

NATIONAL DRUG REGISTER OF UGANDA - HUMAN MEDICINES - JANUARY 2022

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/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	7/1/2013
2	NDA/MAL/HDP/0013	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	IMPLANON NXT	ETONOGESTREL	68MG	N.V. ORGANON-KLOOSTERSTRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	PARENTERAL RETARD IMPLANTS	1.0X68.0 MG IMPLANT	7/1/2015

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3	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	7/1/2014
4	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	7/1/2011
5	NDA/MAL/HDP/0021	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	QUINS	QUININE DIHYDROCHLORIDE	300MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE,1.0X2.0X5.0X2.0 ML AMPOULE	7/1/2013

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6	NDA/MAL/HDP/0022	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE SULPHATE	QUININE SULPHATE	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	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/2009
7	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	7/1/1997
8	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	7/1/2015

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9	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	7/1/2015
10	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,1.0X100.0 X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2007
11	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	7/1/2015

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12	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	7/1/2014
13	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	7/1/2015
14	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	7/1/2013

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15	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	7/1/2015
16	NDA/MAL/HDP/0056	TROIKAA PHARMACEUTICAL S 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.	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	7/1/2015
17	NDA/MAL/HDP/0058	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	WATER FOR INJECTION B.P.	WATER FOR INJECTION	N/A	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE	7/1/1997

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18	NDA/MAL/HDP/0059	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	VAGIBACT CREAM	CLINDAMYCIN PHOSPHATE	2%W/W	NABIQASIM INDUSTRIES (PVT) LTD-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI-PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE + 1 APPLICATOR	7/1/2006
19	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 PREFILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION	7/1/2015
20	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	7/1/2015

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21	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	7/1/2015
22	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	7/1/1999
23	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	7/1/1999

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24	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+POTASSIUM CHLORIDE/ZINC ANHYDROUS	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	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	7/1/2015
25	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	7/1/2013
26	NDA/MAL/HDP/0098	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	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	7/1/2013

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27	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,1.0X100.0 X10.0 CAPSULE BLISTER	7/1/1998
28	NDA/MAL/HDP/0102	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2014
29	NDA/MAL/HDP/0103	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	ATOREM 20	ATORVASTATIN	20MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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30	NDA/MAL/HDP/0104	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2014
31	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	7/1/1998
32	NDA/MAL/HDP/0107	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ASUNRA	DEFERASIROX	400MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERTRASSE	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER	7/1/2015

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33	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	7/1/2013
34	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	7/1/2013
35	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 SCHAFFHAUSERTRASSE 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	7/1/2007

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36	NDA/MAL/HDP/0114	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2013
37	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	7/1/2013
38	NDA/MAL/HDP/0119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+CHLORP HENIRAMINE MALEATE+PARACETA MOL+PSEUDOEPHEDRINE	30MG+4MG+400MG+30MG	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2013

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39	NDA/MAL/HDP/0121	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	BETA HEALTH CARE INTERNATIONAL LIMITED/- PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	TANZANIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2015
40	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2015
41	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	7/1/2013

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42	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	7/1/2013
43	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	7/1/2013
44	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	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2013

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45	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	7/1/2014
46	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	7/1/1998
47	NDA/MAL/HDP/0152	DELORBIS PHARMACEUTICAL S 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	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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48	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	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
49	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	7/1/2013
50	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	7/1/2015

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51	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	7/1/2015
52	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	7/1/2015
53	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	7/1/2013

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54	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	7/1/2015
55	NDA/MAL/HDP/0168	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2014
56	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	7/1/2013

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57	NDA/MAL/HDP/0182	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2014
58	NDA/MAL/HDP/0186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BENZYL AMINE+CATALKONIUM CHLORIDE	1.5%W/V+0.15 %W/V+0.0413 %W/V	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE	7/1/2014
59	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-BOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2014

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60	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	7/1/2013
61	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	7/1/2013
62	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	7/1/2013

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63	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	7/1/2015
64	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	7/1/2015
65	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	7/1/2013

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66	NDA/MAL/HDP/0207	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	LAMIVUDINE + TENOFVIR 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	7/10/2013
67	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	7/1/2013
68	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	7/1/2011

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69	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	7/1/2012
70	NDA/MAL/HDP/0218	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	TENOL-100	ATENOLOL	100MG	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	1.0X10.0X10.0 TABLET BLISTER	7/1/2015
71	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	7/1/2013

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72	NDA/MAL/HDP/0230	STRIDES SHASUN LIMITED	DELMAR 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 BLISTER 1.0X30.0X18.0	7/1/2013
73	NDA/MAL/HDP/0232	TORRENT PHARMACEUTICALS 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	7/1/2013
74	NDA/MAL/HDP/0233	MEDOCHIMIE LTD	BOOTS PHARMACEUTICALS LIMITED	CEFIMED 400	CEFIXIME TRIHYDRATE	400MG	MEDOCHIMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	7/1/2014

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75	NDA/MAL/HDP/0234	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	CEFIMED 200	CEFIXIME TRIHYDRATE	200MG	MEDOCHÉMIE 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	7/1/2014
76	NDA/MAL/HDP/0235	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	7/1/2014
77	NDA/MAL/HDP/0244	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	HYOCIN	HYOSCINE BUTYLBROMIDE	20MG/ML	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 AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	7/1/2013

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78	NDA/MAL/HDP/0245	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 4	GLIMEPIRIDE	4MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2014
79	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	7/1/2013
80	NDA/MAL/HDP/0250	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DIKON	DICLOFENAC	1%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 GELS AND SOLS	1.0X20.0 G CONTAINER	7/1/2013

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81	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	7/1/2014
82	NDA/MAL/HDP/0253	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TENLOW-5	AMLODIPINE BESYLATE	5MG	LINCOLN PHARMACEUTICALS LIMITED-TRIMUL ESTATE KHATRAJ KALOL GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
83	NDA/MAL/HDP/0254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARATE	5MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250 64293 DARMSTADT	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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84	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	7/1/2001
85	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	7/1/2014
86	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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	7/1/2001

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87	NDA/MAL/HDP/0271	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BETT	TETANUS VACCINE ADSORBED	40 I.U	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHAR (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X10.0 ML AMPOULE,1.0X24.0X1 0.0 ML AMPOULE,1.0X5.0 ML VIAL (10 DOSES)	7/1/2001
88	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	7/1/2011
89	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	7/1/2013

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90	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	7/1/1998
91	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	7/1/2013
92	NDA/MAL/HDP/0287	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	POWER HEAT	METHYL SALICYLATE	15%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	1.0X25.0 G TUBE,1.0X30.0 G TUBE	1/7/2013

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93	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/1997
94	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	7/1/2014
95	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	7/1/1998

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96	NDA/MAL/HDP/0298	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	SEFIXI-50 DRY SYRUP	CEFIXIME	50MG	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 DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	7/1/2013
97	NDA/MAL/HDP/0301	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 10	MONTELUKAST SODIUM	10MG	HETERO LABS LTD. UNIT (V) S.NO.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	7/1/2013
98	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	7/1/2014

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99	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	7/1/2013
100	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	7/1/2013
101	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	7/1/2013

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102	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	7/1/2013
103	NDA/MAL/HDP/0317	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	CIPROFLOXACIN-UF	CIPROFLOXACIN	2MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2013
104	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	7/1/2013

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105	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	7/1/2013
106	NDA/MAL/HDP/0322	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2009
107	NDA/MAL/HDP/0327	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	FLEXILOR 8	LORNOXICAM	8MG	GLENMARK PHARMACEUTICAL LIMITED;--VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2014

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108	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	7/1/2013
109	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	7/1/2014
110	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	7/1/2014

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111	NDA/MAL/HDP/0340	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	SONADAY	CLOBETASOL-17-BUTYRATE + GENTAMYCIN SULPHATE + MICONAZOLE NITRATE	0.05%W/W+0.1%W/W+2%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	1.0X15.0 G TUBE	7/1/2013
112	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	7/1/2014
113	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	7/1/2014

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114	NDA/MAL/HDP/0343	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	WHITFIELD'S OINTMENT B.P	BENZOIC ACID + SALICYLIC ACID	6% W/W + 3% 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	1.0X25.0 G TUBE	7/1/2013
115	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	7/1/2013
116	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	7/1/2015

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117	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	7/1/2014
118	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	7/1/2013
119	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	7/1/2015

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120	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	7/1/2014
121	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	7/1/2014
122	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	7/1/2001

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123	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	7/1/2015
124	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	7/1/2014
125	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	7/1/2014

