 |
| 3208 | NDA/MAL/HDP/6837 | ZEE PHARMACEUTICALS LTD | ZEE PHARMACEUTICALS LIMITED | ZEEL KIT | CLARITHROMYCIN + METRONIDAZOLE + PANTOPRAZOLE SODIUM SESQUIHYDRATE | 250MG + 400MG +40MG | THE MADRAS PHARMACEUTICALS-137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAL INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET STRIP | 01/07/2016 |
| 3209 | NDA/MAL/HDP/6843 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | FYTOBACT | CEFOPERAZONE + SULBACTAM | 0.5 G + 0.5 G | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2009 |

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| 3210 | NDA/MAL/HDP/6845 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | FYTOBACT 2G | SULBACTAM SODIUM + CEFOPERAZONE SODIUM | 1G + 1G | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X2.0 G VIAL | 01/07/2017 |
| 3211 | NDA/MAL/HDP/6857 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRUCIPRO TABLETS | CIPROFLOXACIN | 500MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 10.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3212 | NDA/MAL/HDP/6859 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRUVEL-500 TABLETS | LEVOFLOXACIN HEMIHYDRATE | 500MG | BRAWN LABORATORIES LTD..-13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA -INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 26/09/2018 |

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| 3213 | NDA/MAL/HDP/6862 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | DITS GEL | DICLOFENAC DIETHYLAMINE | 1%W/W | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X15.0 G TUBE,1.0X30.0 G TUBE | 01/07/2017 |
| 3214 | NDA/MAL/HDP/6865 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | DITS INJECTION | DICLOFENAC SODIUM | 25MG/ML | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X3.0 ML AMPOULE | 29/11/2017 |
| 3215 | NDA/MAL/HDP/6870 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | HYDROSONE 100MG | HYDROCORTISONE SODIUM SUCCINATE | 100MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON (1*100MG GLASS VIAL + 1*2ML AMP WFI),1.0X50.0 VIAL CARTON | 29/11/2017 |

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| 3216 | NDA/MAL/HDP/6871 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | VIVAX 100 | SILDENAFIL | 100MG | BRAWN LABORATORIES LTD..-13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA -INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 26/09/2018 |
| 3217 | NDA/MAL/HDP/6872 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | NETRACORTIL EYE/EAR SUSPENSION | OXYTETRACYCLINE HYDROCHLORIDE +HYDROCORTISONE ACETATE+POLYMYXIN B SULPHATE | 10MG+5MG+10000I.U | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | OPHTHALMIC SUSPENSIONS | 1.0X5.0 ML BOTTLE | 01/07/2017 |
| 3218 | NDA/MAL/HDP/6874 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | CITRAX TABLETS | CETIRIZINE HYDROCHLORIDE | 10MG | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3219 | NDA/MAL/HDP /6878 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AMITIVIAN | AMITRIPTYLINE | 25MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/05/2019 |
| 3220 | NDA/MAL/HDP /6879 | RAVIAN LIFE SCIENCE PVT. LTD | ROYAL PHARMA 2011 LIMITED | ORAV-200 | OFLOXACIN | 200MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/05/2019 |
| 3221 | NDA/MAL/HDP /6882 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | VORM-400 | ALBENDAZOLE | 400MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X10.0X1.0 TABLET BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3222 | NDA/MAL/HDP/6897 | BROOKES PHARMACEUTICAL LABORATORIES L | HARLEYS UGANDA LIMITED | PYODINE GARGLE & MOUTH WASH | POVIDONE IODINE | 1G/100ML | BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN | PAKISTAN | ORAL TOPICAL LIQUIDS | 1.0X60.0 ML BOTTLE | 01/07/2017 |
| 3223 | NDA/MAL/HDP/6898 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | RECORMON | EPOETIN BETA | 5000I.U/0.3ML | ROCHE DIAGNOSTICS GMBH MANNHEIM-SANDHOFER STRASSE 116, 68305 MANNHEIM - GERMANY | GERMANY | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X6.0X1.0X0.3 ML PRE- FILLED SYRINGE | 28/05/2019 |
| 3224 | NDA/MAL/HDP/6901 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | ZINKORA KIT | [GLUCOSE ANHYDROUS + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE ] + [ZINC SULPHATE MONOHYDRATE] | [13.5G + 2.9G + 2.6G + 1.5G] + [20MG] | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY COMBINATION PACK POWDERS/GRANULES | 1.0X2.0X20.5 G SACHET + 1*10 TABLET BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3225 | NDA/MAL/HDP/6905 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | NUROFEN | IBUPROFEN | 400MG | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 28/05/2019 |
| 3226 | NDA/MAL/HDP/6907 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | NUROFEN EXPRESS | IBUPROFEN | 400MG | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM | UNITED KINGDOM | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER | 28/05/2019 |
| 3227 | NDA/MAL/HDP/6909 | F.HOFFMANN-LA ROCHE LTD | LABOREX UGANDA LIMITED | HERCEPTIN | TRASFUZUMAB | 600 MG | F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBSSTANDORT KAISERAUGST, 4303 KAIERAUGST | SWITZERLAND | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 27/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3228 | NDA/MAL/HDP/6911 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | SCABION | CROTAMITON + SULPHUR | 10 G + 2 G | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2004 |
| 3229 | NDA/MAL/HDP/6917 | COSMOS LIMITED | ASTRA PHARMA (U) LIMITED | DAPSONE | DAPSONE | 100 MG | COSMOS LTD -RANGWE ROAD OFF LUNGA LUNGA ROAD INDUSTRIAL AREA NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3230 | NDA/MAL/HDP/6919 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MACSUNATE AQ JUNIOR | ARTESUNATE + AMODIAQUINE | 50MG + 135MG | MACLEODS PHARMACEUTICALS LTD.- PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0 TABLET BLISTER,1.0X25.0X 3.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3231 | NDA/MAL/HDP/6920 | I CARE PHARMA LIMITED | AIVEEN (U) LTD - WILSON ROAD | OFZOLE | OFLOXACIN+ORNIDAZOLE | 200MG+500MG | CORONA REMEDIES PVT LTD..-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 07/11/2018 |
| 3232 | NDA/MAL/HDP/6921 | B & O PHARM ZAC | TRIDEM PHARMA UGANDA LIMITED | DUFENAC | DICLOFENAC SODIUM | 75MG | GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES | 1.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 3233 | NDA/MAL/HDP/6922 | EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD | SURGIPHARM (U) LIMITED | FLUCAZOL | FLUCONAZOLE | 50 MG / 5 ML | GRACURE PHARMACEUTICALS LIMITED - E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN-301019 DIST. ALWAR, RAJASTHAN, INDI | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3234 | NDA/MAL/HDP/6923 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MACSUNATE AQ KID | ARTESUNATE + AMODIAQUINE | 25MG + 67.5MG | MACLEODS PHARMACEUTICALS LTD ,.- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER,1.0X25.0X 3.0 TABLET BLISTER | 27/03/2019 |
| 3235 | NDA/MAL/HDP/6924 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | NAC MR | DICLOFENAC POTASSIUM+PARA CETAMOL+CHLORZ OXAZONE | 50MG+325MG+25 0MG | CORONA REMEDIES PVT LIMITED-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3236 | NDA/MAL/HDP/6927 | CRATUS PHARMA PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | GOPAYN MR | ACECLOFENAC BP+TIZANIDINE HYDROCHLORIDE USP+PARACETAM OL BP | 100MG+2MG+500 MG | SAI MIRRA INNOPHARM PVT LIMITED -288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3237 | NDA/MAL/HDP/6928 | SAVA HEALTHCARE LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MOMENAP NS 0.05 | MOMETASONE FUROATE | 0.05%W/V | SAVA HEALTHCARE LIMITED.-PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA | GERMANY | NASAL SYSTEMIC UNIT DOSE AEROSOLS | 1.0X1.0X12.0 ML CANNISTER | 28/05/2019 |
| 3238 | NDA/MAL/HDP/6929 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | RANCV1000 | RANOLAZINE | 1000MG | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3239 | NDA/MAL/HDP/6930 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | TAPAL 50 | TAPENTADOL | 50MG | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3240 | NDA/MAL/HDP/6931 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AMORIV | AMBROXOL HYDROCHLORIDE | 15MG/5ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 27/08/2019 |
| 3241 | NDA/MAL/HDP/6932 | PSYCHOTROPICS INDIA LTD | ABACUS PHARMA (AFRICA) LIMITED | VALATE-200 | SODIUM VALPROATE | 200 MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 25/07/2018 |
| 3242 | NDA/MAL/HDP/6933 | PSYCHOTROPICS INDIA LTD | ABACUS PHARMA (AFRICA) LIMITED | VALATE 500 | SODIUM VALPROATE BP | 500MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3243 | NDA/MAL/HDP/6936 | SAVA HEALTHCARE LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | RANKOF | PARACETAMOL+CAFFEINE, PHENYLEPHRINE + CHLORPHENAMINE MALEATE | 500MG+30MG+10MG+2MG | SAVA HEALTHCARE LIMITED.-PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/05/2019 |
| 3244 | NDA/MAL/HDP/6939 | MSN LABORATORIES PRIVATE LIMITED | METRO PHARMACEUTICALS LIMITED | TAPAL 100 | TAPENTADOL | 100MG | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3245 | NDA/MAL/HDP/6941 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TOLVAT 30 | TOLVAPTAN | 30MG | MSN LABORATORIES PRIVATE LIMITED - -PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT, TELANGANA 502325, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 07/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3246 | NDA/MAL/HDP/6942 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TOLVAT 15 | TOLVAPTAN | 15MG | MSN LABORATORIES PRIVATE LIMITED - -PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT, TELANGANA 502325, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 07/11/2018 |
| 3247 | NDA/MAL/HDP/6943 | ADWIA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ADWIFLAM | DICLOFENAC POTASSIUM | 25MG | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43 | EGYPT | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X5.0 SUPPOSITORY STRIP | 28/05/2019 |
| 3248 | NDA/MAL/HDP/6945 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | TRICK-D | CHOLECALCIFEROL | 5MG/ML | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | OTHER SYSTEMIC LIQUIDS | 1.0X1.0 ML AMPOULE | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3249 | NDA/MAL/HDP /6946 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | FEVERAL | PARACETAMOL | 1OMG/ML | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | PAKISTAN | PARENTERAL ORDINARY I V VIALS | 1.0X1.0X100.0 ML VIAL | 28/05/2019 |
| 3250 | NDA/MAL/HDP /6948 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | D3 MUST 60 K | CHOLECALCIFEROL | 60000IU | MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2017 |
| 3251 | NDA/MAL/HDP /6949 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | MEGAFER | IRON SUCROSE | 100MG/5ML | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X5.0X5.0 ML AMPOULE | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3252 | NDA/MAL/HDP/6953 | SYNOKEM PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MISOFREE | MISOPROSTOL | 200MCG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 28/05/2019 |
| 3253 | NDA/MAL/HDP/6955 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SEVOTROY 250 | SEVOFLURANE | 250 | TROIKAA PHARMACEUTICALS LIMITED..-SANAND - KADI ROAD, THOL, CITY: THOL - 382 728, DIST. MEHSANA, GUJARAT STATE - INDIA | INDIA | OTHER SYSTEMIC LIQUID INHALATIONS | 1.0X250.0 ML BOTTLE | 28/05/2019 |
| 3254 | NDA/MAL/HDP/6956 | TROIKAA PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | NUROTROY SR | MECOBALAMIN + FOLIC ACID + PYRIDOXINE HYDROCHLORIDE | 1500MCG + 5MG + 20MG | TROIKAA PHARMACEUTICALS LIMITED,,-C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3255 | NDA/MAL/HDP /6957 | WILSHIRE LABORATORIES (PVT) LTD | HEALTHCARE LTD. | ZEECIN | AZITHROMYCIN DIHYDRATE | 250MG | WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X3.0 TABLET BLISTER | 28/05/2019 |
| 3256 | NDA/MAL/HDP /6958 | WILSHIRE LABORATORIES (PVT) LTD | HEALTHCARE LTD. | ZEECIN | AZITHROMYCIN DIHYDRATE | 500MG | WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 28/05/2019 |
| 3257 | NDA/MAL/HDP /6962 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ROXONE- S | CEFTRIAXONE SODIUM + SULBACTAM SODIUM | 1G+0.5G | ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 ML VIAL | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3258 | NDA/MAL/HDP /6963 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | LANAC | LANSOPRAZOLE | 30MG | ZIM LABS LTD.-B 21/22, MIDC AREA, KALMESHWAR 441501, DIST-NAGPUR | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 28/05/2019 |
| 3259 | NDA/MAL/HDP /6968 | F.HOFFMANN-LA ROCHE LTD | LABOREX UGANDA LIMITED | MABTHERA® SC 1400MG | RITUXIMAB | 1400MG/13.4ML | F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBSSTANDORT KAISERAUGST, 4303 KAIERAUGST | SWITZERLAND | PARENTERAL ORDINARY S C VIALS | 1.0X1.0X13.4 ML VIAL | 27/08/2019 |
| 3260 | NDA/MAL/HDP /6970 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | VOMIKIND ORAL SOLUTION | ONDANSETRON | 4MG/5ML | MANKIND PHARMA LTD-- UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X50.0 ML BOTTLE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3261 | NDA/MAL/HDP/6973 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNIFED DM SYRUP 120ML | TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN | 1.25MG + 30MG + 10MG/5ML | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 21/11/2019 |
| 3262 | NDA/MAL/HDP/6974 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | VOMIKIND-MD 4 | ONDANSETRON | 4MG | MANKIND PHARMA LIMITED, UNIT-II. -VILLAGE KISHANPURA, P.O JAMNIWALA, PAONTA SAHIB IN H.P. | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3263 | NDA/MAL/HDP/6976 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | KETORIV SOAP | KETOCONAZOLE | 2%W/W | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | TOPICAL EXTERNAL SOLID SOAPS/BARS | 1.0X75.0 G SACHET | 28/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3264 | NDA/MAL/HDP /6980 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | KETORIV | KETOCONAZOLE | 2.0%W/W | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | NASAL TOPICAL CREAMS | 1.0X1.0X15.0 G TUBE | 28/08/2019 |
| 3265 | NDA/MAL/HDP /6981 | ZIFAM PINNACLE PTY. LTD. | DELMAW ENTERPRISES LIMITED | KIT LANZ | LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE | 30MG + 250MG + 500MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY OTHER SPECIAL FORMS | 1.0X7.0X6.0 TABLET BLISTER PACK HAS BOTH CAPSULES AND TABLETS | 27/08/2019 |
| 3266 | NDA/MAL/HDP /6982 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | DEXARIV | DEXAMETHASONE SODIUM PHOSPHATE | 0.5 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3267 | NDA/MAL/HDP /6983 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | FASICON | FLUCONAZOLE | 200 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 27/08/2019 |
| 3268 | NDA/MAL/HDP /6985 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | COLDRID SYRUP | CETIRIZINE DIHYDROCHLORIDE + PHENYLEPHRINE HCL + PARACETAMOL | 2.5MG + 5MG + 125MG | MEDLEY PHARMACEUTICALS, LTD-PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3269 | NDA/MAL/HDP /6986 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | REPRAZ 20 TABLETS | RABEPRAZOLE SODIUM | 20MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3270 | NDA/MAL/HDP/6987 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | PORAZ CAPSULES | OMEPRAZOLE | 20MG | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES | 1.0X10.0X10.0 CAPSULE STRIP | 01/07/2017 |
| 3271 | NDA/MAL/HDP/6989 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNIFED EXPECTORANT SYRUP 120ML | TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + GUAIFENESIN | 1.25MG+30MG+100MG/5ML | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 21/11/2019 |
| 3272 | NDA/MAL/HDP/6990 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ESORIV-40 | ESOMEPRAZOLE MAGNESIUM | 40MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3273 | NDA/MAL/HDP /6991 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ESORIV-20 | ESOMEPRAZOLE MAGNESIUM | 20MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 28/05/2019 |
| 3274 | NDA/MAL/HDP /6992 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | AZIRIV-200 | AZITHROMYCIN | 200MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X15.0 ML BOTTLE | 28/05/2019 |
| 3275 | NDA/MAL/HDP /6994 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PERLEX DRY SYRUP | CEFALEXIN MONOHYRATE | 125MG/5ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3276 | NDA/MAL/HDP /6995 | STALLION LABORATORIES PVT LTD | HARLEYS UGANDA LIMITED | T-MEF | TRANEXAMIC ACID + MEFENAMIC ACID | 250MG + 500MG | ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/08/2019 |
| 3277 | NDA/MAL/HDP /6997 | HETERO LABS LTD | AIVEEN (U) LIMITED | EC-PRAM 10 | ESCITALOPRAM OXALATE | 10MG | HETERO LABS LTD. UNIT (V)-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X1.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3278 | NDA/MAL/HDP /6998 | STALLION LABORATORIES PVT LTD | HARLEYS UGANDA LIMITED | L-DIPIN-55 | LOSARTAN POTASSIUM + AMLODIPINE BESILATE | 50MG + 5MG | ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3279 | NDA/MAL/HDP/7002 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LOPINAVIR AND RITONAVIR | LOPINAVIR + RITONAVIR | 40MG + 10MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X120.0 CAPSULE BOTTLE | 27/08/2019 |
| 3280 | NDA/MAL/HDP/7003 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | NAC-SP | DICLOFENAC POTASSIUM + SERRATIOPEPTIDASE | 50MG + 10MG | CORONA REMEDIES PVT LTD..-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 07/11/2018 |
| 3281 | NDA/MAL/HDP/7004 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | DUOCETZ | PARACETAMOL+TRAMADOL HYDROCHLORIDE | 325MG+37.5MG | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED..-515/1 MOO 4, SOI 8, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG | THAILAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3282 | NDA/MAL/HDP /7005 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE | ABACAVIR + DOLUTEGRAVIR + LAMIVUDINE | 600MG + 50MG + 300MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 27/08/2019 |
| 3283 | NDA/MAL/HDP /7006 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | PREDNIMAX | PREDNISOLONE | 5MG | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3284 | NDA/MAL/HDP /7007 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EPNONE 50 | EPLERENONE | 50MG | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3285 | NDA/MAL/HDP /7009 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DARUNAVIR TABLETS | DARUNAVIR ETHANOLATE | 600 MG | CIPLA LTD ,.-PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET CONTAINER | 27/08/2019 |
| 3286 | NDA/MAL/HDP /7011 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | URSOLIV 250 | URSODEOXYCHOLIC ACID | 250MG | MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED..-515/1 MOO 4, SOI 8, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG | THAILAND | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X10.0 CAPSULE BLISTER | 27/03/2019 |
| 3287 | NDA/MAL/HDP /7012 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | MYHEP DVIR | DACLATASVIR + SOFOSBUVIR | 60MG + 400MG | MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X28.0 TABLET BOTTLE | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3288 | NDA/MAL/HDP/7013 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AZITHRAA 500 | AZITHROMYCIN | 500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 29/11/2017 |
| 3289 | NDA/MAL/HDP/7014 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | ACEAAR 100 TABLET | ACECLOFENAC | 100MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET STRIP | 29/11/2017 |
| 3290 | NDA/MAL/HDP/7015 | KOPRAN LIMITED | TATA UGANDA LIMITED | LOKIT | OMEPRAZOLE | 20MG | KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3291 | NDA/MAL/HDP /7018 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | AXYLIN | AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM | 125MG + 125MG | LABORATORY & ALLIED LTD - PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA | KENYA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 27/08/2019 |
| 3292 | NDA/MAL/HDP /7019 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | LECOTRIM | SULFAMETHOXAZOLE + TRIMETHOPRIM | 200MG + 40MG / 5ML | LABORATORY & ALLIED LTD - PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA | KENYA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X50.0 ML BOTTLE | 27/08/2019 |
| 3293 | NDA/MAL/HDP /7020 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | KEMOXYL 250 DT | AMOXICILLIN TRIHYDRATE | 250MG | LABORATORY AND ALLIED LTD ..-PLOT 209/10349, OFF MOMBASA ROAD | KENYA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 27/08/2019 |

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| 3294 | NDA/MAL/HDP/7021 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | PINNOFEC PLUS | ACECLOFENAC+PARACETAMOL | 100MG+500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3295 | NDA/MAL/HDP/7022 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | PINNAFLAM PLUS | DICLOFENAC SODIUM+PARACETAMOL | 50MG+500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3296 | NDA/MAL/HDP/7023 | EXPHAR SA. | SURGIPHARM (U) LIMITED | VERZOL ORAL SUSPENSION | ALBENDAZOLE | 200 MG / 5 ML | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X10.0 ML BOTTLE,1.0X20.0X 10.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3297 | NDA/MAL/HDP/7024 | EXPHAR SA. | SURGIPHARM (U) LIMITED | MICOZAL | KETOCONAZOLE | 2%W/W | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 29/11/2017 |
| 3298 | NDA/MAL/HDP/7028 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | DEXAFLOX | OFLOXACIN + DEXAMETHASONE | 3MG + 1MG PER ML | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | OPHTHALMIC LIQUIDS | 1.0X5.0 ML BOTTLE | 02/09/2019 |
| 3299 | NDA/MAL/HDP/7037 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | O2 | OFLOXACIN + ORNIDAZOLE | 50MG + 125MG | MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X30.0 ML BOTTLE | 27/08/2019 |

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| 3300 | NDA/MAL/HDP/7039 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | O2 | OFLOXACIN + ORNIDAZOLE | 200MG + 500MG | MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3301 | NDA/MAL/HDP/7044 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | R.B. TONE HAEMATINIC CAPSULES | FERROUS GLUCONATE + FOLIC ACID + CALCIUM LACTATE + ZINC SULFATE + VITAMIN B12 | 259MG + 0.5MG + 100MG + 33MG + 2.5MG | MEDLEY PHARMACEUTICALS LTD..-PLOT NO. 18 & 19, SURVEY NO. 378 / 7 & 8 & 379 / 2& 3, ZARI CAUSEWAY ROAD, KACHIGAM, DAMAN (U.T) 396210 - INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X2.0X15.0 CAPSULE BLISTER | 27/08/2019 |
| 3302 | NDA/MAL/HDP/7046 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | XEMADERM 0.1% CREAM | MOMETASONE FUROATE | 0.1%W/W | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3303 | NDA/MAL/HDP/7047 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | XEMADERM0.1% OINTMENT | MOMETASONE FUROATE | 0.1%W/W | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE | 01/07/2017 |
| 3304 | NDA/MAL/HDP/7050 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | PANDERM SKIN OINTMENT | NYSTATIN+NEOMYCIN SULFATE+GRAMICIDIN+TRIAMCINOLONE | 10,000,000I.U+2.5MG+0.25MG+1MG | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 01/07/2017 |
| 3305 | NDA/MAL/HDP/7051 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | DEXIPAN CREAM | DEXPANTHENOL | 0.05%W/W | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH | UNITED ARAB EMIRATES | TOPICAL EXTERNAL CREAMS | 1.0X20.0 G TUBE | 01/07/2017 |

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| 3306 | NDA/MAL/HDP /7053 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | KETOVID CREAM | KETOCONAZOLE | 2%W/W | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2017 |
| 3307 | NDA/MAL/HDP /7055 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | VIREST 400 | ACICLOVIR | 400MG | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 5.0X5.0 TABLET BLISTER | 31/01/2018 |
| 3308 | NDA/MAL/HDP /7057 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | VIREST CREAM 5% | ACICLOVIR | 5%W/W | HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | TOPICAL EXTERNAL CREAMS | 1.0X5.0 G TUBE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3309 | NDA/MAL/HDP/7063 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | GRISEOFULVIN 500MG FILM-COATED TABLET | GRISEOFULVIN | 500MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3310 | NDA/MAL/HDP/7064 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLIMICRON 80MG TABLET | GLICLAZIDE | 80MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2018 |
| 3311 | NDA/MAL/HDP/7065 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | BRIMO | BRIMONIDINE TARTRATE | 2%W/V | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | OPHTHALMIC LIQUIDS | 1.0X5.0 ML BOTTLE | 02/09/2019 |

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| 3312 | NDA/MAL/HDP /7066 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MABRON SR | TRAMADOL HYDROCHLORIDE | 100MG | MEDOCHEMIE (FACTORY AZ). 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID RETARD CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER | 27/08/2019 |
| 3313 | NDA/MAL/HDP /7067 | MERIDIAN ENTERPRISES PRIVATE LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | SUPPOL 125 | PARACETAMOL | 125MG | MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X2.0X5.0 SUPPOSITORY STRIP | 27/08/2019 |
| 3314 | NDA/MAL/HDP /7070 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIABETMIN 1000 MG FILM-COATED TABLET | METFORMIN HYDROCHLORIDE | 1000MG | HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 31/01/2018 |

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| 3315 | NDA/MAL/HDP /7071 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FORACORT-200 | FORMOTEROL FUMARATE DIHYDRATE + BUDESONIDE | 6MCG + 200MCG | CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA. | INDIA | LUNG ADMINISTRATION METERED-DOSE POWDER INHALER | 1.0X1.0X120.0 METERED DOSE CANNISTER | 25/07/2018 |
| 3316 | NDA/MAL/HDP /7074 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FORACORT-100 | FORMETEROL FUMARATE DIHYDRATE + BUDESONIDE | 6 MCG+100 MCG | CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA. | INDIA | LUNG ADMINISTRATION METERED-DOSE POWDER INHALER | 1.0X1.0X120.0 METERED DOSE CANNISTER | 25/07/2018 |
| 3317 | NDA/MAL/HDP /7075 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | Q-TAB-200 | QUETIAPINE FUMARATE | 200MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X1.0X8.0 TABLET BLISTER | 28/08/2019 |

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| 3318 | NDA/MAL/HDP /7077 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | FORACORT-400 | FORMOTEROL FUMARATE DIHYDRATE + BUDESONIDE | 6MCG + 400MCG | CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA. | INDIA | LUNG ADMINISTRATION METERED-DOSE POWDER INHALER | 1.0X1.0X120.0 METERED DOSE CANNISTER | 25/07/2018 |
| 3319 | NDA/MAL/HDP /7080 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | Q-TAB-100 | QUETIAPINE FUMARATE | 100MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/08/2019 |
| 3320 | NDA/MAL/HDP /7083 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | ETROBAX 90 | ETORICOXIB | 90MG | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/08/2019 |

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| 3321 | NDA/MAL/HDP/7085 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | DYSEN SUSPENSION | SECNIDAZOLE | 750MG | NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE | 27/08/2019 |
| 3322 | NDA/MAL/HDP/7087 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | Q-TAB-25 | QUETIAPINE FUMARATE | 25MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/08/2019 |
| 3323 | NDA/MAL/HDP/7088 | PINNACLE LIFE SCIENCE PVT. LTD | METRO PHARMACEUTICALS LIMITED | PINNOX 200 | OFLOXACIN | 200MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 30/05/2018 |

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| 3324 | NDA/MAL/HDP/7089 | PHARMACTIV FZCO | JEET PHARMACEUTICALS LIMITED | ES-LOPROT | ESOMEPRAZOLE SODIUM | 40MG | NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NACL) | 27/08/2019 |
| 3325 | NDA/MAL/HDP/7091 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AARLEFLOX 500 TABLETS | LEVOFLOXACIN HEMIHYDRATE | 500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3326 | NDA/MAL/HDP/7092 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | PATMAC | PANTOPRAZOLE SODIUM | 40MG | NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN | PAKISTAN | PARENTERAL ORDINARY DRY VIALS | 1.0X40.0 MG VIAL (+ 1*10ML AMPOULE OF 0.9% NACL) | 27/08/2019 |

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| 3327 | NDA/MAL/HDP/7094 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | GLANDIN-E2 | DINOPROSTONE | 2MG | NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN | PAKISTAN | TOPICAL EXTERNAL GELS AND SOLS | 1.0X3.0 G PRE-FILLED SYRINGE | 27/08/2019 |
| 3328 | NDA/MAL/HDP/7095 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | FREMOL EXTRA | PARACETAMOL + CAFFEINE | 500MG + 65MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X25.0X 4.0 CAPLET STRIP | 21/11/2019 |
| 3329 | NDA/MAL/HDP/7096 | GAMA PHARMACEUTICALS (U) LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DEXAPHEN SYRUP | DEXAMETHASONE + CHLORPHENIRAMINE MALEATE | 10MG + 40MG/100ML | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2017 |

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| 3330 | NDA/MAL/HDP/7098 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | ACEFORCE SP | ACECLOFENAC+PARACETAMOL+SERRATIOPEPTIDASE | 100MG+325MG+15MG | AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3331 | NDA/MAL/HDP/7101 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | ASTHAREN | SALBUTAMOL SULPHATE | 4MG | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3332 | NDA/MAL/HDP/7102 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REPRAZINE | CHLORPROMAZINE HYDROCHLORIDE | 100MG | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 3333 | NDA/MAL/HDP/7103 | MACARTHYS LABORATORIES LTD | LABOREX UGANDA LIMITED | CAFFEINE CITRATE 10MG/ML SOLUTION FOR INJECTION | CAFFEINE CITRATE | 10MG/ML | MACARTHYS LABORATORIES LIMITED T\A MARTINDALE PHARMA-BAMPTON ROAD, ROMFORD, ESSEX RM3 8UG, | UNITED KINGDOM | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 21/11/2019 |
| 3334 | NDA/MAL/HDP/7104 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPISOPT | DOROZOLAMIDE + TIMOLOL | 20MG/1ML + 5MG/1ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT | EGYPT | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 30/05/2018 |
| 3335 | NDA/MAL/HDP/7105 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TRAMACETAL TABLETS | ACETAMINOPHEN +TRAMADOL HYDROCHLORIDE | 325MG+37.5MG | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 29/01/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3336 | NDA/MAL/HDP/7106 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REVIVE | GLUCOSE ANHYDROUS + TRISODIUM CITRATE DIHYDRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE | 13.5G + 2.9G + 2.6G + 1.5G | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA | UGANDA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X1.0 SACHET CARTON | 01/07/2016 |
| 3337 | NDA/MAL/HDP/7107 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | FEBUMAC 40 | FEBUXOSTAT | 40 MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3338 | NDA/MAL/HDP/7109 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | BRUTAFLAM-60 | ETORICOXIB | 60MG | MANKIND PHARMA LTD, UNIT II ,-VILLAGE-KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3339 | NDA/MAL/HDP/7110 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNIFED EXTRA SYRUP 120ML | TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN + GUAIFENESIN | 1.25MG + 10MG + 7.5MG + 50MG/5ML | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 21/11/2019 |
| 3340 | NDA/MAL/HDP/7112 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | ETROBAX 60 | ETORICOXIB | 60MG | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3341 | NDA/MAL/HDP/7115 | INTAS, PHARMACEUTICALS LTD | STAR BIOTECH UGANDA LTD | SARTEL 40H | TELMISARTAN +HYDROCHLOROTHIAZIDE | (40+12.5)MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 07/11/2018 |

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| 3342 | NDA/MAL/HDP /7116 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNIFED SYRUP 120ML | TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE | 1.25MG + 30MG/5ML | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 21/11/2019 |
| 3343 | NDA/MAL/HDP /7117 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | UNIFED TABLETS | TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE | 2.5MG+60MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3344 | NDA/MAL/HDP /7118 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | BRUTAFLAM-90 | ETORICOXIB | 90MG | MANKIND PHARMA LTD, UNIT II ,-VILLAGE-KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3345 | NDA/MAL/HDP/7119 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | OLMAT-40 H | OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3346 | NDA/MAL/HDP/7120 | BESINS HEALTHCARE BENELUX SA | SURGIPHARM (U) LIMITED | ANDROGEL | TESTOSTERONE | 16.2MG/G | BESINS MANUFACTURING BELGIUM (BMB)-GROOT BIJGAARDENSTRAAT, 128. 1620 | BELGIUM | TOPICAL EXTERNAL EMULSION GELS | 1.0X88.0 G CANNISTER | 21/11/2019 |
| 3347 | NDA/MAL/HDP/7123 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | MARTINEZ 10 | MONTELUKAST SODIUM | 10MG | AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 28/03/2018 |

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| 3348 | NDA/MAL/HDP/7124 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VITAMIN E 400 MG. | VITAMIN E | 400 MG | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT.<br>P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X2.0X12.0 CAPSULE BLISTER | 01/07/2017 |
| 3349 | NDA/MAL/HDP/7125 | SYNOKEM PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | I-FREE 72 | LEVONORGESTREL | 1.5MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 29/01/2019 |
| 3350 | NDA/MAL/HDP/7127 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CASPOGIN 50 | CASPOFUNGIN ACETATE | 50MG | CIPLA LTD-UNIT IX, M-61, M-62 & M-63,<br>VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE<br>GOA 403 722 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 07/11/2018 |

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| 3351 | NDA/MAL/HDP /7128 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | COTRIKANT-960 | TRIMETHOPRIM+SULFAMETHOXAZOLE | 800MG+160MG | S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 26/09/2018 |
| 3352 | NDA/MAL/HDP /7131 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | SPOTCLAV OS | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 125MG + 31.25MG/5ML | SPARSH BIO-TECH PVT. LTD.--PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 26/09/2018 |
| 3353 | NDA/MAL/HDP /7132 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CASPOGIN 70 | CASPOFUNGIN ACETATE | 70MG | CIPLA LTD-UNIT IX, M-61, M-62 & M-63, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 07/11/2018 |

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| 3354 | NDA/MAL/HDP/7133 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | WELLNESS | DAY TABLET: PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE NIGHT TABLET: PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE | DAY TABLET: 325MG + 30MG + 4.5MG NIGHT TABLET : 500MG + 30MG + 25MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER (5 DAY TABLETS + 5 NIGHT TABLETS) | 29/01/2019 |
| 3355 | NDA/MAL/HDP/7135 | UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD) | PLANET PHARMACEUTICALS UGANDA LTD | CILACAR *10 | CILNIDIPINE | 10MG | UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 29/08/2019 |
| 3356 | NDA/MAL/HDP/7136 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | AMIKACIN 100 MG / 2ML | AMIKACIN SULPHATE | 100MG/2ML | EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O -- 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X1.0X2.0 ML VIAL | 25/07/2018 |

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| 3357 | NDA/MAL/HDP /7145 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | LEVOTOP 0.5% | LEVOFLOXACIN | 0.5%W/V | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 28/03/2019 |
| 3358 | NDA/MAL/HDP /7147 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | BIMAT | BIMATOPROST | 0.03% W/V | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X3.0 ML VIAL | 30/05/2018 |
| 3359 | NDA/MAL/HDP /7148 | SUNRISE INTERNATIONAL LABS LTD | ROYAL PHARMA 2011 LIMITED | OMEPSUN | OMEPRAZOLE | 20 MG | SUNRISE INTERNATIONAL LABS LTD.-PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051 | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0X 10.0 TABLET STRIP | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3360 | NDA/MAL/HDP /7149 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | OLOPAT OD | OLOPATADINE HYDROCHLORIDE | 0.2% W/V | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | OPHTHALMIC DROPS | 1.0X1.0X3.0 ML VIAL | 30/05/2018 |
| 3361 | NDA/MAL/HDP /7150 | SAKAR HEALTHCARE LIMITED | ROYAL PHARMA 2011 LIMITED | SEFIXI - SB 1500 | CEFTRIAXONE SODIUM +SULBACTAM SODIUM | 1000 MG +500MG | SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL + 1X10ML FFS PLASTIC BOTTLE FOR WFI | 29/08/2019 |
| 3362 | NDA/MAL/HDP /7151 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | APDROPS DX | MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE SODIUM PHOSPHATE | 5MG+1MG/ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML VIAL | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3363 | NDA/MAL/HDP/7152 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | MINOXIN PLUS | MINOXIDIL | 50MG/ML | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | TOPICAL EXTERNAL LIQUIDS | 1.0X1.0X60.0 ML BOTTLE | 29/01/2019 |
| 3364 | NDA/MAL/HDP/7154 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CIPROFLOXACIN HYDROCHLORIDE | CIPROFLOXACIN HYDROCHLORIDE | 2MG/ML | ABARIS HEALTHCARE PVT LTD - -SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT-382740 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 29/11/2017 |
| 3365 | NDA/MAL/HDP/7162 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | TEXAVIR | TENOFOVIR DISOPROXIL FUMARATE | 300MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2017 |