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126	NDA/MAL/HDP/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROTHAZI DE	5MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2010
127	NDA/MAL/HDP/0372	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	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	7/1/2009
128	NDA/MAL/HDP/0373	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	TEMELIN	CETIRIZINE HYDROCHLORIDE	10MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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129	NDA/MAL/HDP/0375	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	FENAMON SR	NIFEDIPINE	20MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2014
130	NDA/MAL/HDP/0376	EMCURE PHARMACEUTICAL S 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	7/1/2014
131	NDA/MAL/HDP/0380	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AVERNOL	CARVEDILOL	6.25NG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2014

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132	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	7/1/2014
133	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	7/1/2014
134	NDA/MAL/HDP/0386	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	LOMOH-80	ENOXAPARIN SODIUM	80MG/ 0.8ML	EMCURE PHARMACEUTICALS LTD - PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	7/1/2014

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135	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,1.0X100.0 X10.0 CAPSULE BLISTER	7/1/1997
136	NDA/MAL/HDP/0389	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANMOL INFUSION IV	PARACETAMOL	1000MG/100 ML	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2014
137	NDA/MAL/HDP/0397	EMCURE PHARMACEUTICAL S 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	7/1/2013

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138	NDA/MAL/HDP/0400	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBSOL 1.2	MESALAMINE DELAYED RELEASE	1.2GM	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2013
139	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	7/1/2013
140	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	7/1/2015

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141	NDA/MAL/HDP/0407	NEON LABORATORIES 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	7/1/2013
142	NDA/MAL/HDP/0408	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	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	7/1/2013
143	NDA/MAL/HDP/0409	NEON LABORATORIES 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	7/1/2013

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144	NDA/MAL/HDP/0410	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 20	ROSUVASTATIN CALCIUM	20MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
145	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	1.0X10.0X1.0X2.0X75.0 MG IMPLANT	7/1/2003
146	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	7/1/2013

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147	NDA/MAL/HDP/0415	MACK BROWN PHARMECEUTICAL S PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRAMINE HYDROCHLORIDE+AM MONIUM CHLORIDE+SODIUM CITRATE+MENTHOL	14.03MG+138 MG+57.03MG +0.90MG	TORQUE PHARMACEUTICALS LTD - ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997
148	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	7/1/2013
149	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	7/1/2013

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150	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	7/1/2013
151	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,1.0X100.0X10 .0 CAPSULE BLISTER	7/1/2013
152	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	7/1/1998

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153	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, TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2015
154	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	7/1/2013
155	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	1.0X10.0X10.0 TABLET BLISTER	7/1/2014

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156	NDA/MAL/HDP/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC+PARA CETAMOL	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	7/1/2013
157	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	7/1/2014
158	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,1.0X10.0X10.0 CAPSULE STRIP	7/1/2010

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159	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	7/1/2015
160	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	7/1/2014
161	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	7/1/2015

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162	NDA/MAL/HDP/0442	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ZIK-ZAK-50	SILDENAFIL CITRATE	50MG	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	1.0X4.0 TABLET BLISTER	7/1/2014
163	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	7/1/2015
164	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	7/1/2014

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165	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	7/1/2014
166	NDA/MAL/HDP/0460	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE	7/1/2009
167	NDA/MAL/HDP/0463	GITTOES PHARMACEUTICAL S 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,1.0X100.0 X10.0 CAPSULE BLISTER	7/1/2011

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168	NDA/MAL/HDP/0467	DAWA PHARMACEUTICAL S LIMITED	SUPER MEDIC LTD	CURAMOL PLUS	PARACETAMOL/CAFF EINE	500MG/60MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	50.0X2.0 TABLET STRIP	7/1/1997
169	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	DENMARK	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	7/1/2014
170	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	DENMARK	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	7/1/2014

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171	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	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL,1.0X0.5 ML VIAL	7/1/2015
172	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	7/1/2015
173	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	7/1/2014

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174	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	7/1/2014
175	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	7/1/2014
176	NDA/MAL/HDP/0497	LABORATORY&ALLI ED LTD	HARLEYS UGANDA LIMITED	KEMOXYL DRY SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	LABORATORY & ALLIED LTD- PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2014

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177	NDA/MAL/HDP/0499	NVS KENYA LTD	SURGIPHARM (U) LIMITED	BANEOCIN OINTMENT	BACITRACIN ZINC+NEOMYCIN SULPHATE	250I.U + 5000I.U	LEK PHARMACEUTICALS DD-VEROVSKOVA 57, SI-1526 LJUBLJANA MERCK KGAA & CO.-HOSSLGASSE 20 9800 SPITTAL DRAU/ AUSTRIA	AUSTRIA SLOVENIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	7/1/2014
178	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	7/1/2013
179	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	7/1/2004

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180	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	7/1/2014
181	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	7/1/2015
182	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2014

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183	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,1.0X1.0X10.0 TABLET BLISTER	7/1/2013
184	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	7/1/2013
185	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	7/1/2014

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186	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	7/1/2013
187	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 HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
188	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, RUHRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER (COMBIPACK),1.0X3.0 X4.0 TABLET BLISTER	7/1/2013

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189	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	7/1/2012
190	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	7/1/2014
191	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)	7/1/2013

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192	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	7/1/2013
193	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	7/1/2013
194	NDA/MAL/HDP/0566	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJURAT,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	7/1/2013

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195	NDA/MAL/HDP/0569	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCELLRIDIN LINCTUS	PHOLCODINE	10MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE	7/1/2014
196	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)	7/1/2013
197	NDA/MAL/HDP/0571	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL KAOPEC	LIGHT KAOLIN + PECTIN (CITRUS)	1G + 20MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	7/1/2015

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198	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	7/1/2010
199	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	7/1/2014
200	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	7/1/2013

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201	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	7/1/2015
202	NDA/MAL/HDP/0580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDIENT	MULTINGREDI ENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/1997
203	NDA/MAL/HDP/0582	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC+PARA CETAMOL+SERRATIOPEPTIDASE	100MG + 500MG + 15MG	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, 1.0X10.0X10.0 TABLET BLISTER	7/1/2015

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204	NDA/MAL/HDP/0584	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 1	GLIMEPIRIDE+PIOGLIT AZONE+METFORMIN HYDROCHLORIDE	1MG+15MG+5 00MG	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	7/1/2014
205	NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLONE ACETATE	1%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI â€” 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	7/1/2013
206	NDA/MAL/HDP/0589	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 2	GLIMEPIRIDE+PIOGLIT AZONE+METFORMIN HYDROCHLORIDE	2MG+15MG+5 00MG	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	7/1/2014

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207	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	7/1/2013
208	NDA/MAL/HDP/0593	ARISTO PHARMACEUTICAL S 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	7/1/2014
209	NDA/MAL/HDP/0595	ARISTO PHARMACEUTICAL S 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	7/1/2015

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210	NDA/MAL/HDP/0596	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN/HYDRO CHLOROTHIAZIDE	40MG/12.5M G	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	1/7/2011
211	NDA/MAL/HDP/0598	INTAS PHARMACEUTICAL S 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	7/1/2003
212	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	7/1/2013

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213	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	7/1/2015
214	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	7/1/1999
215	NDA/MAL/HDP/0604	DAWA PHARMACEUTICALS LIMITED	SUPER MEDIC LTD-MBARARA	TRIMOXOL	CO-TRIMOXAZOLE	480MG	MEDICO REMEDIES PVT LTD,--8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE-401404, MAHARSHITRA DAWA LIMITED -16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/1997

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216	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	7/1/2015
217	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	7/1/2015
218	NDA/MAL/HDP/0611	GALPHAR LABORATORIES LTD	AIVEEN (U) LIMITED	GALCIPRO 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	GALPHA LABORATORIES LIMITED-VILLAGE – THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2015

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219	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/SY RUPS/DROPS	1.0X70.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/1998
220	NDA/MAL/HDP/0622	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	TENOL-50	ATENOLOL	50MG	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	1.0X10.0X10.0 TABLET BLISTER	7/1/2014
221	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	7/1/2015

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222	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	7/1/2015
223	NDA/MAL/HDP/0630	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEO LORIDIN	DESLOTRADINE	5MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10. 0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2011
224	NDA/MAL/HDP/0634	MEDLEY PHARMACEUTICAL S	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	7/1/2014

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225	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2009
226	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	7/1/2014
227	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	7/1/1997

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228	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	7/1/2013
229	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	7/1/2013
230	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	7/1/2013

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231	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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2013
232	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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	7/1/2013
233	NDA/MAL/HDP/0667	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL MICONAZOLE	MICONAZOLE NITRATE	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	7/1/2013

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234	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	7/1/2013
235	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	7/1/2014
236	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,1.0X100.0X10.0 TABLET BLISTER	7/1/2013

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237	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2013
238	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	7/1/2015
239	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	7/1/2014

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240	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 MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE, 1.0X5.0 G TUBE	7/1/2014
241	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, 1.0X100.0X10.0 CAPSULE BLISTER	7/1/2013
242	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	7/1/2013

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243	NDA/MAL/HDP/0685	FERRER INTERNACIONAL S.A	LABOREX 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	7/1/2015
244	NDA/MAL/HDP/0687	FERRER INTERNACIONAL S.A	LABOREX 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	7/1/2015
245	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	7/1/2014

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246	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	7/1/2013
247	NDA/MAL/HDP/0690	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	HEALTHLEASE CREAM	BECLOMETHASONE DIPROPIONATE + 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	7/1/2014
248	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	7/1/2013

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249	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	7/1/2015
250	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	7/1/2014
251	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,1.0X10.0X10.0 TABLET CARTON	7/1/2013

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252	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	7/1/2014
253	NDA/MAL/HDP/0698	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/2003
254	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)	7/1/2015

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255	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	7/1/2014
256	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	7/1/2013
257	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) MAHABOONNAGAR 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,10.0X1.0X5.0 TABLET BLISTER	7/1/2013

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258	NDA/MAL/HDP/0705	LINCOLN PHARMACEUTICAL S 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	7/1/2011
259	NDA/MAL/HDP/0706	INTAS PHARMACEUTICAL S 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	7/1/2013
260	NDA/MAL/HDP/0710	INTAS PHARMACEUTICAL S 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	7/1/2013

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261	NDA/MAL/HDP/0712	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	100MG/5ML	FARMACLAIR -440 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	7/1/1997
262	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	7/1/2015
263	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	7/1/2015

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264	NDA/MAL/HDP/0716	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-1	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	1MG + 500MG	LINCOLN PHARMACEUTICALS L.T.D- TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2014
265	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	7/1/2014
266	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	7/1/2011

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267	NDA/MAL/HDP/0720	STEDMAN PHARMACEUTICAL S 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	7/1/2013
268	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	7/1/2014
269	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	7/1/2014

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270	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	7/1/2014
271	NDA/MAL/HDP/0727	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELLADONA DRY EXTRACT+THYMOL+M ENTHOL	140MG+9MG+ 0.15MG+0.2/5 ML	TORQUE PHARMACEUTICALS LTD- ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X225.0 ML BOTTLE	7/1/2013
272	NDA/MAL/HDP/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUINE 25/67.5	ARTESUNATE+AMODI AQUINE	25MG+67.5M G	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	7/1/2013

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273	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	7/1/2013
274	NDA/MAL/HDP/0733	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC	ACECLOFENAC	100MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2013
275	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	7/1/2015

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276	NDA/MAL/HDP/0736	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	7/1/2013
277	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	7/1/2014
278	NDA/MAL/HDP/0740	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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, 1.0X10.0X10. 0 TABLET BLISTER	7/1/2013

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279	NDA/MAL/HDP/0741	MEDOCHEMIE LTD	SHREEJI PHARMACEUTICALS LIMITED	MEDOCIPRIN	CIPROFLOXACIN	500MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	7/1/2013
280	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	7/1/2013
281	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	7/1/2013

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282	NDA/MAL/HDP/0749	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEROGRAM 1000	MEROPENEM	1000MG	AURONEXT PHARMA PVT LTD.-A- 1128 RIICO INDUSTRIAL AREA, PHASE III, DISTALWAR, BHIWADI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2014
283	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	7/1/2013
284	NDA/MAL/HDP/0751	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN	ACECLOFENAC	100MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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285	NDA/MAL/HDP/0753	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEROGRAM 500	MEROPENEM	500MG	AURONEXT PHARMA PRIVATE LIMITED,-A-1128, RIICO INDUSTRIAL AREA, PHASE-III,BHIWADI-301019, DISTRICT- ALWAR (RAJASTHAN), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.OX500.0 MG VIAL	7/1/2014
286	NDA/MAL/HDP/0754	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TORAS DENK 10	TORASEMIDE	10MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.OX3.0X10.0 TABLET BLISTER	7/1/2015
287	NDA/MAL/HDP/0757	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 150	TOLPERISONE	150MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.OX10.0X10.0 TABLET BLISTER	7/1/2014

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288	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	7/1/2011
289	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	7/1/1999
290	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	7/1/2014

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291	NDA/MAL/HDP/0774	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NODON	NEBIVOLOL	10MG	CADILA HEALTH CARE LIMITED -PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER	7/1/2012
292	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	7/1/2014
293	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	7/1/1999

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294	NDA/MAL/HDP/0780	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVA TABLETS	ATORVASTATIN	10MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X1.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2001
295	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	7/1/2013
296	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	7/1/2013

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297	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	7/1/2013
298	NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGDEX	TOBRAMYCIN/DEXAMETHASONE	3MG+1MG/ML	REMINGTON PHARMACEUTICALS (PVT) LTD-18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/2014
299	NDA/MAL/HDP/0795	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	MILAN LABORATORIES (INDIA) PVT LTD .-PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2013

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300	NDA/MAL/HDP/0796	HETERO LABS LTD	AIVEEN (U) LIMITED	AMLOSIN 5	AMLODIPINE BESILATE	5MG	HETERO LABS LTD. UNIT (V) .-S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2013
301	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) MAHABOORNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2013
302	NDA/MAL/HDP/0802	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE HCT 5MG/ 160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHAZIDE	5MG+ 160MG+ 12.5MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRASSE 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	7/1/2015

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303	NDA/MAL/HDP/0811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
304	NDA/MAL/HDP/0816	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 2	GLIMEPIRIDE	2MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2012
305	NDA/MAL/HDP/0821	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 3	GLIMEPIRIDE	3MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2012

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306	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	7/1/2014
307	NDA/MAL/HDP/0823	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAP TABLETS	TRAMADOL HCL + PARACETAMOL	37.5MG+325MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2013
308	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	7/1/2013

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309	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	7/1/2013
310	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	7/1/2015
311	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	CHINA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X1000.0 CAPSULE CONTAINER	7/1/2013

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312	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	7/1/2015
313	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	7/1/2013
314	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	7/1/2013

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315	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2012
316	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	7/1/2013
317	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	7/1/2013

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318	NDA/MAL/HDP/0843	MACLEODS PHARMACEUTICAL S 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	7/1/2013
319	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, 1.0X5.0X1.0X 10.0 TABLET BLISTER	7/1/2013
320	NDA/MAL/HDP/0846	MACLEODS PHARMACEUTICAL S 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	7/1/2014

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321	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	7/1/2014
322	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)	7/1/2012
323	NDA/MAL/HDP/0854	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-50	BECLOMETASONE	50MCG PER ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA,BADDI- NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	7/1/2013

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324	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	7/1/2013
325	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	7/1/2000
326	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 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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327	NDA/MAL/HDP/0866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	LIZOLID	LINEZOLID	2MG/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	1.0X300.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2013
328	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	7/1/2013
329	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	7/1/2013

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330	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	7/1/2010
331	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 AHMABAD 382213 GUJARATI NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2009
332	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2014

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333	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	7/1/2007
334	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	NULL
335	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	7/1/2012

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336	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	7/1/2012
337	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	7/1/2014
338	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	7/1/2015

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339	NDA/MAL/HDP/0897	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+ 100MG/G	VIRCHOW BIOTECH PVT, - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/2015
340	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	7/1/2013
341	NDA/MAL/HDP/0902	GITTOES PHARMACEUTICAL S 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	7/1/2013

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342	NDA/MAL/HDP/0906	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) 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	7/1/2015
343	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	7/1/2015
344	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	7/1/2015

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345	NDA/MAL/HDP/0915	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SANDOZ GMBH- BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X2.0 TABLET STRIP	7/1/2014
346	NDA/MAL/HDP/0920	TROIKAA PHARMACEUTICAL S 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	7/1/2012
347	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	7/1/2004

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348	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.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	7/1/2013
349	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	7/1/2011
350	NDA/MAL/HDP/0938	FEROZSONS LABORATORIES LTD	HARLEYS UGANDA LIMITED	ESOMEGA 20MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	20MG	FEROZSONS LABORATORIES LTD-AMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	7/1/2013

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351	NDA/MAL/HDP/0939	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ARH	ALPHA -BETA ARTEETHER	150MG /2ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJURAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE	7/1/2012
352	NDA/MAL/HDP/0940	FEROZSONS LABORATORIES LTD	HARLEYS UGANDA LIMITED	ESOMEGA 40MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	40MG	FEROZSONS LABORATORIES LTD-AMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	7/1/2013
353	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	7/1/2013

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354	NDA/MAL/HDP/0942	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	ARH FORTE	ALPHA -BETA ARTEETHER	225MG/ 3ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJURAT,IND IA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X3.0 ML AMPOULE	7/1/2012
355	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	7/1/2013
356	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	7/1/2013