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| 3366 | NDA/MAL/HDP /7163 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | STODIL | LOPERAMIDE HYDROCHLORIDE | 2MG | TRIVENI FORMULATIONS LTD-PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 27/08/2019 |
| 3367 | NDA/MAL/HDP /7165 | TRIVENI FORMULATIONS LIMITED | AIVEEN (U) LIMITED | ERYMAC | ERYTHROMYCIN STEARATE | 250MG | TRIVENI FORMULATIONS LTD-PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3368 | NDA/MAL/HDP /7167 | SPARSH BIO-TECH PVT.LTD. | ABACUS PHARMA (AFRICA) LIMITED | SPOTCLAV DS | AMOXICILLIN TRIHYDRATE + CLAVULANATE | 200MG + 28.5MG PER 5ML | SPARSH BIO-TECH PRIVATE LIMITED,.-PLOT NO.1, SURVEY NO. 242/243/244, VILLAGE LAKHABVAD, JAMNAGAR 361006 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 27/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3369 | NDA/MAL/HDP/7170 | WOCKHARD LTD | ROYAL PHARMA 2011 LIMITED | PHYTON 4.5G | PIPERACILLIN + TAZOBACTAM | 4.0G + 0.5G | ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON +1X20ML WFI AMPOULE | 27/08/2019 |
| 3370 | NDA/MAL/HDP/7175 | PSYCHOTROPICS INDIA LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | TELPRESS-AM 40/5 | TELMISARTAN + AMLODIPINE BESYLATE | 40MG + 5MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 25/07/2018 |
| 3371 | NDA/MAL/HDP/7179 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | AVONZA | TENOFOVIR DISOPROXIL FUMARATE+LAMIVUDINE+EFAVIRENZ | 300MG+300MG+400MG | MYLAN LABORATORIES LIMITEDD ,-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER | 07/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3372 | NDA/MAL/HDP /7181 | SURGE LAB (PVT) LIMITED | JEET PHARMACEUTICALS LIMITED | SURGIBION | VITAMIN B1 + VITAMIN B6 + VITAMIN B12 | 100MG, + 100MG + 1000MCG | SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN. | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X5.0X3.0 ML AMPOULE | 27/08/2019 |
| 3373 | NDA/MAL/HDP /7184 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | EVOKE TABLETS | SILDENAFIL | 50MG | LABORATORY & ALLIED LTD - PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, NEXT TO LIBRA HOUSE, MOMBASA ROAD- NAIROBI - KENYA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 28/05/2019 |
| 3374 | NDA/MAL/HDP /7188 | HETERO LABS LTD | AIVEEN (U) LIMITED | TELMILO 80 | TELMISARTAN | 80 MG | HETERO LABS LTD (UNIT-V) SY-SY. NO. 438, 439, 440 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3375 | NDA/MAL/HDP /7191 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROSOL | HYPROMELLOSE | 0.7%W/V | AUROLAB .-NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020 | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X10.0 ML VIAL | 29/01/2019 |
| 3376 | NDA/MAL/HDP /7192 | EXPHAR SA. | SURGIPHARM (U) LIMITED | TINAZOL | TINIDAZOLE | 500 MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 28/05/2019 |
| 3377 | NDA/MAL/HDP /7193 | EXPHAR SA. | SURGIPHARM (U) LIMITED | FLUOXINE | CIPROFLOXACIN | 500 MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 28/05/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3378 | NDA/MAL/HDP /7194 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENSCRUB SOLUTION | LINEZOLID ,CHLORHEXIDINE GLUCONATE | 200 MG/100 ML ,4%W/V | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | TOPICAL EXTERNAL LIQUIDS | 1.0X500.0 ML BOTTLE | 29/01/2019 |
| 3379 | NDA/MAL/HDP /7195 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 986ML - 1100KCAL | AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANINE + | [7.0G + 6.0G + 5.5G + 1.5G + 2.5G + 3.7G + 3.3G + 2.2G + 2.6G + 5.6G + 3.2G + 0.50G + 2.2G + 1.0G + 0.2G + 3.1G + 0.28G + 2.1G + 0.6G + 2.2G + 1.7G + 0.0065G] + [42%] + [11.3G + 11.3G + 9.4G + 5.6G] | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X986.0 ML BAG :(1*[500ML AMINO ACID SOLUTION WITH ELECTROLYTES + 298ML GLUCOSE 42% SOLUTION + 188ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3380 | NDA/MAL/HDP /7196 | SUNRISE INTERNATIONAL LABS LTD | ROYAL PHARMA 2011 LIMITED | LORMAN | LORATADINE | 10MG | SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/08/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3381 | NDA/MAL/HDP/7197 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | RABIVAX-S | PURIFIED RABIES ANTIGEN (RABIES VIRUS PITMAN-MOORE STRAIN 3218) | NOT LESS THAN 2.5 I.U / DOSE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X5.0X1.0 DOSE VIAL + IML DILUENT AMPOULE | 27/08/2019 |
| 3382 | NDA/MAL/HDP/7198 | UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD) | PLANET PHARMACEUTICALS UGANDA LTD | SILBECOR | SILVER SULFADIAZINE | 1%W/W | UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X50.0 G TUBE | 29/08/2019 |
| 3383 | NDA/MAL/HDP/7199 | EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES - | GAMA PHARMACEUTICALS (U) LIMITED | PREGAVALEX 75 | PREGABALIN | 75MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3384 | NDA/MAL/HDP /7200 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN,1477ML - 1600KCAL | AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANINE + | "[10.5G + 9.0G + 8.2G + 2.2G + 3.8G + 5.6G + 5.0G + 3.2G + 3.8G + 8.4G + 4.9G + 0.75G + 3.3G + 1.5G + 0.30G + 4.6G + 0.42G + 3.1G + 0.90G + 3.4G + 2.6G + 0.0097G] + [42%W/V] + [16.9G + 16.9G + 14.1G + | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1477.0 ML BAG :(1*[750ML AMINO ACID SOLUTION WITH ELECTROLYTES + 446ML GLUCOSE 42% SOLUTION + 281ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3385 | NDA/MAL/HDP /7201 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | MEASLES AND RUBELLA VACCINE | LIVE, ATTENUATED MEASLES VIRUS + LIVE ATTENUATED RUBELLA VIRUS | NLT 1000 CCID50 + 1000 CCID50 / DOSE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0X10.0 DOSE VIAL + 5ML DILUENT,1.0X50.0X 1.0 DOSE VIAL + 1ML DILUENT | 27/08/2019 |
| 3386 | NDA/MAL/HDP /7202 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | VILDAGLIPTIN | VILDAGLIPTIN | 50MG | NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X14.0 TABLET BLISTER | 01/07/2017 |

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| 3387 | NDA/MAL/HDP /7203 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 2463ML - 2700KCAL | AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANINE + | [17.5 G + 15.0 G + 13.8 G + 3.7 G + 6.2 G + 9.4 G + 8.4 G + 5.4 G + 6.4 G + 14.0 G + 8.1 G + 1.2 G + 5.4 G + 2.5 G + 0.49 G + 7.6 G + 0.69 G + 5.2 G + 1.5 G + 5.7 G + 4.2 G + 0.016 G] + [42 %] + 313 G + 28.1 G + 28.1 G + 23.4 G + 14.0 G] | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X2463.0 ML BAG :(1*[1250ML AMINO ACID SOLUTION WITH ELECTROLYTES + 744ML GLUCOSE 42% SOLUTION + 469ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3388 | NDA/MAL/HDP /7205 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 1970ML - 2200KCAL | AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANINE + | [14G + 12.0G + 11.0G + 3.0G + 5.0G + 7.4G + 6.6G + 4.3G + 5.1G + 11.2G + 6.5G + 1.0G + 4.4G + 2.0G + 0.40G + 6.2G + 0.56G + 4.2G + 1.2G + 4.5G + 3.4G + 0.013G] + [42%] + [22.5G + 22.5G + 18.8G + 11.3G] | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1970.0 ML BAG :(1*[1000ML AMINO ACID SOLUTION WITH ELECTROLYTES + 595ML GLUCOSE 42% SOLUTION + 375ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3389 | NDA/MAL/HDP /7206 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | LOS ANGIO | LOSARTAN POTASSIUM | 50MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 29/08/2019 |

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| 3390 | NDA/MAL/HDP /7208 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED - | SURGIPHARM (U) LIMITED | SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION, 1448ML-1000KCAL | [GLUCOSE MONOHYDRATE] + AMINO ACID SOLUTION WITH ELECTROLYTES: [ALANINE + ARGININE + GLYCINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + | [13%] + [6.4G + 5.5G + 5.1G + 1.3G + 2.3G + 3.3G + 2.3G + 3.3G+ 3.0G + 1.9G + 2.3G + 5.1G + 3.0G + 0.46G + 2.0G + 0.91G + 0.17G + 2.9G + 0.26G + 1.9G + 0.55G + 2.0G + 1.6G + 0.006G] + [12.3G + | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1448.0 ML BAG :(1*[788ML GLUCOSE 13% + 456ML AMINO ACID SOLUTION WITH ELECTROLYTES + 204ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3391 | NDA/MAL/HDP /7211 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | PYODINE GEL | POVIDONE-IODINE | 5GM/100GM | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X20.0 G TUBE | 27/03/2019 |
| 3392 | NDA/MAL/HDP /7212 | PHARMACO DISTRIBUTION (PTY) LTD | ECHO PHARMACY (U) LIMITED | PHARMALGAN | PARACETAMOL | 10MG/ML | AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 31/01/2018 |

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| 3393 | NDA/MAL/HDP/7214 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED - | SURGIPHARM (U) LIMITED | SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION, 1904ML - 1300KCAL | [GLUCOSE MONOHYDRATE] + AMINO ACID SOLUTION WITH ELECTROLYTES: [ALANINE + ARGININE + GLYCINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + | [13%] + [8.4G + 7.2G + 6.6G + 1.8G + 3.0G + 4.4G + 4.0G + 2.6G + 3.1G + 6.7G + 3.9G + 0.60G + 2.6G + 1.2G + 0.24G + 3.7G + 0.34G + 2.5G + 0.72G + 2.7G + 2.0G + 0.008G] + [16.1G + 16.1G + 13.4G + | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | AUSTRIA SWEDEN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1904.0 ML BAG :(1*[1036ML GLUCOSE 13% + 600ML AMINO ACID SOLUTION WITH ELECTROLYTES + 268ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS) | 04/02/2019 |
| 3394 | NDA/MAL/HDP/7216 | SHIN POONG PHARMACEUTICALS CO.LTD | AAFIYA (A) LIMITED | PYRAMAX | PYRONARIDINE TETRAPHOSPHATE + ARTESUNATE | 60MG + 20MG | SHIN POONG PHARM. CO., LTD-70, SANDAN-RO, 19 BEON-GIL, DANWON-GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA | SOUTH KOREA | ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES | 1.0X90.0 SACHET CARTON | 27/08/2019 |
| 3395 | NDA/MAL/HDP/7217 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AARPANTO 40 | PANTOPRAZOLE | 40MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3396 | NDA/MAL/HDP/7218 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AARTMIN 500 | METFORMIN | 500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3397 | NDA/MAL/HDP/7222 | I-CARE PHARMA LTD | AIVEEN (U) LIMITED | SAMSUNATE | ARTESUNATE | 60MG | SAMRUDH PHARMACEUTICALS PVT LTD-J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X5.0 ML VIAL OF ARTESUNATE +(1*1ML AMPOULE OF SODIUM BICARBONATE BP 5%W/V)+(1*5ML SODIUM CHLORIDE BP 0.9%W/V) | 21/11/2019 |
| 3398 | NDA/MAL/HDP/7223 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | DOLUTEGRAVIR | DOLUTEGRAVIR | 50MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE | 21/11/2019 |

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| 3399 | NDA/MAL/HDP /7225 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LUMITER 80/480 | ARTEMETHER + LUMEFANTRINE | 80MG + 480MG | OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X6.0 TABLET BLISTER | 21/11/2019 |
| 3400 | NDA/MAL/HDP /7226 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | ELICA-M | MOMETASONE FUROATE + MICONAZOLE NITRATE | 0.1%W/W + 2%W/W | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | TOPICAL EXTERNAL CREAMS | 1.0X30.0 G TUBE | 27/11/2019 |
| 3401 | NDA/MAL/HDP /7229 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | AARCIFLOX 500 | CIPROFLOXACIN | 500MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3402 | NDA/MAL/HDP /7231 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | LIGNAT 2% | LIDOCAINE HYDROCHLORIDE | 2% W/V | NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA | NEPAL | PARENTERAL ORDINARY VIALS | 1.0X30.0 ML VIAL | 01/07/2017 |
| 3403 | NDA/MAL/HDP /7232 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | CIFF-100 DS | CEFIXIME | 100MG/5ML | PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS & PHARMACEUTICALS PVT. LTD.) -B-21/22, MIDC AREA, KALMESHWAR-441 501, NAGPUR, MAHARASHTRA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 29/08/2019 |
| 3404 | NDA/MAL/HDP /7235 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | OPTIDEX-T | DEXAMETHASONE + TOBRAMYCIN | 0.1W/V + 0.3%W/V | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | OPHTHALMIC SUSPENSIONS | 1.0X5.0 ML BOTTLE | 27/11/2019 |

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| 3405 | NDA/MAL/HDP /7237 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | CONTUS PAEDIATRIC | CHLORPHENAMINE MALEATE + PHENYLEPHRINE HYDROCHLORIDE | 1MG + 2.5MG | STEDMAN PHARMACEUTICALS PVT. LTD.-C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE | 21/11/2019 |
| 3406 | NDA/MAL/HDP /7238 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILONG-10 | NEBIVOLOL HYDROCHLORIDE | 10MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/03/2018 |
| 3407 | NDA/MAL/HDP /7239 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | GAVISCON PEPPERMINT LIQUID | SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE | 500MG + 267MG + 160MG | ABBOTT -DAMSON LANE,HULL, HUB HU8 7DS | UNITED KINGDOM | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X12.0X10.0 ML SACHET,1.0X200.0 ML BOTTLE | 28/05/2019 |

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| 3408 | NDA/MAL/HDP/7240 | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED | GITTOES PHARMACEUTICALS LIMITED | GAVISCON DOUBLE ACTION | SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE | 250MG + 106.5MG + 187.5MG | ABBOTT -DAMSON LANE,HULL, HUB HU8 7DS | UNITED KINGDOM | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X8.0 TABLET BLISTER | 28/05/2019 |
| 3409 | NDA/MAL/HDP/7242 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | AMINORICH | MULTIVITAMINS, MINERALS | NA | STEDMAN PHARMACEUTICALS PVT. LTD.-C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X15.0 CAPSULE BLISTER,1.0X1.0X2.0 CAPSULE BLISTER | 21/11/2019 |
| 3410 | NDA/MAL/HDP/7243 | BAL PHARMA LIMITED - | PLANET PHARMACEUTICALS UGANDA LTD | EMTRIM | TRIMETHOPRIM + SULPHAMETHOXAZOLE | 80MG+ 400MG | BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3411 | NDA/MAL/HDP/7245 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | CEFAKIND-500 | CEFUROXIME AXETIL | 500MG | COPMED PHARMACEUTICALS PVT LTD-UNIT-II, PLOT NO. 50, GONDPUR INDUSTRIAL AREA, TEHSIL-PAONTA SAHIB, DISTT. SIRMOUR,HIMACHAI PRADESH-173025, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 29/01/2019 |
| 3412 | NDA/MAL/HDP/7247 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | VITAFIL-Z | MULTIVITAMINS, MINERALS | NA | STEDMAN PHARMACEUTICALS PVT. LTD.-C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE | 21/11/2019 |
| 3413 | NDA/MAL/HDP/7248 | EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES | GAMA PHARMACEUTICALS (U) LIMITED | ESOMELODAN 20 | ESOMEPRAZOLE | 20MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 25/07/2018 |

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| 3414 | NDA/MAL/HDP/7249 | EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES | GAMA PHARMACEUTICALS (U) LIMITED | ESOMELODAN 40 | ESOMEPRAZOLE MAGNESIUM | 40MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 25/07/2018 |
| 3415 | NDA/MAL/HDP/7250 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DOLUTEGRAVIR SODIUM, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | DOLUTEGRAVIR SODIUM +LAMIVUDINE +TENOFOVIR DISOPROXIL FUMARATE | 50MG + 300MG + 300MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE | 21/11/2019 |
| 3416 | NDA/MAL/HDP/7253 | MANKIND PHARM LTD | TATA UGANDA LIMITED | MONTICOPE | MONTELUKAST SODIUM + LEVOCETIRIZINE DIHYDROCHLORIDE | 10MG + 5MG | MANKIND PHARMA LTD, UNIT II ,-VILLAGE-KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3417 | NDA/MAL/HDP/7257 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | PAARPIN TABLET | PARACETAMOL | 650 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3418 | NDA/MAL/HDP/7258 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | DESCOVY 200MG/10MG | EMTRICITABINE + TENOFOVIR ALAFENAMIDE | 200MG/10MG | PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 ROTTENDORF PHARMA GMBH-OSTENFELDER STRAßE 51-61,59320 ENNIGERLOH,GERMANY | CANADA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 31/01/2018 |
| 3419 | NDA/MAL/HDP/7259 | FERRER INTERNATIONAL, S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ENEAS 10/20 | ENALAPRIL + NIFEDIPINE | 10MG + 20MG | FERRER INTERNATIONAL S.A ..-JOAN BUSCALLA, 1 - 9, 08173 SANT CUGAT DEL VALLES, BARCELONA | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3420 | NDA/MAL/HDP/7260 | MICRO LABS LTD | LABOREX UGANDA LIMITED | ESOFAG-40 | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 40MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3421 | NDA/MAL/HDP/7264 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MIOPAN PLUS SUSPENSION | MAGALDRATE+SIMETHICONE | 540MG + 40MG/5ML | PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3422 | NDA/MAL/HDP/7267 | MICRO LABS LTD | LABOREX UGANDA LIMITED | ESOFAG-20 | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE | 20MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3423 | NDA/MAL/HDP /7269 | EXPHAR SA. | SURGIPHARM (U) LIMITED | FEBRILEX SYRUP | PARACETAMOL+DEXTROMETORPHAN HYDROBROMIDE+ CHLORPHENAMINE MALEATE | 125MG+5MG+1MG /5 ML | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X150.0 ML BOTTLE | 01/07/2017 |
| 3424 | NDA/MAL/HDP /7270 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | MYPAID | IBUPROFEN +PARACETAMOL | 200 MG +250 MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 07/11/2018 |
| 3425 | NDA/MAL/HDP /7271 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TURBOVAS CP | ROSUVASTATIN CALCIUM + CLOPIDOGREL | 5MG + 75MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |

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| 3426 | NDA/MAL/HDP /7274 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ZENTAIR 0.5MG | ENTECAVIR | 0.5MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3427 | NDA/MAL/HDP /7275 | MICRO LABS LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TILYPTIN 20 | TENELIGLIPTIN HYDROBROMIDE HYDRATE | 20MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | TOPICAL EXTERNAL TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3428 | NDA/MAL/HDP /7277 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | ALERINIT | LEVOCETIRIZINE HYDROCHLORIDE | 5MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X20.0 TABLET BLISTER | 27/08/2019 |

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| 3429 | NDA/MAL/HDP /7278 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | NEUTROSEC | DL-METHIONINE + CHOLINE BITARTRATE + THIAMINE MONO NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORIDE + NICOTINAMIDE + DEXPANTHENOL + BIOTIN + FOLIC ACID + | 200MG + 200MG +3MG + 3MG + 1.5MG + 22.5MG + 4.5MG + 0.1MG + 0.5MG + 3MCG + 7.5.I.U | TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH- | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/11/2019 |
| 3430 | NDA/MAL/HDP /7283 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | ASTYMIN-M FORTE | L-THREONINE + L-VALINE + DL-METHIONINE + L-ISOLEUCINE + L-LEUCINE + L-PHENYLALANINE + L-TRYPTOPHAN + L-LYSINE HYDROCHLORIDE + THIAMINE NITRATE + RIBOFLAVIN + | 4.2MG + 6.7MG + 18.4MG + 5.9MG + 18.3MG + 5.0MG + 5.0MG + 25MG + 5MG + 3MG + 1.5MG + 25MG + 5MG+ 0.75MG + 2.5MCG+ 40MG + 2500 IU+ 200 IU + 7.5 IU + 0.1MG+ 20.5MG+ 4MG+ 1.4MG+ 7.425MG+ | TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH- | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 27/11/2019 |
| 3431 | NDA/MAL/HDP /7284 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LTD | LIVERCOL 10 | ROSUVASTATIN CALCIUM | 10MG | İLKO İLAÇ SANAYI VE TICARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 25/07/2018 |

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| 3432 | NDA/MAL/HDP/7286 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TOBRIN OPHTHALMIC OINTMENT | TOBRAMYCIN | 3MG/G | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT | EGYPT | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 01/07/2017 |
| 3433 | NDA/MAL/HDP/7287 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EPISTIGMIN 0.05% | NEOSTIGMINE METHYLSULPHATE | 0.05%W/V | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X1.0 ML AMPOULE | 01/07/2017 |
| 3434 | NDA/MAL/HDP/7288 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KETESSE FILM COATED TABLETS | DEXKETOPROFEN TROMETAMOL | 25MG | A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.I-VIA CAMPO DI PILE 67100 L'AQUILA | ITALY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/11/2017 |

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| 3435 | NDA/MAL/HDP /7289 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | PEGLEC | POLYETHYLENE GLYCOL + SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM BICARBONATE + ANHYDROUS SODIUM SULFATE | 118.0G +2.93G +1.484G + 3.370G + 11.360G / SACHET | TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH- | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X1.0X137.15 G SACHET | 27/11/2019 |
| 3436 | NDA/MAL/HDP /7292 | LEBEN LABORATORIES PVT LTD | MALIX PHARMA (U) LIMITED | IBUPLUS SUSPENSION | IBUPROFEN+.PARA CETAMOL | 100MG + 125MG / 5ML | LEBEN LABORATORIES PVT LTD .-L-14 PHASE III MIDC AKOLA 444 104 | NULL | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE | 21/11/2019 |
| 3437 | NDA/MAL/HDP /7293 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LTD | ALRINAST | DESLORATADINE | 5MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/11/2017 |

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| 3438 | NDA/MAL/HDP/7295 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | LAMIFEN | TERBINAFINE HYDROCHLORIDE | 1%W/W | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 27/11/2019 |
| 3439 | NDA/MAL/HDP/7296 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MEDAXONUM 2G | CEFTRIAXONE SODIUM | 2G | MEDOCHEMIE (FACTORY C)- 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X2.0 G VIAL | 29/01/2019 |
| 3440 | NDA/MAL/HDP/7298 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | NEBILONG-2.5 | NEBIVOLOL HYDROCHLORIDE | 2.5 MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |

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| 3441 | NDA/MAL/HDP /7301 | HETERO LABS LTD | AIVEEN (U) LIMITED | PACLITERO 300 | PACLITAXEL | 60 MG/ML | HETERO LABS LIMITED UNIT-VI -APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X50.0 ML VIAL | 26/09/2018 |
| 3442 | NDA/MAL/HDP /7306 | HETERO LABS LTD | AIVEEN (U) LIMITED | PACLITERO 100 | PACLITAXEL | 100 MG/16.7 ML | HETERO LABS LIMITED UNIT-VI -APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X16.7 ML VIAL | 26/09/2018 |
| 3443 | NDA/MAL/HDP /7307 | EXPHAR SA. | SURGIPHARM (U) LIMITED | VERZOL | ALBENDAZOLE | 400 MG | GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0 TABLET BLISTER | 28/05/2019 |

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| 3444 | NDA/MAL/HDP/7308 | STALLION LABORATORIES PVT LTD | HARLEYS UGANDA LIMITED | APSIDASE | ACECLOFENAC + PARACETAMOL + SERRATIOPEPTIDASE | 100MG + 500MG + 10MG | ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/08/2019 |
| 3445 | NDA/MAL/HDP/7311 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | FLUCA OPTHALMIC SUSPENSION | FLUOROMETHOLON + SODIUM CROMOGLICATE | 1%W/V + 2%W/V | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | OPHTHALMIC SUSPENSIONS | 1.0X5.0 ML BOTTLE | 27/11/2019 |
| 3446 | NDA/MAL/HDP/7312 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | BETADINE OINTMENT 5%W/W | POVIDONE IODINE | 5%W/W | G.S PHAMBUTOR PVT LTD .-B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE,1.0X125.0 G TUBE,1.0X250.0 G JAR | 01/07/2017 |

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| 3447 | NDA/MAL/HDP/7316 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | I-UP TABLETS | FERROUS ASCORBATE + FOLIC ACID | 100MG + 1.5MG | CACHET PHARMACEUTICAL PVT LTD. -VILLAGE-THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/11/2019 |
| 3448 | NDA/MAL/HDP/7317 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EMITINO TABLETS 8MG | ONDANSETRON | 8MG | CACHET PHARMACEUTICAL PVT LTD. -VILLAGE-THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3449 | NDA/MAL/HDP/7318 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MOXICLAV 625 | AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID | 500MG + 125MG | MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE STRIP | 29/01/2019 |

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| 3450 | NDA/MAL/HDP /7319 | DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. | BUFFALO HEALTH CARE LTD | SIPROSAN 500 | CIPROFLOXACIN HYDROCHLORIDE | 500MG | DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.-ESENBOGA MERKEZ MAH CUBUK CAD NO.31 CUBUK ANKARA -TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X5.0 TABLET BLISTER | 31/01/2018 |
| 3451 | NDA/MAL/HDP /7321 | GLENMARK PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | ASCORIL DRY COUGH AND COLD SYRUP | DEXTROMETHORPHAN HYDROBROMIDE + TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + MENTHOL | 10MG + 1.25MG + 30MG + 1.5MG / 5ML | GLENMARK PHARMACEUTICALS LTD .- PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 27/11/2019 |
| 3452 | NDA/MAL/HDP /7325 | DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. | BUFFALO HEALTH CARE LTD | DALMAN AQ NASAL SPRAY | FLUTICASONE PROPIONATE | 0.05%W/V | DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. --ESENBOĞA MERKEZ MAH. ÇUBUK CADDESI NO: 31 06760 ANKARA - TURKEY | TURKEY | NASAL SYSTEMIC UNIT DOSE AEROSOLS | 1.0X1.0X120.0 METERED DOSE BOTTLE | 25/07/2018 |

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| 3453 | NDA/MAL/HDP/7329 | DAWA LIMITED | SUPER MEDIC LTD | ACEPAR- MR | PARACETAMOL +ACECLOFENAC+CHLORZOXAZONE | 500 MG+100 MG +375 MG | DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/03/2018 |
| 3454 | NDA/MAL/HDP/7332 | DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. | BUFFALO HEALTH CARE LTD | DIVATOR 20MG FILM TABLET | ATORVASTATIN | 20MG | DROGSAN ILACLARI SAN VE TIC. A.S.-ESENBOGA MERKEZ MAHALLESI CUBUK CADDESI NO: 31 CUBUK / ANKARA - TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/01/2019 |
| 3455 | NDA/MAL/HDP/7336 | MODI NUNDIPHARMA PVT LTD | SURGIPHARM (U) LIMITED | BETADINE GERMICIDE GARGLE 2% MINT | POVIDONE IODINE | 2%W/V | G.S PHAMBUTOR PVT LTD-G.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA | INDIA | ORAL TOPICAL LIQUIDS | 1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 31/01/2018 |

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| 3456 | NDA/MAL/HDP /7338 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | IBUPLUS | IBUPROFEN + PARACETAMOL | 400MG + 325MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X15.0X2.0X20.0 TABLET BLISTER | 27/08/2019 |
| 3457 | NDA/MAL/HDP /7339 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ADERAN 16 | CANDESARTAN CILEXETIL | 16 MG | AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3458 | NDA/MAL/HDP /7340 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | HIFEN -200 | IBUPROFEN | 200MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101 KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3459 | NDA/MAL/HDP/7342 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | ZEALARGY | RUPATADINE FUMERATE | 10 MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3460 | NDA/MAL/HDP/7343 | WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO | KAIYUANTANG (U) LIMITED | GLEVIX | LEVOFLOXACIN + SODIUM CHLORIDE | 0.5G + 0.9G | WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE | CHINA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 21/11/2019 |
| 3461 | NDA/MAL/HDP/7345 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | DELTACEF | CEFEPIME | 1G | MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 21/11/2019 |

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| 3462 | NDA/MAL/HDP /7346 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | REZN TABLETS | ZINC SULFATE MONOHYDRATE | 20MG | RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA | UGANDA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3463 | NDA/MAL/HDP /7348 | MSD (PTY) LTD | SURGIPHARM (U) LIMITED | ISENTRESS 25 MG | RALTEGRAVIR POTASSIUM | 25MG | MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685<br>SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X60.0 TABLET BOTTLE | 28/03/2018 |
| 3464 | NDA/MAL/HDP /7350 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | SULCEF | CEFOPERAZONE+ SULBACTUM | 1G+1G | MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X1.0 ML VIAL | 27/03/2019 |

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| 3465 | NDA/MAL/HDP/7351 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | TRYFIX CV DS | CEFIXIME+CLAVULANIC ACID | 50MG+31.25MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3466 | NDA/MAL/HDP/7353 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOPHAGE XR 500MG | METFORMIN HYDROCHLORIDE | 500MG | MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT<br>MERCK SANTÉ S.A.S.-2 RUE DU PRESSOIR VERT<br>45400 SEMOY<br>FRANCE | GERMANY | ORAL SOLID RETARD TABLETS | 1.0X6.0X15.0 TABLET BLISTER | 28/03/2018 |
| 3467 | NDA/MAL/HDP/7355 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN SUSPENSION | ARTEMETHER+LUMEFANTRINE | 180MG+1080MG | AJANTA PHARMA LIMITED.-B-41516, MIDC INDUSTRIAL AREA,<br>PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA,INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 31/01/2018 |

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| 3468 | NDA/MAL/HDP/7356 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIABETMIN TABLET 500MG | METFORMIN HYDROCHLORIDE | 500MG | HOVID BERHAD-121, JALAN TUNKU ABDUL RAHMAN, 30010 IPOH, PERAK, MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X20.0 TABLET BLISTER | 01/07/2017 |
| 3469 | NDA/MAL/HDP/7357 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PAMAGIN-C SYRUP | CETIRIZINE HYDROCHLORIDE+DEXTROMETHORPHAN HYDROBROMIDE+ACETAMINOPHEN+PHENYLEPHRINE HYDROCHLORIDE+ZINC GLUCONATE+MENTHOL | 2.5MG+7.5MG+125MG+5MG+7.5MG+2.5MG/5ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 31/01/2018 |
| 3470 | NDA/MAL/HDP/7359 | INDCHEMIE HEALTH SPECIALITIES PVT. LTD. | NUMED STORES SMC LIMITED | INDCLAV 625 | AMOXICILLIN+CLAVULANATE POTASSIUM | 500MG+125MG | INDCHEMIE HEALTH SPECIALITIES PVT LTD-VILLAGE THANA TEHSIL BADDI DIST SOLAN HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER | 01/07/2017 |

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| 3471 | NDA/MAL/HDP/7360 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | GAVISCON DOUBLE ACTION LIQUID | SODIUM ALGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE | 500MG + 213MG + 325MG/10ML | ABBOTT -DAMSON LANE,HULL, HUB HU8 7DS | UNITED KINGDOM | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X150.0 ML BOTTLE,1.0X300.0 ML BOTTLE,1.0X12.0X 10.0 ML SACHET | 21/11/2019 |
| 3472 | NDA/MAL/HDP/7361 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | DOLUTEGRAVIR | DOLUTEGRAVIR SODIUM | 50MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET BOTTLE | 21/11/2019 |
| 3473 | NDA/MAL/HDP/7363 | INDCHEMIE HEALTH SPECIALITIES PVT. LTD. | NUMED STORES SMC LIMITED | INDCLAV 228 | AMOXICILLIN+CLAVULANATE POTASSIUM | 200MG+28MG/5ML | INDCHEMIE HEALTH SPECIALITIES PVT. LTD.-VILLAGE & P.O – THANA, TEHSIL – BADDI, DIST- SOLAN, HIMACHAL | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |

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| 3474 | NDA/MAL/HDP /7364 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | MOKSEFEN 400 MG | MOXIFLOXACIN HYDROCHLORIDE | 400MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0 TABLET BLISTER | 01/07/2017 |
| 3475 | NDA/MAL/HDP /7365 | OCHOA LABORATORIES LIMITED - | SUPER MEDIC LTD | DOLOACT MR | PARACETAMOL+ DICLOFENAC POTASSIUM+CHLO RZOXAZONE | 500 MG+50 MG+250 MG | AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED-58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/01/2019 |
| 3476 | NDA/MAL/HDP /7366 | TWENTY FIRST CENTURY PHARMACEUTICAL S PVT.LTD | SWASTIK PHARMACEUTICA L LTD | TRYFIX | CEFIXIME | 200MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2017 |

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| 3477 | NDA/MAL/HDP/7367 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | TRYFIX 100 DS | CEFIXIME | 100MG/5ML | TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3478 | NDA/MAL/HDP/7369 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | XOMOX CV DS | AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE | 200MG+28.5MG/5ML | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3479 | NDA/MAL/HDP/7370 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | XOMOX CV 625 | AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE | 500MG+125MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2017 |

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| 3480 | NDA/MAL/HDP/7381 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | BETADINE ANTISEPTIC CREAM 5% | POVIDONE-IODINE | 5%W/W | G.S PHAMBUTOR PVT LTD .-B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE,1.0X20.0 G TUBE | 01/07/2017 |
| 3481 | NDA/MAL/HDP/7384 | YURIA-PHARM LTD | PHARMA VILLE LIMITED | TIVORTIN | ARGININE HYDROCHLORIDE | 42MG/ML | YURIA-PHARM LLC MANUFACTURING SITE NO. 1-108, KOBZARSKA STREET, CHERKASY, 18030 | UKRAINE | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 28/03/2018 |
| 3482 | NDA/MAL/HDP/7386 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | TRYLEXIN 125 DS | CEFALEXIN MONOHYDRATE | 125MG/5ML | TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |