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357	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.OX10.0 ML VIAL	7/1/2013
358	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.OX20.0 ML VIAL	7/1/2013
359	NDA/MAL/HDP/0957	MACK BROWN PHARMACEUTICAL S 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.OX200.0 ML BOTTLE	7/1/2012

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360	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,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER	7/1/2013
361	NDA/MAL/HDP/0963	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD	ARTESUNATE+AMODIAQUINE	50MG+135MG	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0 TABLET BLISTER	7/1/2013
362	NDA/MAL/HDP/0964	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 25 / 67.5	ARTESUNATE + AMODIAQUINE	25 MG + 67.5 MG	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X1.0X3.0 TABLET BLISTER	7/1/2013

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363	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	7/1/2005
364	NDA/MAL/HDP/0986	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	100MG	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	7/1/2013
365	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	7/1/2013

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366	NDA/MAL/HDP/0997	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GENUPHIL	GLUCOSAMINE SULPHATE SODIUM CHLORIDE+METHYLSULPHONYLMETHANE+CHONDROITIN SULPHATE	375MG+375MG+300MG	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	7/1/2013
367	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	7/1/2014
368	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,1.0X5.0X2.5 ML AMPOULE	7/1/2012

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369	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	7/1/2013
370	NDA/MAL/HDP/1006	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRIPRIIDE-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	7/1/2012
371	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	7/1/2013

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372	NDA/MAL/HDP/1009	TROIKAA PHARMACEUTICAL S 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	7/1/2012
373	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	7/1/2012
374	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	7/1/2013

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375	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	7/1/2013
376	NDA/MAL/HDP/1017	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYCLOX	AMPICILLIN/CLOXACIL LIN	125MG/125M G	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2015
377	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	7/1/1997

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378	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	7/1/2012
379	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	7/1/2013
380	NDA/MAL/HDP/1030	LABORATORIOS SALVAT SA	LABOREX UGANDA LIMITED	MALACUR	DIHYDROARTEMISINI N + PIPERAQUINE PHOSPHATE	40MG + 320MG	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LIMITED-PLOT NO. 35-37, 43-45, CFC-B, DEWAN UDHYOG NAGAR, ALIYALI, PALGHAR – 401404, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	7/1/2014

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381	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	7/1/2013
382	NDA/MAL/HDP/1032	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ARTHFREE 20	LEFLUNOMIDE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2013
383	NDA/MAL/HDP/1033	PLEX LIFE PROVIDER	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	7/1/2015

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384	NDA/MAL/HDP/1035	GUILIN PHARMACEUTICAL CO.LTD	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	7/1/2014
385	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	7/1/2013
386	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	7/1/2013

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387	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 NUZHAT SAHAB AL- RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	7/1/2013
388	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	7/1/2013
389	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	7/1/2012

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390	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	7/1/2013
391	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	7/1/2013
392	NDA/MAL/HDP/1053	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .-PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2013

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393	NDA/MAL/HDP/1054	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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 CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	7/1/2011
394	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	7/1/2013
395	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	7/1/2010

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396	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	7/1/2013
397	NDA/MAL/HDP/1065	BLISS GVS PHARMA LIMITED	DELMAN 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	7/1/2007
398	NDA/MAL/HDP/1067	MACK BROWN PHARMECEUTICAL S PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PARACET AMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTD- ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2010

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399	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	7/1/2014
400	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	7/1/2013
401	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	7/1/2013

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402	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	7/1/2013
403	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	7/1/2013
404	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	7/1/2000

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405	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	7/1/2009
406	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	7/1/2013
407	NDA/MAL/HDP/1083	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	CHOCOFER SYRUP	IRON + FOLIC ACID	50MG + 0.5MG /5ML	GALPHA LABORATORIES LIMITED-VILLAGE – THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2013

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408	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2013
409	NDA/MAL/HDP/1085	AGIO PHARMACEUTICAL S LTD	ROYAL PHARMA 2011 LIMITED	DICLOGEN 1% GEL	DICLOFENAC GEL BP	1%W/W	AGIO PHARMACEUTICALS LTD :-A-82, MIDC, BHOSARI, PUNE-411026	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X20.0 G TUBE,1.0X30.0 G TUBE	7/1/2013
410	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	7/1/2012

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411	NDA/MAL/HDP/1087	GITTOES PHARMACEUTICAL S 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.OX15.0 G TUBE	7/1/2013
412	NDA/MAL/HDP/1088	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	RESTUM	CEFUROXIME SODIUM	750MG	ALKEM LABORATORIES LTD- VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.OX750.0 MG VIAL	7/1/2015
413	NDA/MAL/HDP/1093	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	EMTRICITABINE+TEN OFVIR DISOPROXIL FUMARATE	200MG+300M G	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.OX30.0 TABLET CONTAINER	7/1/2013

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414	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	7/1/2013
415	NDA/MAL/HDP/1095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2012
416	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	7/1/2012

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417	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	NULL
418	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	7/1/2014
419	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	7/1/2013

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420	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)	7/1/2005
421	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	7/1/2014
422	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	7/1/2013

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423	NDA/MAL/HDP/1113	MACK BROWN PHARMECEUTICAL S 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	7/1/1997
424	NDA/MAL/HDP/1114	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/METHYL SALICYLATE/MENTHO L/CAPSICUM OLEORESIN	10MG/80MG/ 60MG/0.15M G	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	7/1/2012
425	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	7/1/2013

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426	NDA/MAL/HDP/1123	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPAR	PARACETAMOL	500 MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER	7/1/2012
427	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	7/1/2013
428	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	7/1/2013

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429	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	7/1/2012
430	NDA/MAL/HDP/1132	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-CALZ	CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFEROL	1000MG+100 MG+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	7/1/2012
431	NDA/MAL/HDP/1136	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOS CAB 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	7/1/2013

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432	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	7/1/2013
433	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	7/1/2013
434	NDA/MAL/HDP/1140	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVATE-N	BETAMETHASONE+NE- OMYCIN 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	7/1/2013

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435	NDA/MAL/HDP/1141	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CALBONE	CALCIUM CARBONATE + COLECALCIFEROL	250MG+125MG/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 SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2012
436	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	7/1/2013
437	NDA/MAL/HDP/1143	LINCOLN P'CALLS 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	7/1/2012

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438	NDA/MAL/HDP/1148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 10	MONTELUKAST	10MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2012
439	NDA/MAL/HDP/1154	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BACQUIRE	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	7/1/2012
440	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	CAPSULE BLISTER, AMPOULE AMPOULE	7/1/2012

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441	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	7/1/2012
442	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	7/1/2013
443	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	7/1/2013

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444	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	7/1/2013
445	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	7/1/2010
446	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	7/1/2009

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447	NDA/MAL/HDP/1169	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	NEBI 5	NEBIVOLOL HYDROCHLORIDE	5MG	ARISTO PHARMACEUTICALS 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,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X3.0X10.0 TABLET BLISTER	7/1/2013
448	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,MANDIDEEP PRADESH	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE	7/1/2013
449	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	7/1/2010

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450	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	7/1/2013
451	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 PREFILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	7/1/2015
452	NDA/MAL/HDP/1182	TORRENT PHARMACEUTICALS 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	7/1/2013

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453	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	7/1/2013
454	NDA/MAL/HDP/1185	DAWA LIMITED	SUPER MEDIC LTD	DACOF DRY	DIPHENHYDRAMINE + DEXTROMETHORPHA N + 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	7/1/2013
455	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	7/1/2013

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456	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	7/1/2013
457	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	7/1/2009
458	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	7/1/2008

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459	NDA/MAL/HDP/1206	THE MENTHOLATUM 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	7/1/2013
460	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 PHARMACEUTICALS 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	7/1/2011
461	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	1/7/2011

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462	NDA/MAL/HDP/1211	ASTRA ZENECA	MACNAUGHTON LIMITED	BRILINTA	TICAGRELOR	90MG	ASTRA ZENECA AB-SE-151 85 SODERTALIE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	7/1/2011
463	NDA/MAL/HDP/1212	GUILIN PHARMACEUTICAL S CO.LTD	TRIDEM PHARMA UGANDA LIMITED	GLINTHER	ARTEMETHER	80MG/ML	GUILIN PHARMACEUTICAL CO.,LTD-NO 43 QILIDIAN ROAD GUILIN 541002, GUANGXI	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X15.0 ML AMPOULE	7/1/2011
464	NDA/MAL/HDP/1214	FERRER INTERNACIONAL S.A	LABOREX 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	7/1/2015

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465	NDA/MAL/HDP/1215	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE+NEOMYCIN SULPHATE+NYSTATIN	500MG+65,000IU+100,000IU	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	7/1/2013
466	NDA/MAL/HDP/1219	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH & CO.KG--PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2014
467	NDA/MAL/HDP/1220	BLISS GVS PHARMA LIMITED	DELMAN 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	7/1/2008