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| 3483 | NDA/MAL/HDP/7388 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | TRYFIX CV 200 | CEFIXIME+CLAVULANIC ACID | 200MG+125MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET STRIP | 01/07/2017 |
| 3484 | NDA/MAL/HDP/7389 | EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES - | GAMA PHARMACEUTICALS (U) LIMITED | GAROPRIDE | ITOPRIDE HYDROCHLORIDE | 50MG | EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3485 | NDA/MAL/HDP/7391 | EMCURE PHARMACEUTICALS LTD | HARLEYS UGANDA LIMITED | TAVIN-EM | TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE | 300MG + 200MG | EMCURE PHARMACEUTICALS LTD .-PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 27/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3486 | NDA/MAL/HDP/7406 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ARENA | ADRENALINE | 0.1% W/V | LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X1.0 ML AMPOULE | 01/07/2017 |
| 3487 | NDA/MAL/HDP/7407 | HETERO LABS LTD | AIVEEN (U) LIMITED | MONAST 5 | MONTELUKAST SODIUM | 5MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO DRUGS LTD. -VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, TEHSIL NALAGARH, DIST. SOLAN, HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3488 | NDA/MAL/HDP/7409 | S K AGE EXPORTS | DAVIMED PHARMA LIMITED | LARIACT DISPERSIBLE | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | S KANT HEALTHCARE LTD-PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X6.0 TABLET BLISTER | 28/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3489 | NDA/MAL/HDP/7410 | MEDOPHARM, INDIA | PLANET PHARMACEUTICALS UGANDA LTD | COTRIMOXAZOLE TABLETS BP 960 MG | TRIMETHOPRIM +SULPHAMETHOXAZOLE | 960MG | WATERLAND LABORATORIES-34 B, INDUSTRIAL AREA, MALUR - 563160, KARNATAKA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 26/09/2018 |
| 3490 | NDA/MAL/HDP/7411 | S K AGE EXPORTS | DAVIMED PHARMA LIMITED | LARIACT 180-1080 | ARTEMETHER + LUMEFANTRINE | 180MG + 1080MG /60ML | S KANT HEALTHCARE LTD-PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 28/11/2019 |
| 3491 | NDA/MAL/HDP/7413 | S K AGE EXPORTS | DAVIMED PHARMA LIMITED | LARIACT | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | S KANT HEALTHCARE LTD-PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X24.0 TABLET BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3492 | NDA/MAL/HDP/7417 | INTAS PHARMACUITICALS LTD | STAR BIOTECH UGANDA LTD | SARTEL-40 | TELMISARTAN | 40MG | INTAS PHARMACEUTICALS LTD ...,-CAMP ROAD, SELAQUI, DEHRADUN-248197, UTTARKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3493 | NDA/MAL/HDP/7421 | PINNACLE LIFE SCIENCE PVT. LTD. | METRO PHARMACEUTICALS LIMITED | GESIC ADL 200 | IBUPROFEN | 200MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3494 | NDA/MAL/HDP/7424 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ZINC SULFATE TABLETS USP 20MG | ZINC SULFATE MONOHYDRATE | 20MG | MACLEODS PHARMACEUTICALS LTD - - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3495 | NDA/MAL/HDP/7425 | OCHOA LABORATORIES LIMITED - | AIVEEN (U) LIMITED | DOLOACT PLUS | ACECLOFENAC + PARACETAMOL | 100MG + 500MG | AUROCHEM PHARMACEUTICALS (I)-PLOT NO. 58, PTICE LTD PALGHAR 401404, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3496 | NDA/MAL/HDP/7426 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MEDOFED | GUAIFENESIN + DEXTROMETHORPHAN HYDROBROMIDE + PSEUDOEPHEDRINE HYDROCHLORIDE AND + TRIPROLIDINE HYDROCHLORIDE | 100MG + 15MG + 20MG + 1.25MG/5ML | MEDOCHEMIE ACTORY).....-1-10 CONSTANTINOUPOLEOS STREET, 3011, LIMASSOL | CYPRUS | ORAL LIQUID ORDINARY LIQUIDS | 1.0X100.0 ML BOTTLE | 21/11/2019 |
| 3497 | NDA/MAL/HDP/7431 | WIN-MEDICARE PVT LTD | SURGIPHARM (U) LIMITED | MOVICOL | MACROGOL 3350 (POLYETHYLENE GLYCOL)+SODIUM CHLORIDE+SODIUM BICARBONATE+ POTASSIUM CHLORIDE | 13.125G+350.7MG +178.5MG+46.6MG | WIN-MEDICARE PVT. LTD-MODIPURAM-250 110, UTTAR PRADESH,INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X10.0X13.81 G SACHET | 26/09/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3498 | NDA/MAL/HDP /7432 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | MENAFRIVAC | MENINGOCOCCAL A POLYSACCHARIDE + TETANUS TOXOID | 5µG + 5µG /0.5ML | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X5.0 ML VIAL + 1*5ML AMPOULE FOR DILUENT | 21/11/2019 |
| 3499 | NDA/MAL/HDP /7433 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED - | SURGIPHARM (U) LIMITED | KETOSTERIL | MULTIINGREDIENT | MULTIINGREDIENT | LABESFAL LABORATORIOS SLMIRO, S.A ,.-ZONA INDUSTRIAL DO LAGEDO 3465-157 SANTIAGO DE BESTEIROS | PORTUGAL | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X20.0 TABLET BLISTER | 21/11/2019 |
| 3500 | NDA/MAL/HDP /7439 | DAWA PHARMACEUTICALS LIMITED | SUPER MEDIC LTD | LORVIC | LORATADINE | 5MG/5ML | DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3501 | NDA/MAL/HDP/7440 | MANKIND | TATA UGANDA LIMITED | TOTACEF-1000 | CEFEPIME | 1000MG | MANKIND PHARMA LTD.-VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH | INDIA | PARENTERAL RETARD DRY VIALS | 1.0X1000.0 MG VIAL | 28/11/2019 |
| 3502 | NDA/MAL/HDP/7441 | VIRCHOW HEALTHCARE PVT LTD | SURGIPHARM (U) LIMITED | HYORTH XL | SODIUM HYALURONATE | 8MG/ML | VIRCHOW BIOTECH PVT LTD-SURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MANDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X6.0 ML PRE-FILLED SYRINGE | 29/11/2017 |
| 3503 | NDA/MAL/HDP/7442 | DAWA LIMITED- | SUPER MEDIC LTD | NERVILIN NT | PREGABALIN + NORTRIPTYLINE HYDROCHLORIDE | 75MG + 10MG | DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3504 | NDA/MAL/HDP /7447 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | LORADIN 10 | LORATADINE | 10MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3505 | NDA/MAL/HDP /7448 | OCHOA LABORATORIES LIMITED - | SUPER MEDIC LTD | SORID OINTMENT | CALCIPOTRIOL MONOHYDRATE + BETAMETHASONE DIPROPIONATE | 50MCG +0.5MG | AUROCHEM LABORATORIES (I) PVT LTD-8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X30.0 G TUBE | 29/11/2017 |
| 3506 | NDA/MAL/HDP /7449 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LAMIVUDINE/ TENOFOVIR DF 300/300MG | LAMIVUDINE+TENOFOVIR DISOPROXIL FUMARATE | 300MG+300MG | CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED--PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3507 | NDA/MAL/HDP/7450 | OCHOA LABORATORIES | SUPER MEDIC LTD | DOLOACT GEL | KETOPROFEN + CAPSICUM OLEORESIN | 2.50%W/W + 0.25%W/W | AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X30.0 G TUBE | 29/11/2017 |
| 3508 | NDA/MAL/HDP/7453 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ANTIDIAZOX | NITAZOXANIDE | 100MG/5ML | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 01/07/2017 |
| 3509 | NDA/MAL/HDP/7455 | GETZ PHARMA PVT LTD | MU PHARMA CO - SMC LIMITED | GETRYL 4MG | GLIMEPIRIDE | 4 MG | GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 29/08/2022 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3510 | NDA/MAL/HDP /7456 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | INFUTRAX | CEFTRIAXONE SODIUM | 1G | M/S ZEISS PHARMACEUTICALS PVT LTD,,-PLOT 72, EPIP PHASE 1, JHARMAJRI BADDI, DIST: SOLAN HP-INDIA VENUS REMEDIES LIMITED ,.-HILL TOP, INDUSTRIAL ESTATE, JHARMAJRI, EPIP, PHASE 1, EXT. BBATOLI KALAN, BADDI-SOLAN HIMACHAL PRADESH, INDIA PIN 173205 INNOVA CAPTAB PVT. LTD-1281/1, | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 21/11/2019 |
| 3511 | NDA/MAL/HDP /7457 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLADON | PARACETAMOL EFFERVESCENT | 1000MG | CIPLA LTD ,,-PLOT NO. 9,10,15 INDORE SPECIAL ECONOMIC ZONE PHASE II PITHAMPUR DISTRICT DHAR MADHYA PRADESH PIN. 454775 | INDIA | ORAL SOLID ORDINARY EFFERVESCENT TABLETS | 1.0X6.0X4.0 TABLET BLISTER | 21/11/2019 |
| 3512 | NDA/MAL/HDP /7460 | INVENTIA HEALTHCARE PVT LTD | EUROPA HEALTHCARE (U) LTD | SEGABIN SR 75 | PREGABALIN | 75MG | INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3513 | NDA/MAL/HDP/7463 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | ACURON | ATRACURIUM BESYLATE | 10MG/ML | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 27/08/2019 |
| 3514 | NDA/MAL/HDP/7464 | INVENTIA HEALTHCARE PVT LTD | EUROPA HEALTHCARE (U) LTD | SEGABIN M 75 | PREGABALIN + METHYCOBALAMIN | 75MG + 1500MCG | INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE | INDIA | ORAL SOLID RETARD TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3515 | NDA/MAL/HDP/7465 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | P-ALAXIN TS | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 120MG + 960MG | M/S BLISS GVS PHARMA LIMITED -PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X3.0 TABLET BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3516 | NDA/MAL/HDP/7467 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | TEZOLE CREAM | KETOCONAZOLE | 20 MG | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 27/08/2019 |
| 3517 | NDA/MAL/HDP/7469 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | ECZEMUS 0.03% OINTMENT | TACROLIMUS MONOHYDRATE | 0.03%W/W | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X10.0 G TUBE | 25/07/2018 |
| 3518 | NDA/MAL/HDP/7470 | AKRITI PHARMACEUTICALS PVT LTD | PHARMA VILLE LIMITED | AKSONE | CEFTRIAXONE SODIUM | 1G | AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 21/11/2019 |

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| 3519 | NDA/MAL/HDP /7471 | AMRING FARMA S.R.L | ERIS LTD | BEVACIZUMAB AMRING | BEVACIZUMAB | 100 MG/4 ML | SINERGIUM BIOTECH SA-RUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.U-CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL | ARGENTINA | PARENTERAL ORDINARY VIALS | 1.0X1.0X4.0 ML VIAL | 21/11/2019 |
| 3520 | NDA/MAL/HDP /7472 | AMRING FARMA S.R.L | ERIS LTD | BEVACIZUMAB AMRING | BEVACIZUMAB | 400 MG/16 ML | SINERGIUM BIOTECH SA-RUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.U-CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL | ARGENTINA | PARENTERAL ORDINARY VIALS | 1.0X1.0X16.0 ML VIAL | 21/11/2019 |
| 3521 | NDA/MAL/HDP /7473 | INVENTIA HEALTHCARE PVT LTD | EUROPA HEALTHCARE (U) LTD | AFLODOR 16 | ACECLOFENAC + THIOCOLCHICOSIDE | 200MG + 16MG | INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X6.0X5.0 CAPSULE BLISTER | 21/11/2019 |

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| 3522 | NDA/MAL/HDP/7474 | INVENTIA HEALTHCARE PVT LTD | EUROPA HEALTHCARE (U) LTD | AFLODOR 8 | ACECLOFENAC + THIOCOLCHICOSIDE | 200 MG + 8 MG | INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X6.0X5.0 CAPSULE BLISTER | 21/11/2019 |
| 3523 | NDA/MAL/HDP/7475 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | UMOCLOX 500 | AMPICILLIN TRIHYDRATE+CLOXACILLIN SODIUM | 250MG+250MG | UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2015 |
| 3524 | NDA/MAL/HDP/7477 | CHEPLAPHARM ARZNEIMITTEL GMBH | LABOREX UGANDA LIMITED | ROHYPNOL | FLUNITRAZEPAM | 1 MG | CENEXI S.A.S-52, RUE MARCEL ET JACQUES GAUCHER 94120 FONTENAY-SOUS-BOIS- FRANCE | FRANCE | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |

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| 3525 | NDA/MAL/HDP/7480 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | AMOKLAVIN BID | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 200MG + 28.5MG/5ML | DEVA HOLDING A.S-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG | TURKEY | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X70.0 ML BOTTLE | 21/11/2019 |
| 3526 | NDA/MAL/HDP/7483 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | APISOPT PLUS | DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE | 2%W/V + 0.5%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | OPHTHALMIC LIQUIDS | 1.0X5.0 ML VIAL | 21/11/2019 |
| 3527 | NDA/MAL/HDP/7487 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | BETASALIC | BETAMETHASONE DIPROPIONATE + SALICYLIC ACID | 0.05%W/W + 3%W/W | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X15.0 G TUBE | 21/11/2019 |

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| 3528 | NDA/MAL/HDP/7488 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | FINTAS 5 | FINASTERIDE | 5MG | INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3529 | NDA/MAL/HDP/7489 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | DOLUTEGRAVIR + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50MG + 300MG + 300MG | MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 MACLEODS PHARMACEUTICALS LTD ,.- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X100.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE | 21/11/2019 |
| 3530 | NDA/MAL/HDP/7491 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | CIPRO-DENK 750 | CIPROFLOXACIN HYDROCHLORIDE | 750MG | ALLPHAMED PHARBIL ARZNEIMITTEL GMBH. - HILDEBRANDSTRABE 12 37081 GOTTINGEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3531 | NDA/MAL/HDP/7492 | LINCOLN PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | CYPRODINE | CYPROHEPTADINE HYDROCHLORIDE | 2MG/5ML | LINCOLN PHARMACEUTICAL LIMITED..-LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 27/08/2019 |
| 3532 | NDA/MAL/HDP/7499 | AUROBINDOM PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | CELDOL 200 | CELECOXIB | 200 MG | AUROBINDO PHARMA LTD-UNIT VII ,/-SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |
| 3533 | NDA/MAL/HDP/7510 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | IMAVIR EYE OINTMENT | ACYCLOVIR | 3% | AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN, JORDAN<br><br>MMAN, JORDAN | JORDAN | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 28/05/2019 |

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| 3534 | NDA/MAL/HDP /7514 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | ILFLOX 500 | LEVOFLOXACIN HEMIHYDRATE | 500 MG | ILKO ILAC SANAYI VE TICARET A.S-3.ORGANIZE SANAYI BOLGESI, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 21/11/2019 |
| 3535 | NDA/MAL/HDP /7515 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | HEPBEST | PREGABALIN + NORTRIPTYLINE (AS HYDROCHLORIDE) | 75MG + 10MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 21/11/2019 |
| 3536 | NDA/MAL/HDP /7516 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | ILFLOX 750 | LEVOFLOXACIN HEMIHYDRATE | 750 MG | ILKO ILAC SANAYI VE TICARET A.S-3.ORGANIZE SANAYI BOLGESI, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 21/11/2019 |

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| 3537 | NDA/MAL/HDP/7519 | MACLEODS PHARMACEUTICALS LTDS LTD | VITACARE LIMITED | LEVOFLOXACIN | LEVOFLOXACIN HEMIHYDRATE | 250 MG | MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 27/11/2019 |
| 3538 | NDA/MAL/HDP/7520 | DAWA LIMITED | SUPER MEDIC LTD | LEVOXCIN | LEVOFLOXACIN HEMIHYDRATE | 750 MG | DAWA LIMITED -16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3539 | NDA/MAL/HDP/7522 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DOLUTEGRAVIR | DOLUTEGRAVIR | 50MG | CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X90.0 TABLET CONTAINER | 27/03/2019 |

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| 3540 | NDA/MAL/HDP /7523 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | LEVOFLOX-DENK 5 MG/ML | LEVOFLOXACIN HEMIHYDRATE | 5MG/ML | SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH--INDUSTRIESTR. 3 34212 MELSUNGEN GERMANY | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML VIAL | 01/07/2017 |
| 3541 | NDA/MAL/HDP /7524 | AMMAN PHARMACEUTICALS LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LOPROSTAN | LATANOPROST + TIMOLOL MALEATE | 0.005% W/V + 0.5%W/V | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | OPHTHALMIC LIQUIDS | 1.0X2.5 ML VIAL | 21/11/2019 |
| 3542 | NDA/MAL/HDP /7525 | DAWA LIMITED | SUPER MEDIC LTD | LORVIC | LORATADINE | 10 MG | DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3543 | NDA/MAL/HDP /7526 | I-CARE PHARMA LTD | AIVEEN (U) LIMITED | MANIGRA 100 | SILDENAFIL CITRATE | 100 MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 21/11/2019 |
| 3544 | NDA/MAL/HDP /7527 | I-CARE PHARMA LTD | AIVEEN (U) LIMITED | MANIGRA 50 | SILDENAFIL CITRATE | 50 MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 21/11/2019 |
| 3545 | NDA/MAL/HDP /7528 | I-CARE PHARMA LTD | AIVEEN (U) LIMITED | MANIGRA PLUS | SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE | 100MG + 60MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 21/11/2019 |

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| 3546 | NDA/MAL/HDP/7529 | FDC LTD | AIVEEN (U) LIMITED | MOSI EYE DROPS | MOXIFLOXACIN HYDROCHLORIDE | 5 MG/ML | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X5.0 ML VIAL | 21/11/2019 |
| 3547 | NDA/MAL/HDP/7530 | HETERO LABS LTD | AIVEEN (U) LIMITED | DOLUTEGRAVIR TABLETS 50MG | DOLUTEGRAVIR | 50MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO LABS LTD UNIT III-22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH , | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 07/11/2018 |
| 3548 | NDA/MAL/HDP/7535 | ACME FORMULATION PVT. LTD. | MARIE STOPES UGANDA LIMITED | MARIPRIST | MIFEPRISTONE + MISOPROSTOL | 200MG + 200MCG | ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X1.0X4.0 TABLET BLISTER | 27/08/2019 |

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| 3549 | NDA/MAL/HDP/7536 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | SPINESIA-D | BUPIVACAINE HYDROCHLORIDE + DEXTROSE | 5MG + 80MG /ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116, DIST: BHARUCH, INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X10.0X4.0 ML AMPOULE,1.0X10.0X4.0 ML AMPOULE,1.0X1.0X5.0X5.0X4.0 ML AMPOULE,1.0X5.0X4.0 ML AMPOULE | 01/07/2017 |
| 3550 | NDA/MAL/HDP/7571 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | NEUROVIT FILM-COATED TABLET | THIAMINE MONONITRATE + PYRIDOXINE HCL + CYANOCOBALAMINE | 97MG + 50MG + 100MG | HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 3551 | NDA/MAL/HDP/7586 | OCHOA LABORATORIES | SUPER MEDIC LTD | CLEAR-T GEL | CLINDAMYCIN PHOSPHATE + TRETINOIN | 1.0%W/W + 0.025%W/W | AUROCHEM LABORATORIES LTD -PLOT 08 PALGHAR 401404 MAHARASHTRA, INDIA | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE | 29/11/2017 |

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| 3552 | NDA/MAL/HDP /7587 | DAWA LIMITED | SUPER MEDIC LTD | NERVILIN 75 | PREGABALIN | 75 MG | DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |
| 3553 | NDA/MAL/HDP /7588 | OCHOA LABORATORIES LIMITED - | SUPER MEDIC LTD | EXEVATE-MF OINTMENT | BETAMETHASONE DIPROPIONATE + SALICYLIC ACID + UREA + LACTIC ACID + SODIUM LACTATE SOLUTION | 0.05 % W/W + 3.0 % W/W + 10.0 % W/W + 3.0 % W/W + 2.0 % W/W | AUROCHEM LABORATORIES (I) PVT LTD-8, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401404 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X20.0 G TUBE | 29/11/2017 |
| 3554 | NDA/MAL/HDP /7589 | OCHOA LABORATORIES | SUPER MEDIC LTD | LACX SYRUP | LACTULOSE | 10G/15ML | AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE | 29/11/2017 |

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| 3555 | NDA/MAL/HDP /7595 | AMMAN PHARMACEUTICALS LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LOPROST | LATANOPROST | 0.005% W/V | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | OPHTHALMIC VIALS | 1.0X2.5 ML VIAL | 21/11/2019 |
| 3556 | NDA/MAL/HDP /7598 | STEDMAN PHARMACEUTICALS PVT. LTD | VEERAM HEALTHCARE (U) LIMITED | RABEFLUX-DSR | RABEPRAZOLE SODIUM + DOMPERIDONE | 20MG + 30MG | STEDMAN PHARMACEUTICALS PVT. LTD.-C-4, SIDCO PHARMACEUTICALS COMPLEX, ALATHUR, THIRUPORUR- 603 110, TAMIL NADU INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |
| 3557 | NDA/MAL/HDP /7599 | AMRING FARMA S.R.L | ERIS LTD | RITUXIMAB AMRING | RITUXIMAB AMRING | 100 MG/10 ML | SINERGIUM BIOTECH SA-RUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.U-CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL | ARGENTINA | PARENTERAL ORDINARY VIALS | 1.0X2.0X10.0 ML VIAL | 21/11/2019 |

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| 3558 | NDA/MAL/HDP /7601 | AMRING FARMA S.R.L | ERIS LTD | RITUXIMAB AMRING | RITUXIMAB | 500 MG/50 ML | SINERGIUM BIOTECH SA-RUTA 9 KM 38.7, B1619IEA, GARIN, BUENOS AIRES - ARGENTINA MABXIENCE S.A.U-CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL | ARGENTINA | PARENTERAL ORDINARY VIALS | 1.0X1.0X50.0 ML VIAL | 21/11/2019 |
| 3559 | NDA/MAL/HDP /7607 | FDC LTD | AIVEEN (U) LIMITED | TEARMAX EYE DROPS | CARMELLOSE SODIUM | 5MG/ML | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X10.0 ML VIAL | 21/11/2019 |
| 3560 | NDA/MAL/HDP /7610 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | TERBIDERM FORTE | TERBINAFINE HYDROCHLORIDE | 250 MG | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |

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| 3561 | NDA/MAL/HDP/7614 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | TOPCLIN | CLINDAMYCIN PHOSPHATE | 1 %W/W | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL EMULSION GELS | 1.0X25.0 G TUBE | 21/11/2019 |
| 3562 | NDA/MAL/HDP/7615 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVCLAV-625 | AMOXICILLIN + CLAVULANIC ACID | 500MG + 125MG | MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP) AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER | 21/11/2019 |
| 3563 | NDA/MAL/HDP/7617 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EFAVIRENZ, LAMIVUDINE & TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 MG/300 MG /300 MG | EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 600 MG + 300 MG + 300 MG | CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED--PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 28/03/2018 |

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| 3564 | NDA/MAL/HDP /7618 | INCEPTA PHARMACUTICALS LIMITED | PHARMA VILLE LIMITED | XIMEPROX 200 | CEFPODOXIME PROXETIL | 200MG | INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA | BANGLADESH | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X4.0 TABLET BLISTER | 26/11/2019 |
| 3565 | NDA/MAL/HDP /7622 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | MONTELAIR 5 | MONTELUKAST SODIUM | 5MG | HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2018 |
| 3566 | NDA/MAL/HDP /7631 | ADWIA | WIDE SPECTRUM ENTERPRISES (U) LIMITED | AMADOL 100MG SR TABLET | TRAMADOL HYDROCHLORIDE | 100MG | ADWIA CO. S.A.E-10TH OF RAMADAN CITY, INDUSTRIAL AREA A2, EGYPT | EGYPT | ORAL SOLID RETARD TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 25/07/2018 |

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| 3567 | NDA/MAL/HDP /7632 | SANDOZ GMBH, KUNDL | SURGIPHARM (U) LIMITED | BISOPROLOL 2.5 MG FILM-COATED TABLETS | BISOPROLOL FUMARATE | 2.5MG | LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X15.0 TABLET BLISTER | 01/07/2017 |
| 3568 | NDA/MAL/HDP /7634 | SANDOZ GMBH, KUNDL | SURGIPHARM (U) LIMITED | BISOPROLOL | BISOPROLOL | 5 MG | LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X25.0 TABLET BLISTER | 01/07/2017 |
| 3569 | NDA/MAL/HDP /7635 | SANDOZ GMBH, KUNDL | SURGIPHARM (U) LIMITED | BISOPROLOL 10MG FILM-COATED TABLETS | BISOPROLOL FUMARATE | 10MG | LEK S.A-95 - 010 STRYKÓW, PODLIPIE 16, POLAND | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X25.0 TABLET BLISTER | 01/07/2017 |

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| 3570 | NDA/MAL/HDP /7652 | MSD (PTY) LTD | SURGIPHARM (U) LIMITED | JANUVIA 100 | SITAGLIPTIN | 100MG | MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685 | SOUTH AFRICA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3571 | NDA/MAL/HDP /7653 | MSD (PTY) LTD | SURGIPHARM (U) LIMITED | JANUVIA 50 | SITAGLIPTIN | 50MG | MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685 | SOUTH AFRICA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3572 | NDA/MAL/HDP /7656 | A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | SPASMOMEN | OTILONIUM BROMIDE | 40MG | A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA CAMPO DI PILE, L'AQUILA (AQ), ITALY | ITALY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X15.0 TABLET BLISTER | 01/07/2017 |

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| 3573 | NDA/MAL/HDP/7663 | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ZENTAIR | ENTECAVIR MONOHYDRATE | 1.0MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3574 | NDA/MAL/HDP/7673 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | VALSARTAN | VALSARTAN | 80MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3575 | NDA/MAL/HDP/7674 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABLEVOX | LEVOFLOXACIN HEMIHYDRATE | 5G/L | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2017 |

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| 3576 | NDA/MAL/HDP/7675 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | VALSARTAN | VALSARTAN | 160MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN | SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3577 | NDA/MAL/HDP/7681 | ZEE PHARMACEUTICALS LTD | ZEE PHARMACEUTICALS LIMITED | ZEECEL 200 | CELECOXIB | 200MG | THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 3578 | NDA/MAL/HDP/7683 | GLOBAL NAPI PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DELAREX | DESLORATADINE | 5MG | GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA, | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3579 | NDA/MAL/HDP/7686 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OPTIGENT EYE/EAR DROPS | GENTAMICIN SULPHATE | 0.3W/V | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 01/07/2017 |
| 3580 | NDA/MAL/HDP/7688 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOPHAGE 850MG TABLET | METFORMIN HYDROCHLORIDE | 850MG | NKUNZI PHARMACEUTICALS-259 DAVIDSON ROAD, WADEVILLEGERMISTON, 1428 SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X300.0 TABLET CONTAINER,1.0X60.0 TABLET CONTAINER,1.0X4.0X15.0 TABLET BLISTER | 01/07/2017 |
| 3581 | NDA/MAL/HDP/7689 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | CUFO LOZENGES(LEMON) | 2, 4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL | 1.2MG + 0.6MG | UNIQUE PHARMACEUTICALS LABORATORIES-SURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA | INDIA | ORAL SOLID ORDINARY LOZENGES | 1.0X2.0X12.0 LOZENGE BLISTER | 01/07/2017 |

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| 3582 | NDA/MAL/HDP/7695 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | CORTUM 500 | CEFUROXIME AXETIL | 500MG | MALIK LIFESCIENCES PRIVATE LIMITED-PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3583 | NDA/MAL/HDP/7706 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACEF 200 | CEFPODOXIME PROXETIL | 200MG | ALKEM LABORATORIES LIMITED -VILLAGE- THANA BADDI, YEH NALAGAR, DISTRICT SOLAN, HIMACHAL PRADESH<br><br>INDIA<br>INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X6.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3584 | NDA/MAL/HDP/7708 | LEBEN LABORATORIES PVT.LTD | MALIX PHARMA (U) LIMITED | LAMPYKLOX CAPSULES | AMPICILLIN TRIHYDRATE+CLOXACILLIN SODIUM | 250MG+250MG | LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS). | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2017 |

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| 3585 | NDA/MAL/HDP/7711 | HOVID BHD | UNITED HEALTHCARE DISTRIBUTORS LTD | DIABETMIN 850 MG | METFORMIN HYDROCHLORIDE | 850MG | HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA | MALAYSIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3586 | NDA/MAL/HDP/7714 | NEOMI PHARMACEUTICALS PVT LTD | ROYAL PHARMA 2011 LIMITED | ROXONE 1GM | CEFTRIAXONE SODIUM | 1 G | ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 07/11/2018 |
| 3587 | NDA/MAL/HDP/7716 | CORE ACCESS LIMITED | CORE ACCESS LTD | ALRINAST 2.5 MG / 5 ML SYRUP | DESLORATIDINE | 2.5 MG / 5 ML | NOBEL İLAÇ SAN. VE TIC. A.Ş-SANCAKLAR, DÜZCE, 81100 | TURKEY | ORAL LIQUID ORDINARY SYRUPS | 1.0X150.0 ML BOTTLE | 29/11/2017 |

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| 3588 | NDA/MAL/HDP /7726 | NTICALS LTD. | VITACARE LIMITED | LOPINAVIR + RITONAVIR | LOPINAVIR + RITONAVIR | 100MG + 25MG | MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2017 |
| 3589 | NDA/MAL/HDP /7727 | AMANTA HEALTHCARE LTD | PHARMA VILLE LIMITED | RINGER LACTATE | COMPOUND SODIUM LACTATE | MULTI-INGREDIENT | AMANTA HEALTHCARE LIMITED (FORMERLY KNOWN AS MARCK BIOSCIENCES LTD)-PLOT NO. 876, N.H. NO. 8, VILLAGE - HARIYALA, DIST - KHEDA 387411, GUJARAT | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X500.0 ML BOTTLE | 01/07/2017 |
| 3590 | NDA/MAL/HDP /7735 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | IBUMOL 400 | PARACETAMOL + IBUPROFEN | 325MG + 400MG | AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3591 | NDA/MAL/HDP /7745 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | TAZOGARD | PIPERACILLIN +TAZOBACTAM | 4G + 0.5G | AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X4.5 G VIAL ,2X10ML LDPE AMPOULES OF WFI | 01/07/2017 |
| 3592 | NDA/MAL/HDP /7747 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | THERMODOL | PARACETAMOL | 1.0%W/V | AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3593 | NDA/MAL/HDP /7751 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | UNODEX COUGH SYRUP | BROMHEXINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + AMMONIUM CHLORIDE | 8MG + 10MG + 100MG | AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3594 | NDA/MAL/HDP/7760 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | OZACE MD 10 | OLANZAPINE | 10MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND PSYCHOTROPICS INDIA LTD PLOT--NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3595 | NDA/MAL/HDP/7784 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | LORATOL | LORATADINE | 5MG/5ML | NOBEL ILAC DUZCE-SANAYIINVE TICARET A.S SANCAKLAR 81100 DUZCE | TURKEY | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2017 |
| 3596 | NDA/MAL/HDP/7903 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MELMET-1000SR | METFORMIN HYDROCHLORIDE | 1000MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID RETARD COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2009 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3597 | NDA/MAL/HDP /7905 | NABIQASIM INDUSTRIES (PVT) LTD. | JEET PHARMACEUTICALS LIMITED | ACEFYL | ACEFYLINE PIPERAZINE + DIPHENHYDRAMINE HYDROCHLORIDE | 45MG +8MG | NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 01/07/2016 |
| 3598 | NDA/MAL/HDP /7907 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | HUCOG 5000 HP | CHORIONIC GONADOTROPHIN | 5000 I.U/ VIAL | BHARAT SERUMS & VACCINES LIMITED -PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (E) MAHARASHTRA STATE 421501 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X5000.0 I.U VIAL + 1*1ML 0.9%W/V NACL AMBER GLASS AMPOULE | 01/07/2017 |
| 3599 | NDA/MAL/HDP /7909 | SANOFI-AVENTIS KENYA | SURGIPHARM (U) LIMITED | LANTUS | INSULIN GLARGINE | 100 UNITS/ML | SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY | GERMANY | PARENTERAL ORDINARY S C VIALS | 1.0X10.0 ML VIAL | 01/07/2017 |

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| 3600 | NDA/MAL/HDP/7910 | SANOFI-AVENTIS KENYA | SURGIPHARM (U) LIMITED | LANTUS | INSULIN GLARGINE | 100 UNITS/ML | SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY | GERMANY | PARENTERAL ORDINARY CARTRIDGES | 1.0X5.0X3.0 ML CARTRIDGE | 01/07/2017 |
| 3601 | NDA/MAL/HDP/7911 | SANOFI-AVENTIS KENYA | SURGIPHARM (U) LIMITED | LANTUS SOLOSTAR | INSULIN GLARGINE | 100 UNITS/ML | SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY | GERMANY | PARENTERAL ORDINARY PRE-FILLED PENS | 1.0X5.0X3.0 ML PREFILLED PEN | 01/07/2017 |
| 3602 | NDA/MAL/HDP/8015 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | D-FEN | DICLOFENAC SODIUM | 25MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X3.0 ML AMPOULE,1.0X10.0X1.0X10.0X3.0 ML AMPOULE | 01/07/2011 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3603 | NDA/MAL/HDP/8023 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | AMOXICLAV-DENK 500/62.5 | AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE | 500 MG + 62.5 MG | PENCEF PHARMA GMBH-BRITENBACHSTR ASSE 13 D-13509 BERLIN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X8.0 TABLET BLISTER | 01/07/2011 |
| 3604 | NDA/MAL/HDP/8043 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | RABEZOL | RABEPRAZOLE SODIUM | 20MG | BİLİM PHARMACEUTICALS-GOSB 41480 GEBZE-KOCAELİ/TURKE | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3605 | NDA/MAL/HDP/8061 | PFIZER LABORATORIES (PTY) LTD | LABOREX UGANDA LIMITED | LYRICA 25MG | PREGABALIN | 25 MG | PFIZER GMBH ARZEIMITELWORK - MOOSWADALLE 179090, FREIBERG GERMANY | GERMANY | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X14.0 CAPSULE BLISTER | 01/07/2007 |

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| 3606 | NDA/MAL/HDP/8073 | NOVARTIS PHARMA AG | SURGIPHARM (U) LIMITED | TRILEPTAL | OXCARBAZEPINE | 300MG | NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY | ITALY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X50.0 TABLET CONTAINER | 01/07/1997 |
| 3607 | NDA/MAL/HDP/8085 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | CIPROL-500 | CIPROFLOXACIN | 500MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA | UGANDA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 3608 | NDA/MAL/HDP/8089 | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD | KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED | KAM-AMOXY | AMOXYCILLIN | 250MG | KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER | 01/07/1997 |

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| 3609 | NDA/MAL/HDP/8091 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | RENEGEL SUSPENSION | ALUMINIUM HYDROXIDE+MAGNESIUM TRISILICATE | 120MG+250MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X100.0 ML BOTTLE | 01/07/2001 |
| 3610 | NDA/MAL/HDP/8092 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | KEMOXYL 250MG | AMOXYCILLIN | 250MG | LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA. | KENYA | ORAL SOLID ORDINARY CAPSULES | 1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER | 01/07/1997 |
| 3611 | NDA/MAL/HDP/8095 | DENK PHARMA GMB H &CO. KG | BENLE CONSULT LIMITED | COLOSAR-DENK 100/12.5 | LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE | 100MG + 12.5MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2016 |

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| 3612 | NDA/MAL/HDP/8096 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | BENZALIN | BENZATHINE BENZYLPENICILLIN SODIUM | 2.4MEGA/ VIAL | REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0 VIAL CARTON,1.0X100.0 X2.4 VIAL CARTON,1.0X10.0X 2.4 VIAL CARTON | 01/07/2011 |
| 3613 | NDA/MAL/HDP/8097 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | REPOITIN 5000 | ERYTHROPOIETIN | 5000IU/ 0.5ML | SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X6.0X0.5 ML PRE- FILLED SYRINGE | 01/07/2016 |
| 3614 | NDA/MAL/HDP/8103 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | WELQUINE 500 | LEVOFLOXACIN | 500MG | AKUMS DRUGS & PHARMACEUTICALS LTD.-PLANT III, PLOT NO. 19, 20, 21, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 3615 | NDA/MAL/HDP/8104 | ABACUS PHARMA (AFRICA) LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TELPRESS 40 | TELMISARTAN | 40MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3616 | NDA/MAL/HDP/8105 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | XERIN | LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM | 5MG + 10MG | AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3617 | NDA/MAL/HDP/8107 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | WELRAB 20 | RABEPRAZOLE SODIUM | 20MG | AKUMS DRUGS & PHARMACEUTICALS LTD --19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY ENTERIC-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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| 3618 | NDA/MAL/HDP /8109 | ABACUS PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | IRON FOLATE | FERROUS SULPHATE + FOLIC ACI | 200MG + 0.4MG | MEDICAMEN BIOTECH LTD-SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET JAR | 01/07/2017 |
| 3619 | NDA/MAL/HDP /8112 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MOXICLAV | AMOXICILLIN + CLAVULANIC ACID | 156.25MG/5ML | MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL | CYPRUS | ORAL SOLID ORDINARY POWDERS | 1.0X100.0 ML BOTTLE | 01/07/2016 |
| 3620 | NDA/MAL/HDP /8113 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | MOXICLAV FORTE | AMOXICILLIN + CLAVULANIC ACID | 312.5MG/5ML | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY POWDERS | 1.0X100.0 ML BOTTLE | 01/07/2016 |

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| 3621 | NDA/MAL/HDP/8114 | MEDOCHEMIE LTD | LABOREX UGANDA LIMITED | RUPAN | IBUPROFEN | 400MG | MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2016 |
| 3622 | NDA/MAL/HDP/8116 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE | EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE | 200MG + 300MG | MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2013 |
| 3623 | NDA/MAL/HDP/8118 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LOPINAVIR + RITONAVIR | LOPINAVIR + RITONAVIR | 200MG + 50MG | MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X120.0 TABLET BOTTLE | 01/07/2013 |

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| 3624 | NDA/MAL/HDP/8119 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | HALOPERIDOL DECANOATE | HALOPERIDOL DECANOATE | 50MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X1.0 ML AMPOULE,1.0X10.0X1.0 ML AMPOULE | 01/07/2017 |
| 3625 | NDA/MAL/HDP/8121 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | SWISSQUINE | QUININE | 300MG/ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 01/07/2011 |
| 3626 | NDA/MAL/HDP/8127 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | LIDOCAINE HYDROCHLORIDE | LIDOCAINE HYDROCHLORIDE | 2% W/V | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X30.0 ML VIAL | 01/07/2016 |

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| 3627 | NDA/MAL/HDP /8130 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | DEGRA 100 | SILDENAFIL CITRATE | 100MG | DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 30/05/2018 |
| 3628 | NDA/MAL/HDP /8131 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | DEGRA | SILDENAFIL CITRATE | 50MG | DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY | TURKEY | ORAL SOLID ORDINARY TABLETS | 1.0X4.0 TABLET BLISTER | 01/07/2017 |
| 3629 | NDA/MAL/HDP /8133 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | MYHEP | SOFOSBUVIR | 400MG | MYLAN LABORATORIES LIMITEDD ,-F-4 & F-12,MIDC, MALEGAON,SIRRRRAR, NASHIK -422113 MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X28.0 TABLET BOTTLE | 01/07/2017 |

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| 3630 | NDA/MAL/HDP /8135 | BAL PHARMA LIMITED - | PLANET PHARMACEUTICALS UGANDA LTD | REGAMOL | PARACETAMOL | 500MG | BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3631 | NDA/MAL/HDP /8142 | BAYER EAST AFRICA LTD | SURGIPHARM (U) LIMITED | XARELTO | RIVAROXABAN | 2.5MG | BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3632 | NDA/MAL/HDP /8143 | NAARI LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | LYDIA POSTPIL | LEVONORGESTREL | 1.5MG | NAARI PHARMA PRIVATE LIMITED-PLOT NO. 14-16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0 TABLET BLISTER | 01/07/2013 |

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| 3633 | NDA/MAL/HDP /8144 | NAARI LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | MA KARE | MIFEPRISTONE + MISOPROSTOL | 200MG+ 200MCG | NAARI PHARMA PRIVATE LIMITED-PLOT NO. 14-16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0 TABLET BLISTER | 01/07/2017 |
| 3634 | NDA/MAL/HDP /8145 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DENK- AIR 10 | MONTELUKAST SODIUM | 10MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3635 | NDA/MAL/HDP /8146 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DENK- AIR JUNIOR 4 | MONTELUKAST SODIUM | 4MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |

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| 3636 | NDA/MAL/HDP/8147 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | DENK- AIR JUNIOR 5 | MONTELUKAST SODIUM | 5 MG | DENK PHARMA GMBH & COMPANY KG - GOLLSTR. 1, 84529 TITTMONING - GERMANY | GERMANY | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3637 | NDA/MAL/HDP/8148 | SPARSH BIO-TECH PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | FLUCLOXACILLIN | FLUCLOXACILLIN | 500MG | SPARSH BIO-TECH PVT. LTD.--PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 01/07/2017 |
| 3638 | NDA/MAL/HDP/8150 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | JAKAVI | RUXOLITINIB | 20MG | NOVARTIS PHARMA STEIN AG-CH. 4002 STEIN, SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X14.0 TABLET BLISTER | 01/07/2017 |

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| 3639 | NDA/MAL/HDP/8151 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGO-C | VITAMIN C | 100MG | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP | 01/07/2005 |
| 3640 | NDA/MAL/HDP/8152 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | JAKAVI | RUXOLITINIB | 15MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3641 | NDA/MAL/HDP/8154 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | AGOGCORT | HYDROCORTISONE ACETATE | 1%W/W | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2013 |

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| 3642 | NDA/MAL/HDP/8155 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | JAKAVI | RUXOLITINIB | 5MG | NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND | SWITZERLAND | ORAL SOLID ORDINARY TABLETS | 1.0X4.0X14.0 TABLET BLISTER | 01/07/2017 |
| 3643 | NDA/MAL/HDP/8156 | TATA UGANDA LIMITED | GITTOES PHARMACEUTICALS LIMITED | DIPHTHERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE | DIPHTHERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE | 25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+11MCG | BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078 | INDIA | PARENTERAL ORDINARY I M VIALS | 1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0X5.0 ML VIAL (10 DOSE VIAL) | 01/07/2014 |
| 3644 | NDA/MAL/HDP/8157 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | D LYTE- PLAIN | ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE + POTASSIUM CHLORIDE | 13.50G + 2.60G + 2.90G +1.50G/ 1L | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X20.5 G SACHET | 01/07/2016 |

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| 3645 | NDA/MAL/HDP/8159 | AUROBINDO PHARMA LIMITED | GITTOES PHARMACEUTICALS LIMITED | LOPINAVIR + RITONAVIR | LOPINAVIR + RITONAVIR | 100MG + 25MG | AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X60.0 TABLET BOTTLE | 01/07/2017 |
| 3646 | NDA/MAL/HDP/8160 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ULGICID (CHERRY FLAVOUR) | ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE | 200MG+250MG+250MG+250MG+125MG/15ML | STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 01/07/2017 |
| 3647 | NDA/MAL/HDP/8162 | BHARAT SERUMS AND VACCINES LTD | ABACUS PHARMA (AFRICA) LIMITED | HUMOG 75 HP | HIGHLY PURIFIED MENOTROPHIN [ CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU] /150 I.U | 75 IU + 75 IU/ 150 I.U VIAL | BHARAT SERUMS AND VACCINES LTD- PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E ) 412 501 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1*1 ML AMPOULE OF 0.9%W/V NACL | 01/07/2017 |

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| 3648 | NDA/MAL/HDP/8163 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | BETADINE SURGICAL SCRUB | POVIDONE-IODINE | 7.5%W/W | G,S PHARMBUTOR PVT LTD - B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN | INDIA | TOPICAL EXTERNAL LIQUIDS | 1.0X1.0X50.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 26/09/2018 |
| 3649 | NDA/MAL/HDP/8165 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | CUFO BLACK CURRANT | 2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL | 1.2MG + 0.6MG | UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)- SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210 | INDIA | ORAL SOLID ORDINARY LOZENGES | 1.0X2.0X12.0 LOZENGE BLISTER | 01/07/2017 |
| 3650 | NDA/MAL/HDP/8166 | UNIQUE PHARMACEUTICALS LABORATORIES | PLANET PHARMACEUTICALS UGANDA LTD | CUFO ORANGE | 2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESO | 1.2MG + 0.6MG | UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)- SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210 | INDIA | ORAL SOLID ORDINARY LOZENGES | 1.0X2.0X12.0 LOZENGE BLISTER | 01/07/2017 |

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| 3651 | NDA/MAL/HDP/8167 | MODI MUNDI PHARMA PVT LTD | SURGIPHARM (U) LIMITED | BETADINE STANDARDISED MICROBICIDAL SOLUTION 10% W/V | POVIDONE-IODINE | 10%W/W | G,S PHARMBUTOR PVT LTD - B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN | INDIA | TOPICAL EXTERNAL LIQUIDS | 1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE | 01/07/1997 |
| 3652 | NDA/MAL/HDP/8170 | PRISMA PHARMA FZE | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ULGICID (PINEAPPLE FLAVOUR) | ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE | 200MG+250MG+250MG+250MG+125MG/15ML | STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 01/07/2017 |
| 3653 | NDA/MAL/HDP/8177 | MEGA LIFESCIENCES (AUSTRALIA) PTY LTD | ABACUS PHARMA (AFRICA) LIMITED | CILZEC PLUS | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2016 |

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| 3654 | NDA/MAL/HDP/8178 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | NYSTAGO TABLETS | NYSTATIN | 500,000I.U | AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET BOTTLE,1.0X10.0X 10.0 TABLET BLISTER | 01/07/2005 |
| 3655 | NDA/MAL/HDP/8184 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | TETRASIM | TETRACYCLINE HYDROCHLORIDE | 250MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000. 0 CAPSULE CONTAINER,1.0X50 0.0 CAPSULE CONTAINER | 01/07/2008 |
| 3656 | NDA/MAL/HDP/8185 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | INDOSIM | INDOMETHACIN | 25MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000. 0 CAPSULE CONTAINER | 01/07/1997 |

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| 3657 | NDA/MAL/HDP/8193 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ECOX 400 | ETHAMBUTOL | 400MG | MACLEODS PHARMACEUTICALS LTD.- PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. MACLEODS PHARMACEUTICALS LTD- - PLOT 25-27, SURVEY NO. 306, PREMIER INDUSTRIAL | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER | 01/07/2017 |
| 3658 | NDA/MAL/HDP/8194 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | SOLONEX-100 | ISONIAZID | 100MG | OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 MACLEODS PHARMACEUTICALS LTD .- PLOT 1 & 2 MAHIM ROAD NEAR KULDEEP NAGAR, PALGHAR (W) 401 404 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X24.0X28.0 TABLET BLISTER | 01/07/2005 |
| 3659 | NDA/MAL/HDP/8195 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RH-COM | RIFAMPICIN & ISONIAZID | 150MG +75MG | MACLEODS PHARMACEUTICALS LTD- BLOCK N3, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET STRIP,1.0X24.0X28.0 TABLET BLISTER,1.0X3.0X28.0 TABLET BLISTER | 01/07/2005 |

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| 3660 | NDA/MAL/HDP/8197 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | AMIKACIN | AMIKACIN SULPHATE | 500MG/2ML | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA | EGYPT | PARENTERAL ORDINARY VIALS | 1.0X2.0 ML VIAL | 01/07/2017 |
| 3661 | NDA/MAL/HDP/8198 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | XYMEX DROPS | MULTI-INGREDIENT | MULTI-INGREDIENT | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE | 01/07/1999 |
| 3662 | NDA/MAL/HDP/8199 | MEDLEY PHARMACEUTICALS LTD | MEDVIN PHARMA LIMITED | XYMEX SYRUP | MULTIVITAMIN/ DIASTASE/PEPSIN | MULTI-INGREDIENT | MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 01/07/2000 |

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| 3663 | NDA/MAL/HDP/8201 | CIRON DRUGS AND PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | CENTROZINE | CETIRIZINE HYDROCHLORIDE | 5MG/5ML | CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X60.0 ML BOTTLE | 01/07/2017 |
| 3664 | NDA/MAL/HDP/8202 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | ISONIAZID | ISONIAZID | 300MG | MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. OXALIS LABS--VILLAGE THEDA,P.O.LODHIMAJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X28.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X24.0X 28.0 TABLET BLISTER | 01/07/2017 |
| 3665 | NDA/MAL/HDP/8204 | FRESENIUS KABI MANUFACTURING S.A (PTY) LTD | SURGIPHARM (U) LIMITED | DOPAMINE HCL FRESENIUS | DOPAMINE HYDROCHLORIDE | 200MG/5ML | FRESNIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD KORSTEN PORT ELIZABETH 6020 | SOUTH AFRICA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X5.0 ML AMPOULE | 01/07/2017 |

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| 3666 | NDA/MAL/HDP/8206 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRULEXIN | CEFALEXIN MONOHYDRATE | 125MG/5ML | BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2018 |
| 3667 | NDA/MAL/HDP/8207 | NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | ZOMETA | ZOLEDRONIC ACID | 4MG/5ML | NOVARTIS PHARMA STEIN AG ;-SCHAFFHAUSERSTRASSE CH 4332 STEIN-SWITZERLAND | SWITZERLAND | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0 VIAL CARTON | 01/07/2017 |
| 3668 | NDA/MAL/HDP/8210 | CIRON DRUGS & PHARMACEUTICALS PVT LTD | RENE PHARMACY LTD | HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION BP | HYDROCORTISONE | 100MG | CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X50.0X100.0 MG VIAL | 01/07/2007 |

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| 3669 | NDA/MAL/HDP/8211 | SHELYS PHARMACEUTICALS LTD | BETA HEALTHCARE UGANDA LIMITED | MUCO-ASTHALIN SYRUP | SALBUTAMOL + BROMHEXINE | 2MG/5ML + 4MG/5ML | BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA | KENYA | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 01/07/2010 |
| 3670 | NDA/MAL/HDP/8212 | FDC LIMITED - | AIVEEN (U) LIMITED | BACTIGEN EYE/EAR DROPS | GENTAMICIN | 0.3%W/V | FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA. | INDIA | OPHTHALMIC VIALS | 1.0X5.0 ML VIAL,1.0X10.0 ML VIAL | 01/07/1998 |
| 3671 | NDA/MAL/HDP/8213 | FDC LTD | AIVEEN (U) LIMITED | ZOCON 200 | FLUCONAZOLE | 200MG | FDC LTD.-L-56/L-57,PHASE II-D, VERNA INDUSTRIAL ESTATE,VERNA-403722, SALCETE,GOA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X2.0 TABLET BLISTER | 01/07/2001 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3672 | NDA/MAL/HDP/8216 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | SEFOTAX | CEFOTAXIME SODIUM | 1G | SWISS PARENTERALS LTD, UNIT- II-PLOT NO. 402,412-414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 01/07/2017 |
| 3673 | NDA/MAL/HDP/8221 | NATIONAL HEALTHCARE PVT LTD | MALIX PHARMA (U) LIMITED | NEMADOL | TRAMADOL HYDROCHLORIDE | 50MG/ML | NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA | NEPAL | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X2.0 ML AMPOULE | 01/07/2017 |
| 3674 | NDA/MAL/HDP/8224 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OPTIGENT OINTMENT | GENTAMICIN SULFATE | 0.3%W/W | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT | EGYPT | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3675 | NDA/MAL/HDP/8225 | LINCOLN PARENTERAL LIMITED | METRO PHARMACEUTICALS LIMITED | ARTELIN 60 | ARTESUNATE | 60MG | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X60.0 MG VIAL + 1*1 ML AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION B.P + 1*5 ML AMPOULE OF 0.9%W/V NACL | 01/07/2017 |
| 3676 | NDA/MAL/HDP/8226 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | SALRES | SALBUTAMOL SULPHATE | 120.5MCG/SPRAY | DEVA HOLDING A. S.-ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY | TURKEY | LUNG ADMINISTRATION CFC-FREE METERED DOSE INHALER | 1.0X200.0 METERED DOSE CANNISTER | 01/07/2017 |
| 3677 | NDA/MAL/HDP/8227 | HETERO LABS LTD | AIVEEN (U) LIMITED | ALZER 5 | DONEPEZIL HYDROCHLORIDE | 5MG | HETERO LABS LTD. UNIT (V) .-S.N0.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3678 | NDA/MAL/HDP/8228 | AFRICURE PHARMACEUTICALS (INDIA) LTD | ROYAL PHARMA 2011 LIMITED | VITAMIN B-COMPLEX (BEEKO) | VITAMINS B1 + B2 + B6 + NIACINAMIDE | 1MG +1MG +1MG +15MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3679 | NDA/MAL/HDP/8235 | DAWA LIMITED- | SUPER MEDIC LTD | ACEPAR | ACECLOFENAC + SERRATIOPEPTIDASE + PARACETAMOL | 100MG + 15MG + 500MG | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET BLISTER | 01/07/2017 |
| 3680 | NDA/MAL/HDP/8243 | OCHOA LABORATORIES LIMITED - | SUPER MEDIC LTD | TX-MF | TRANEXAMIC ACID + MEFENAMIC ACID | 500MG + 250MG | AUROCHEM PHARMACEUTICALS INDIA PRIVATE LIMITED-58, PALGHAR TALUKA INDUSTRIAL CO - OPERATIVE ESTATE LIMITED PALGHAR, DISTRICT - PALGHAR, 401 404 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3681 | NDA/MAL/HDP/8244 | MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA | KIMSY MEDS LTD | HERTRAZ 440 | TRASTUZUMAB (R-DNA ORIGIN) | 440MG | BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X440.0 MG VIAL ,1X2X10ML VIALS OF WFI | 01/07/2017 |
| 3682 | NDA/MAL/HDP/8247 | SAKAR HEALTH CARE PVT .LTD | ROYAL PHARMA 2011 LIMITED | E-DOL | TRAMADOL HYDROCHLORIDE | 50MG/ML | SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X2.0 ML AMPOULE | 01/07/2017 |
| 3683 | NDA/MAL/HDP/8248 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ACINET DRY SYRUP 457MG/5ML | AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM | 457MG/5ML | INDCHEMIE HEALTH SPECIALITIES PVT. LTD-VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3684 | NDA/MAL/HDP/8250 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LUMARTEM DT | ARTEMETHER+LUMEFANTRINE | 20MG+120MG | CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775 | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X12.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER | 01/07/2017 |
| 3685 | NDA/MAL/HDP/8252 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | PARACETAMOL FRESENIUS | PARACETAMOL | 10MG/ML | FRESENIUS KABI AUSTRIA GMBH-AUSTRIA GMBH HAFNERSTRASSEM 36 8055 GRAZ | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X10.0X50.0 ML VIAL,1.0X10.0X100.0 ML VIAL | 01/07/2017 |
| 3686 | NDA/MAL/HDP/8254 | MICRO LABS LTD | LABOREX UGANDA LIMITED | GRAMOCEF-CV | CEFIXIME TRIHYDRATE + CLAVULANIC ACID | 200MG + 125MG | MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0 TABLET STRIP | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3687 | NDA/MAL/HDP /8264 | CACHET PHARMA PVT LTD | ABACUS PHARMA (AFRICA) LIMITED | EMITINO ORAL SOLUTION | ONDANSETRON | 2MG/5ML | CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X30.0 ML BOTTLE | 01/07/2017 |
| 3688 | NDA/MAL/HDP /8274 | HETERO LABS LTD | AIVEEN (U) LIMITED | BICATERO 50 | BICALUTAMIDE | 50MG | HETERO LABS LTD (UNIT-VI)- "SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2013 |
| 3689 | NDA/MAL/HDP /8275 | HETERO LABS LTD | AIVEEN (U) LIMITED | LETERO | LETROZOLE | 2.5MG | HETERO LABS LTD (UNIT-VI)- "SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 01/07/2013 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3690 | NDA/MAL/HDP /8276 | HETERO LABS LTD | AIVEEN (U) LIMITED | GEMTERO 1G | GEMCITABINE | 1G | HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 G VIAL | 01/07/2013 |
| 3691 | NDA/MAL/HDP /8277 | HETERO LABS LTD | AIVEEN (U) LIMITED | GEMTERO 200MG | GEMCITABINE | 200MG | HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X200.0 MG VIAL | 01/07/2013 |
| 3692 | NDA/MAL/HDP /8299 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | DICLOFENAC TABLETS BP | DICLOFENAC SODIUM | 50MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3693 | NDA/MAL/HDP/8300 | AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | CIPRONE-500 | CIPROFLOXACIN HYDROCHLORIDE | 500MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2007 |
| 3694 | NDA/MAL/HDP/8308 | NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED | ROYAL PHARMA 2011 LIMITED | PREDNISOLONE 5MG | PREDNISOLONE | 5MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 01/07/2008 |
| 3695 | NDA/MAL/HDP/8312 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | TRICORT 40 | TRIAMCINOLONE ACETONIDE | 40MG/ML | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 ML VIAL | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3696 | NDA/MAL/HDP/8316 | AUROBINDOM PHARMA LIMITED | GITTOES PHARMACEUTICALS LIMITED | DOLUTEGRAVIR 50 MG/ LAMIVUDINE 300 MG/ TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50MG + 300MG + 300MG | "AUROBINDO PHARMA LIMITED-UNIT –VII, SEZ, TSIIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P & 458/P,GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT -509 302 TELANGANA STATE, INDIA" AUROBINDO PHARMA LTD, UNIT X-NO. 16, APIIC MULTI | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE | 30/05/2018 |
| 3697 | NDA/MAL/HDP/8319 | KOPRAN LIMITED | TATA UGANDA LIMITED | ERYKO-250 | ERYTHROMYCIN STEARATE TABLETS BP | 250MG | KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER | 29/11/2017 |
| 3698 | NDA/MAL/HDP/8321 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | PROSTAR- 200 CAPSULES | PROGESTERONE | 200 MG | AKUMS DRUGS & PHARMACEUTICALS LTD .- PLOT NO. 47, 48, SECTOR 6A, IIE, SIDCUL HARIDWAR, UTTRAKHAND – 249403, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER | 31/01/2018 |

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| 3699 | NDA/MAL/HDP/8322 | GLENMARK PHARMACEUTICALS LTD | STAR PHARMACEUTICALS LTD | GLEMONT L | MONTELUKAST SODIUM+LEVOCETIRIZINE DIHYDROCHLORIDE | 10 MG + 5 MG | GLENMARK PHARMACEUTICALS LIMITED-UNIT III-VILLAGE KISHANPURA, BADDI-NALAGARH ROAD TEHSIL BADDI, DIST. SOLAN, BADDI 173205 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X7.0 TABLET BOTTLE | 29/11/2017 |
| 3700 | NDA/MAL/HDP/8324 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | LOOBID TABLETS | OFLOXACIN + ORNIDAZOLE | 200MG + 500 MG | CACHET PHARMACEUTICAL PVT LTD. HIMACHAL-THANA, BADDI, HIMACHAL PRADESH-173 205, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3701 | NDA/MAL/HDP/8326 | MEDOPHARM PRIVATE LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | MEDOMOX 250 DT | AMOXICILLIN | 250MG | MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER (EMBOSSED WITH "GOU NOT FOR SALE" & NON-EMBOSSED) | 29/11/2017 |

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| 3702 | NDA/MAL/HDP /8331 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | TORSINEX-20 | TORSEMIDE | 20MG | MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3703 | NDA/MAL/HDP /8332 | DEVA HOLDING A.S | SHREEJI PHARMACEUTICALS LIMITED | AZITRO 500 MG | AZITHROMYCIN | 500MG | DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKIRDAĞ/ TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 29/11/2017 |
| 3704 | NDA/MAL/HDP /8333 | MICRO LABS LTD 92 SIPCOT INDUSTRIAL | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | AVAS-20 | ATORVASTATIN | 20MG | MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3705 | NDA/MAL/HDP/8335 | RIVA PHARMA FREE ZONE | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RIVAMOX | AMOXICILLIN TRIHYDRATE | 500MG | RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT | EGYPT | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X10.0 CAPSULE BLISTER | 31/01/2018 |
| 3706 | NDA/MAL/HDP/8340 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MONTEMAC 5 | MONTELUKAST SODIUM | 5 MG | MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3707 | NDA/MAL/HDP/8341 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | GENVOYA | ELVITEGRAVIR+COBICISTAT+EMTRICISTABINE+TENOFOVIR ALAFENAMIDE | 150MG + 150MG + 200MG + 10MG | PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 | CANADA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3708 | NDA/MAL/HDP/8342 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ANCOLIN 75 | PREGABALIN | 75MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 30/05/2018 |
| 3709 | NDA/MAL/HDP/8343 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | XYKAA EXTEND 1000 | PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE) | 325MG+675MG | TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER | 29/11/2017 |
| 3710 | NDA/MAL/HDP/8344 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CELZA DRY SYRUP | CEFUROXIME AXETIL USP | 125 MG/5 ML | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X50.0 ML BOTTLE | 29/11/2017 |

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| 3711 | NDA/MAL/HDP/8345 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CELZA 500 | CEFUROXIME AXETIL USP | 500 MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3712 | NDA/MAL/HDP/8346 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ADERAN 8 | CANDESARTAN CILEXETIL | 8MG | AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3713 | NDA/MAL/HDP/8347 | YICHANGHUMANWELL PHARMACEUTICAL CO., LTD. | KAIYUANTANG (U) LIMITED | FENTWELL 0.05MG/ML | FENTANYL CITRATE | 0.05MG/ML | YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.-NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X10.0 ML AMPOULE | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3714 | NDA/MAL/HDP/8348 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | IRBECOR PLUS 300MG/12.5MG | IRBESARTAN + HYDROCHLOROTHIAZIDE | 300MG + 12.5MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 29/11/2017 |
| 3715 | NDA/MAL/HDP/8349 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | ASTYMIN-C DROPS | L-LEUCINE USP + L-ISOLEUCINE USP + L-LYSINE HYDROCHLORIDE USP + L-PHENYLALANINE USP + L-THREONINE USP + L-VALINE USP+ L-TRYPTOPHAN USP + DL-METHIONINE USP + ASCORBIC | 0.84M+1.43MG+1.84MG+1.18MG+3.66MG+1.00MG+1.00MG+5.00MG+100MG | TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA | INDIA | ORAL LIQUID ORDINARY DROPS | 1.0X15.0 ML BOTTLE | 29/11/2017 |
| 3716 | NDA/MAL/HDP/8350 | YICHANGHUMAN WELL PHARMACEUTICAL CO., LTD. | KAIYUANTANG (U) LIMITED | FENTWELL 0.05MG/ML | FENTANYL CITRATE | 0.05MG/ML | YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.-NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3717 | NDA/MAL/HDP/8351 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | ASTYMIN SYRUP | L-LEUCINE+L-ISOLEUCINE+L-LYSINE HYDROCHLORIDE+L-PHENYLALNINE+L-THREONINE+L-METHIONINE+L-TRYPTOPHAN+L-VALINE+THIAMINE HYDROCHLORIDE+RIBOFLAVING | 10.3MG + 5.9MG + 25MG + 5MG + 4.2MG + 9.2MG + 5MG + 6.7MG + 5MG + 1.5MG +25MG + 5MG + 2.5MCG + 0.75MG + 200IU AND 7.5IU | TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X200.0 ML BOTTLE | 29/11/2017 |
| 3718 | NDA/MAL/HDP/8352 | MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A. | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KETESSE | DEXKETOPROFEN TROMETAMOL | 50MG/2ML | A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA SETTE SANTI 3, 50131 FIRENZE | ITALY | PARENTERAL ORDINARY AMPOULES | 1.0X1.0 AMPOULE CARTON,1.0X6.0 AMPOULE CARTON,1.0X20.0 AMPOULE CARTON,1.0X5.0 AMPOULE CARTON | 21/11/2019 |
| 3719 | NDA/MAL/HDP/8353 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | FEDATE CAPSULES | CARBONYL IRON + FOLIC ACID + VITAMIN B12 + VITAMIN C + ZINC SULFATE MONOHYDRATE | 100MG+1.5 MG + 15 MCG + 75 MG + 61.8 MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 29/11/2017 |

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| 3720 | NDA/MAL/HDP/8356 | UNOSOURCE PHARMA LTD | MEDVIN PHARMA LIMITED | LORFACT-D | DESLORATIDINE | 5MG, | AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 29/11/2017 |
| 3721 | NDA/MAL/HDP/8357 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | FRESENIUS PROPOVEN 1% | PROPOFOL | 1% W/V | FRESENIUS KABI AUSTRIA GMBH PLANT GRAZ-HAFNERSTRASSE 36 A-8055 GRAZ AUSTRIA FRESENIUS KABI AB PLANT UPPSALA-RAPSGATAN 7S-75174 UPPSALA SWEDEN | AUSTRIA | PARENTERAL ORDINARY OTHER INFUSIONS | 1.0X10.0X20.0 ML VIAL,1.0X10.0X50.0 ML VIAL,1.0X10.0X100.0 ML VIAL | 29/11/2017 |
| 3722 | NDA/MAL/HDP/8358 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | ASTYMIN FORTE | MULTI-INGREDIENT | MULTI-INGREDIENT | TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITOOR DISTRICT-ANDRA PRADESH-517588, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X3.0X10.0 CAPSULE BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3723 | NDA/MAL/HDP /8359 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ASUNATE 120 | ARTESUNATE | 120MG | LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X120.0 MG VIAL + 1*10 ML SODIUM CHLORIDE IN GLASS AMPOULE + 1*2 ML SODIUM BICARBONATE IN GLASS AMPOULE | 29/11/2017 |
| 3724 | NDA/MAL/HDP /8392 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | IRBECOR PLUS 150MG/12.5MG | IRBESARTAN + HYDROCHLOROTHIAZIDE | 150MG + 12.5MG | İLKO İLAÇ SANAYI VE TICARET A. Ş-3. ORGANIZE SANAYI BÖLGESI KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 29/11/2017 |
| 3725 | NDA/MAL/HDP /8394 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS | RIFAMPICIN + ISONIAZID + PYRAZINAMIDE | 75MG + 50MG + 150MG | MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X3.0X28.0 TABLET BLISTER,1.0X24.0X28.0 TABLET BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3726 | NDA/MAL/HDP/8395 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | RIFAMPICIN 75 MG ISONIAZID 50 MG DISPERSABLE TABLETS | RIFAMPICIN + ISONIAZID | 75MG + 50MG | OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X3.0X28.0 TABLET BLISTER | 29/11/2017 |
| 3727 | NDA/MAL/HDP/8396 | MARIE STOPES INTERNATIONAL | MARIE STOPES UGANDA LIMITED | BACK-UP | LEVONORGESTREL | 1.5MG | ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0 TABLET BLISTER | 29/11/2017 |
| 3728 | NDA/MAL/HDP/8407 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | TORTAS 20 | TORSEMIDE | 20MG | INTAS PHARMACEUTICALS LTD -CAMP ROAD, SELAQUI – 248 197 DEHRADUN (UK) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 29/11/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3729 | NDA/MAL/HDP/8411 | LABORATORY & ALLIED LTD | HARLEYS UGANDA LIMITED | RHEUMAC GEL | DICLOFENAC | 1%W/W | LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA | KENYA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X20.0 G TUBE | 29/11/2017 |
| 3730 | NDA/MAL/HDP/8419 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | VB COMPLEX | VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+PANTOTHENOL | 10MG +1MG +1MG +16MG +0.5MG | KIVI PHARM CO. LTD .-NO.5 HANGTIAN STREET, DONGSHAN HIGH TECH INDUSTRIAL DEVELOPMENT ZONE,SHALINGZI TOWN, XUANHUA,ZHANGJIAKOU CITY,HEBEI 075100, CHINA *SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE,1.0X100.0X2.0 ML AMPOULE | 01/07/2018 |
| 3731 | NDA/MAL/HDP/8424 | LINCOLN PARENTERAL LIMITED | METRO PHARMACEUTICALS LIMITED | HAEMRICH | FERRIC AMMONIUM CITRATE+ FOLIC ACID+PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE | 50MG + 0.55MG +2.4MG + 1.2MG +11MG /5ML | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X90.0 ML BOTTLE | 01/07/2017 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3732 | NDA/MAL/HDP /8434 | DAWA LIMITED | SUPER MEDIC LTD | DACINAZOLE | MICONAZOLE NITRATE | 2%W/W | DAWA LTD-BABA DOGO ROAD RUARAKA | KENYA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 01/07/2009 |
| 3733 | NDA/MAL/HDP /8473 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | NYSTATIN VAGINAL INSERTS | NYSTATIN | 100000 I.U | S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT | INDIA | VAGINAL TABLETS | 1.0X10.0X10.0 TABLET STRIP | 31/01/2018 |
| 3734 | NDA/MAL/HDP /8475 | LINCOLN PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | OROCAN | MICONAZOLE | 2%W/W | LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA | INDIA | ORAL TOPICAL GELS AND SOLS | 1.0X15.0 G TUBE | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3735 | NDA/MAL/HDP/8477 | WOCKHARDT LTD | ABACUS PHARMA (AFRICA) LIMITED | GLARITUS 100IU/ML | INSULIN GLARGINE | 100IU/ML | WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA | INDIA | PARENTERAL ORDINARY CARTRIDGES | 1.0X10.0 ML VIAL | 31/01/2018 |
| 3736 | NDA/MAL/HDP/8481 | LINCOLN PARENTERAL LIMITED | METRO PHARMACEUTICALS LIMITED | PARACETAMOL BP INJECTION | PARACETAMOL | 150MG/ML | LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 31/01/2018 |
| 3737 | NDA/MAL/HDP/8483 | SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC | SURGIPHARM (U) LIMITED | GLIMEPIRIDE 2MG | GLIMEPIRIDE | 2MG | LEK S.A--U1, PODLIPIE 16, 95-0140 STRYKOW POLAND | POLAND | ORAL SOLID ORDINARY TABLETS | 1.0X9.0X10.0 TABLET BLISTER | 31/01/2018 |

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| 3738 | NDA/MAL/HDP/8485 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACHMAX-400 | CEFIXIME | 400MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY COATED TABLETS | 1.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3739 | NDA/MAL/HDP/8487 | BAL PHARMA LIMITED - | PLANET PHARMACEUTICALS UGANDA LTD | EMTRIM FORTE | SULFAMETHOXAZOLE + TRIMETHOPRIM | 800MG + 160MG | BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR<br>UDHAM SINGH NAGAR, RUDRAPUR-263153<br>UTTARAKHAND-INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 31/01/2018 |
| 3740 | NDA/MAL/HDP/8488 | ZIM LABORATORIES LTD | REDDYS PHARMA LIMITED | CEFRAZ 200 | CEFIXIME TRIHYDRATE | 200MG | ZIM LABORATORIES LIMITED-B-21122, MIDC AREA, KALMESHWAR -441 501, DIST. NAGPUR,INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3741 | NDA/MAL/HDP /8489 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | MEDOL | TRAMADOL HYDROCHLORIDE | 100 MG / 2 ML | SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0 ML AMPOULE,1.0X5.0 X2.0 ML AMPOULE | 31/01/2018 |
| 3742 | NDA/MAL/HDP /8490 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | SODIUM CHLORIDE | SODIUM CHLORIDE | 0.9% W/V | ALTHEA PHARMA PVT LTD -- PLOT NO. 374 SHED NO. E,.ALPHA INDUSTRIAL PARK , ATHIYAWAD DABHEL ,NANI DAMAN (U.T) 396210, INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 31/01/2018 |
| 3743 | NDA/MAL/HDP /8491 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CETROTIDE 0.25MG | CETRORELIX | 0.25MG | ABBOTT BIOLOGICALS B.V VEERWEG -12,NL-8121 AA OLST THE NETHERLANDS PIERRE FABRE MEDICAMENT - AQUITAINE PHARM INTERNATIONAL SITE 1 | FRANCE | PARENTERAL ORDINARY COMBINATION PACK VIALS | 1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3744 | NDA/MAL/HDP/8493 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | DESCOVY 200MG/25MG | EMTRICITABINE/TENOFOVIR ALAFENAMIDE | 200MG + 25 MG | PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 ROTTENDORF PHARMA GMBH-OSTENFELDER STRAßE 51-61,59320 ENNIGERLOH,GERMANY | CANADA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 31/01/2018 |
| 3745 | NDA/MAL/HDP/8495 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | CACEF 50 | CEFPODOXIME PROXETIL USP | 50MG / 5ML | ALKEM LABORATORIES LTD.-VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X30.0 ML BOTTLE | 31/01/2018 |
| 3746 | NDA/MAL/HDP/8497 | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD | SWASTIK PHARMACEUTICAL LTD | TRYOXIM 500 | CEFUROXIME AXETIL | 500 MG | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD --UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 31/01/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3747 | NDA/MAL/HDP/8498 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR) | OMASI MED LIMITED | TRIAXONE 0.5G | CEFTRIAXONE | 0.5G | GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E | UNITED ARAB EMIRATES | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 5 ML AMPOULE OF WATER FOR INJECTION | 31/01/2018 |
| 3748 | NDA/MAL/HDP/8499 | YELURI FORMULATIONS PVT LTD | QUALITY CHEMICALS LTD | SOLOCEF 1000 MG | CEFTRIAXONE SODIUM | 1000MG | YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA. | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0 ML VIAL | 31/01/2018 |
| 3749 | NDA/MAL/HDP/8504 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | LEDVIR | LEDIPASVIR + SOFOSBUVIR | 90MG + 400MG | MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X28.0 TABLET BOTTLE | 29/11/2017 |

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| 3750 | NDA/MAL/HDP/8522 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | DAYPENAM | MEROPENEM | 500MG | ZEISS PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 72 EPIP-PHASE-1 JHARMAJRI BADDI DISTRICT SOLAN (H.P.) - INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL | 07/01/2017 |
| 3751 | NDA/MAL/HDP/8566 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | AZINOWEL | AZITHROMYCIN | 200MG/5ML | AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT.: HARIDWAR, UTTARAKHAND | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X15.0 ML BOTTLE | 21/11/2019 |
| 3752 | NDA/MAL/HDP/8569 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | TERBINOL® | TERBINAFINE HYDROCHLORIDE | 1%W/W | NOBEL İLAÇ SAN. VE TIC. A.Ş-SANCAKLAR, DÜZCE, 81100 | TURKEY | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 21/11/2019 |

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| 3753 | NDA/MAL/HDP/8637 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | AGYCIN | AZITHROMYCIN DIHYDRATE | 40MG/ML | BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X15.0 ML BOTTLE | 28/03/2018 |
| 3754 | NDA/MAL/HDP/8639 | MSD (PTY) LTD | SURGIPHARM (U) LIMITED | ISENTRESS 100MG | RALTEGRAVIR POTASSIUM | 100MG | MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685<br>SOUTH AFRICA | SOUTH AFRICA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X1.0X60.0 TABLET BOTTLE | 28/03/2018 |
| 3755 | NDA/MAL/HDP/8641 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | TELI H | TELMISARTAN + HYDROCHLOROTHIAZIDE | 40MG + 12.5MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/03/2018 |