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468	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	7/1/2005
469	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	7/1/2013
470	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	

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471	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	7/1/2007
472	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	7/1/2013
473	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	7/1/2014

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474	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	7/1/2014
475	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	7/1/2014
476	NDA/MAL/HDP/1247	GITTOES PHARMACEUTICAL S 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	7/1/2012

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477	NDA/MAL/HDP/1250	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	STRIMOL EXTRA	PARACETAMOL+CAFFEINE	500MG+30MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAWADICROSS ANEKAL TALUK BANYALURE-562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	7/1/2014
478	NDA/MAL/HDP/1252	MACK BROWN PHARMACEUTICALS 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	7/1/2013
479	NDA/MAL/HDP/1254	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM TABLETS	CO-TRIMOXAZOLE	480MG	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 CONTAINER	7/1/1998

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480	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	7/1/1997
481	NDA/MAL/HDP/1264	CENTAUR PHARMACEUTICAL S 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	7/1/2000
482	NDA/MAL/HDP/1265	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	COMBIPLX	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2008

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483	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	7/1/1997
484	NDA/MAL/HDP/1278	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	D-ARTEPP	DIHYDROARTEMESINI N + 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,1.0X25.0X1.0 X9.0 TABLET BLISTER	7/1/2013
485	NDA/MAL/HDP/1285	SANCE LABORATORIES PVT LTD	DELMAN 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	7/1/2012

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486	NDA/MAL/HDP/1287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	7/1/2014
487	NDA/MAL/HDP/1288	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMINAT SYRUP	VITAMIN B COMPLEX	MULT- INGREDIENT	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	7/1/1998
488	NDA/MAL/HDP/1290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2013

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489	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	7/1/2012
490	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	7/1/2012
491	NDA/MAL/HDP/1299	SANCE LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	SANAXONE PLUS-1000	CEFTRIAXONE+SULBACTAM	1000MG+500 MG	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	7/1/2012

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492	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	7/1/1997
493	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	7/1/2013
494	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	7/1/2012

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495	NDA/MAL/HDP/1307	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL 40	TELMISARTAN	40MG	MICRO LABS LTD ...-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
496	NDA/MAL/HDP/1312	BLISS GVS PHARMA LIMITED	DELMAN 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	7/1/2007
497	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	7/1/1997

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498	NDA/MAL/HDP/1324	MACK BROWN PHARMECEUTICAL S PVT LTD	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	7/1/2005
499	NDA/MAL/HDP/1325	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	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	1.0X60.0 TABLET BOTTLE	7/1/2016
500	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 L'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)	7/1/1997

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501	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	7/1/1997
502	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	7/1/2012
503	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	7/1/2016

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504	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	7/1/2010
505	NDA/MAL/HDP/1348	TORRENT PHARMACEUTICALS 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	7/1/2009
506	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	7/1/2014

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507	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	7/1/2014
508	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)	7/1/2015
509	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	7/1/2016

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510	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	7/1/2016
511	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	7/1/2013
512	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 ,20ML VIAL OF SOLVENT	7/1/2016

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513	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.OX10.0 TABLET BLISTER	7/1/2013
514	NDA/MAL/HDP/1372	AXA PARENTERALS LTD	VITACARE LIMITED	RL	LACTIC ACID + SODIUM HYDROXIDE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE	(0.24 + 0.115 + 0.6 + 0.04 + 0.027)G/100M L	AXA PARENTERALS LTD- KISHNPUR, JAMALPUR ROORKEE- 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.OX500.0 ML BOTTLE	7/1/2014
515	NDA/MAL/HDP/1377	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	WATER FOR INJECTION	WATER FOR INJECTION	N/A	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD- VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.OX10.0 ML AMPOULE	7/1/2014

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516	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	7/1/2013
517	NDA/MAL/HDP/1387	INTAS PHARMACEUTICAL S 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	7/1/2004
518	NDA/MAL/HDP/1390	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	5MG	IPR PHARMACEUTICALS INC,-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2010

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519	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	7/1/1997
520	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	7/1/2013
521	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	7/1/2010

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522	NDA/MAL/HDP/1399	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ASTHALIN	SALBUTAMOL	100MCG/DOS E	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	7/1/2010
523	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	7/1/2015
524	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	7/1/2015

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525	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	7/1/2014
526	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	7/1/2007
527	NDA/MAL/HDP/1411	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPUIM	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	7/1/2011

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528	NDA/MAL/HDP/1413	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	PODINE MOUTH WASH	POVIDONE IODINE	0.1%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	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE	7/1/2014
529	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	7/1/2011
530	NDA/MAL/HDP/1417	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS 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	7/1/2001

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531	NDA/MAL/HDP/1418	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	AMINOPHYLLINE 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2011
532	NDA/MAL/HDP/1419	GLOBAL NAPI PHARMACEUTICAL S	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	7/1/2005
533	NDA/MAL/HDP/1423	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXYCILLIN + POTASSIUM CLAVULANATE	500MG+125M G	SANDOZ GMBH- BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X2.0 TABLET BLISTER	7/1/2016

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534	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2011
535	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,1.0X100.0X1. 0 ML VIAL	7/1/1997
536	NDA/MAL/HDP/1436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARATE	10MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250 64293 DARMSTADT	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2014

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537	NDA/MAL/HDP/1441	AXA PARENTERALS LTD	VITACARE LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9%W/V	AXA PARENTERALS LTD- KISHNPUR, JAMALPUR ROORKEE- 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2014
538	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	7/1/2003
539	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	7/1/2015

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540	NDA/MAL/HDP/1447	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITONA PLUS	VITAMINS + MINERALS	MULTI-INGREDIENT	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	7/1/2014
541	NDA/MAL/HDP/1450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMMONIUM	1%W/V	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	7/1/1997
542	NDA/MAL/HDP/1451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSRERTRASSE CH- 4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	7/1/1997

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543	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	7/1/2003
544	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	7/1/2006
545	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	7/1/2014

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546	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	7/1/2015
547	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, 1.0X10.0X10.0 TABLET BLISTER	7/1/2014
548	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	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	7/1/1998

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549	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	7/1/2016
550	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	7/1/2016
551	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	7/1/2001

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552	NDA/MAL/HDP/1482	SANOPI PASTEUR	LABOREX UGANDA LIMITED	STAMARIL PASTEUR	YELLOW FEVER VIRUS 17D-204 STRAIN(LIVE ATTENUATED)	NLT 1000 I.U	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A-2,AVENUE PONT PASTEUR 69007 LYON-FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF SOLVENT IN PRE-FILLED SYRINGE,1.0X10.0X10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	7/1/1997
553	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	7/1/2011
554	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	7/1/2000

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555	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 GRONAU-LEIRE, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	7/1/1998
556	NDA/MAL/HDP/1493	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICALS LIMITED	KOACT 1000	AMOXICILLIN/CLAVUL ANATE POTASSIUM	875MG/125M G	AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X5.0 TABLET BLISTER	7/1/2007
557	NDA/MAL/HDP/1494	FERRER INTERNACIONAL S.A	LABOREX 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	7/1/2013

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558	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	7/1/1997
559	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	7/1/1997
560	NDA/MAL/HDP/1499	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZINE	PROMETHAZINE HYDROCHLORIDE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	7/1/2005

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561	NDA/MAL/HDP/1500	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ATRIPLA	EFAVIRENZ+EMTRICIT ABINE + TENOFOVIR	600MG +200MG+300 MG	PATHEON INC- MISSISSAUGA,ON L5N 7K9 CANADA	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2008
562	NDA/MAL/HDP/1503	MEDICAL UNION PHARMACUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT CREAM	HYDROCORTISONE+CI NCHOCAINE	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	7/1/2003
563	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	7/1/2007

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564	NDA/MAL/HDP/1506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 2000	RECOMBINANT HUMAN ERYTHROPOIETIN	2000 IU	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	7/1/2011
565	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	7/1/2009
566	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2007

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567	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	7/1/2011
568	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	7/1/1998
569	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	7/1/2007

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570	NDA/MAL/HDP/1526	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINO BUTYRIC 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	7/1/2015
571	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	7/1/2007
572	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	7/1/1997

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573	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	7/1/2014
574	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	7/1/2007
575	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	7/1/2011

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576	NDA/MAL/HDP/1538	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/2003
577	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	7/1/2004
578	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	7/1/1999

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579	NDA/MAL/HDP/1549	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	PREDNICOL EYE DROPS	PREDNISOLONE/CHLO RAMPHENICOL	5MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	7/1/1999
580	NDA/MAL/HDP/1551	EMCURE PHARMACEUTICAL S 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	7/1/2004
581	NDA/MAL/HDP/1553	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	VIFEX	SALBUTAMOL + BROMHEXINE + GUAIFENESIN	1MG/5ML+2M G/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	7/1/2004