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| 3756 | NDA/MAL/HDP /8642 | EGYPHAR | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LORAFAST | DESLORATADINE | 2.5MG/5ML | EGYPHAR FACTORY-OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X100.0 ML BOTTLE | 21/11/2019 |
| 3757 | NDA/MAL/HDP /8643 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | ARTESUNATE 60MG | ARTESUNATE | 60MG | BLISS INDAS LIFESCIENCE P. LTD..-PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3 | 28/03/2018 |
| 3758 | NDA/MAL/HDP /8644 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | LOOBID SUSPENSION | OFLOXACIN + ORNIDAZOLE | 50MG + 125MG / 5ML | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X30.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3759 | NDA/MAL/HDP/8645 | EGYPHAR | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MODAZAR | LOSARTAN + HYDROCHLOROTHIAZIDE | 100MG + 25MG | EGYPHAR FACTORY-OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT | EGYPT | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X4.0 TABLET STRIP | 21/11/2019 |
| 3760 | NDA/MAL/HDP/8647 | EGYPHAR | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ZISROCIN | AZITHROMYCIN DIHYDRATE | 100MG/5ML | EGYPHAR FACTORY-OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT | EGYPT | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X30.0 ML BOTTLE | 21/11/2019 |
| 3761 | NDA/MAL/HDP/8648 | UNOSOURCE PHARMA LTD. | ABACUS PHARMA (AFRICA) LIMITED | UNODEX PLUS | TERBUTALINE SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN | 2.5MG + 8MG + 100MG | AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3762 | NDA/MAL/HDP /8649 | ASTRA PHARMA (U) LIMITED | ASTRA PHARMA (U) LIMITED | CEFCARE | CEFTRIAXONE SODIUM | 1G | INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT | INDIA | PARENTERAL ORDINARY VIALS | 1.0X10.0 ML VIAL | 31/01/2018 |
| 3763 | NDA/MAL/HDP /8650 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | CEFDIA 400MG | CEFIXIME TRIHYDRATE | 400MG | NOBEL İLAÇ SAN. VE TIC. A.Ş.-81100 SANCAKLAR, DÜZCE-TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X5.0 TABLET BLISTER,1.0X2.0X1.0X5.0 TABLET BLISTER | 28/03/2018 |
| 3764 | NDA/MAL/HDP /8653 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | LEFLOXIN 500 | LEVOFLOXACIN HEMIHYDRATE | 500MG | ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3765 | NDA/MAL/HDP/8655 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | GLUCOPHAGE XR 1000MG | METFORMIN HYDROCHLORIDE | 1000MG | MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT<br>MERCK SANTÉ S.A.S.-2 RUE DU PRESSOIR VERT<br>45400 SEMOY<br>FRANCE | GERMANY | ORAL SOLID RETARD TABLETS | 1.0X4.0X15.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER | 28/03/2018 |
| 3766 | NDA/MAL/HDP/8658 | SANDOZ GMBH, KUNDL | SURGIPHARM (U) LIMITED | METFORMIN 1000MG | METFORMIN HYDROCHLORIDE | 1000MG | LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X4.0X15.0 TABLET BLISTER | 28/03/2018 |
| 3767 | NDA/MAL/HDP/8659 | SANDOZ GMBH, KUNDL | SURGIPHARM (U) LIMITED | METFORMIN 500MG | METFORMIN HYDROCHLORIDE | 500MG | LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X6.0X10.0 TABLET BLISTER | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3768 | NDA/MAL/HDP/8660 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | VEMLIDY | TENOFOVIR ALAFENAMIDE | 25MG | PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 | CANADA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 28/03/2018 |
| 3769 | NDA/MAL/HDP/8661 | AUROBINDO PHARMA LIMITED | GITTOES PHARMACEUTICALS LIMITED | DOLUTEGRAVIR TABLETS 50MG | DOLUTEGRAVIR SODIUM | 50MG | AUROBINDO PHARMA LTD UNIT VII (SEZ) APIIC-PLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOOBNAGAR DISTRICT ANDHRA PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 28/03/2018 |
| 3770 | NDA/MAL/HDP/8662 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | AMOXIREN-DS | AMOXICILLIN TRIHYDRATE | 250MG/5ML | RENE INDUSTRIES LTD .-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 28/03/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3771 | NDA/MAL/HDP/8665 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | PAMAGIN-C | CETIRIZINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + ACETAMINOPHEN + PHENYLEPHRINE HYDROCHLORIDE + ZINC GLUCONATE | 5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG | CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 28/03/2018 |
| 3772 | NDA/MAL/HDP/8685 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | RANCV 500 | RANOLAZINE | 500 MG | MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3773 | NDA/MAL/HDP/8688 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | DURART 600 | DARUNAVIR | 600 MG | MYLAN LABORATORIES LTD -- H-12 & H-13, MIDC, WALUJ,AURANGABAD-431136 MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0 TABLET BOTTLE | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3774 | NDA/MAL/HDP/8689 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | DURART 800 | DARUNAVIR | 800 MG | MYLAN LABORATORIES LTD -- H-12 & H-13, MIDC, WALUJ,AURANGABAD-431136 MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 30/05/2018 |
| 3775 | NDA/MAL/HDP/8690 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ARTESUNATE SUPPOSITORIES 100MG | ARTESUNATE | 100MG | CIPLA LIMITED.,-PLOT NO.D-7 MIDC INDUSTRIAL AREA, KURKUMBH,DIST:PUNE 413802,INDIA | INDIA | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X2.0 BLISTER CARTON | 26/09/2018 |
| 3776 | NDA/MAL/HDP/8691 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | QUETRA 1000 | LEVETIRACETAM | 1000MG | REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS | CYPRUS | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3777 | NDA/MAL/HDP /8692 | GOODMAN INTERNATIONAL (U) LTD | GOODMAN INTERNATIONAL LTD | PARAFUSIV | PARACETAMOL | 10 MG/ML | S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO-POTENZA (PZ) ITALY | ITALY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X50.0 ML VIAL,1.0X100.0 ML VIAL | 30/05/2018 |
| 3778 | NDA/MAL/HDP /8693 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | QUETRA 100MG/ML | LEVETIRACETAM | 100 MG/ML | REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS | CYPRUS | ORAL LIQUID ORDINARY LIQUIDS | 1.0X300.0 ML BOTTLE | 30/05/2018 |
| 3779 | NDA/MAL/HDP /8694 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | ERBITUX | CETUXIMAB | 5MG/ML | MERCK KGAA-250 FRANKFURTERSTRASSE, D-6100 DARMSTADT | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X20.0 ML VIAL | 07/11/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3780 | NDA/MAL/HDP/8696 | PHARCO PHARMACEUTICALS | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BABY COL | SIMETICONE | 40MG/0.6ML | PHARCO PHARMACEUTICALS-KILO 31 ALEXANDRIA-CAIRO DESERT ROAD AMRIYA ALEXANDRIA | EGYPT | ORAL LIQUID ORDINARY EMULSIONS | 1.0X1.0X15.0 ML BOTTLE | 30/05/2018 |
| 3781 | NDA/MAL/HDP/8699 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | ACETAZOLAMIDE | ACETAZOLAMIDE | 250 MG | REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3782 | NDA/MAL/HDP/8743 | CADILA PHARMACEUTICALS LIMITED | KARURI PHARMACEUTICALS LTD. | ISONIAZID | ISONIAZID | 300 MG | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 01/07/2010 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3783 | NDA/MAL/HDP /8779 | M/S HETERO LABS LIMITED | AIVEEN (U) LIMITED | STATINOR 20 | ROSUVASTATIN | 20MG | HETERO LABS LIMITED UNIT V-TSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) –509301, TELANGANA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/05/2019 |
| 3784 | NDA/MAL/HDP /8780 | HETERO DRUGS LTD | AIVEEN (U) LIMITED | STATINOR 10 | ROSUVASTATIN CALCIUM | 10 MG | HETERO LABS LIMITED UNIT V-TSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) –509301, TELANGANA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 27/03/2019 |
| 3785 | NDA/MAL/HDP /8781 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVXIM-400 | CEFIXIME | 400MG | ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X10.0X 10.0 TABLET BLISTER,1.0X10.0X 1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3786 | NDA/MAL/HDP/8783 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVCLAV-375 | AMOXICILLIN + CLAVULANIC ACID | 250MG + 125MG | MEDICEF PHARMA-NO. 28, PHASE 1, EPIP, JHARRMAJRI, BADDI, DIST SOLAN (HP) AMN LIFE SCIENCE PVT LTD-67/P-1, MALAV, AREA-BHILAD, VALSAD-396105, GUJARAT | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X7.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3787 | NDA/MAL/HDP/8784 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVCEF-500 | CEFUROXIME AXETIL | 500MG | ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3788 | NDA/MAL/HDP/8785 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVCEF SUSPENSION | CEFUROXIME AXETIL | 125MG/5ML | ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 21/11/2019 |

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| 3789 | NDA/MAL/HDP/8787 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVXIM-200 | CEFIXIME | 200MG | ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3790 | NDA/MAL/HDP/8788 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | AIVPOD-200 | CEFPODOXIME PROXETIL | 200MG | ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3791 | NDA/MAL/HDP/8795 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ARTEFAN 60/360 | ARTEMETHER + LUMEFANTRINE | 60MG + 360MG | AJANTA PHARMA LIMITED-B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128 AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT: BHARUCH,GUJARAT-392130 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X30.0X1.0X6.0 TABLET BLISTER | 26/11/2019 |

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| 3792 | NDA/MAL/HDP/8796 | PSYCHOTROPICS INDIA LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | AMITRIP-25 | AMITRIPTYLINE HYDROCHLORIDE | 25MG | PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49, SECTOR-6A,IIE, SIDCUL,HARIDWAR - 249403( UTTARAKHARD) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3793 | NDA/MAL/HDP/8814 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ACRIPTEGA | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50MG + 300MG + 300MG | MYLAN LABORATORIES LIMITEDD ,-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE | 30/05/2018 |
| 3794 | NDA/MAL/HDP/8815 | ZIM LABORATORIES LTD | REDDYS PHARMA LIMITED | ZIMAGRA – ODS 50 | SLIDENAFIL CITRATE | 50 MG | ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA, | INDIA | OTHER SYSTEMIC SPECIAL SOLIDS | 1.0X1.0X10.0 SACHET CARTON | 30/05/2018 |

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| 3795 | NDA/MAL/HDP/8816 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | ABPARA | PARACETAMOL | 1%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1.0X100.0 ML BOTTLE | 30/05/2018 |
| 3796 | NDA/MAL/HDP/8818 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | LEVOTOP-PF | LEVOFLOXACIN HEMIHYDRATE | 1.5%W/V | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML VIAL | 30/05/2018 |
| 3797 | NDA/MAL/HDP/8819 | UNOSOURCE PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | LORFACT-D SYRUP | DESLORATADINE | 5MG/5ML | AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 30/05/2018 |

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| 3798 | NDA/MAL/HDP/8820 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | T-DOL P RAPID | TRAMADOL HYDROCHLORIDE + PARACETAMOL | 37.5MG + 325MG | TROIKAA PHARMACEUTICALS LTD .-C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 30/05/2018 |
| 3799 | NDA/MAL/HDP/8822 | ABACUS PARENTERAL DRUGS LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | ALIDO | LIDOCAINE HYDROCHLORIDE | 2%W/V | LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X30.0 ML VIAL | 30/05/2018 |
| 3800 | NDA/MAL/HDP/8823 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | EPCLUSA | SOFOSBUVIR + VELPATASIR | 400MG + 100MG | PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 | CANADA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X28.0 TABLET BOTTLE | 30/05/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3801 | NDA/MAL/HDP /8824 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | NEPAFLAM | NEPAFENAC | 0.1% W/V | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA | INDIA | OPHTHALMIC SUSPENSIONS | 1.0X1.0X5.0 ML VIAL | 30/05/2018 |
| 3802 | NDA/MAL/HDP /8825 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | LAXALINK | LACTULOSE | 3.35G/5ML | LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA. | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X150.0 ML BOTTLE | 30/05/2018 |
| 3803 | NDA/MAL/HDP /8826 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ABACAVIR SULFATE AND LAMIVUDINE TABLETS FOR ORAL SUSPENSION 120/60 MG | ABACAVIR SULFATE + LAMIVUDINE | 120MG + 60MG | CIPLA LIMITED -PLOT NO A – 33, A – 2 (UNIT – I), MIDC PATALGANGA, DISTRICT RAIGAD, 410 220 MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X1.0X60.0 TABLET BOTTLE | 30/05/2018 |

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| 3804 | NDA/MAL/HDP/8829 | HETERO LABS LTD | AIVEEN (U) LIMITED | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50MG + 300MG + 300MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE | 27/11/2018 |
| 3805 | NDA/MAL/HDP/8830 | HETERO LABS LTD | AIVEEN (U) LIMITED | IRBIS-HT | IRBESARTAN + HYDROCHLOROTHIAZIDE | 300MG + 12.5MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3806 | NDA/MAL/HDP/8831 | HETERO LABS LTD | AIVEEN (U) LIMITED | PREGA 75 | PREGABALIN | 75MG | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE HETERO LABS LIMITED (UNIT I)-VILLAGE KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN, HIMACHAL PRADESH, PIN CODE 173205 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |

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| 3807 | NDA/MAL/HDP /8836 | EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD | SURGIPHARM (U) LIMITED | GASTRICID | FAMOTIDINE BP + MAGNESIUM HYDROXIDE BP + CALCIUM CARBONATE BP | 10 MG + 165 MG + 800 MG | MILAN LABORATORIES (INDIA ) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA | INDIA | ORAL SOLID ORDINARY CHEWABLE TABLETS | 1.0X4.0 TABLET STRIP | 07/11/2018 |
| 3808 | NDA/MAL/HDP /8838 | HETERO LABS LTD | AIVEEN (U) LIMITED | PREGA 150 | PREGABALIN | 150MG | HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE HHETERO LABS LIMITED (UNIT III)-KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN, HIMACHAL PRADESH INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |
| 3809 | NDA/MAL/HDP /8844 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VENAXAN 500 MG | LEVOFLOXACIN HEMIHYDRATE | 500 MG | SOUTH EGYPT DRUG INDUSTRIES CO-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY, EGYPT. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 07/11/2018 |

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| 3810 | NDA/MAL/HDP/8845 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | FUROSEMIDE | FUROSEMIDE | 10MG/ML | SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 21/11/2019 |
| 3811 | NDA/MAL/HDP/8914 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | PEFLOREN 400 | PEFLOXACIN MESILATE DIHYDRATE | 400 MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X10.0 TABLET BLISTER | 25/07/2018 |
| 3812 | NDA/MAL/HDP/8915 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ATOXIA 120 MG | ETORICOXIB | 120 MG | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD--P.O. BOX 69 AMMAN 11591 - AL-RAGEEM SAHAB - JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X7.0 TABLET BLISTER | 25/07/2018 |

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| 3813 | NDA/MAL/HDP/8916 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | TAMSUMAC 0.4 | TAMSULOSIN HYDROCHLORIDE | 0.4MG | MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA | INDIA | ORAL SOLID RETARD CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER | 25/07/2018 |
| 3814 | NDA/MAL/HDP/8917 | SVIZERA LABS PRIVATE LTD | GITTOES PHARMACEUTICALS LIMITED | SCC-2 LLW TABLETS | RIFAMPICIN + ISONIAZID | 150MG + 75MG | SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 25/07/2018 |
| 3815 | NDA/MAL/HDP/8918 | SVIZERA LABS PRIVATE LTD | GITTOES PHARMACEUTICALS LIMITED | SCC-3 LLW TABLETS | RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE | 150MG + 75MG + 275MG | SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 25/07/2018 |

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| 3816 | NDA/MAL/HDP/8919 | SVIZERA LABS PRIVATE LTD | GITTOES PHARMACEUTICALS LIMITED | SCC-4 TABLETS | RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE | 150MG + 75MG + 400MG + 275MG | SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 25/07/2018 |
| 3817 | NDA/MAL/HDP/8920 | MERCK | UNITED HEALTHCARE DISTRIBUTORS LTD | CRINONE 8% GEL | PROGESTERONE | 90MG/APPLICATOR | DENDRON BRANDS LIMITED-94 RICKMANSWORTH ROAD,WATFORD , WD18 7JJ, UNITED KINGDOM | UNITED KINGDOM | VAGINAL GELS AND SOLS | 1.0X1.0X15.0 POUCH CARTON | 25/07/2018 |
| 3818 | NDA/MAL/HDP/8921 | SUN PHARMACEUTICAL LTD | STAR PHARMACEUTICALS LTD | VESIZEN 5 | SOLIFENACIN SUCCINATE | 5 MG | SUN PHARMACEUTICALS LTD-,-SEZ UNIT –I, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3819 | NDA/MAL/HDP/8927 | BIOLOGICAL E. LTD | GITTOES PHARMACEUTICALS LIMITED | DIPHTHERIA AND TETANUS VACCINE (ADSORBED REDUCED ANTIGEN(S) CONTENT) | DIPHTHERIA TOXOID + TETANUS TOXOID | 2 LF ( NOT LESS THAN 2 IU) + 8.8 LF (NOT LESS THAN 20 IU)/ 0.5ML | BIOLOGICAL E. LIMITED--PLOT NO.1 SHAPOORJI PALLONJI BIOTECH PARK PHASE II, KOLTHUR VILLAGE, SHAMEERPET, MANDAL, R.R. DISTRICT, ANDRA PRADESH 500078, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X24.0X1.0X10.0 DOSE VIAL,1.0X48.0X1.0 DOSE VIAL | 25/07/2018 |
| 3820 | NDA/MAL/HDP/8929 | OCTAPHARMA AG | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ALBUNORM | HUMAN ALBUMIN | 20%W/V | OCTAPHARMA PRODUKTIONSGESELLSCHAFT DEUTSCHLAND MBH--WOLFGANG-MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 25/07/2018 |
| 3821 | NDA/MAL/HDP/8931 | CARITAS HEALTHCARE PVT. LTD | REDDYS PHARMA LIMITED | SODIUM CHLORIDE INTRAVENOUS INFUSION BP | SODIUM CHLORIDE | 0.9%W/V | SICHUAN KELUN PHARMACEUTICAL CO., LTD-SOUTH OF NO.2 ROAD, XINDU SATELLITE CITY INDUSTRIAL DEVELOPMENT ZONE, CHENGDU, SICHUAN PROVINCE 610500, P. R. CHINA | CHINA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BOTTLE | 25/07/2018 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3822 | NDA/MAL/HDP/8933 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | Q-TIB | SULFAMETHOXAZOLE + TRIMETHOPRIM + ISONIAZID + PYRIDOXINE HYDROCHLORIDE | 800MG + 160MG + 300MG +25MG | CIPLA LTD ,.-PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA CIPLA LIMITED>-A-33, A-37/2/2 & A-2, M.I.D.C, PATALANGA 410 220, DISTRICT RAIGAD, M.S, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 25/07/2018 |
| 3823 | NDA/MAL/HDP/8934 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | CYCLO P EYE DROPS | CYCLOPENTOLATE HYDROCHLORIDE | 1.0%W/V | ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA. | UGANDA | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML VIAL | 25/07/2018 |
| 3824 | NDA/MAL/HDP/8935 | AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD | HEALTHCARE LTD. | FECLO GEL | DICLOFENAC DIETHYLAMMONIUM SALT | 1%W/W | AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN | PAKISTAN | TOPICAL EXTERNAL EMULSION GELS | 1.0X1.0X20.0 G TUBE,1.0X1.0X15.0 G TUBE | 25/07/2018 |

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| 3825 | NDA/MAL/HDP/8939 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | RHINOCOLD | PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE + CAFFEINE (ANHYDROUS) | 500MG + 10MG + 2MG + 30MMG | FREDUN PHARMACEUTICALS LTD --14, 15, 16, ZORABIAN INDUSTRIAL COMPLEX, VILLAGE, VEOOR, PALGHAR (EAST)<br>DIST: THANE – 401 404 - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X4.0 TABLET BLISTER | 25/07/2018 |
| 3826 | NDA/MAL/HDP/8940 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | RABIZA 20MG | RABEPRAZOLE SODIUM | 20MG | İLKO İLAÇ SANAYI VE TICARET A. Ş.-3. 42050 SELÇUKLU / KONYA<br>TURKEY | TURKEY | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 25/07/2018 |
| 3827 | NDA/MAL/HDP/8941 | İLKO İLAÇ SANAYI VE TICARET A. Ş. | CORE ACCESS LIMITED | LIVERCOL 20MG | ROSUVASTATIN CALCIUM | 20MG | İLKO İLAÇ SANAYI VE TICARET A. Ş.-3. 42050 SELÇUKLU / KONYA<br>TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 25/07/2018 |

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| 3828 | NDA/MAL/HDP/8943 | HETERO LABS LTD | AIVEEN (U) LIMITED | IRBIS-HT 150/12.5 | IRBESARTAN + HYDROCHLOROTHIAZIDE | 150MG + 12.5MG | HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOOBNAGAR, DISTRICT ANDHRA PRADESH 509301 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3829 | NDA/MAL/HDP/8944 | GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD | TRIDEM PHARMA UGANDA LIMITED | GAMOK 625MG | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 500MG + 125MG | SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 25/07/2018 |
| 3830 | NDA/MAL/HDP/8946 | B & O PHARM ZAC | TRIDEM PHARMA UGANDA LIMITED | GAMOK 0.6G | AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM | 500MG + 100MG | SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X0.6 G VIAL | 25/07/2018 |

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| 3831 | NDA/MAL/HDP/8947 | B & O PHARM ZAC | TRIDEM PHARMA UGANDA LIMITED | GAMOK 1.2G | AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM | 1G + 0.2G | SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD-OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X1.2 G VIAL | 25/07/2018 |
| 3832 | NDA/MAL/HDP/8948 | GULF PHARMACEUTICAL INDUSTRIES(JULPHAR). | OMASI MED LIMITED | JULMENTIN ES | AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM | 600 MG / 5 ML + 42.9 MG / 5 ML | GULF PHARMACEUTICAL INDUSTRIES (JULPHAR) -- DIGDAGA, AIRPORT STREET RAS AL KHAIMAH UNITED ARAB EMIRATES | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X100.0 ML BOTTLE | 25/07/2018 |
| 3833 | NDA/MAL/HDP/8949 | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CETAL SUPOSITORIES | PARACETAMOL | 120MG | EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT | EGYPT | RECTAL SYSTEMIC SUPPOSITORIES | 1.0X1.0X5.0 SUPPOSITORY BLISTER | 25/07/2018 |

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| 3834 | NDA/MAL/HDP/8953 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN CHILDREN'S WET COUGH | GUAIFENESIN | 100MG PER 10ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 25/07/2018 |
| 3835 | NDA/MAL/HDP/8954 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN WET COUGH | GUAIFENESIN | 200MG PER 10ML | JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA | SOUTH AFRICA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE | 25/07/2018 |
| 3836 | NDA/MAL/HDP/9053 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | MABTHERA® 100MG/10ML | RITUXIMAB | 100MG/10ML | ROCHE DIAGNOSTICS GMBH MANNHEIM--SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY. | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X2.0X10.0 ML VIAL | 26/09/2018 |

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| 3837 | NDA/MAL/HDP /9054 | F. HOFFMANN LA-ROCHE | LABOREX UGANDA LIMITED | MABTHERA® 500MG/50ML | RITUXIMAB | 500MG/50ML | ROCHE DIAGNOSTICS GMBH MANNHEIM--SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY. | GERMANY | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X50.0 ML VIAL | 26/09/2018 |
| 3838 | NDA/MAL/HDP /9057 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP® | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 60MG + 480MG | GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X6.0X2 5.0 TABLET BLISTER | 26/09/2018 |
| 3839 | NDA/MAL/HDP /9058 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | D-ARTEPP® DISPERSIBLE | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 30MG + 240MG | GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X2.0X3.0 TABLET BLISTER,1.0X3.0X2 5.0 TABLET BLISTER | 26/09/2018 |

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| 3840 | NDA/MAL/HDP/9059 | CRATUS PHARMA PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | CLASSMOX DROPS | AMOXICILLIN TRIHYDRATE | 125MG/ML | TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - -UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.- HARIDWAR, UTTARAKHAND | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X10.0 ML BOTTLE | 26/09/2018 |
| 3841 | NDA/MAL/HDP/9062 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ADERAN 32 | CANDESARTAN CILEXETIL | 32 MG | AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 26/09/2018 |
| 3842 | NDA/MAL/HDP/9063 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 MG | TENOFOVIR DISOPROXIL FUMARATE | 300 MG | LAURUS LABS LIMITED, (UNIT-2) - -PLOT NO:19, 20 & 21,WESTERN SECTOR, APSEZ, ATCHUTAPURAM MANDAL, VISAKHAPATNAM-DISTRICT-531011, ANDHRA PRADESH, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 26/09/2018 |

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| 3843 | NDA/MAL/HDP/9129 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LOXAMOX | LEVOFLOXACIN HEMIHYDRATES | 250MG/50ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X50.0 ML BAG | 21/11/2019 |
| 3844 | NDA/MAL/HDP/9130 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | MFLOX-DM | MOXIFLOXACIN + DEXAMETHASONE SODIUM PHOSPHATE | 0.5%W/V + 0.1%W/V | AUROLAB LIMITED-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA | INDIA | OPHTHALMIC DROPS | 1.0X5.0 ML BOTTLE | 21/11/2019 |
| 3845 | NDA/MAL/HDP/9137 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | DOM R | RABEPRAZOLE SODIUM + DOMPERIDONE SR | 20MG + 30MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3846 | NDA/MAL/HDP /9140 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | CLOMIPHENE CITRATE | CLOMIPHENE CITRATE | 50MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3847 | NDA/MAL/HDP /9141 | I CARE PHARMA LIMITED | AIVEEN (U) LIMITED | RABZOLE | RABEPRAZOLE SODIUM + LEVOSULPIRIDE | 20MG + 75MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |
| 3848 | NDA/MAL/HDP /9146 | MICRO LABS LTD | PHARMA VILLE LIMITED | ISONIAZID | ISONIAZID | 300MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X24.0X 28.0 TABLET BLISTER,1.0X1000. 0 TABLET BOTTLE | 21/11/2019 |

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| 3849 | NDA/MAL/HDP/9147 | SERUM INSTITUTE OF INDIA LTD. | NORVIK ENTERPRISES LIMITED | HUMAN ROTAVIRUS REASSORTANT | LIVE ATTENUATED BOVINE - HUMAN ROTAVIRUS REASSORTANT [G1, G2, G3, G4 AND G9] | ≥105.6 FFU / SEROTYPE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X2.5 ML VIAL (1DOSE),1.0X1.0X5.0 ML VIAL (2 DOSES) | 21/11/2019 |
| 3850 | NDA/MAL/HDP/9165 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | VAGID-100 | CLOTRIMAZOLE | 100 MG | M/S BLISS GVS PHARMA LIMITED -PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404 | INDIA | VAGINAL SUPPOSITORIES | 1.0X1.0X7.0 PESSARY BLISTER,1.0X1.0X6.0 PESSARY BLISTER | 21/11/2019 |
| 3851 | NDA/MAL/HDP/9169 | CADILA PHARMACEUTICALS LIMITED | PLANET PHARMACEUTICALS UGANDA LTD | PROCTICAD | LACTITOL MONOHYDRATE | 10 GM/15ML | CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE | 27/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3852 | NDA/MAL/HDP/9172 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | DOXYDERMA | DOXYCYCLINE MONOHYDRATE | 100MG | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3853 | NDA/MAL/HDP/9173 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | PRODEXA-T | DEXAMETHASONE | 0.5MG | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 27/08/2019 |
| 3854 | NDA/MAL/HDP/9174 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | ULCOZOL 20MG | OMEPRAZOLE | 20MG | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3855 | NDA/MAL/HDP/9175 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | ERITROMICINE | ERYTHROMYCIN ESTOLATE | 250MG | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY TABLETS | 1.0X5.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3856 | NDA/MAL/HDP/9176 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | PIROCUTAN | PIROXICAM | 20MG | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3857 | NDA/MAL/HDP/9177 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | TETRA | TETRACYCLINE HYDROCHLORIDE | 1%W/V | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | OPHTHALMIC OINTMENTS | 1.0X5.0 G TUBE | 21/11/2019 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3858 | NDA/MAL/HDP/9178 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | LORADE | LORATIDINE,LORATIDINE | 10MG,10MG | PROFARMA SH.A-MYSLYMKETA,TIRANA | ALBANIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 21/11/2019 |
| 3859 | NDA/MAL/HDP/9190 | SAKAR HEALTHCARE LIMITED | TATA UGANDA LIMITED | RABEKAR | RABEPRAZOLE SODIUM | 20MG | SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHEMABAD 382213 GUJARATI | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE | 08/09/2020 |
| 3860 | NDA/MAL/HDP/9191 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANDOX-DS 50 | CEFPODOXIME PROXETIL | 50 MG/5ML | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0 ML BOTTLE | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3861 | NDA/MAL/HDP/9192 | SANCE LABORATORIES PVT LTD | DELMAW ENTERPRISES LIMITED | SANDOX- 200 | CEFPODOXIME PROXETIL | 200 MG | SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3862 | NDA/MAL/HDP/9193 | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD | TATA UGANDA LIMITED | LAMIVUDINE AND ZIDOVUDINE TABLETS 150 MG/300 MG | LAMIVUDINE + ZIDOVUDINE | 150 MG + 300 MG | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD-1479 ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE SHANGHAI, CHINA | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X60.0 TABLET CONTAINER | 28/09/2020 |
| 3863 | NDA/MAL/HDP/9194 | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO) | WIDE SPECTRUM ENTERPRISES (U) LIMITED | MAGNABIOTIC | AMOXICILLINTRIHYDRATE + POTASSIUM CLAVULANATE | 875 MG + 125 MG | SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43 | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BOTTLE | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3864 | NDA/MAL/HDP/9195 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | SOBISIS | SODIUM BICARBONATE | 500 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3865 | NDA/MAL/HDP/9196 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | SOBISIS FORTE | SODIUM BICARBONATE | 1000 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3866 | NDA/MAL/HDP/9197 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | SEVLAREN 400 | SEVELAMER CARBONATE | 400 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3867 | NDA/MAL/HDP/9198 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | PBREN 75 | PREGABALIN | 75 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 08/09/2020 |
| 3868 | NDA/MAL/HDP/9199 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | KCHEK | CALCIUM POLYSTYRENE SULPHONATE | 15 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES | 1.0X15.0 G SACHET | 08/09/2020 |
| 3869 | NDA/MAL/HDP/9200 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | LEVIGRESS 250 | LEVETIRACETAM | 250 MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3870 | NDA/MAL/HDP /9201 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | LEVIGRESS 500 | LEVETIRACETAM | 500MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3871 | NDA/MAL/HDP /9202 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | ESCIGRESS 5 | ESCITALOPRAM OXALATE | 5MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3872 | NDA/MAL/HDP /9203 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | ESCIGRESS 10 | ESCITALOPRAM OXALATE | 10MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 08/09/2020 |

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| 3873 | NDA/MAL/HDP/9204 | SUN PHARMACEUTICAL INDUSTRIES LTD | STAR PHARMACEUTICALS LTD | CHERIFLU PLUS WITH VITAMIN C | CHLORPHENAMINE MALEATE + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE +VITAMIN C | 4 MG + 650 MG + 10 MG + 30 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED - INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3874 | NDA/MAL/HDP/9205 | SYNOKEM PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | GASTROSYN | ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE | 250 MG + 250 MG + 50 MG / 5ML | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 08/09/2020 |
| 3875 | NDA/MAL/HDP/9207 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | FLIPTOR 10 | ROSUVASTATIN CALCIUM | 10MG | MADRAS PHARMACEUTICALS -137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |

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| 3876 | NDA/MAL/HDP/9209 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | NOFONG | TERBINAFINE HYDROCHLORIDE | 1%W/W | MADRAS PHARMACEUTICALS -137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X15.0 G TUBE | 08/09/2020 |
| 3877 | NDA/MAL/HDP/9210 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VIVAZAC | IRBESARTAN | 300 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3878 | NDA/MAL/HDP/9211 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HI DEE 10000 IU | CHOLECALCIFEROL | 10,000IU | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X30.0 CAPSULE CONTAINER | 08/09/2020 |

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| 3879 | NDA/MAL/HDP/9212 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HI DEE 50000 IU | CHOLECALCIFEROL | 50,000IU | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X8.0 CAPSULE CONTAINER | 08/09/2020 |
| 3880 | NDA/MAL/HDP/9213 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | COMBIART SUSPENSION | ARTEMETHER + LUMEFANTRINE | 15 MG + 90 MG/5ML | MADRAS PHARMACEUTICALS -137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X60.0 ML BOTTLE | 08/09/2020 |
| 3881 | NDA/MAL/HDP/9214 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HI DEE 2000 IU | CHOLECALCIFEROL | 2000IU | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X1.0X30.0 CAPSULE CONTAINER | 08/09/2020 |

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| 3882 | NDA/MAL/HDP /9215 | UNITED PHARMACEUTICAL MANUFACTURING CO. LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | HI DEE 2000 IU/5 DROPS | CHOLECALCIFEROL | 2000IU/ 5 DROPS | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL LIQUID ORDINARY DROPS | 1.0X1.0X10.0 ML BOTTLE | 08/09/2020 |
| 3883 | NDA/MAL/HDP /9216 | TIL HEALTHCARE PVT LTD | HARLEYS UGANDA LIMITED | URELOG | CALCIUM-4-METHYL-2 OXO-VALERATE + CALCIUM-3-METHYL-2 OXO-BUTYRATE + CALCIUM-2- OXO-3-PHENYL PROPIONATE + CALCIUM-3-METHYL-2 OXO-VALERATE + | 101 MG +86 MG + 68 MG + 67 MG + 59 MG + 105 MG + 53 MG + 38 MG + 30 MG + 23 MG +36 MG 0.05 G | TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R-5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITOOR 517588 ANDHRA PRADESH- | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 28/09/2020 |
| 3884 | NDA/MAL/HDP /9217 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLETS | ABACAVIR SULFATE + DOLUTEGRAVIR SODIUM + LAMIVUDINE | 600 MG + 50 MG + 300 MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3885 | NDA/MAL/HDP/9219 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | TESS | TRIAMCINOLONE ACETONIDE | 0.1% W/W | TROIKAA PHARMACEUTICALS LTD-BLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD-382170, GUJARAT STATE | INDIA | TOPICAL EXTERNAL PASTES | 1.0X1.0X5.0 G TUBE | 08/09/2020 |
| 3886 | NDA/MAL/HDP/9222 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | DARUNAVIR TABLETS | DARUNAVIR | 800 MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER | 08/09/2020 |
| 3887 | NDA/MAL/HDP/9223 | WALLACE PHARMACEUTICALS PVT. LTD | STAR PHARMACEUTICALS LTD | LAXIWAL | LACTULOSE | 10 G/15 ML | WALLACE PHARMACEUTICALS PVT LTD-BHATIAN, NALAGARH, DIST. SOLAN HP 174101 | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE | 28/09/2020 |

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| 3888 | NDA/MAL/HDP /9224 | WILSHIRE LABORATORIES (PVT) LTD | HEALTHCARE LTD. | XAAR | PREGABALIN | 75 MG | WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN | PAKISTAN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X4.0X5.0 CAPSULE BLISTER | 28/09/2020 |
| 3889 | NDA/MAL/HDP /9225 | ZIM LABORATORIES LTD | ROYAL PHARMA 2011 LIMITED | ZIMADOL 50 | TRAMADOL HYDROCHLORIDE | 50 MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 28/09/2020 |
| 3890 | NDA/MAL/HDP /9229 | UNOSOURCE PHARMA LTD. | MEDVIN PHARMA LIMITED | TRADMIN | TRAMADOL HYDROCHLORIDE | 50MG | AKUMS DRUGS & PHARMACEUTICALS LTD-19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 08/09/2020 |

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| 3891 | NDA/MAL/HDP/9234 | CACHET PHARMACEUTICALS PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | I-UP | FERROUS ASCORBATE + FOLIC ACID | 30 MG + 550 MCG/5 ML | CACHET PHARMACEUTICALS PVT LTD .-VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205 | INDIA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 25/09/2020 |
| 3892 | NDA/MAL/HDP/9236 | LUPIN LTD | AIVEEN (U) LIMITED | RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE TABLETS | RIFAMPIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE | 150 MG + 75 MG + 275 MG | LUPIN LIMITED -A-28/1 MIDC CHIKALTHANA AURANGABAD | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 08/09/2020 |
| 3893 | NDA/MAL/HDP/9237 | DENK PHARMA GMBH & CO. KG | BENLE CONSULT LIMITED | AZITHRO-DENK 250 MG | AZITHROMYCIN MONOHYDRATE | 250MG | ARTESAN PHARMA GMBH & CO. KG-WENDLANDSTR.1, 29439, LUCHOW | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 08/09/2020 |

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| 3894 | NDA/MAL/HDP /9238 | DENK PHARMA GMBH & CO KG | BENLE CONSULT LIMITED | AZITHRO-DENK 500 MG | AZITHROMYCIN MONOHYDRATE | 500MG | ARTESAN PHARMA GMBH & CO. KG-WENDLANDSTR.1, 29439, LUCHOW | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 08/09/2020 |
| 3895 | NDA/MAL/HDP /9241 | BKRS PHARMA PVT. LTD. | VEERAM HEALTHCARE (U) LIMITED | LEXAR | LEVOFLOXACIN HEMIHYDRATE | 500MG | AXA PARENTERALS LTD-PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE-247667, DIST. HARIDWAR, UTTARAKHAND | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 08/09/2020 |
| 3896 | NDA/MAL/HDP /9248 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | ESOFAG-D | ESOMEPRAZOLE MAGNESIUM TRIHYDRATE + DOMPERIDONE | 40MG + 30MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE STRIP | 08/09/2020 |

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| 3897 | NDA/MAL/HDP/9249 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | LOXAMOX | LEVOFLOXACIN HEMIHYDRATE | 5 MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY INFUSION BAGS | 1.0X1.0X100.0 ML BAG | 08/09/2020 |
| 3898 | NDA/MAL/HDP/9251 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RIBOFAN | TIROFIBAN HYDROCHLORIDE | 12.5 MG/50ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X1.0X50.0 ML VIAL | 08/09/2020 |
| 3899 | NDA/MAL/HDP/9262 | REDDYS PHARMA LIMITED | REDDYS PHARMA LIMITED | DOMIPAN | PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE | 40 MG + 30 MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X10.0 CAPSULE BLISTER | 28/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3900 | NDA/MAL/HDP/9263 | FREDUN PHARMACEUTICALS LTD | REDDYS PHARMA LIMITED | ETCOX-90 | ETORICOXIB | 90MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 28/09/2020 |
| 3901 | NDA/MAL/HDP/9264 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | APRITANT IV | FOSAPRIPITANT DIMEGLUMINE | 150 MG/VIAL | MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325-TELENGANA, | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 VIAL VIAL | 08/09/2020 |
| 3902 | NDA/MAL/HDP/9266 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | ABACAVIR (AS SULFATE) / LAMIVUDINE DISPERSIBLE TABLETS | ABACAVIR SULFATE + LAMIVUDINE | 120 MG + 60 MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; MYLAN LABORATORIES LIMITED-NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD - 431 136, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X30.0 TABLET CONTAINER,1.0X60.0 TABLET CONTAINER | 08/09/2020 |

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| 3903 | NDA/MAL/HDP/9276 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | ZYLODINE | LIDOCAINE HYDROCHLORIDE | 20MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X25.0X50.0 ML VIAL | 08/09/2020 |
| 3904 | NDA/MAL/HDP/9278 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | CANDIFORCE-100 | ITRACONAZOLE | 100 MG | RA CHEM PHARMA LTD-PLOT NO. A-19/C, ROAD NO. 18, IDA NACHARAM, HYDERABAD-500076, TELENGANA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 08/09/2020 |
| 3905 | NDA/MAL/HDP/9279 | RAPTAKOS, BRETT & CO. LTD. | EUROPA HEALTHCARE (U) LTD | SILVIRIN | SILVER SULFADIAZINE | 1% W/W | RAPTAKOS BRETT & CO.LTD-1ST POKHRAN ROAD,THANE 400 606 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3906 | NDA/MAL/HDP/9280 | RAPTAKOS, BRETT & CO. LTD. | EUROPA HEALTHCARE (U) LTD | NORASH | DIMETHICONE + ZINC OXIDE + CALAMINE + CETRIMIDE | 20% W/W + 7.5% W/W + 1.5% W/W + 1.125% W/W | RAPTAKOS BRETT & CO.LTD-1ST POKHRAN ROAD,THANE 400 606 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X20.0 G TUBE | 08/09/2020 |
| 3907 | NDA/MAL/HDP/9286 | GALENTIC PHARMA LTD | VITACARE LIMITED | SELDRUF | SELENIUM SULFIDE | 2.5% W/V | GALENTIC PHARMA (INDIA) LTD .-R-673, MIDC, TTC, RABALE, THANE-BELAPUR ROAD, NAVI MUMBAI | INDIA | TOPICAL EXTERNAL SUSPENSIONS | 1.0X100.0 ML BOTTLE | 08/09/2020 |
| 3908 | NDA/MAL/HDP/9287 | GLENMARK PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | CANDID-V3 | CLOTRIMAZOLE | 200MG | GLENMARK PHARMACEUTICALS LTD .-PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE | INDIA | VAGINAL TABLETS | 1.0X1.0X3.0 TABLET STRIP | 28/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3909 | NDA/MAL/HDP/9290 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | INFIXIME 200 | CEFIXIME TRIHYDRATE | 200MG | INNOVA CAPTAB PVT. LTD-1281/1, HILTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI-173205 (H.P.) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3910 | NDA/MAL/HDP/9291 | INTAS PHARMACEUTICALS LIMITED | STAR BIOTECH UGANDA LTD | SARTEL-80 LH | TELMISARTAN + HYDROCHLOROTHIAZIDE | 80 MG + 12.5 MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY LAYERED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3911 | NDA/MAL/HDP/9294 | JOHNSON &JOHNSON (PTY) LTD | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | BENYLIN WET COUGH MENTHOL | GUAIFENESIN | 200 MG/10 ML | JOHNSON & JOHNSON (PTY) LTD-241 MAIN ROAD, RETREAT, 7945, CAPE TOWN | SOUTH AFRICA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3912 | NDA/MAL/HDP/9296 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | VAGID-CL | CLINDAMYCIN + CLOTRIMAZOLE | 100 MG + 200 MG | BLISS GVS PHARMA LIMITED-10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PALGHAR,MAHARASHTRA 401404,INDIA | INDIA | VAGINAL SUPPOSITORIES | 1.0X1.0X3.0 SUPPOSITORY STRIP | 08/09/2020 |
| 3913 | NDA/MAL/HDP/9297 | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD | TATA UGANDA LIMITED | MEROPENEM FOR INJECTION USP 500 MG | MEROPENEM TRIHYDRATE | 500 MG/VIAL | KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD-PLOT 14, 2ND PHASE, PEENYA IND. AREA, BANGALORE-560058 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X500.0 MG VIAL | 08/09/2020 |
| 3914 | NDA/MAL/HDP/9305 | KOPRAN LIMITED | TATA UGANDA LIMITED | CELEKOP-200 | CELECOXIB | 200MG | KOPRAN LIMITED-VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 08/09/2020 |

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| 3915 | NDA/MAL/HDP /9306 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | FUNBACT-A | CLOTRIMAZOLE + BETAMETHASONE DIPROPIONATE + NEOMYCIN SULFATE | 1.0 % W/W + 0.05 % W/W + 0.5 % W/W | KREMOINT PHARMA PVT LTD. -B-8, ADDITIONAL AMBERNATH M.I.D.C, OPP. ANAND NAGIAR POLICE CHECK POST, AMBERNATH (E), DIST. THANE. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE | 08/09/2020 |
| 3916 | NDA/MAL/HDP /9307 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | PYL-X OINTMENT | LIDOCAINE + ZINC OXIDE + ALLANTOIN + HYDROCORTISONE ACETATE | 3.0%W/W + 5.0% W/W + 0.5%W/W + 0.25W/W | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X30.0 G TUBE + PRODUCT APPLICATOR | 28/09/2020 |
| 3917 | NDA/MAL/HDP /9308 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | LIDOMAX | LIDOCAINE + PRILOCAINE | 25 MG + 25 MG | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X15.0 G TUBE + SPATULA AND SEPARATOR | 08/09/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3918 | NDA/MAL/HDP/9313 | BLISS GVS PHARMA LIMITED | DELMAW ENTERPRISES LIMITED | GSUNATE-30 | ARTESUNATE | 30 MG/VIAL | BLISS INDAS LIFESCIENCE P. LTD..-PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0 VIAL CARTON + 0.5 ML OF 5.0 %W/V SODIUM BICARBONATE VIAL + 2.5 ML OF 0.9% W/V SODIUM CHLORIDE VIAL | 08/09/2020 |
| 3919 | NDA/MAL/HDP/9315 | CENTAUR PHARMACEUTICALS PVT. LTD | GITTOES PHARMACEUTICALS LIMITED | ACETAMOX | ACETAZOLAMIDE | 250 MG | CENTAUR PHARMACEUTICALS PVT. LTD (PLANT 1)-PLOT 3,5B, 2C TIVIM INDUSTRIAL ESTATE, KARASVADA, MAPUSA, GOA 403526 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/09/2020 |
| 3920 | NDA/MAL/HDP/9316 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | TERBIDERM | TERBINAFINE HYDROCHLORIDE | 1% W/W | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | TOPICAL EXTERNAL CREAMS | 1.0X10.0 G TUBE | 08/09/2020 |

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| 3921 | NDA/MAL/HDP/9319 | AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD | HEALTHCARE LTD. | COFFRID SYRUP | ACEFYLLINE PIPERAZINE +DIPHENHYDRAMINE HYDROCHLORIDE | 45 MG + 8 MG | AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X120.0 ML BOTTLE | 25/09/2020 |
| 3922 | NDA/MAL/HDP/9322 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50 MG + 300 MG + 300 MG | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK | UGANDA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER,1.0X180.0 TABLET CONTAINER | 08/09/2020 |
| 3923 | NDA/MAL/HDP/9324 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PROP PLUS | IBUPROFEN + PARACETAMOL | 400 MG + 325 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X10.0 TABLET BLISTER | 25/09/2020 |

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| 3924 | NDA/MAL/HDP/9325 | BESINS HEALTHCARE SA | SURGIPHARM (U) LIMITED | OESTROGEL | ESTRADIOL HEMIHYDRATE | 0.06W/W | BESINS MANUFACTURING BELGIUM (BMB)-GROOT BIJGAARDENSTRAAT, 128. 1620 | BELGIUM | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X80.0 G CONTAINER | 08/09/2020 |
| 3925 | NDA/MAL/HDP/9327 | ATCO LABORATORIES LIMITED | HARLEYS UGANDA LIMITED | OXCIN-D | MOXIFLOXACIN + DEXAMETHASONE SODIUM PHOSPHATE | 0.5%W/V + 0.1% W/V | ATCO LABS LTD,-B-18, S.I.T.E, KARACHI | PAKISTAN | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML CONTAINER | 08/09/2020 |
| 3926 | NDA/MAL/HDP/9331 | BKRS PHARMA PVT. LTD. | VEERAM HEALTHCARE (U) LIMITED | PARA-BKRS | PARACETAMOL | 1.0%W/V | AXA PARENTERALS LTD-PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE-247667, DIST. HARIDWAR, UTTARAKHAND | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 26/10/2020 |

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| 3927 | NDA/MAL/HDP/9350 | RECKITT BENCKISER HEALTHCARE (UK) LIMITED | GITTOES PHARMACEUTICALS LIMITED | NUROFEN | IBUPROFEN LYSINE | 684MG | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NOTTINGHAMSHIRE, NG90 2DB, UNITED KINGDOM | UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 09/12/2020 |
| 3928 | NDA/MAL/HDP/9353 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | LUMITER DT | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X2.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,30.0X1.0X12.0 TABLET | 09/12/2020 |
| 3929 | NDA/MAL/HDP/9354 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ONCOGEM-200 | GEMCITABINE HYDROCHLORIDE | 200MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X10.0 ML VIAL | 22/12/2020 |

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| 3930 | NDA/MAL/HDP/9356 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | IRIS | DESLORATADINE | 5MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 09/12/2020 |
| 3931 | NDA/MAL/HDP/9365 | HETERO BIOPHARMA LIMITED, | AIVEEN (U) LIMITED | BEVAAS 100 | BEVACIZUMAB | 100MG/4ML | HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X4.0 ML VIAL | 09/12/2020 |
| 3932 | NDA/MAL/HDP/9366 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TOBRASON | TOBRAMYCIN + DEXAMETHASONE | 3 MG + 1 MG/1G | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | INDIA | OPHTHALMIC OINTMENTS | 1.0X1.0X5.0 MG TUBE | 09/12/2020 |

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| 3933 | NDA/MAL/HDP/9367 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | XENAMEX | TRANEXAMIC ACID | 100MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X10.0X5.0 ML VIAL | 09/12/2020 |
| 3934 | NDA/MAL/HDP/9368 | HETERO BIOPHARMA LIMITED, | AIVEEN (U) LIMITED | BEVAAS 400 | BEVACIZUMAB | 400MG/16ML | HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA. | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X16.0 ML VIAL | 09/12/2020 |
| 3935 | NDA/MAL/HDP/9370 | RAINBOW LIFE SCIENCES PVT.LTD. | EUROPA HEALTHCARE (U) LTD | MONTLIV | MONTELUKAST + LEVOCETIRIZINE DIHYDROCHLORIDE | 10 MG+ 5 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 18/12/2020 |

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| 3936 | NDA/MAL/HDP /9376 | KOPRAN LIMITED | TATA UGANDA LIMITED | AZ-1 500 | AZITHROMYCIN DIHYDRATE | 500 MG | KOPRAN LIMITED-VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X1.0X3.0 TABLET BLISTER | 09/12/2020 |
| 3937 | NDA/MAL/HDP /9377 | KOPRAN LIMITED | TATA UGANDA LIMITED | AMYN DT 250 | AMOXICLLIN TRIHYDRATE | 250 MG | KOPRAN LIMITED-VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X3.0X15.0 TABLET STRIP,10.0X10.0 TABLET STRIP | 09/12/2020 |
| 3938 | NDA/MAL/HDP /9379 | KOPRAN LIMITED | TATA UGANDA LIMITED | AMYN DT 125 | AMOXICILLIN TRIHYDRATE | 125 MG | KOPRAN LIMITED-VILLAGE - SAVROLI (KHOPOLI), TALUKA - KHALAPUR, DIST. RAIGAD 410202, MAHARASHTRA INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X3.0X15.0 TABLET STRIP,10.0X10.0 TABLET STRIP | 09/12/2020 |

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| 3939 | NDA/MAL/HDP/9383 | SUN PHARMACEUTICAL INDUSTRIES LTD | STAR PHARMACEUTICALS LTD | DOLUTEGRAVIR, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE TABLETS | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50 MG + 300 MG + 300 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)-VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER,1.0X1.0X90.0 TABLET CONTAINER | 09/12/2020 |
| 3940 | NDA/MAL/HDP/9385 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BRUZOLIN | XYLOMETAZOLINE HYDROCHLORIDE | 0.05% W/V | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | NASAL SYSTEMIC DROPS | 1.0X1.0X15.0 ML BOTTLE | 09/12/2020 |
| 3941 | NDA/MAL/HDP/9387 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | DIPHTHERIA AND TETENUS VACCINE ADSORBED FOR ADULTS AND ADOLESCENTS | DIPHTHERIA + TETANUS + ALUMINIUM PHOSPHATE | ≤ 5 LF (≥ 2 IU) + ≤ 5 LF (≥ 40 IU) + ≤ 1.25 MG/DOSE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0X10.0 DOSE VIAL,1.0X5.0X10.0X1.0 DOSE AMPOULE | 09/12/2020 |

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| 3942 | NDA/MAL/HDP/9389 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | DIPHTHERIA, TETANUS, PERTUSSIS, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINE ADSORBED | DIPHTHERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE + ALUMINIUM PHOSPHATE | ≤ 25 LF (≥ 30 IU) + ≥ 2.5 LF (≥ 40 IU) + ≤ 16 OU (≥ 4.0 IU) + ≥ 10 MCG + ≥ 10 MCG + ≤ 1.25 MG/DOSE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0X10.0 DOSE VIAL | 09/12/2020 |
| 3943 | NDA/MAL/HDP/9393 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | LESS-K | CALCIUM POLYSTYRENE SULFONATE | 5 GM/SACKET | MEGA LIFESCIENCES PUBLIC COMPANY LTD-PLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND | THAILAND | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X100.0X5.0 G SACHET | 18/12/2020 |
| 3944 | NDA/MAL/HDP/9396 | REMEDICA LTD | GOODMAN INTERNATIONAL LTD | KORANDIL | ENALAPRIL MALEATE | 20 MG | REMEDICA LTD-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL | CYPRUS | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 18/12/2020 |

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| 3945 | NDA/MAL/HDP/9397 | ROYAL GROUP TRADING FZC E LOB OFFICE | HARLEYS UGANDA LIMITED | ROGOXONE | CEFTRIAXONE SODIUM | 1GM/VIAL | CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD-NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL | 18/12/2020 |
| 3946 | NDA/MAL/HDP/9401 | BESINS HEALTHCARE SA | SURGIPHARM (U) LIMITED | UTROGESTAN | PROGESTERONE | 100 MG | CYNDEA PHARMA, S.L-POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA) | SPAIN | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X2.0X15.0 CAPSULE BLISTER | 18/12/2020 |
| 3947 | NDA/MAL/HDP/9403 | S K AGE EXPORTS | ABACUS PHARMA (AFRICA) LIMITED | LARTEM | ARTEMETHER + LUMEFANTRINE | 20 MG + 120 MG | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X24.0 TABLET BLISTER | 22/12/2020 |

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| 3948 | NDA/MAL/HDP/9404 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | SOFTDROPS | CARBOXYMETHYLCELLULOSE SODIUM + GLYCERIN | 0.5% W/V + 0.5% W/V | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | OPHTHALMIC DROPS | 1.0X1.0X10.0 ML BOTTLE | 09/12/2020 |
| 3949 | NDA/MAL/HDP/9408 | MEGA LIFESCIENCES PUBLIC COMPANY LTD | ABACUS PHARMA (AFRICA) LIMITED | ZIRIN | CETIRIZINE DIHYDROCHLORIDE | 10 MG | MEGA LIFESCIENCES PUBLIC COMPANY LTD-PLANT 2; 515/1 MOO 4, SOI 8 BANGPOO INDUSTRIAL ESTATE PATTANA 3 ROAD, PHRAEKSA, MUEANG, SAMUTPRAKARN 10280, THAILAND | THAILAND | ORAL SOLID ORDINARY OTHER CAPSULES | 1.0X5.0X10.0 CAPSULE BLISTER | 18/12/2020 |
| 3950 | NDA/MAL/HDP/9409 | HETERO LABS LTD | AIVEEN (U) LIMITED | STAVANCE 500 | VANCOMYCIN HYDROCHLORIDE | 500 MG/VIAL | ASPIRO PHARMA LIMITED-SY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X500.0 MG VIAL | 18/12/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3951 | NDA/MAL/HDP/9410 | HETERO LABS LTD | AIVEEN (U) LIMITED | STAVANCE 1 | VANCOMYCIN HYDROCHLORIDE | 1G/VIAL | ASPIRO PHARMA LIMITED-SY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL | 18/12/2020 |
| 3952 | NDA/MAL/HDP/9411 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR AMLO 5 +5 | BISOPROLOL FUMARATE + AMLODIPINE BESILATE | 5MG + 5MG | EGIS PHARMACEUTICALS PLC-BOKENYFOLDI UT 118-120, 1165 BUDAPEST | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 22/12/2020 |
| 3953 | NDA/MAL/HDP/9412 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | EBASTO - 10 | EBASTINE | 10 MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 09/12/2020 |

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| 3954 | NDA/MAL/HDP /9413 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR AMLO 10 + 5 | BISOPROLOL FUMARATE + AMLODIPINE BESILATE | 10MG + 5MG | EGIS PHARMACEUTICALS PLC-BOKENYFOLDI UT 118-120, 1165 BUDAPEST | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 22/12/2020 |
| 3955 | NDA/MAL/HDP /9415 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR AMLO 10 + 10 | BISOPROLOL FUMARATE + AMLODIPINE BESILATE | 10MG + 10MG | EGIS PHARMACEUTICALS PLC-BOKENYFOLDI UT 118-120, 1165 BUDAPEST | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 22/12/2020 |
| 3956 | NDA/MAL/HDP /9416 | MERCK (PTY) LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | CONCOR AMLO 5 + 10 | BISOPROLOL FUMARATE + AMLODIPINE BESILATE | 5MG + 10MG | EGIS PHARMACEUTICALS PLC-BOKENYFOLDI UT 118-120, 1165 BUDAPEST | HUNGARY | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 22/12/2020 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 3957 | NDA/MAL/HDP/9417 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | UNIBET CREAM | BETAMETHASONE DIPROPIONATE | 0.05 % W/W | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 09/12/2020 |
| 3958 | NDA/MAL/HDP/9418 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS | EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 400 MG + 300 MG + 300 MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER,1.0X180.0 TABLET CONTAINER | 09/12/2020 |
| 3959 | NDA/MAL/HDP/9421 | CADILA HEALTH CARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | MUCOSIL AM | TERBUTALINE SULFATE + GUAIFENESIN + AMBROXOL HYDROCHLORIDE + MENTHOL | 1.25 MG + 50 MG + 15 MG + 2.5 MG/5 ML | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 09/12/2020 |

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| 3960 | NDA/MAL/HDP/9428 | LUPIN LIMITED | AIVEEN (U) LIMITED | RIFAMPIN AND ISONIAZID DISPERSIBLE TABLETS | RIFAMPIN + ISONIAZID | 75 MG + 50 MG | LUPIN LIMITED -A-28/1 MIDC CHIKALTHANA AURANGABAD | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X14.0X6.0 TABLET STRIP | 09/12/2020 |
| 3961 | NDA/MAL/HDP/9430 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | VALK PLUS SP | ACECLOFENAC + PARACETAMOL+ SERRATIOPEPTIDASE | 100 MG + 500 MG +10 MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER | 09/12/2020 |
| 3962 | NDA/MAL/HDP/9431 | INTAS PHARMACEUTICALS LIMITED | NORVIK ENTERPRISES LIMITED | NALTRAS 50 | NALTREXONE HYDROCHLORIDE | 50 MG | INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 18/12/2020 |

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| 3963 | NDA/MAL/HDP/9433 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | ADACIN | ADAPALENE + CLINDAMYCIN PHOSPHATE | 0.1 %W/W + 1.0% W/W | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X15.0 G TUBE | 09/12/2020 |
| 3964 | NDA/MAL/HDP/9434 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | LAVAGEM | BISACODYL | 5MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY ENTERIC COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 09/12/2020 |
| 3965 | NDA/MAL/HDP/9436 | SAKAR HEALTHCARE PVT LTD | TATA UGANDA LIMITED | SEFIXI-200 | CEFIXIME TRIHYDRATE | 200MG | SAKAR HEALTHCARE PVT LIMITED-PLOT 10/13 SARKHEJ-BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 09/12/2020 |

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| 3966 | NDA/MAL/HDP/9440 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | XOLAMOL | DORZOLAMIDE HYDROCHLORIDE + TIMOLOL MALEATE | 2%W/V + 0.5%W/V/ML | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 18/12/2020 |
| 3967 | NDA/MAL/HDP/9441 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | PARAVIN | PARACETAMOL | 10MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X12.0X100.0 ML VIAL,1.0X1.0X100.0 ML VIAL | 09/12/2020 |
| 3968 | NDA/MAL/HDP/9442 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VOMIRAN | ONDANSETRON HYDROCHLORIDE | 2MG/ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X2.0 ML VIAL | 09/12/2020 |

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| 3969 | NDA/MAL/HDP/9447 | JAMJOOM PHARMACEUTICALS COMPANY | MU PHARMA CO - SMC LIMITED | FUSIBACT-B | FUSIDIC ACID + BETAMETHASONE VALERATE | 2% W/W + 0.1% W/W | JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH | SAUDI ARABIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 18/12/2020 |
| 3970 | NDA/MAL/HDP/9450 | ACME FORMULATIONS LIMITED | PHARMA VILLE LIMITED | MIFESO | MIFEPRISTONE + MISOPROSTOL | 200MG + 200MCG | ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 18/12/2020 |
| 3971 | NDA/MAL/HDP/9452 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BNOXIPARIN 40 | ENOXAPARIN SODIUM | 40 MG/0.4 ML | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.4 ML PRE-FILLED SYRINGE | 09/12/2020 |

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| 3972 | NDA/MAL/HDP/9453 | BRAWN LABORATORIES LTD | GOOD DAY PHARMACY LIMITED | BNOXIPARIN 60 | ENOXAPARIN SODIUM | 60 MG/0.6 ML | BRAWN LABORATORIES LIMITED-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA, INDIA | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X0.6 ML PRE-FILLED SYRINGE | 09/12/2020 |
| 3973 | NDA/MAL/HDP/9455 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BISPEC-5 | SOLIFENACIN SUCCINATE | 5MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 03/02/2021 |
| 3974 | NDA/MAL/HDP/9456 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | BISPEC-10 | SOLIFENACIN SUCCINATE | 10MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 03/02/2021 |

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| 3975 | NDA/MAL/HDP/9490 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | IPEN-CIL | IMIPENEM + CILASTATIN | 500 MG + 500 MG/VIAL | ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 04/03/2021 |
| 3976 | NDA/MAL/HDP/9494 | ZIM LABORATORIES LTD | ABACUS PHARMA (AFRICA) LIMITED | ONDANSET ODS 8 | ONDANSETRON HYDROCHLORIDE | 8 MG/STRIP | ZIM LABS LTD.-B 21/22, MIDC AREA, KALMESHWAR 441501, DIST-NAGPUR | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0X1.0 TABLET STRIP | 04/03/2021 |
| 3977 | NDA/MAL/HDP/9501 | BESINS HEALTHCARE SA | SURGIPHARM (U) LIMITED | UTROGESTAN VAGINAL 100 MG | PROGESTERONE | 100 MG | CYNDEA PHARMA, S.L-POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA) | SPAIN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X15.0 CAPSULE BLISTER | 04/03/2021 |

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| 3978 | NDA/MAL/HDP/9502 | BESINS HEALTHCARE SA | SURGIPHARM (U) LIMITED | UTROGESTAN VAGINAL 200 MG | PROGESTERONE | 200 MG | CYNDEA PHARMA, S.L-POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA) | SPAIN | VAGINAL CAPSULES | 1.0X1.0X7.0X1.0X8.0 CAPSULE BLISTER | 04/03/2021 |
| 3979 | NDA/MAL/HDP/9503 | BESINS HEALTHCARE SA | SURGIPHARM (U) LIMITED | UTROGESTAN 200 MG SOFT CAPSULES | PROGESTERONE | 200 MG | CYNDEA PHARMA, S.L-POLIGONO INDUSTRIAL EMILIANO REVILLA SANZ. AVDA. DE AGREDA, 31 OLVEGA 42110 (SORIA) | SPAIN | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X8.0X3.0X7.0 CAPSULE BLISTER | 04/03/2021 |
| 3980 | NDA/MAL/HDP/9504 | BETA HEALTHCARE INTERNATIONAL LIMITED | BETA HEALTHCARE UGANDA LIMITED | BETA COOL DOUBLE ACTION ANTACID SUSPENSION | SODIUM ALGINATE + SODIUM BICARBONATE | (500 MG + 267 MG)/10 ML | BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD | KENYA | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X200.0 ML BOTTLE | 24/02/2021 |

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| 3981 | NDA/MAL/HDP/9505 | CADILA HEALTHCARE LIMITED "ZYDUS TOWER" - | ABACUS PHARMA (AFRICA) LIMITED | ODIMONT-LC | LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST | 5 MG + 10 MG | RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 04/03/2021 |
| 3982 | NDA/MAL/HDP/9506 | TROIKAA PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | TROFENTYL | FENTANYL CITRATE | 50 MCG/ML | TROIKAA PHARMACEUTICALS LIMITED,,-C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X2.0 ML AMPOULE | 24/02/2021 |
| 3983 | NDA/MAL/HDP/9509 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | TOBIDERM | BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + TOLNAFTATE + IODOCHLORHYDROXYQUINOLINE | (0.643 MG + 1.0 MG + 10 MG + 10 MG)/G | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 04/03/2021 |

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| 3984 | NDA/MAL/HDP/9510 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | GEODERM | BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE | (0.5 MG + 1.0 MG + 10.0 MG)/G | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE,1.0X30.0 G TUBE | 04/03/2021 |
| 3985 | NDA/MAL/HDP/9511 | PINNACLE LIFE SCIENCE PVT. LTD | ABACUS PHARMA (AFRICA) LIMITED | SPASNIL FORTE TABLET | MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE | 250 MG + 10 MG | PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/02/2021 |
| 3986 | NDA/MAL/HDP/9513 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | METRONIDAZOLE INFUSION BP | METRONIDAZOLE | 0.5% W/V | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 24/02/2021 |

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| 3987 | NDA/MAL/HDP/9514 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | BACTAFUZ | FUSIDIC ACID | 2% W/W | ENCUBE ETHICALS PVT LTD-PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 24/02/2021 |
| 3988 | NDA/MAL/HDP/9515 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | BACTAFUZ-B | FUSIDIC ACID + BETAMETHASONE VALERATE | 2% W/W + 0.1%W/W | ENCUBE ETHICALS PVT LTD-PLOT C-1, MADKAIM INDUSTRIAL ESTATE, MADKAIM, POST: MARDOL, PONDA GOA-403404 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 24/02/2021 |
| 3989 | NDA/MAL/HDP/9524 | STRIDES PHARMA SCIENCE LIMITED | DELMAW ENTERPRISES LIMITED | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ DOLUTEGRAVIR TABLETS | TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE + DOLUTEGRAVIR SODIUM | 300 MG + 300 MG + 50 MG | STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE | 24/02/2021 |

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| 3990 | NDA/MAL/HDP/9525 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | SPAQ-CO DISP | (SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE | (250 MG + 12.5 MG) +76.5 MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X4.0 TABLET BLISTER | 04/03/2021 |
| 3991 | NDA/MAL/HDP/9526 | SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD | TRIDEM PHARMA UGANDA LIMITED | SPAQ-CO DISP | (SULFADOXINE + PYRIMETHAMINE) + AMODIAQUINE HYDROCHLORIDE | (500 MG + 25 MG) +153 MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X4.0 TABLET BLISTER | 04/03/2021 |
| 3992 | NDA/MAL/HDP/9527 | AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD | HEALTHCARE LTD. | PARASYP | PARACETAMOL | 120 MG/5 ML | AL FAZAL PHARMA INDUSTRIES (PVT) LTD-PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN | PAKISTAN | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE | 04/03/2021 |

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| 3993 | NDA/MAL/HDP/9528 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ONDANSETRON ORAL DISPERSIBLE TABLETS | ONDANSETRON | 8MG | ATHENA DRUG DELIVERY SOLUTIONS PVT LTD ,.-PLOT A-1 TO A-5, MIDC CHEMICAL ZONE, AMBERNATH (W) THANE 421501, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 04/03/2021 |
| 3994 | NDA/MAL/HDP/9533 | LUPIN LTD | AIVEEN (U) LIMITED | ISONIAZID TABLETS BP 100MG | ISONIAZID | 100 MG | LUPIN LTD-A-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD-431210, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 04/03/2021 |
| 3995 | NDA/MAL/HDP/9534 | GUILIN PHARMACEUTICAL CO.LTD | TRIDEM PHARMA UGANDA LIMITED | PHLORO-G | PHLOROGLUCINOL DIHYDRATE | 80MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 24/02/2021 |

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| 3996 | NDA/MAL/HDP/9535 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | ARISTO DURATAZ INJECTION 4.5 G | PIPERACILLIN + TAZOBACTAM | (4 G + 0.5 G)/VIAL | ARISTO PHARMACEUTICALS PVT LTD-PLOT 208, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP 462046 DIST. RAISEN (MP) | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X4.5 G VIAL | 04/03/2021 |
| 3997 | NDA/MAL/HDP/9536 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | LAXMAG | POLYETHYLENE GLYCOL + SODIUM CHLORIDE + SODIUM HYDROGEN CARBONATE + POTASSIUM CHLORIDE | (13.125 G + 350.7 MG + 178.5 MG + 46.6 MG)/SACHET | STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106 | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X10.0X13.72 G SACHET | 04/03/2021 |
| 3998 | NDA/MAL/HDP/9537 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | SENSOCAIN SPINAL 0.5% INJECTION | BUPIVACAINE HYDROCHLORIDE | 5MG/ML | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X4.0 ML AMPOULE | 04/03/2021 |

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| 3999 | NDA/MAL/HDP/9538 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | ECZEMUS 0.1 % OINTMENT | TACROLIMUS MONOHYDRATE | 0.1% W/W | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | TOPICAL EXTERNAL OINTMENTS | 1.0X10.0 G TUBE | 04/03/2021 |
| 4000 | NDA/MAL/HDP/9541 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ERLOCIP 25 | ERLOTINIB HYDROCHLORIDE | 25MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 04/03/2021 |
| 4001 | NDA/MAL/HDP/9542 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ERLOCIP 100 | ERLOTINIB HYDROCHLORIDE | 100MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 04/03/2021 |

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| 4002 | NDA/MAL/HDP/9543 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ERLOCIP 150 | ERLOTINIB HYDROCHLORIDE | 150MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 04/03/2021 |
| 4003 | NDA/MAL/HDP/9546 | STRIDES PHARMA SCIENCE LIMITED | DELMAW ENTERPRISES LIMITED | ALU 80/480 | ARTEMETHER + LUMEFANTRINE | 80MG + 480MG | STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X6.0 IMPLANT BLISTER | 24/02/2021 |
| 4004 | NDA/MAL/HDP/9549 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | DUOSKIN | ISOCONAZOLE NITRATE + DIFLUCORTOLONE VALERATE | 1% W/W + 0.1% W/W | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 24/02/2021 |

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| 4005 | NDA/MAL/HDP/9550 | OCTOBER PHARMA- | ABACUS PHARMA (AFRICA) LIMITED | BRONCHOPRO | AMBROXOL HYDROCHLORIDE | 7.5MG/ML | OCTOBER PHARMA-1ST INDUSTRIAL ZONE, STREET 25 PLOT 190, 6TH OCTOBER CITY CAIRO, ARAB REPUBLIC OF EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X30.0 ML BOTTLE | 04/03/2021 |
| 4006 | NDA/MAL/HDP/9551 | DEVA HOLDING A.S- | SHREEJI PHARMACEUTICALS LIMITED | LUXAT | MONTELUKAST SODIUM | 10MG | DEVA HOLDING A.S-CERKEZKOY ORGANIZE SANAYI BOLGESI, KARAAGAC MAH., ATATURK CAD., NO.: 32 KAPAKLI TEKIRDAG | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 04/03/2021 |
| 4007 | NDA/MAL/HDP/9552 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | HOPEIN 1000 MG | MEROPENEM TRIHYDRATE | 1000MG | ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 G VIAL | 04/03/2021 |

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| 4008 | NDA/MAL/HDP/9576 | SAVA HEALTHCARE LIMITED - | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | FLUTIAIR | FLUTICASONE PROPIONATE | 0.05%W/V | SAVA HEALTHCARE LIMITED.-PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA | INDIA | NASAL TOPICAL SPRAYS WITHOUT GAS | 1.0X1.0X10.0 ML VIAL | 03/06/2021 |
| 4009 | NDA/MAL/HDP/9586 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | AMVA DENK 5/160 MG | AMLODIPINE + VALSARTAN | 5 MG + 160 MG | BALKANPHARMA-DUPNITSA AD-3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA | BULGARIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 03/06/2021 |
| 4010 | NDA/MAL/HDP/9587 | GOODMAN INTERNATIONAL LTD | GOODMAN INTERNATIONAL LTD | TAFIXYL™ 500 MG | TRANEXAMIC ACID | 500 MG | LABIANA PHARMACEUTICALS, S.L.U.-C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA) | SPAIN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER | 04/06/2021 |

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| 4011 | NDA/MAL/HDP /9588 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | AMVA DENK 10/160 MG | AMLODIPINE BESILATE + VALSARTAN | 10 MG + 160 MG | BALKANPHARMA-DUPNITSA AD-3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA | BULGARIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 03/06/2021 |
| 4012 | NDA/MAL/HDP /9589 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | CLOFAZIMINE TABLETS 100MG | CLOFAZIMINE | 100 MG | OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET STRIP | 04/06/2021 |
| 4013 | NDA/MAL/HDP /9590 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | AMVA DENK 5/80 MG | AMLODIPINE BESILATE + VALSARTAN | 5 MG + 80 MG | BALKANPHARMA-DUPNITSA AD-3, SAMOKOVSKO SHOSSE STR. 2600 DUPNITSA | BULGARIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X14.0 TABLET BLISTER | 03/06/2021 |