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582	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	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2010
583	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	7/1/2008
584	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	7/1/2014

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585	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+DIPHTHERIA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+13MCG+8MCG+5MCG+0.5MG	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'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)	7/1/2010
586	NDA/MAL/HDP/1559	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DOLOMOL	PARACETAMOL	500MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 X1.0X10.0 TABLET BLISTER	7/1/2003
587	NDA/MAL/HDP/1561	LINCOLN P'CALLS 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	7/1/2004

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588	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1997
589	NDA/MAL/HDP/1566	GITTOES PHARMACEUTICAL S 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	7/1/2009
590	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)	7/1/2013

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591	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	7/1/2011
592	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	7/1/2003
593	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	7/1/2011

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594	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	7/1/2006
595	NDA/MAL/HDP/1582	LINCON PHARMCEUTICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CEEPRO-500	CIPROFLOXACIN	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	7/1/2005
596	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	7/1/2010

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597	NDA/MAL/HDP/1589	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIMETHI CONE	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	7/1/1997
598	NDA/MAL/HDP/1591	CENTAUR PHARMACEUTICALS 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	7/1/1997
599	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	7/1/2005

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600	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	7/1/2005
601	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	7/1/2011
602	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	7/1/2004

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603	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	7/1/2011
604	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	7/1/2007
605	NDA/MAL/HDP/1632	ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1000MG +200MG	ALKEM LABORATORIES LTD ,,-VILLAGE THANA BADDI DIST-SOLAN TEHSIL NALAGARH HIMACHAL PRADESH 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF WFI	7/1/2005

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606	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	7/1/1997
607	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-BOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	7/1/2005
608	NDA/MAL/HDP/1639	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL EXTRA WITH OPTIZORB	PARACETAMOL + CAFFEINE	500MG + 65MG	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA GRANULES INDIA LIMITED- SY. NO. 160/A, 161/E, 162 & 174/A GAGILLAPUR VILLAGE, DUNDIGAL- GANDIMASAMMA MANDAL, MEDCHAL - MALKHAJGIRI DISTRICT - 500043 TELANGANA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CARTON	7/1/2003

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609	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	7/1/2004
610	NDA/MAL/HDP/1646	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE+DIL OXANIDE	200MG+250M G	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	7/1/2002
611	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	7/1/2006

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612	NDA/MAL/HDP/1652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	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	7/1/2009
613	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	7/1/2015
614	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,1.0X100.0 X10.0 TABLET STRIP	7/1/2005

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615	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	7/1/2007
616	NDA/MAL/HDP/1663	MACK BROWN PHARMACEUTICALS 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	7/1/2003
617	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	7/1/1998

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618	NDA/MAL/HDP/1673	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL	AMOXYCILLIN	250MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE GLAXO WELLCOME PRODUCTION- ZI DE LA PEYENNIERE, 53100, MAYENNE	FRANCE	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	7/1/2005
619	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,1.0X10.0X 10.0 CAPSULE BLISTER	7/1/1997
620	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	7/1/2007

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621	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	7/1/1997
622	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, 1.0X10.0X1.0 X10.0 TABLET BLISTER	7/1/2005
623	NDA/MAL/HDP/1685	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL	KETOCONAZOLE	200MG	LINCOLN PHARMACEUTICALS LTD- 10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ- 382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2005

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624	NDA/MAL/HDP/1689	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	OMESK	OMEPRAZOLE	20MG	S.KANT HEALTHCARE LTD- PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	7/1/2010
625	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	7/1/2004
626	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	7/1/2011

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627	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	7/1/2007
628	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	7/1/2005
629	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	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2005

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630	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	7/1/2014
631	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	7/1/2005
632	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	7/1/2011

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633	NDA/MAL/HDP/1708	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	DENTAMOL	ACETAMINOPHEN	500MG	LABORATORY & ALLIED LTD- PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/1997
634	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	7/1/1997
635	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	7/1/1997

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636	NDA/MAL/HDP/1713	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 OXALIS LABS - VILLAGE THEDA P.O LODHIMAJRA, THESIL BADDI DISTRICT SOLAN HIMACHAL PRADESH	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 BLISTER,1.0X1.0X18.0	7/1/2007
637	NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHE NIRAMINE+DEXTROM ETHORPHAN+BROMH EXINE	50MG+2MG+5 MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD -- PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA SHELYS PHARMACEUTICALS LTD,- NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32 P.O.BOX	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	7/1/2011
638	NDA/MAL/HDP/1716	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMIN 5S	MULTI-INGREDIENT	MULTI- INGREDIENT	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)-VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2010

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639	NDA/MAL/HDP/1719	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMIN 10 PLUS	MULTI-INGREDIENT	MULTI- INGREDIENT	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)-VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2010
640	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	7/1/2000
641	NDA/MAL/HDP/1724	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACT UATION	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	7/1/2009

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642	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	7/1/2000
643	NDA/MAL/HDP/1728	ARISTO PHARMACEUTICAL S 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	7/1/2007
644	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	7/1/2008

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645	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	7/1/1997
646	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	7/1/1999
647	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,PS OT,SATYAVEDU MANDAL,CHITTOOR 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	7/1/1997

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648	NDA/MAL/HDP/1739	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	7/1/2009
649	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	7/1/2005
650	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	7/1/2005

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651	NDA/MAL/HDP/1748	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 CAPSULES	1.0X3.0 CAPSULE BLISTER	7/1/2011
652	NDA/MAL/HDP/1749	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX	VITAMIN B COMPLEX	N/A	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	7/1/2005
653	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	7/1/2005

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654	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	7/1/2005
655	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	7/1/2005
656	NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCAT	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005

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657	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	7/1/2005
658	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	7/1/2005
659	NDA/MAL/HDP/1761	EMCURE PHARMACEUTICAL S 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	7/1/2014

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660	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	7/1/2005
661	NDA/MAL/HDP/1763	LABORATORY&ALLI ED 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	7/1/1997
662	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	7/1/2006

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663	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	7/1/2012
664	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	7/1/2005
665	NDA/MAL/HDP/1767	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PROSTETROL	ALFUZOSIN HYDROCHLORIDE	10MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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666	NDA/MAL/HDP/1769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'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)	7/1/1997
667	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	7/1/2000
668	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	7/1/2005

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669	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	7/1/2003
670	NDA/MAL/HDP/1778	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 500MG CAPSULES	AMOXYCILLIN TRIHYDRATE	500MG	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 CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	7/1/1998
671	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	7/1/2006

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672	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	7/1/2010
673	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	7/1/1997
674	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	7/1/2005

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675	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	7/1/1997
676	NDA/MAL/HDP/1786	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGONAC TABLETS (THANE)	DICLOFENAC	50MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER	7/1/2001
677	NDA/MAL/HDP/1790	REGAL PHARMACEUTICALS 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	7/1/1997

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678	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	7/1/1997
679	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X1.0 X6.0 TABLET BLISTER	7/1/2006
680	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	7/1/2010

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681	NDA/MAL/HDP/1798	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	CARDITAS RETARD	NIFEDIPINE	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997
682	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	7/1/2001
683	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	7/1/2009

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684	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	7/1/1997
685	NDA/MAL/HDP/1804	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL	LISINOPRIL	5MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2001
686	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	7/1/1997

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687	NDA/MAL/HDP/1809	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVIT-6	PYRIDOXINE	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2004
688	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	7/1/2010
689	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	7/1/2001

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690	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	7/1/2003
691	NDA/MAL/HDP/1816	MACK BROWN PHARMECEUTICAL S 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	7/1/1998
692	NDA/MAL/HDP/1825	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMOL+CHLO RPHENIRAMINE MALEATE+PSEUDOEP HEDRINE HYDROCHLORIDE	120MG+2MG+ 15MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2005

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693	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	7/1/2006
694	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	7/1/2011
695	NDA/MAL/HDP/1841	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	FUNGIL CREAM	CLOTRIMAZOLE	1%W/W	TORQUE PHARMACEUTICALS LTD- ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2000

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696	NDA/MAL/HDP/1842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICALS INDUSTRIES-PLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2002
697	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	7/1/2005
698	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	7/1/2011

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699	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	7/1/2013
700	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	7/1/1997
701	NDA/MAL/HDP/1853	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS ORAL SOLUTION	DESLOTRADINE	0.5MG/ML	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	7/1/2007

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702	NDA/MAL/HDP/1854	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	FUROSEMIDE INJECTION	FUROSEMIDE	10MG/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,1.0X100.0X2.0 ML AMPOULE	7/1/2004
703	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	7/1/1998
704	NDA/MAL/HDP/1861	GUILIN PHARMACEUTICALS CO LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHOXAZOLE / TRIMETHOPRIM	SULFAMETHOXAZOLE / 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	7/1/2011