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| 4014 | NDA/MAL/HDP /9594 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | ROSUVASTATIN DENK 10 MG | ROSUVASTATIN CALCIUM | 10 MG | PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |
| 4015 | NDA/MAL/HDP /9595 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | ROSUVASTATIN DENK 20 MG | ROSUVASTATIN CALCIUM | 20 MG | PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |
| 4016 | NDA/MAL/HDP /9596 | DENK PHARMA GMBH & CO | BENLE CONSULT LIMITED | ROSUVASTATIN DENK 5 MG | ROSUVASTATIN CALCIUM | 5 MG | PHARMACEUTICAL WORKS POLPHARMA SA (ZAKLADY FARMACEUTYCZNE POLPHARMA SA)-19 PELPLINSKA STREET, 83-200 STAROGARD GDANSKI | POLAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |

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| 4017 | NDA/MAL/HDP/9600 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VIVAZAC 150 MG | IRBESARTAN | 150 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 02/06/2021 |
| 4018 | NDA/MAL/HDP/9601 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SENERGY 5/160MG | AMLODIPINE BESYLATE + VALSARTAN | 5 MG + 160 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |
| 4019 | NDA/MAL/HDP/9602 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SENERGY 10/160MG | AMLODIPINE BESYLATE + VALSARTAN | 10 MG + 160 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |

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| 4020 | NDA/MAL/HDP/9603 | MYLAN LABORATORIES LIMITED | KIMSY MEDS LTD | KOCITAF | DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE FUMARATE | 50 MG + 200 MG + 25 MG | MYLAN LABORATORIES LTD-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH; | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 03/06/2021 |
| 4021 | NDA/MAL/HDP/9604 | AMRING FARMA S.R.L | ERIS LTD | PROPOFOL AMRING | PROPOFOL | 10 MG/ML | BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITED-CHACHARWADI - VASANA, AHMEDABAD, IN 382213 | INDIA | PARENTERAL ORDINARY OTHER INFUSIONS | 1.0X5.0X20.0 ML VIAL | 03/06/2021 |
| 4022 | NDA/MAL/HDP/9605 | SAKAR HEALTHCARE LIMITED - | ROYAL PHARMA 2011 LIMITED | PENTOKAR | PANTOPRAZOLE SODIUM SESQUIHYDRATE | 40 MG/VIAL | SAKAR HEALTHCARE PVT LTD-BLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X40.0 MG VIAL | 03/06/2021 |

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| 4023 | NDA/MAL/HDP/9609 | ZIM LABORATORIES LTD | ABACUS PHARMA (AFRICA) LIMITED | CETRIZIM L ODS | LEVOCETIRIZINE DIHYDROCHLORIDE | 5 MG | ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS | 1.0X10.0 TABLET STRIP | 03/06/2021 |
| 4024 | NDA/MAL/HDP/9610 | REDDYS PHARMA LIMITED | REDDYS PHARMA LIMITED | LASOFLOX-O | OFLOXACIN + ORNIDAZOLE | 200 MG + 500 MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 03/06/2021 |
| 4025 | NDA/MAL/HDP/9611 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ESOMAC-40 MUPS | ESOMEPRAZOLE MAGNESIUM DIHYDRATE | 40 MG | CIPLA LIMITED.-PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |

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| 4026 | NDA/MAL/HDP/9612 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ESOMAC-20 MUPS | ESOMEPRAZOLE MAGNESIUM DIHYDRATE | 20 MG | CIPLA LIMITED.-PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X2.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER | 03/06/2021 |
| 4027 | NDA/MAL/HDP/9613 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | IVABEAT 5 | IVABRADINE HYDROCHLORIDE | 5 MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 03/06/2021 |
| 4028 | NDA/MAL/HDP/9614 | CIPLA LTD | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | IVABEAT 7.5 | IVABRADINE HYDROCHLORIDE | 7.5 MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X14.0 TABLET BLISTER | 03/06/2021 |

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| 4029 | NDA/MAL/HDP/9615 | ARTEPHARM CO., LTD., | BHL HEALTHCARE LIMITED | ARTEQUICK | ARTEMISININ + PIPERAQUINE | 62.5 MG + 375 MG | ARTEPHARM CO. LTD-4 ROAD STREET AVENUE ECONOMY DEVELOPMENT ZONE OF FENGSHUN COUNTY MEIZHOU CITY GUANGDONG PRONVINCE | CHINA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 02/06/2021 |
| 4030 | NDA/MAL/HDP/9618 | MSN LABORATORIES PRIVATE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EMCAP 500 | CAPECITABINE | 500 MG | MSN LABORATORIES PRIVATE LIMITED-UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY DISTRICT, PIN CODE, 509 228, TELENGANA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 02/06/2021 |
| 4031 | NDA/MAL/HDP/9619 | AUROLAB | SWASTIK PHARMACEUTICAL LTD | AUROMIDE PLUS | TROPICAMIDE + PHENYLEPHRINE HYDROCHLORIDE | 0.8% W/V + 5%W/V | AUROLAB LIMITED-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU INDIA | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X5.0 ML CONTAINER | 02/06/2021 |

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| 4032 | NDA/MAL/HDP/9620 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | DOLUTEGRAVIR TABLETS | DOLUTEGRAVIR SODIUM | 50 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)- VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 03/06/2021 |
| 4033 | NDA/MAL/HDP/9621 | FDC LIMITED - | AIVEEN (U) LIMITED | ELECTRAL-Z KIT | ZINC SULPHATE MONOHYDRATE + (SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM CITRATE + ANHYDROUS GLUCOSE) | 20 MG + (2.6 G + 1.5 G + 2.9 G + 13.5 G)/SACHET | FDC LTD.-L-56&L-57, PHASE II- D, VERNA INDUSTRIAL ESTATE, VERNA-403 722, SALCETE, GOA | INDIA | ORAL LIQUID ORDINARY SOLUBLE POWDERS | 1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X2 1.8 G SACHET COMBIPACK | 03/06/2021 |
| 4034 | NDA/MAL/HDP/9622 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | VITALIPID NOVUM ADULT | VITAMIN A + VITAMIN D2 + VITAMIN E + VITAMIN K1 | 330 IU + 20 IU + 1 IU + 15 µG/ML | FRESENIUS KABI AB-RAPSGATAN 7, 751 74 UPPSALA - SWEDEN | SWEDEN | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0 ML AMPOULE | 03/06/2021 |

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| 4035 | NDA/MAL/HDP /9623 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | VITALIPID NOVUM INFANT | VITAMIN A + VITAMIN D2 + VITAMIN E + VITAMIN K1 | 230 IU + 40 IU + 0.7 IU + 20 µG/ML | FRESENIUS KABI AB-RAPSGATAN 7, UPPSALA, SE-751 74 | SWEDEN | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0 ML AMPOULE | 03/06/2021 |
| 4036 | NDA/MAL/HDP /9624 | ADCOCK INGRAM LIMITED | SURGIPHARM (U) LIMITED | ADCO-IBUPROFEN 400 MG | IBUPROFEN | 400 MG | ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE<br><br>560099, KARNATAKA STATE, INDIA | INDIA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X1.0X12.0 TABLET BLISTER | 03/06/2021 |
| 4037 | NDA/MAL/HDP /9626 | GILEAD SCIENCES INC | MEDICAL ACCESS (UGANDA) LIMITED | BIKTARVY | BICTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE | 50 MG + 200 MG + 25 MG | GILEAD SCIENCES IRELAND UC,CORK-IDA BUSINESS & TECHNOLOGY PARK, CARRIGTOHILL, COUNTY CORK, | IRELAND | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 03/06/2021 |

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| 4038 | NDA/MAL/HDP/9627 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RIMEXA | ROCURONIUM BROMIDE | 50 MG/5ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X10.0X5.0 ML VIAL | 03/06/2021 |
| 4039 | NDA/MAL/HDP/9628 | UNICHEM LABORATORIES LIMITEDv | EUROPA HEALTHCARE (U) LTD | MPLIFY 20 | TADALAFIL | 20 MG | UNICHEM LABORATORIES LTD-PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X1.0 TABLET BLISTER | 03/06/2021 |
| 4040 | NDA/MAL/HDP/9629 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | DECOZAL | XYLOMETAZOLINE HYDROCHLORIDE | 0.5 MG/ML | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | NASAL SYSTEMIC METERED-DOSE LIQUIDS | 1.0X1.0X10.0 ML BOTTLE | 02/06/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4041 | NDA/MAL/HDP /9631 | DAWA LIMITED | SUPER MEDIC LTD | DAWASOLONE | PREDNISOLONE SODIUM PHOSPHATE | 5 MG/5 ML | DAWA LIMITED-PLOT NO. 7879/8 BABADOGO ROAD, RUARAKA P. O. BOX 16633-00620 NAIROBI, KENYA | KENYA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X60.0 ML BOTTLE | 02/06/2021 |
| 4042 | NDA/MAL/HDP /9632 | AGIO PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | CANISON VAGINAL 100 | CLOTRIMAZOLE | 100 MG | AGIO PHARMACEUTICALS LIMITED.-T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA | INDIA | VAGINAL TABLETS | 1.0X1.0X6.0 TABLET STRIP | 03/06/2021 |
| 4043 | NDA/MAL/HDP /9633 | AGIO PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | AGILAX | LACTULOSE SOLUTION | 3.35G/5ML | AGIO PHARMACEUTICALS LIMITED.-T- 81, 82, MIDC, BHOSARI, PUNE - 411 026 INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 03/06/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4044 | NDA/MAL/HDP/9634 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | RABISHIELD - 100 | RABIES HUMAN MONOCLONAL ANTIBODY (RDNA) | 40 IU/ ML | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X2.5 ML VIAL | 03/06/2021 |
| 4045 | NDA/MAL/HDP/9636 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | ALTHEMOL | PARACETAMOL | 1.0 % W/V (1G/100 ML) | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 02/06/2021 |
| 4046 | NDA/MAL/HDP/9637 | SERUM INSTITUTE OF INDIA PVT LTD | NORVIK ENTERPRISES LIMITED | PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE | PNEUMOCOCCAL SACCHARIDE FOR SEROTYPE 1, 5, 6A, 7F, 9V, 14, 19A, 19F AND 23F + SACCHARIDE FOR SEROTYPE 6B | (2 MCG OF PNEUMOCOCCAL SACCHARIDE FOR SEROTYPE 1, 5, 6A, 7F, 9V, 14, 19A, 19F AND 23F + 4 MCG OF SACCHARIDE FOR SEROTYPE 6B)/ DOSE | SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X50.0X1.0 DOSE VIAL,1.0X50.0X5.0 DOSE VIAL | 03/06/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4047 | NDA/MAL/HDP /9638 | LUPIN LIMITED- | AIVEEN (U) LIMITED | RIFAMPICIN AND ISONIAZID TABLETS | RIFAMPICIN + ISONIAZID | 150 MG + 75 MG | LUPIN LTD-A-28/1, M.I.D.C., CHIKALTHANA, AURANGABAD-431210, MAHARASHTRA, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X24.0X28.0 TABLET BLISTER | 03/06/2021 |
| 4048 | NDA/MAL/HDP /9640 | BERLIN-CHEMIE AG - | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PRILIGY 30 MG | DAPOXETINE HYDROCHLORIDE | 30 MG | MENARINI - VON HEYDEN GMBH-LEIPZIGER STRABE 7-13, 01097 DRESDEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 02/06/2021 |
| 4049 | NDA/MAL/HDP /9641 | BERLIN-CHEMIE AG - | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PRILIGY 60 MG | DAPOXETINE HYDROCHLORIDE | 60 MG | MENARINI - VON HEYDEN GMBH-LEIPZIGER STRABE 7-13, 01097 DRESDEN | GERMANY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X3.0 TABLET BLISTER | 02/06/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4050 | NDA/MAL/HDP/9643 | SUN PHARMACEUTICAL INDUSTRIES LIMITED | STAR PHARMACEUTICALS LTD | ABACAVIR (AS SULFATE) AND LAMIVUDINE TABLETS | ABACAVIR SULFATE + LAMIVUDINE | 600MG + 300 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)- VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X90.0 TABLET CONTAINER | 03/06/2021 |
| 4051 | NDA/MAL/HDP/9644 | PLANET PHARMACEUTICALS UGANDA LTD | PLANET PHARMACEUTICALS UGANDA LTD | HYDROMAX | HYDROCORTISONE | 1.0 % W/W | KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506 | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 03/06/2021 |
| 4052 | NDA/MAL/HDP/9645 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | HALOPERIDOL INJECTION BP 5 MG/ML | HALOPERIDOL | 5 MG/ML | SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X1.0 ML AMPOULE,1.0X10.0X1.0 ML AMPOULE | 04/06/2021 |

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| 4053 | NDA/MAL/HDP/9651 | PT SANBE FARMA | MEDVIN PHARMA LIMITED | SANTOCYN | OXYTOCIN | 10 IU/ML | PT SANBE FARMA UNIT 3.-JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG | INDONESIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X1.0 ML AMPOULE | 02/06/2021 |
| 4054 | NDA/MAL/HDP/9652 | SUN PHARMACEUTICAL INDUSTRIES LIMITED - | STAR PHARMACEUTICALS LTD | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE 300 MG/300 MG TABLETS | LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 300 MG + 300 MG | SUN PHARMACEUTICAL INDUSTRIES LIMITED (FORMERLY RANBAXY LABORATORIES LIMITED)- VILLAGE GANGUWALA. PAONTA SAHIB DISTRICT SIRMOUR - 173025 (H.P), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET BLISTER | 04/06/2021 |
| 4055 | NDA/MAL/HDP/9653 | LABORATE PHARMACEUTICALS INDIA LIMITED | HEALTHCARE LTD. | FERROUS SULPHATE WITH FOLIC ACID TABLETS | FERROUS SULPHATE + FOLIC ACID | 60 MG + 0.6 MG | LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 04/06/2021 |

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| 4056 | NDA/MAL/HDP/9655 | ABACUS PHARMA (A) LTD. | ABACUS PHARMA (AFRICA) LIMITED | METOCLOPRAMIDE INJECTION BP 5 MG/ML | METOCLOPRAMIDE HYDROCHLORIDE | 5 MG/ML | PSYCHOTROPICS INDIA LTD-PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 04/06/2021 |
| 4057 | NDA/MAL/HDP/9659 | FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED | SURGIPHARM (U) LIMITED | VOLUVEN | POLY (O-2-HYDROXYETHYL) STARCH (HES 130/0.4) | 60 G/1000 ML | FRESENIUS KABI MANUFACTURING SA (PTY) LTD,,-6 GLOBAL ROAD, KORSTEN, PORT ELIZABETH, 6014 | SOUTH AFRICA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X500.0 ML BAG | 04/06/2021 |
| 4058 | NDA/MAL/HDP/9663 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | POVIREN | POVIDONE + IODINE | 10% W/V | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | TOPICAL EXTERNAL LIQUIDS | 1.0X200.0 ML BOTTLE,1.0X1000.0 ML BOTTLE | 04/06/2021 |

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| 4059 | NDA/MAL/HDP/9665 | CADILA HEALTH CARE LIMITED | ABACUS PHARMA (AFRICA) LIMITED | ZYNAC-SP | ACECLOFENAC + PARACETAMOL + SERRATIOPEPTIDASE | 100 MG + 325 MG + 15 MG | RAVIAN LIFE SCIENCE PVT. LIMITED-PLOT NO. 34, SECTOR: 8A, SIDCUL, IIE, HARIDWAR - 249403, UTTARAKHAND | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 04/06/2021 |
| 4060 | NDA/MAL/HDP/9668 | LABORATE PHARMACEUTICALS INDIA LIMITED | HEALTHCARE LTD. | AZILAB-200 | AZITHROMYCIN DIHYDRATE | 200MG/5ML | LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER | 04/06/2021 |
| 4061 | NDA/MAL/HDP/9671 | SUNRISE INTERNATIONAL LABS LTD | ROYAL PHARMA 2011 LIMITED | RISOPINE | CARBAMAZEPINE | 200 MG | SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE-II, IDA, CHERLAPALLY INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 04/06/2021 |

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| 4062 | NDA/MAL/HDP/9672 | TROIKAA PHARMACEUTICALS LIMITED | ABACUS PHARMA (AFRICA) LIMITED | NASO B12 | METHYLCOBALAMIN | 250 MCG/ACTUATION | TROIKAA PHARMACEUTICALS LIMITED..-SANAND - KADI ROAD, THOL, CITY: THOL - 382 728, DIST. MEHSANA, GUJARAT STATE - INDIA | INDIA | NASAL SYSTEMIC UNIT DOSE AEROSOLS | 1.0X1.0X2.3 ML BOTTLE | 04/06/2021 |
| 4063 | NDA/MAL/HDP/9673 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | DOXORUBICIN 100 MG/50ML | DOXORUBICIN HYDROCHLORIDE | 100 MG/50ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X50.0 ML VIAL | 02/06/2021 |
| 4064 | NDA/MAL/HDP/9674 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | DOXORUBICIN 50 MG/25ML | DOXORUBICIN HYDROCHLORIDE | 50 MG/25ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X25.0 ML VIAL | 02/06/2021 |

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| 4065 | NDA/MAL/HDP /9676 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | DOCETAXEL 10 MG/ML | DOCETAXEL | 160 MG/16 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X8.0 ML VIAL | 02/06/2021 |
| 4066 | NDA/MAL/HDP /9678 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | AXABAN-DENK 2.5 MG | APIXABAN | 2.5 MG | COMBINO PHARM (MALTA) LIMITED-HF60 HAL FAR INDUSTRIAL ESTATE BBG3000 | MALTA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X60.0 TABLET CONTAINER | 04/06/2021 |
| 4067 | NDA/MAL/HDP /9679 | DENK PARMA GMBH & CO. KG | BENLE CONSULT LIMITED | AXABAN-DENK 5 MG | APIXABAN | 5MG | COMBINO PHARM (MALTA) LIMITED-HF60 HAL FAR INDUSTRIAL ESTATE BBG3000 | MALTA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X60.0 TABLET CONTAINER | 04/06/2021 |

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| 4068 | NDA/MAL/HDP/9682 | SYNOKEM PHARMACEUTICALS LIMITED | ROYAL PHARMA 2011 LIMITED | ROTRAMIC | TRANEXAMIC ACID | 500 MG | SYNOKEM PHARMACEUTICALS LIMITED - PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 23/06/2021 |
| 4069 | NDA/MAL/HDP/9684 | CELLTRION, INC | MELO GROUP AFRICA LIMITED | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 300 MG/300 MG | LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 300 MG + 300 MG | CELLTRION PHARM, INC.-82, 2 SANDAN-RO, OCHANG-EUP, CHEONGWON-GU, CHEONGJU-SI – SOUTH KOREA | SOUTH KOREA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 02/06/2021 |
| 4070 | NDA/MAL/HDP/9685 | CELLTRION, INC | MELO GROUP AFRICA LIMITED | DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 50 MG/300 MG/300 MG | DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE | 50 MG + 300 MG + 300 MG | AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA CELLTRION PHARM, INC.-82, 2 SANDAN-RO, OCHANG-EUP, CHEONGWON-GU, CHEONGJU-SI – SOUTH KOREA | SOUTH KOREA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER | 02/06/2021 |

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| 4071 | NDA/MAL/HDP/9688 | FREDUN PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | FREDNISOL TABLETS | PREDNISOLONE | 5MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X2.0X5.0X10.0 TABLET BLISTER | 19/07/2021 |
| 4072 | NDA/MAL/HDP/9712 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | QUININE DIHYDROCHLORIDE INJECTION | QUININE DIHYDROCHLORIDE | 600MG/2ML | SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA | CHINA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X2.0 ML AMPOULE | 13/09/2021 |
| 4073 | NDA/MAL/HDP/9713 | I CARE PHARMA LIMITED | SUPER MEDIC LTD | AZOL 400 | ALBENDAZOLE | 400MG | MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA WEST COAST PHARMACEUTICAL WORKS LTD-1143,MELDI ESTATE,NR PRASANG PARTY PLOT,GOTA, AHMEDEBAD | INDIA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X1.0 TABLET BLISTER | 15/09/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4074 | NDA/MAL/HDP /9722 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | SEKROL 30 MG/5 ML | AMBROXOL HYDROCHLORIDE | 30 MG/5 ML | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X150.0 ML BOTTLE | 05/10/2021 |
| 4075 | NDA/MAL/HDP /9723 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | SEKROL 15MG/5 ML | AMBROXOL HYDROCHLORIDE | 15MG/5ML | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 05/10/2021 |
| 4076 | NDA/MAL/HDP /9725 | ABACUS PARENTERAL DRUGS LIMITED | ABACUS PARENTERAL DRUGS LIMITED | MOCIN | MOXIFLOXACIN HYDROCHLORIDE | 0.5%W/V | ABACUS PARENTERAL DRUGS LTD (APDL)-PLOT 114, BLOCK 191, KINGA - MUKONO | UGANDA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4077 | NDA/MAL/HDP /9726 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | ABLEPT – 300 | GABAPENTIN | 300MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 05/10/2021 |
| 4078 | NDA/MAL/HDP /9731 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | MELANOV-M | GLICLAZIDE + METFORMIN HYDROCHLORIDE | 80MG + 500MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4079 | NDA/MAL/HDP /9733 | SWISS PARENTERALS PVT. LTD. | SHREEJI CARE LIMITED | KEMIN | KETAMINE HYDROCHLORIDE | 50MG/ML | SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X10.0 ML VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4080 | NDA/MAL/HDP /9734 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | 5-FLUOROURACIL 500MG/10ML | 5-FLUOROURACIL | 500 MG/10 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X10.0 ML VIAL | 05/10/2021 |
| 4081 | NDA/MAL/HDP /9735 | SANOFI AVENTIS KENYA | SURGIPHARM (U) LIMITED | FEXINIDAZOLE WINTHROP | FEXINIDAZOLE | 600MG | ALCAMI CAROLINAS CORPORATION-1726 NORTH 23RD STREET WILMINGTON, NORTH CAROLINA 28405 | UNITED STATES | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X12.0 TABLET BLISTER,1.0X1.0X14.0 TABLET PACK [A PACK CONTAINS (1*8 + 1*6) TABLET BLISTERS] | 05/10/2021 |
| 4082 | NDA/MAL/HDP /9746 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | 5-FLUOROURACIL 1000MG/20ML | 5-FLUOROURACIL | 1000 MG/20 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X20.0 ML VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4083 | NDA/MAL/HDP /9747 | GUILIN PHARMACEUTICALS CO.LTD. | TRIDEM PHARMA UGANDA LIMITED | ARGESUN 60 MG | ARTESUNATE | 60MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X60.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE | 05/10/2021 |
| 4084 | NDA/MAL/HDP /9748 | GUILIN PHARMACEUTICALS CO.LTD. | TRIDEM PHARMA UGANDA LIMITED | ARGESUN 30 MG | ARTESUNATE | 30MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X30.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE | 05/10/2021 |
| 4085 | NDA/MAL/HDP /9749 | GUILIN PHARMACEUTICALS CO.LTD. | TRIDEM PHARMA UGANDA LIMITED | ARGESUN 120 MG | ARTESUNATE | 120MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X120.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4086 | NDA/MAL/HDP/9750 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | VAXATO 15 MG | RIVAROXABAN | 15MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4087 | NDA/MAL/HDP/9751 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | VAXATO 20 MG | RIVAROXABAN | 20 MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4088 | NDA/MAL/HDP/9752 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | ATROZEMB 10 MG/10 MG | ATORVASTATIN + EZETIMIDE | 10 MG + 10 MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4089 | NDA/MAL/HDP/9753 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | ATROZEMB 20 MG/10 MG | ATORVASTATIN + EZETIMIBE | 20 MG + 10 MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4090 | NDA/MAL/HDP/9754 | PROFARMA .SH.A | JOINT MEDICAL STORE (UPMB - UCMB) | LUMINAL | PHENOBARBITAL SODIUM | 200 MG/2 ML | PROFARMA SH.A-MYSLYM KETA,TIRANA | ALBANIA | PARENTERAL ORDINARY AMPOULES | 1.0X2.0X5.0X2.0 ML AMPOULE | 05/10/2021 |
| 4091 | NDA/MAL/HDP/9755 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | ORILAM ODT-100 | LAMOTRIGINE | 100MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4092 | NDA/MAL/HDP /9756 | MICRO LABS LIMITED | LABOREX UGANDA LIMITED | ORILAM ODT-25 | LAMOTRIGINE | 25MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4093 | NDA/MAL/HDP /9757 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | GLYFERON 850 | METFORMIN HYDROCHLORIDE | 850MG | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4094 | NDA/MAL/HDP /9763 | HEALTH LINK PHARMACY LIMITED | HEALTH LINK PHARMACY LIMITED | ROLXIN 40/320 | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | 40 MG + 320 MG | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X9.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4095 | NDA/MAL/HDP/9764 | HEALTH LINK PHARMACY LIMITED | HEALTH LINK PHARMACY LIMITED | ROLXIN 90/720 | DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE | (90 MG + 720 MG)/60 ML | EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA | INDIA | ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS | 1.0X1.0X60.0 ML BOTTLE,1.0X1.0X80.0 ML BOTTLE | 05/10/2021 |
| 4096 | NDA/MAL/HDP/9765 | PANACEA BIOTEC LTD | VITACARE LIMITED | LIVOLUK | LACTULOSE | 10.0 G/15 ML | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL LIQUID ORDINARY LIQUIDS | 1.0X1.0X100.0 ML BOTTLE | 05/10/2021 |
| 4097 | NDA/MAL/HDP/9766 | S KANT HEALTHCARE LTD - | ABACUS PHARMA (AFRICA) LIMITED | NEOMYCIN SULFATE CREAM USP | NEOMYCIN SULPHATE | 0.5%W/W | S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X30.0 G TUBE | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4098 | NDA/MAL/HDP/9769 | FERRING INTERNATIONAL CENTER SA | MACNAUGHTON LIMITED | CARBETOCIN FERRING, 100 µG/ML | CARBETOCIN | 100 µG/ML | M/S STERIL-GENE LIFE SCIENCES (P) LTD-45, MAIN ROAD, MANGALAM VILLAGE, VILLIANUR COMMUNE, PUDUCHERRY-605110 | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X1.0 ML AMPOULE | 05/10/2021 |
| 4099 | NDA/MAL/HDP/9774 | I-CARE PHARMA LTD | AIVEEN (U) LIMITED | DOLOFIT | PARACETAMOL + DICLOFENAC SODIUM | 500MG + 50MG | MEDICO REMEDIES PVT LTD,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4100 | NDA/MAL/HDP/9775 | LABORATOIRE AGUETTANT | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | PHENYLEPHRINE AGUETTANT | PHENYLEPHRINE HYDROCHLORIDE | 500µG/10ML | LABORATOIRE AGUETTANT-1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE | FRANCE | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X10.0X10.0 ML PRE- FILLED SYRINGE | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4101 | NDA/MAL/HDP /9776 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DEFAL DROPS | DEFLAZACORT | 22.75MG/ML | FAES FARMA SA-MAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN | SPAIN | ORAL LIQUID ORDINARY SUSPENSIONS | 1.0X1.0X13.0 ML BOTTLE | 05/10/2021 |
| 4102 | NDA/MAL/HDP /9777 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DEFAL 30 MG | DEFLAZACORT | 30MG | FAES FARMA SA-MAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4103 | NDA/MAL/HDP /9778 | FAES FARMA S.A | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DEFAL 6MG | DEFLAZACORT | 6 MG | FAES FARMA SA-MAXIMO AGUIRRE 14. 48940 LEIOA – SPAIN | SPAIN | ORAL SOLID ORDINARY TABLETS | 1.0X2.0X10.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4104 | NDA/MAL/HDP/9779 | BAYER EAST AFRICA LTD | SURGIPHARM (U) LIMITED | EYLEA | AFLIBERCEPT | 40 MG/ML | BAYER AG, BERLIN-MULLERSTRABE 178, 13353 BERLIN - GERMANY | GERMANY | PARENTERAL ORDINARY VIALS | 1.0X1.0 ML VIAL | 05/10/2021 |
| 4105 | NDA/MAL/HDP/9782 | LUPIN LIMITED- | AIVEEN (U) LIMITED | ATAZANAVIR SULFATE AND RITONAVIR TABLETS 300 MG AND 100 MG | ATAZANAVIR SULFATE + RITONAVIR | 300 MG + 100 MG | LUPIN LTD-PLOT NO. 6A, SECTOR 17, SPECIAL ECOOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHSTRA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 05/10/2021 |
| 4106 | NDA/MAL/HDP/9785 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VAROXA-10 | RIVAROXABAN | 10MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4107 | NDA/MAL/HDP/9786 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | VAROXA-20 | RIVAROXABAN | 20MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 05/10/2021 |
| 4108 | NDA/MAL/HDP/9788 | AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD | ROYAL PHARMA 2011 LIMITED | CHLOROSIM-250 | CHLORAMPHENICOL | 250MG | AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA. | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 05/10/2021 |
| 4109 | NDA/MAL/HDP/9790 | PANACEA BIOTEC PHARMA LTD | VITACARE LIMITED | WILLGO CR | ACECLOFENAC | 200MG | PANACEA BIOTEC PHARMA LIMITED-MALPURI BADDI, DISTRICT SOLAN, HIMACHAL PRADESH-173205 - INDIA | INDIA | ORAL SOLID RETARD FILM-COATED TABLETS | 1.0X5.0X2.0X10.0 TABLET BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4110 | NDA/MAL/HDP /9791 | IMPACT RH360 | UNITED HEALTHCARE DISTRIBUTORS LTD | AVIBELA | LEVONORGESTREL | 52 MG/ SYSTEM | ODYSSEA PHARMA SPRL-RUE DU TRAVAIL 16, 4460 GRACE-HOLLOGNE | BELGIUM | VAGINAL INTRA UTERINE DEVICES | 1.0X1.0X52.0 MG DEVICE | 05/10/2021 |
| 4111 | NDA/MAL/HDP /9792 | ACINO AG | GOODMAN INTERNATIONAL LTD | NBAXO 500 G IV | MEROPENEM TRIHYDRATE | 500MG/VIAL | DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS | GREECE | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X500.0 MG VIAL | 05/10/2021 |
| 4112 | NDA/MAL/HDP /9793 | ACINO AG | GOODMAN INTERNATIONAL LTD | NBAXO 1000 G IV | MEROPENEM TRIHYDRATE | 1000MG/VIAL | DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS | GREECE | PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES | 1.0X1.0X1000.0 MG VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4113 | NDA/MAL/HDP /9794 | VERVE HUMAN CARE LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | VERMOR-10 | MORPHINE SULPHATE | 10MG/ML | VERVE HUMAN CARE LABORATORIES-PLOT 15A, PHARMACY, SELAQUI DEHRADUN-248011, UTTARAKHAND | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X10.0X1.0 ML AMPOULE | 05/10/2021 |
| 4114 | NDA/MAL/HDP /9796 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | APDROPS | MOXIFLOXACIN HYDROCHLORIDE | 0.5%W/V | CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA | INDIA | OPHTHALMIC DROPS | 1.0X1.0X5.0 ML BOTTLE | 05/10/2021 |
| 4115 | NDA/MAL/HDP /9799 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VOMIRAN 8 MG/ 4ML | ONDANSETRON HYDROCHLORIDE DIHYDRATE | 8MG/4ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X4.0 ML VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4116 | NDA/MAL/HDP /9801 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LENOSIDE 10 | LENALIDOMIDE | 10MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X7.0 CAPSULE BLISTER | 05/10/2021 |
| 4117 | NDA/MAL/HDP /9802 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LENOSIDE 15 | LENALIDOMIDE | 15MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X7.0 CAPSULE BLISTER | 05/10/2021 |
| 4118 | NDA/MAL/HDP /9803 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | LENOSIDE 25 | LENALIDOMIDE | 25MG | CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X1.0X7.0 CAPSULE BLISTER | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4119 | NDA/MAL/HDP/9804 | LABORATOIRE AGUETTANT | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ATROPINE SULFATE AGUETTANT | ATROPINE SULFATE | 0.5MG/5ML | LABORATOIRE AGUETTANT-1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE | FRANCE | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X10.0X5.0 ML PRE- FILLED SYRINGE | 05/10/2021 |
| 4120 | NDA/MAL/HDP/9805 | INTERNATIONAL PARTNERSHIP FOR MICROBICIDES SOUTH AFRICA NON-PROFIT COMPANY | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | DAPIRING | DAPIVIRINE | 25MG/RING | QPHARMA AB-AGNESLUNDSVAGEN 27, MALMO, 21215 - SWEDEN | SWEDEN | VAGINAL OTHER SPECIAL FORMS | 1.0X1.0X25.0 MG RING | 05/10/2021 |
| 4121 | NDA/MAL/HDP/9806 | SANDOZ GMBH, KUNDL | KIMSY MEDS LTD | DOCETAXEL 160 MG/16 ML | DOCETAXEL | 160 MG/16 ML | EBEWE PHARMA GES.M.B.H. NFG.KG-MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA | AUSTRIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X16.0 ML VIAL | 05/10/2021 |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 4122 | NDA/MAL/HDP/9807 | LABORATOIRE AGUETTANT | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | EPHEDRINE AGUETTANT | EPHEDRINE HYDROCHLORIDE | 30MG/10ML | LABORATOIRE AGUETTANT-1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE | FRANCE | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X10.0X10.0 ML PRE- FILLED SYRINGE | 05/10/2021 |
| 4123 | NDA/MAL/HDP/9820 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | PHENYTOIN INJECTION BP 50 MG/ML, 5 ML | PHENYTOIN SODIUM | 50 MG/ML | SWISS PARENTERALS PVT LTD -809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD-380220 GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X5.0X5.0 ML AMPOULE | 05/10/2021 |
| 4124 | NDA/MAL/HDP/9822 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ONDANSETRON ORAL DISPERSIBLE TABLETS | ONDANSETRON | 4MG | ATHENA DRUG DELIVERY SOLUTIONS PVT LTD ,.-PLOT A-1 TO A-5, MIDC CHEMICAL ZONE, AMBERNATH (W) THANE 421501, MAHARASHTRA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 05/10/2021 |

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| 4125 | NDA/MAL/HDP/9823 | ABACUS PHARMA (AFRICA) LIMITED | ABACUS PHARMA (AFRICA) LIMITED | HEDON PLUS | PARACETAMOL + ASPIRIN + ANHYDROUS CAFFEINE | 500 MG + 500 MG + 50 MG | RATNAMANI HEALTHCARE PRIVATE LIMITED-SURVEY NO. 750/1, AHMEDABAD - MEHSANA HIGHWAY, VILLAGE-INDRAD, NR. CHHATRAL G.I.D.C., TALUKA-KADI, DIST-MEHSANA, PIN-382721 (NG), GUJARAT - INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X1.0X2.0 TABLET STRIP | 05/10/2021 |
| 4126 | NDA/MAL/HDP/9828 | SWISS PARENTERALS LTD | SHREEJI CARE LIMITED | OXYTOCIN INJECTION BP 10 IU/ML | OXYTOCIN | 10 IU/ML | SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X1.0X10.0X1.0 ML AMPOULE | 05/10/2021 |
| 4127 | NDA/MAL/HDP/9829 | RENATA LIMITED | MARIE STOPES UGANDA LIMITED | WELL-PLAN | LEVONORGESTREL + ETHINYLESTRADIOL | 0.15MG + 0.03 MG | RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED-NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH | BANGLADESH | ORAL SOLID ORDINARY COATED TABLETS | 1.0X1.0X28.0 TABLET BLISTER | 05/10/2021 |

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| 4128 | NDA/MAL/HDP/9831 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | ABACAVIR (AS SULFATE) AND LAMIVUDINE DISPERSIBLE TABLETS 120/60 MG | ABACAVIR SULFATE + LAMIVUDINE | 120 MG + 60 MG | CIPLA LTD ,.-PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA | INDIA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X30.0 TABLET BOTTLE | 05/10/2021 |
| 4129 | NDA/MAL/HDP/9832 | SAGA LABORATORIES | ABACUS PHARMA (AFRICA) LIMITED | FEBEX | FERROUS FUMARATE + VITAMIN B12 + FOLIC ACID + DIBASIC CALCIUM PHOSPHATE | 300MG + 15MCG + 1.5MG + 100MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 05/10/2021 |
| 4130 | NDA/MAL/HDP/9843 | DAFRA PHARMA GMBH | MULTIPHAR UGANDA LIMITED | HACTOSEC | LEVODROPROPIZINE | 30MG/5ML | BILIM ILAC SAN.VE TIC.A.S-GEBZE ORGANIZE SANAYI BOLGESI (GOSB), 1900 SOKAK NO 1904, KOCAELI, TURKEY | TURKEY | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X150.0 ML BOTTLE | 16/12/2021 |