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705	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-BOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	7/1/2004
706	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	7/1/2009
707	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	7/1/2007

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708	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	7/1/2004
709	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	7/1/2004
710	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	7/1/2004

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711	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	7/1/2004
712	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 BLISTER	7/1/1997
713	NDA/MAL/HDP/1889	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PRED SOL	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	7/1/1997

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714	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	7/1/2005
715	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	7/1/2012
716	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2007

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717	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	7/1/2001
718	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,1.0X10.0X10.0 CAPSULE STRIP	7/1/2007
719	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	7/1/2013

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720	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	7/1/1997
721	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/1998
722	NDA/MAL/HDP/1912	MACK BROWN PHARMECEUTICAL S 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	7/1/2008

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723	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	7/1/2003
724	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	7/1/1999
725	NDA/MAL/HDP/1920	STRIDES ARCOLAB LTD	ROYAL PHARMA 2011 LIMITED	ASCORBIC ACID TABLET	ASCORBIC ACID	100MG	STRIDES ARCO LAB LTD- K.R.S GARDENS SURAGAJAKKANAHALLI,INDIA LAWADI CROSS ANEKAL TALUK,BANGALORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/1997

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726	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	7/1/2013
727	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	
728	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 + 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	7/1/2013

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729	NDA/MAL/HDP/1929	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 40	ATORVASTATIN	40MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2012
730	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	7/1/2010
731	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	7/1/2005

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732	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	7/1/2013
733	NDA/MAL/HDP/1940	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLOXACILLIN CAPSULES	CLOXACILLIN SODIUM	250MG	REMEDICA LTD-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	7/1/2001
734	NDA/MAL/HDP/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOX 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	7/1/2005

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735	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	7/1/2009
736	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	7/1/2009
737	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	7/1/1998

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738	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	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	7/1/1998
739	NDA/MAL/HDP/1949	MACLEODS PHARMACEUTICAL S 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	7/1/2011
740	NDA/MAL/HDP/1951	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	CLOPI 75	CLOPIDOGREL	75MG	MACLEODS PHARMACEUTICALS -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP,3.0X10.0 TABLET STRIP	7/1/2006

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741	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	7/1/2011
742	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 STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER	7/1/2006
743	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 STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2005

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744	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 STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X 10.0 TABLET BLISTER	7/1/2005
745	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	7/1/2003
746	NDA/MAL/HDP/1963	MILAN LABERATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	DICLOFENAC GEL	DICLOFENAC	1%W/W	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO- OP. INDUSTRIAL STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X35.0 G TUBE	7/1/2006

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747	NDA/MAL/HDP/1964	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CLONEX	CLOTRIMAZOLE	1%W/W	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2007
748	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	7/1/2005
749	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	7/1/2005

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750	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998
751	NDA/MAL/HDP/1974	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL	CEFUROXIME AXETIL	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	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2013
752	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	7/1/2007

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753	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	7/1/2011
754	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	7/1/2004
755	NDA/MAL/HDP/1988	KUNMING PHARMACEUTICALS CORP	SUPER PHARMACEUTICALS LIMITED	ARTEMEDINE INJECTION	ARTEMETHER	80MG/ML	KUNMING PHARMACEUTICAL CORP.- QIGONGLI, WEST SURBURB, KUNMING 650106 - YUNNAM PROVINCE, P.R. CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X8.0X1.0 ML AMPOULE	7/1/1999

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756	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	7/1/2014
757	NDA/MAL/HDP/1990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X2.0 TABLET BLISTER	7/1/2005
758	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".)	7/1/2011

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759	NDA/MAL/HDP/1999	TORRENT PHARMACEUTICALS 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	7/1/2000
760	NDA/MAL/HDP/2000	TORRENT PHARMACEUTICALS 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	7/1/2000
761	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	7/1/2005

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762	NDA/MAL/HDP/2007	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	B-COX TABLETS	VITAMIN B COMPLEX	BCP FORMULA	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	7/1/2001
763	NDA/MAL/HDP/2008	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- CREAM	CLOTRIMAZOLE + BECLOMETASONE DIPROPIONATE 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	7/1/2004
764	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/SY RUPS/DROPS	1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE	7/1/2010

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765	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	7/1/2004
766	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	7/1/2009
767	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	7/1/2000

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768	NDA/MAL/HDP/2018	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	ORAXIN SYRUP	CYPROHEPTADINE+TR ICHOLINE CITRATE	2MG+275MG	CENTAUR PHARMACEUTICALS LTD,-- KARASWADA MAPUSA GOA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/1997
769	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	7/1/2011
770	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	7/1/1997

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771	NDA/MAL/HDP/2021	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGVIT ZINC	MULTIVITAMIN/MINERALS	MULT- INGREDIENT	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 CAPSULES	1.0X12.0X2.0 CAPSULE BLISTER	7/1/2000
772	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	7/1/1997
773	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	7/1/2004

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774	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	7/1/1997
775	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	7/1/2009
776	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	7/1/2013

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777	NDA/MAL/HDP/2031	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOZID TABLETS	ISONIAZID	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	1.0X1000.0 TABLET CONTAINER,1.0X10.0X 10.0 TABLET BLISTER	7/1/2004
778	NDA/MAL/HDP/2033	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-50	LOSARTAN POTASSIUM	50MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	7/1/2009
779	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,1.0X50.0X3.0 TABLET BLISTER	7/1/2004

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780	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	7/1/1998
781	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,1.0X30.0X24.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X12.0	7/1/2006
782	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	7/1/1997

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783	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	7/1/1998
784	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	7/1/2005
785	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	7/1/2011

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786	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	7/1/2005
787	NDA/MAL/HDP/2053	EMCURE PHARMACEUTICAL S 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	7/1/2005
788	NDA/MAL/HDP/2055	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	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	7/1/2011

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789	NDA/MAL/HDP/2056	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	BRO-ZEDEX	TERBUTALINE SULPHATE +BROMHEXINE HYDROCHLORIDE+GU AIPHENESIN+MENTH OL	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	7/1/1997
790	NDA/MAL/HDP/2058	MACLEODS PHARMACEUTICAL S 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	7/1/2006
791	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN PAEDIATRIC SYRUP	DEXTROMETHORPHA N 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	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	7/1/2006

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792	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	7/1/1997
793	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	7/1/2005
794	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	7/1/1999

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795	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	7/1/1999
796	NDA/MAL/HDP/2069	SK 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	7/1/2010
797	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	7/1/2009

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798	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	7/1/2000
799	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	7/1/1997
800	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	7/1/1998

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801	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	7/1/2006
802	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2006
803	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,MANDIDEEP PRADESH	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2007

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804	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 KOLTHAR (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)	7/1/2015
805	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	7/1/2013
806	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	7/1/2005

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807	NDA/MAL/HDP/2091	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CAMSTON	CLOTRIMAZOLE	1%W/W	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES LTD-PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2001
808	NDA/MAL/HDP/2093	CADILA PHARMACEUTICAL S LIMITED	KARURI PHARMACEUTICALS LTD.	TRIGAN-D TABLET	PARACETAMOL + DICLOMINE	500MG + 20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP	7/1/1999
809	NDA/MAL/HDP/2094	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT-750	LEVOFLOXACIN HEMIHYDRATE	750MG	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	7/1/2010

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810	NDA/MAL/HDP/2095	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	PARACETAMOL	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	1.0X1000.0 TABLET CONTAINER	7/1/2010
811	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2006
812	NDA/MAL/HDP/2101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2010

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813	NDA/MAL/HDP/2102	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING 625	AMOXYCILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MEDREICH LIMITED –UNIT I-12TH MILE, OLD MADRAS ROAD, VIRGONAGAR BANGALORE-560 049, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2006
814	NDA/MAL/HDP/2103	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING 1000 TAB	AMOXYCILLIN + CLAVULANATE POTASSIUM	875 MG + 125 MG	MEDREICH LIMITED –UNIT I-12TH MILE, OLD MADRAS ROAD, VIRGONAGAR BANGALORE-560 049, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2006
815	NDA/MAL/HDP/2104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE/NEVIRAPINE /ZIDOVUDINE DISPERSIBLE TABLETS	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD-1-F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2009

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816	NDA/MAL/HDP/2111	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR / RITONAVIR	LOPINAVIR / RITONAVIR	200MG /50MG	HETERO LABS LTD. UNIT (V) .-S.NO.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	7/1/2011
817	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	7/1/2008
818	NDA/MAL/HDP/2116	MACLEODS PHARMACEUTICAL S 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,1.0X10.0X10. 0 TABLET STRIP	7/1/2005