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| 4131 | NDA/MAL/HDP /9845 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | ALTLEVO | LEVOFLOXACIN HEMIHYDRATE | 500MG/100ML | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BOTTLE | 08/12/2021 |
| 4132 | NDA/MAL/HDP /9848 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | STERILIZED WATER FOR INJECTION | WATER FOR INJECTION | N/A | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X10.0 ML AMPOULE | 08/12/2021 |
| 4133 | NDA/MAL/HDP /9849 | HETERO BIOPHARMA LIMITED, | AIVEEN (U) LIMITED | PAMERA 40 | ADALIMUMAB (R-DNA ORIGIN) | 40MG/ SYRINGE | HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA. | INDIA | PARENTERAL ORDINARY PRE-FILLED SYRINGES | 1.0X1.0X0.8 ML SYRINGE | 08/12/2021 |

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| 4134 | NDA/MAL/HDP /9853 | RENE INDUSTRIES LIMITED | RENE INDUSTRIES LIMITED | MYCOREN V | NYSTATIN | 100,000 IU | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | PESSARIES | 1.0X1.0X15.0 PESSARY BLISTER | 08/12/2021 |
| 4135 | NDA/MAL/HDP /9854 | RENE INDUSTRIES LTD | RENE INDUSTRIES LIMITED | FLUZOLE | FLUCONAZOLE | 200MG | RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA | UGANDA | ORAL SOLID ORDINARY CAPSULES | 1.0X5.0X4.0 CAPSULE STRIP | 08/12/2021 |
| 4136 | NDA/MAL/HDP /9855 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | TRADOX | TRAMADOL HYDROCHLORIDE | 10 MG/2 ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X2.0 ML VIAL | 08/12/2021 |

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| 4137 | NDA/MAL/HDP/9858 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | TIVICAY 25MG | DOLUTEGRAVIR SODIUM | 25MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE, SG12 ODJ | SPAIN UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 08/12/2021 |
| 4138 | NDA/MAL/HDP/9859 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | TIVICAY 10MG | DOLUTEGRAVIR SODIUM | 10MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE, SG12 ODJ GLAXO WELLCOME S.A-AVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN | SPAIN UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 08/12/2021 |
| 4139 | NDA/MAL/HDP/9860 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | CLINDACIN 300 MG | CLINDAMYCIN HYDROCHLORIDE | 300 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY CAPSULES | 1.0X2.0X8.0 CAPSULE BLISTER | 08/12/2021 |

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| 4140 | NDA/MAL/HDP/9866 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | JULUCA 50MG/25MG | DOLUTEGRAVIR SODIUM + RILPIVIRINE HYDROCHLORIDE | 50MG + 25MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE, SG12 ODJ | SPAIN UNITED KINGDOM | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 08/12/2021 |
| 4141 | NDA/MAL/HDP/9868 | PHARMA BAVARIA INTERNACIONAL PORTUGAL | GOODMAN INTERNATIONAL LTD | CADEN 6MG/2ML | ADENOSINE | 6MG/2ML | VALDEPHARM-PARC INDUSTRIEL D'INCARVILLE, PARC DE LA FRINGALE, CS10606, 27100 VAL DE REUIL - FRANCE | FRANCE | PARENTERAL ORDINARY VIALS | 1.0X1.0X6.0X2.0 ML VIAL | 08/12/2021 |
| 4142 | NDA/MAL/HDP/9869 | PHARMA BAVARIA INTERNATIONAL GMBH - | GOODMAN INTERNATIONAL LTD | FOSMOL | FOSFOMYCINTROMETAMOL | 3000 MG | LABIANA PHARMACEUTICALS, S.L.U.-C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA) | SPAIN | ORAL SOLID ORDINARY GRANULES | 1.0X3000.0 MG SACHET,1.0X2.0X3000.0 MG SACHET | 08/12/2021 |

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| 4143 | NDA/MAL/HDP/9870 | PHARMA BAVARIA INTERNATIONAL GMBH - | GOODMAN INTERNATIONAL LTD | TAFIXYL | TRANEXAMIC ACID | 500MG/5ML | LABIANA PHARMACEUTICALS, S.L.U.-C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA) | SPAIN | PARENTERAL ORDINARY I V AMPOULES | 1.0X1.0X5.0X5.0 ML AMPOULE | 08/12/2021 |
| 4144 | NDA/MAL/HDP/9871 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | RETALEX | ATRACURIUM BESYLATE | 50MG/5ML | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY VIALS | 1.0X5.0X5.0 ML VIAL | 08/12/2021 |
| 4145 | NDA/MAL/HDP/9872 | SAGA LIFESCIENCES LTD | ABACUS PHARMA (AFRICA) LIMITED | COL-COL | PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE USP + CAFFEINE ANHYDROUS | 500MG + 5MG + 2MG + 15MG | SAGA LIFESCIENCES LIMITED-SURVEY NO. 198/2 & 198/3, CHACHRAWADI VASNA, TA-SANAND, DIST. AHMEDABAD - 382210, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X4.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER | 08/12/2021 |

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| 4146 | NDA/MAL/HDP/9873 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | OMISEC | OMEPRAZOLE SODIUM | 40MG/VIAL | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY DRY VIALS | 1.0X40.0 MG VIAL,1.0X5.0X40.0 MG VIAL | 08/12/2021 |
| 4147 | NDA/MAL/HDP/9875 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | TALIMUS 0.1% | TACROLIMUS | 0.1% W/W | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X10.0 G TUBE | 08/12/2021 |
| 4148 | NDA/MAL/HDP/9876 | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED | REDDYS PHARMA LIMITED | LENIOL | PARACETAMOL | 1000MG/100 ML | OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED-SURVEY NO. 199 TO 201 & 208 TO 210, MF01 AND MF02 VILLAGE- VASNA CHACHARWADI, TAL. SANAND DISTRICT. AHMEDABAD-382 213 | INDIA | PARENTERAL ORDINARY INFUSION VIALS/BOTTLES | 1.0X1.0X100.0 ML BAG | 08/12/2021 |

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| 4149 | NDA/MAL/HDP /9877 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | LACOMA-T | LATANOPROST + TIMOLOL MALEATE | (50MCG + 5MG)/ML | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE | INDIA | OPHTHALMIC DROPS | 1.0X1.0X2.5 ML BOTTLE | 08/12/2021 |
| 4150 | NDA/MAL/HDP /9878 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | LACOMA | LATANOPROST | 0.005%W/V | CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, MAHARASHTRA STATE | INDIA | OPHTHALMIC DROPS | 1.0X1.0X2.5 ML BOTTLE | 08/12/2021 |
| 4151 | NDA/MAL/HDP /9880 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | LEFLOXIN 750 | LEVOFLOXACIN HEMIHYDRATE | 750MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BOTTLE | 08/12/2021 |

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| 4152 | NDA/MAL/HDP/9881 | HETERO LABS LTD | AIVEEN (U) LIMITED | DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS 50MG/200MG/25MG | DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFOVIR ALAFENAMIDE HEMIFUMARATE | 50MG+200MG+25MG | HETERO LABS LIMITED (UNIT III)...-22-110, I.D.A, JEEDIMETLA, HYDERABAD-500 055, ANDHRA PRADESH, INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET BOTTLE | 08/12/2021 |
| 4153 | NDA/MAL/HDP/9882 | AJANTA PHARMA LIMITED | ABACUS PHARMA (AFRICA) LIMITED | KAMAGRA CT 50 | SILDENAFIL CITRATE | 50MG | AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA. | INDIA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X1.0X4.0 TABLET BLISTER | 08/12/2021 |
| 4154 | NDA/MAL/HDP/9885 | AMMAN PHARMACEUTICAL INDUSTRIES | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BECLOCORT | BECLOMETHASONE DIPROPIONATE | 50MCG/METERED DOSE | AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN | JORDAN | NASAL TOPICAL METERED-DOSE LIQUIDS | 1.0X1.0X30.0 ML BOTTLE | 08/12/2021 |

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| 4155 | NDA/MAL/HDP/9889 | AJANTA PHARMA LTD | ABACUS PHARMA (AFRICA) LIMITED | MOMADERM | MOMETASONE FUROATE | 0.1%W/W | AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM) | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X15.0 G TUBE | 08/12/2021 |
| 4156 | NDA/MAL/HDP/9898 | LINCOLN PARENTERAL LIMITED | METRO PHARMACEUTICALS LIMITED | NOSIL 0.1% | XYLOMETAZOLINE HYDROCHLORIDE | 0.1%W/V | LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT | INDIA | NASAL TOPICAL DROPS | 1.0X1.0X10.0 ML BOTTLE | 08/12/2021 |
| 4157 | NDA/MAL/HDP/9899 | MEDICAL UNION PHARMACEUTICALS. | KARURI PHARMACEUTICALS LTD. | MUCOSOL ADULT SYRUP | CARBOCYSTEINE | 250MG/5ML | MEDICAL UNION PHARMACEUTICAL CO.-PLANT: ABU-SULTAN, ISMAILIA, EGYPT | EGYPT | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X120.0 ML BOTTLE | 08/12/2021 |

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| 4158 | NDA/MAL/HDP/9902 | LA RENON HEALTHCARE PRIVATE LIMITED | AIVEEN (U) LIMITED | SEVLAREN 800 | SEVELAMER CARBONATE | 800MG | STANFORD LABORATORIES PVT LIMITED-8,INDUSTRIAL AREA,MEHATPUR-174 315, HIMACHAL PRADESH. | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/12/2021 |
| 4159 | NDA/MAL/HDP/9903 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA U LIMITED | MEDICLOAMP 500MG | AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM | 250MG + 250MG | REGAL PHARMACEUTICALS LTD -PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X10.0X10.0 CAPSULE BLISTER | 08/12/2021 |
| 4160 | NDA/MAL/HDP/9906 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | NEBTAS-5 | NEBIVOLOL HYDROCHLORIDE | 5MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/12/2021 |

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| 4161 | NDA/MAL/HDP/9911 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BISOPROL® 5 | BISOPROLOL FUMARATE | 5MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/12/2021 |
| 4162 | NDA/MAL/HDP/9913 | MANKIND PHARMA LIMITED | TATA UGANDA LIMITED | BRUTAFLAM-120 | ETORICOXIB | 120MG | MANKIND PHARMA LTD, UNIT II ,-VILLAGE-KISHANPURA, PAONTA SAHIB, DIST. SIRMOUR, HP | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 08/12/2021 |
| 4163 | NDA/MAL/HDP/9920 | BROOKES PHARMA (PRIVATE) LIMITED | HARLEYS UGANDA LIMITED | CIS-CURON | CIS-ATRACURIUMBESYLATE | 10MG/5ML | BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900 | PAKISTAN | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 08/12/2021 |

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| 4164 | NDA/MAL/HDP/9922 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | PALONOSETRON HYDROCHLORIDE INJECTION | PALONOSETRON HYDROCHLORIDE | 0.25MG/5ML | CIPLA LIMITED.-PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722 | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X5.0 ML VIAL | 08/12/2021 |
| 4165 | NDA/MAL/HDP/9924 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | OPTIZOLINE EYE DROPS | TETRAHYDROZOLINE HYDROCHLORIDE | 0.5%W/V | XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA | MALAYSIA | OPHTHALMIC DROPS | 1.0X5.0 ML VIAL | 17/01/2022 |
| 4166 | NDA/MAL/HDP/9925 | XEPA SOUL PATTISON (M) SDN BHD | DELMAW ENTERPRISES LIMITED | TUSSIDEX LINCTUS | DEXTROMETHORPHAN | 10MG | XEPA-SOUL PATTINSON (MALAYSIA) SDN.BHD.-1-5 CHENG INDUSTRIAL ESTATE, 75250, MELAKA | MALAYSIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X120.0 ML BOTTLE | 17/01/2022 |

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| 4167 | NDA/MAL/HDP/9927 | LINCOLN PHARMACEUTICALS LTD | ABACUS PHARMA (AFRICA) LIMITED | NYSTATIN | NYSTATIN | 500,000 I.U | MEDICAMEN BIOTECH LTD .-SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X100.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER | 02/02/2022 |
| 4168 | NDA/MAL/HDP/9931 | MERIDIAN ENTERPRISES PRIVATE LIMITED. | ABACUS PHARMA (AFRICA) LIMITED | CLOSUPP 100 | CLOTRIMAZOLE | 100MG | MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA | INDIA | VAGINAL TABLETS | 1.0X1.0X6.0 PESSARY STRIP | 24/03/2022 |
| 4169 | NDA/MAL/HDP/9932 | INFUGEN PHARMA PVT. LTD. | TATA UGANDA LIMITED | INFUDEXA | DEXAMETHASONE | 0.5MG | FREDUN PHARMACEUTICALS LIMITED-14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4170 | NDA/MAL/HDP /9933 | THE UNITED PHARMACEUTICALS MFG, CO. LTD, | WIDE SPECTRUM ENTERPRISES (U) LIMITED | BISOPROL® 10 | BISOPROLOL FUMARATE | 10MG | UNITED PHARMACEUTICAL MANUFACTURING COMPANY-JORDAN - NUZHAT SAHAB | JORDAN | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4171 | NDA/MAL/HDP /9934 | MICRO LABS LIMITED | PHARMA VILLE LIMITED | ISONIAZID 100 MG BP | ISONIAZID 100 MG BP | 100MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X1000.0 TABLET CONTAINER | 24/03/2022 |
| 4172 | NDA/MAL/HDP /9937 | NORTH CHINA PHARMACEUTICAL CO., LTD. | VITACARE LIMITED | AMOXICILLIN SODIUM AND CLAVULANATE POTASSIUM FOR INJECTION 0.6G | AMOXICILLIN SODIUM + SODIUM CLAVULANATE | (500MG+ 100MG)/ VIAL | NORTH CHINA PHARMACEUTICAL CO., LTD-NO.388 HEPING ROAD, SHIJIAZHUANG, HEBEI PROVINCE, P.R. CHINA. (NORTH BEST BRANCH) | CHINA | PARENTERAL ORDINARY DRY VIALS | 1.0X10.0X0.6 G VIAL | 24/03/2022 |

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| 4173 | NDA/MAL/HDP/9939 | CELOGEN PHARMA PVT LTD | OMAB UGANDA LIMITED | MELOXICAM TABLETS 7.5 MG | MELOXICAM | 7.5MG | CELOGEN GENERICS PVT. LIMITED-646/1 & 2. AGRAWAL INDUSTRIAL ESTATE, SOMNATH ROAD, DABHEL, DAMAN (UT) – 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4174 | NDA/MAL/HDP/9940 | CELOGEN PHARMA PVT LTD | OMAB UGANDA LIMITED | MELOXICAM TABLETS 15MG | MELOXICAM | 15MG | CELOGEN GENERICS PVT. LIMITED-646/1 & 2. AGRAWAL INDUSTRIAL ESTATE, SOMNATH ROAD, DABHEL, DAMAN (UT) – 396210 INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4175 | NDA/MAL/HDP/9941 | ALTHEA PHARMA PVT LTD. | JOINT MEDICAL STORE (UPMB - UCMB) | STERILIZED WATER FOR INJECTION | WATER FOR INJECTION | WATER FOR INJECTION | ALTHEA PHARMA PRIVATE LIMITED-WORKS: PLOT NO. 374, SHED NO. 'E', ALPHA INDL. PARK, ATHIAWAD, DABHEL, NANI DAMAN - 396210 (U.T.), INDIA | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X20.0X5.0X5.0 ML AMPOULE | 24/03/2022 |

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| 4176 | NDA/MAL/HDP /9942 | FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD | TRIDEM PHARMA UGANDA LIMITED | GLUMAC DISPERSIBLE TABLETS | ARTEMETHER + LUMEFANTRINE | 20MG + 120MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 24/03/2022 |
| 4177 | NDA/MAL/HDP /9943 | FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD | TRIDEM PHARMA UGANDA LIMITED | GLUMAC DISPERSIBLE TABLETS | ARTEMETHER + LUMEFANTRINE | 40MG + 240MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 24/03/2022 |
| 4178 | NDA/MAL/HDP /9944 | FOSUN PHARMACEUTICAL DISTRIBUTION JIANGSU CO. LTD | TRIDEM PHARMA UGANDA LIMITED | GLUMAC DISPERSIBLE TABLETS | ARTEMETHER + LUMEFANTRINE | 60MG + 360MG | GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004 | CHINA | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X6.0 TABLET BLISTER | 24/03/2022 |

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| 4179 | NDA/MAL/HDP/9945 | NEOMI PHARMACEUTICALS PVT LTD | ROYAL PHARMA 2011 LIMITED | ROSUNATE-30 | ARTESUNATE | 30MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X30.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE | 24/03/2022 |
| 4180 | NDA/MAL/HDP/9946 | NEOMI PHARMACEUTICALS PVT LTD | ROYAL PHARMA 2011 LIMITED | ROSUNATE-60 | ARTESUNATE | 60MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X60.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE | 24/03/2022 |
| 4181 | NDA/MAL/HDP/9947 | NEOMI PHARMACEUTICALS PVT LTD | ROYAL PHARMA 2011 LIMITED | ROSUNATE-120 | ARTESUNATE | 120MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X120.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE | 24/03/2022 |

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| 4182 | NDA/MAL/HDP /9948 | BLISS GVS PHARMA LIMITED | MEDVIN PHARMA LIMITED | SANTRIAX-1000 | CEFTRIAXONE SODIUM | 1000MG/VIAL | INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X25.0X1000.0 MG VIAL,1.0X10.0 ML VIAL | 24/03/2022 |
| 4183 | NDA/MAL/HDP /9949 | LABORATE PHARMACEUTICALS INDIA LIMITED | HEALTHCARE LTD. | GENTAM | GENTAMICIN SULPHATE | 80MG/2ML | LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH | INDIA | PARENTERAL ORDINARY AMPOULES | 1.0X10.0X2.0 ML AMPOULE | 24/03/2022 |
| 4184 | NDA/MAL/HDP /9950 | XL LABORATORIES PRIVATE LIMITED | ROYAL PHARMA 2011 LIMITED | RETOVIT | VITAMIN A | 200000 IU | XL LABORATORIES PRIVATE LIMITED-A-141, EPIP INDUSTRIAL AREA, NEEMRANA, DIST. ALWAR, RAJASTHAN - 301705 (INDIA) | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 CAPSULE BLISTER | 24/03/2022 |

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| 4185 | NDA/MAL/HDP/9951 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | ARCELIA ARTESUNATE FOR INJECTION | ARTESUNATE | 60MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X60.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE | 24/03/2022 |
| 4186 | NDA/MAL/HDP/9952 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | DEXAMETHASONE SODIUM PHOSPHATE INJECTION 4 MG/ML | DEXAMETHASONE SODIUM PHOSPHATE | 8MG/2ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X100.0X2.0 ML VIAL | 24/03/2022 |
| 4187 | NDA/MAL/HDP/9953 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | ARCELIA AMIKACIN SULFATE INJECTION USP 500MG/2ML | AMIKACIN SULFATE | 500MG/2ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X2.0 ML VIAL | 24/03/2022 |

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| 4188 | NDA/MAL/HDP/9954 | JEVIANA HEALTH CARE LLP, | MARVIN PHARMA LIMITED | MARISUNATE 30MG | ARTESUNATE | 30MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X30.0 MG VIAL + 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE OF SODIUM CHLORIDE | 24/03/2022 |
| 4189 | NDA/MAL/HDP/9955 | VEERAM HEALTHCARE (U) LIMITED | VEERAM HEALTHCARE (U) LIMITED | DICLONI | DICLOFENAC DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL | 1.16%W/W+ 1.0% W/W+3.0%W/W+ 10%W/W+2.0% W/W | KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT | INDIA | TOPICAL EXTERNAL GELS AND SOLS | 1.0X1.0X30.0 G TUBE,1.0X1.0X15.0 G TUBE | 24/03/2022 |
| 4190 | NDA/MAL/HDP/9956 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | ARCELIA OMEPRAZOLE FOR INJECTION | OMEPRAZOLE SODIUM | 40 MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X40.0 MG VIAL +10ML GLASS AMPOULE OF WATER FOR INJECTION | 24/03/2022 |

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| 4191 | NDA/MAL/HDP/9957 | INDCHEMIE HEALTH SPECIALITIES PVT. LTD. | NUMED STORES SMC LIMITED | TERBICON CREAM | TERBINAFINE HYDROCHLORIDE | 1.0%W/W | INDCHEMIE HEALTH SPECIALITIES PVT. LTD-VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205. | INDIA | TOPICAL EXTERNAL CREAMS | 1.0X1.0X10.0 G TUBE | 24/03/2022 |
| 4192 | NDA/MAL/HDP/9958 | INDCHEMIE HEALTH SPECIALITIES PVT. LTD. | NUMED STORES SMC LIMITED | MUPRICON | MUPIROCIN | 2.0%W/W | INDCHEMIE HEALTH SPECIALITIES PVT. LTD-VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205. | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X5.0 G TUBE | 24/03/2022 |
| 4193 | NDA/MAL/HDP/9959 | JEVIANA HEALTH CARE LLP, | MARVIN PHARMA LIMITED | MARISUNATE 60MG | ARTESUNATE | 60MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE | 24/03/2022 |

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| 4194 | NDA/MAL/HDP /9960 | JEVIANA HEALTH CARE LLP, | MARVIN PHARMA LIMITED | MARISUNATE 120MG | ARTESUNATE | 120MG/VIAL | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON + 1, CLEAR GLASS AMPOULE OF SODIUM BICARBONATE + 1 CLEAR GLASS AMPOULE SODIUM CHLORIDE | 24/03/2022 |
| 4195 | NDA/MAL/HDP /9961 | FDC LIMITED - | AIVEEN (U) LIMITED | ALLERCROM EYE DROPS | SODIUM CROMOGLICATE | 2%W/V | FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD | INDIA | OPHTHALMIC LIQUIDS | 1.0X1.0X10.0 ML BOTTLE | 24/03/2022 |
| 4196 | NDA/MAL/HDP /9962 | ARCELIA LIFE SCIENCES LTD. | PLUTO PHARMACEUTICALS LIMITED | ARTEMETHER INJECTION 80 MG/ML | ARTEMETHER | 80MG/ML | SANJAR PHARMA LLP-SURVEY NO. 622/2/1/4, DEDHROTA, TA-HIMATNAGAR, DIST SABARKANTHA, GUJARAT, INDIA | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X2.0X3.0X1.0 ML AMPOULE | 24/03/2022 |

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| 4197 | NDA/MAL/HDP/9963 | SEARLE PAKISTAN LIMITED | HEALTHCARE LTD. | SEA-MOX | MOXIFLOXACIN HYDROCHLORIDE | 400MG | SEARLE PAKISTAN LIMITED,-F-319, SITE KARACHI | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X5.0 TABLET BLISTER | 24/03/2022 |
| 4198 | NDA/MAL/HDP/9964 | GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD | UNITED HEALTHCARE DISTRIBUTORS LTD | TIVICAY 5 MG | DOLUTEGRAVIR SODIUM | 5MG | GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)-PRIORY STREET, WARE, SG12 ODJ GLAXO WELLCOME S.A-AVENIDA EXTREMADURA 3, 09400 ARANDA DE DUERO - SPAIN | SPAIN | ORAL SOLID ORDINARY SOLUBLE TABLETS | 1.0X1.0X60.0 TABLET CONTAINER | 24/03/2022 |
| 4199 | NDA/MAL/HDP/9965 | EMCURE PHARMACEUTICALS LTD - | HARLEYS UGANDA LIMITED | C-TRI 1.0G | CEFTRIAXONE SODIUM | 1.0G/VIAL | SAMRUDH PHARMACEUTICALS PVT LTD-J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506 | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL | 24/03/2022 |

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| 4200 | NDA/MAL/HDP/9967 | MACLEODS PDHARMACEUTICALS LT | VITACARE LIMITED | VENTOMAC 100 | SALBUTAMOL SULFATE | 100MCG PER ACTUATION | OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA | INDIA | LUNG ADMINISTRATION METERED-DOSE LIQUIDS | 1.0X1.0X200.0 METERED DOSE CANNISTER | 24/03/2022 |
| 4201 | NDA/MAL/HDP/9968 | ARISTO PHARMACEUTICALS PVT LTD | NORVIK ENTERPRISES LIMITED | MAXICEF | CEFEPIME HYDROCHLORIDE | 1G | ARISTO PHARMACEUTICALS PVT LTD .-PLOT 208, NEW INDUSTRIAL AREA, NO. II, MANDIDEEP 462046 DIST-RAISEN, RAISEN, MADHYA PRADESH | INDIA | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X1.0 G VIAL | 24/03/2022 |
| 4202 | NDA/MAL/HDP/9969 | PRIVATE JOINT-STOCK COMPANY "ON THE PRODUCTION OF INSULIN "INDAR" | PLUTO PHARMACEUTICALS LIMITED | HUMODAR R 100R | INSULIN HUMAN (RDNA ORIGIN) | 100IU/ML | PRIVATE JOINT STOCK COMPANY "INDAR"-5, ZROSHUVALNA STR. KYIV, 02099 - UKRAINE | UKRAINE | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0X10.0 ML VIAL | 24/03/2022 |

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| 4203 | NDA/MAL/HDP/9970 | PRIVATE JOINT-STOCK COMPANY "ON THE PRODUCTION OF INSULIN "INDAR" | PLUTO PHARMACEUTICALS LIMITED | HUMODAR B 100R | INSULIN HUMAN (RDNA ORIGIN) | 100IU/ML | PRIVATE JOINT STOCK COMPANY "INDAR"-5, ZROSHUVALNA STR. KYIV, 02099 - UKRAINE | UKRAINE | PARENTERAL ORDINARY VIALS | 1.0X1.0X10.0 ML VIAL | 24/03/2022 |
| 4204 | NDA/MAL/HDP/9971 | PRIVATE JOINT-STOCK COMPANY "ON THE PRODUCTION OF INSULIN "INDAR" | PLUTO PHARMACEUTICALS LIMITED | HUMODAR C25 100R | INSULIN HUMAN (RDNA ORIGIN) | 100IU/ML | PRIVATE JOINT STOCK COMPANY "INDAR"-5, ZROSHUVALNA STR. KYIV, 02099 - UKRAINE | UKRAINE | PARENTERAL ORDINARY VIALS | 1.0X1.0X10.0 ML VIAL | 24/03/2022 |
| 4205 | NDA/MAL/HDP/9972 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | OLMESAR 20 | OLMESARTAN MEDOXOMIL | 20MG | MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4206 | NDA/MAL/HDP/9973 | MICRO LABS LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | ARBITEL 80 H | TELMISARTAN + HYDROCHLOROTHIAZIDE | 80MG + 12.5MG | MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4207 | NDA/MAL/HDP/9974 | INTAS PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | NEBTAS-H | NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROTHIAZIDE | 5MG + 12.5 MG | INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND) | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4208 | NDA/MAL/HDP/9975 | STRIDES SHASUN LIMITED | DELMAW ENTERPRISES LIMITED | RENERVE-P | PREGABALIN + MECOBALAMIN | 75MG + 750MG | CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223 | INDIA | ORAL SOLID ORDINARY CAPSULES | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4209 | NDA/MAL/HDP/9976 | UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED | WIDE SPECTRUM ENTERPRISES (U) LIMITED | EZIFLO | TAMSULOSIN HYDROCHLORIDE | 0.4 MG | UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4210 | NDA/MAL/HDP/9977 | LAURUS LABS LIMITED - | BEYOND LOGISTICS LTD | EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE TABLETS 200 MG/ 300 MG | EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE | 200MG + 300MG | LAURUS LABS LTD (UNIT 2)-PLOT NO. 19, 20 & 21 WESTERN SECTOR, APSEZ, ATCHUTAPURAM, 531011, VISAKHAPTNAM, ANDRA PRADESH, | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER | 24/03/2022 |
| 4211 | NDA/MAL/HDP/9978 | ASPIRO PHARMA LIMITED | AIVEEN (U) LIMITED | PALOX | PALONOSETRON HYDROCHLORIDE | 0.25MG/5ML | ASPIRO PHARMA LIMITED-SY. NO. 321, BIOTECH PARK, PHASE-III, KARKAPATLA, MARKOOK MANDAL, SIDDIPET DISTRICT-502 281, TELANGANA, INDIA | INDIA | PARENTERAL ORDINARY VIALS | 1.0X1.0X0.25 MG VIAL | 24/03/2022 |

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| 4212 | NDA/MAL/HDP /9979 | ROYAL PHARMA 2011 LIMITED | ROYAL PHARMA 2011 LIMITED | PRILIS 10 | LISINOPRIL DIHYDRATE | 10 MG | GLOBELA PHARMA PVT.LTD.-357, 358, ROAD NO. 3, SACHIN G.I.D.C., SACHIN, SURAT - 394230, GUJARAT INDIA | INDIA | ORAL SOLID ORDINARY TABLETS | 1.0X10.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4213 | NDA/MAL/HDP /9980 | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD | TATA UGANDA LIMITED | EFAVIRENZ TABLETS USP | EFAVIRENZ | 600MG | SHANGHAI DESANO BIO-PHARMACEUTICAL CO., LTD-1479 ZHANGHENG ROAD, CHINA (SHANGHAI) PILOT FREE TRADE ZONE SHANGHAI, CHINA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X1.0X30.0 TABLET CONTAINER | 24/03/2022 |
| 4214 | NDA/MAL/HDP /9981 | MS PHARMA JORDAN CO.LTD | WIDE SPECTRUM ENTERPRISES (U) LIMITED | VELOCE | LORNOXICAM | 8MG PER VIAL | MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL-HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE. | JORDAN | PARENTERAL ORDINARY DRY VIALS | 1.0X1.0 VIAL CARTON | 24/03/2022 |

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| 4215 | NDA/MAL/HDP /9982 | RUSAN PHARMA LTD | NORVIK ENTERPRISES LIMITED | RUSAMIN 850 | METFORMIN HYDROCHLOIRDE | 850 MG | RUSAN PHARMA LIMITED-PLOT NO. 59 TO 65 SECTOR II KANDLA SPECIAL ECONOMIC ZONE GANDHIDHAM (KUTCH, GUJARAT 370230) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X10.0X10.0 BLISTER CARTON | 24/03/2022 |
| 4216 | NDA/MAL/HDP /9983 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 25 MG/1000 MG | EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE | 25MG + 1000MG | CIPLA LIMITED.-PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722 | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X60.0 TABLET BOTTLE | 24/03/2022 |
| 4217 | NDA/MAL/HDP /9984 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 12.5 MG/1000 MG | EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE | 12.5MG + 1000MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X60.0 TABLET BOTTLE | 24/03/2022 |

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| 4218 | NDA/MAL/HDP/9985 | CIPLA LIMITED | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 5 MG/1000 MG | EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE | 5MG + 1000MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X60.0 TABLET BOTTLE | 24/03/2022 |
| 4219 | NDA/MAL/HDP/9986 | CIPLA LTD. | CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED | EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS 10 MG/1000 MG | EMPAGLIFLOZIN + METFORMIN HYDROCHLORIDE | 10MG + 1000MG | CIPLA LTD, GOA UNIT V & UNIT X-L-139, S-103&M-62 VERNA INDUSTRIAL ESTATE, VERNA SALCETTE GOA | INDIA | ORAL SOLID ORDINARY OTHER TABLETS | 1.0X60.0 TABLET BOTTLE | 24/03/2022 |
| 4220 | NDA/MAL/HDP/9987 | AMOUN PHARMACEUTICAL COMPANY | WIDE SPECTRUM ENTERPRISES (U) LIMITED | SACROFER | IRON SUCROSE | 100MG/5ML | AMOUN PHARMACEUTICAL COMPANY...-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, CAIRO | EGYPT | PARENTERAL ORDINARY AMPOULES | 1.0X5.0X5.0 ML AMPOULE | 24/03/2022 |

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| 4221 | NDA/MAL/HDP/9988 | LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS | GOODMAN INTERNATIONAL LTD | GLYBOFEN | GLYBURIDE (GLIBENCLAMIDE) + METFORMIN HYDROCHLORIDE | 5MG+ 1000MG | LIPTIS EGYPY FOR PHARMACEUTICALS AND MEDICAL PRODUCTS-PLOT NO. 2/B, 6TH INDUSTRIAL ZONE, 6TH OF OCTOBER CITY | EGYPT | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4222 | NDA/MAL/HDP/9989 | AGIO PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | IVANOVA 5 | IVABRADINE HYDROCHLORIDE | 5MG | AGIO PHARMACEUTICALS LTD .-A-82, MIDC, BHOSARI, PUNE-411026 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4223 | NDA/MAL/HDP/9990 | AGIO PHARMACEUTICALS LTD | PLANET PHARMACEUTICALS UGANDA LTD | IVANOVA 7.5 | IVABRADINE HYDROCHLORIDE | 7.5MG | AGIO PHARMACEUTICALS LTD .-A-82, MIDC, BHOSARI, PUNE-411026 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4224 | NDA/MAL/HDP/9991 | CACHET PHARMACEUTICALS PVT LIMITED | ABACUS PHARMA (AFRICA) LIMITED | EASCOF-LS | LEVOSALBUTAMOL SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIPHENESIN | 1MG + 30MG + 50 MG | CACHET PHARMACEUTICALS PVT LTD .-VILLAGE THANA, BADDI, TEHSIL-NALAGARH DIST. SOLAN, HIMACHAL PRADESH-173205 | INDIA | ORAL LIQUID ORDINARY SYRUPS | 1.0X1.0X100.0 ML BOTTLE | 24/03/2022 |
| 4225 | NDA/MAL/HDP/9992 | REGAL PHARMACEUTICALS LTD | REGAL PHARMA U LIMITED | ASPEC EXTRA | ASPIRIN + PARACETAMOL + CAFFEINE ANHYDROUS | 300MG + 250MG + 30MG | REGAL PHARMACEUTICALS LTD -PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI | KENYA | ORAL SOLID ORDINARY TABLETS | 1.0X50.0X2.0 TABLET STRIP | 24/03/2022 |
| 4226 | NDA/MAL/HDP/9993 | AUROBINDOM PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KLAR 250 | CLARITHROMYCIN | 250MG | AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE) | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4227 | NDA/MAL/HDP/9994 | AUROBINDOM PHARMA LIMITED | PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED | KLAR 500 | CLARITHROMYCIN | 500MG | AUROBINDO PHARMA LTD, UNIT III -SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090 | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4228 | NDA/MAL/HDP/9995 | GITTOES PHARMACEUTICALS LIMITED | GITTOES PHARMACEUTICALS LIMITED | LYDIA FINE TABLET | LEVONORGESTREL + ETHINYLESTRADIOL | 0.15 MG + 0.03MG | RAJENDRAPUR POTENT PRODUCT FACILITY (RPPF), RENATA LIMITED-NOYAPARA, BHAWAL MIRZAPUR, RAJENDRAPUR, GAZIPUR 1700 - BANGLADESH | INDIA | ORAL SOLID ORDINARY OTHER COATED TABLETS | 1.0X1.0X28.0 TABLET BLISTER | 24/03/2022 |
| 4229 | NDA/MAL/HDP/9996 | MACLEODS PHARMACEUTICALS LTD | VITACARE LIMITED | MONTEMAC 4 | MONTELUKAST SODIUM | 4MG | MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 | INDIA | ORAL SOLID ORDINARY CHEWABLE COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |

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| 4230 | NDA/MAL/HDP/9997 | INTAS, PHARMACEUTICALS LTD | NORVIK ENTERPRISES LIMITED | RIVATAS 10 | RIVAROXABAN | 10MG | INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, & 191/218P,VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA | INDIA | ORAL SOLID ORDINARY FILM-COATED TABLETS | 1.0X3.0X10.0 TABLET BLISTER | 24/03/2022 |
| 4231 | NDA/MAL/HDP/9998 | LINCOLN PHARMACEUTICALS LTD | METRO PHARMACEUTICALS LIMITED | DERMOCIN | MUPIROCIN | 2.0%W/W | LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR KHATRAJ CHOWKADI, KHATRAJ-382721, GHANDINAGAR, GUJARAT, INDIA | INDIA | TOPICAL EXTERNAL OINTMENTS | 1.0X1.0X15.0 G TUBE | 24/03/2022 |