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819	NDA/MAL/HDP/2122	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/1997
820	NDA/MAL/HDP/2125	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	BECLATE 100	BECLOMETASONE	100MCG/DOS E	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	7/1/2009
821	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	7/1/2010

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822	NDA/MAL/HDP/2133	NOVO NORDISK	STAR PHARMACEUTICALS LTD	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	7/1/1997
823	NDA/MAL/HDP/2136	MEDICAL UNION PHARMACEUTICAL S	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	7/1/2003
824	NDA/MAL/HDP/2141	CENTAUR PHARMACEUTICAL S 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	7/1/2005

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825	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	7/1/2014
826	NDA/MAL/HDP/2149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPROGESTER ONE HEXANOATE	250MG	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	7/1/1997
827	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	7/1/1999

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828	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	7/1/2000
829	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	7/1/2000
830	NDA/MAL/HDP/2156	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRPID 10 INTRAVENOUS FAT EMULSION	SOYA OIL	10%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2011

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831	NDA/MAL/HDP/2158	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRPID	INTRAVENOUS FAT EMULSION	20%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2010
832	NDA/MAL/HDP/2160	EMCURE PHARMACEUTICAL S 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	7/1/2005
833	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	7/1/1997

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834	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	7/1/2014
835	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	7/1/2011
836	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	7/1/2003

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837	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 Â€"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	7/1/2005
838	NDA/MAL/HDP/2176	INTAS PHARMACEUTICALS 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	7/1/2011
839	NDA/MAL/HDP/2181	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PHEN	PHENOXYMETHYLPEN ICILLIN	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	7/1/1997

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840	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 BOIOLOGICALS-S.A RUE DE L'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	7/1/2013
841	NDA/MAL/HDP/2186	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	7MG+67.5MG/5ML	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2008
842	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	7/1/2008

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843	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	7/1/1997
844	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 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	7/1/1997
845	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	1/7/2013

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846	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	7/1/2010
847	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	7/1/2005
848	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	7/1/2005

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849	NDA/MAL/HDP/2214	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	GENTAMICIN INJECTION	GENTAMICIN SULPHATE	40MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	7/1/1997
850	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	7/1/2005
851	NDA/MAL/HDP/2217	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMINOPHYLINE	AMINOPHYLLINE	20MG	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	7/1/2005

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852	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	7/1/1997
853	NDA/MAL/HDP/2220	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 5	AMLODIPINE BESYLATE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	7/1/2003
854	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	7/1/2004

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855	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	7/1/2011
856	NDA/MAL/HDP/2235	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-N	INSULIN HUMAN(RECOMBINANT DNA ORIGIN)	100IU/ML	WOCKHARDT-WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	7/1/2006
857	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	7/1/1997

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858	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	7/1/2006
859	NDA/MAL/HDP/2239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL ORAL SUSPENSION	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	7/1/2006
860	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	7/1/1997

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861	NDA/MAL/HDP/2248	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	TETRACYCLINE OPTHALMIC	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	7/1/2004
862	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	7/1/2006
863	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	7/1/1998

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864	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/SY RUPS/DROPS	1.0X1.0X70.0 ML BOTTLE	7/1/2010
865	NDA/MAL/HDP/2258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300M G/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 GREEN STONE LIMITED-PLOT NO. 11.12&13 INDORE SPECIAL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X30.0 TABLET BOTTLE	7/1/2009
866	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	7/1/2001

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867	NDA/MAL/HDP/2265	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR/ LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG + 300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.OX30.0 TABLET BOTTLE	7/1/2010
868	NDA/MAL/HDP/2267	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG+300M G	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.OX30.0 TABLET BOTTLE	7/1/2007
869	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/SY RUPS/DROPS	1.OX100.0 ML BOTTLE	7/1/1997

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870	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	7/1/2010
871	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	7/1/2005
872	NDA/MAL/HDP/2280	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	BETADROP-N	BETAMETHASONE + NEOMYCIN	0.1 %W/V + 0.5 %W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	7/1/1999

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873	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	7/1/2007
874	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	7/1/2011
875	NDA/MAL/HDP/2283	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA TETANUS PERTUSIS	DIPHTHERIA 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)	7/1/1997

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876	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	7/1/1997
877	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	7/1/2008
878	NDA/MAL/HDP/2292	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING 1200	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	1000MG + 200MG	NATCO PHARMA LTD- VIJAYAPUR, NORTH NAGARIJUNA SAGA,INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0X20.0 ML VIAL	7/1/2007

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879	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	7/1/2005
880	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	7/1/2013
881	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	7/1/2008

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882	NDA/MAL/HDP/2298	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2013
883	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	7/1/2013
884	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	7/1/2014

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885	NDA/MAL/HDP/2304	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOROTHAZI DE	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	7/1/2014
886	NDA/MAL/HDP/2305	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOROTHAZI DE	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	7/1/2014
887	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	7/1/2010

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888	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	7/1/2006
889	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	7/1/2006
890	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	7/1/2005

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891	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/SY RUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2006
892	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	7/1/2006
893	NDA/MAL/HDP/2319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMOL	120MG/5ML	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	7/1/1998

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894	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2006
895	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	7/1/2007
896	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	7/1/2011

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897	NDA/MAL/HDP/2326	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	SYLATE-500	ETAMSYLATE	50MG	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	7/1/2004
898	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 MAHALLESİ İHLA VADİSİ SOKAK, NO.2, 34912 KURTKOY, İSTANBUL - TURKEY	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0X24. 0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X36.0X6.0 TABLET BLISTER,1.0X3.0X8.0 TABLET BLISTER,1.0X30.0X12. 0 TABLET BLISTER,1.0X30.0X18.	7/1/2005
899	NDA/MAL/HDP/2333	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA & TETANUS VACCINE ADSORBED(PEDIATR IC)	DIPHTHERIA 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)	7/1/1997

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900	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	7/1/1997
901	NDA/MAL/HDP/2335	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEN TABLETS(THANE)	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	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	7/1/2001
902	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	7/1/2003

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903	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	7/1/2007
904	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	7/1/2007
905	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)	7/1/2005

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906	NDA/MAL/HDP/2352	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP 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	7/1/2007
907	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	7/1/2013
908	NDA/MAL/HDP/2354	STRIDES SHASUN LIMITED	DELMAR ENTERPRISES LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2006

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909	NDA/MAL/HDP/2356	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE	QUININE DIHYDROCHLORIDE	600MG/2ML	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	7/1/2005
910	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	7/1/2003
911	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	7/1/2007

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912	NDA/MAL/HDP/2360	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/2002
913	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	7/1/2007
914	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	7/1/2009

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915	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,1.0X10.0X1 0.0X2.0 ML AMPOULE	7/1/2005
916	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	7/1/2015
917	NDA/MAL/HDP/2367	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2007

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918	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	7/1/2007
919	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	7/1/2007
920	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	7/1/2010

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921	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	7/1/2014
922	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	7/1/1997
923	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	7/1/2007

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924	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	7/1/2000
925	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	7/1/2010
926	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/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	7/1/2011

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927	NDA/MAL/HDP/2390	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMISINI N/ 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/SY RUPS/DROPS	1.0X80.0 ML BOTTLE,1.0X120.0 ML BOTTLE	7/1/2008
928	NDA/MAL/HDP/2391	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HEAD AID 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	7/1/1997
929	NDA/MAL/HDP/2394	MERCK SHARP & DOHME BV.	SURGIPHARM (U) LIMITED	STOCRIN	EFAVIRENZ	600MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD- XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLESÂ€™ REPUBLIC OF CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2004

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930	NDA/MAL/HDP/2395	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	STAR PHARMACEUTICALS LTD	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	7/1/2005
931	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	7/1/2005
932	NDA/MAL/HDP/2400	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIDIC 2%	FUSIDIC ACID	20MG/G	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2007

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933	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	7/1/2005
934	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	7/1/2005
935	NDA/MAL/HDP/2409	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	DEPLATT	CLOPIDOGREL	75MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2004

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936	NDA/MAL/HDP/2411	STEDMAN PHARMACEUTICAL S 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	7/1/2010
937	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998
938	NDA/MAL/HDP/2415	CENTAUR PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/1997

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939	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	7/1/2011
940	NDA/MAL/HDP/2426	MACK BROWN PHARMACEUTICALS 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	7/1/2000
941	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	7/1/1997

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942	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	7/1/1998
943	NDA/MAL/HDP/2429	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOLE	100MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 PESSARY CARTON	7/1/1998
944	NDA/MAL/HDP/2431	CADILA HEALTH CARE 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	7/1/2007

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945	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	7/1/2007
946	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	7/1/2006
947	NDA/MAL/HDP/2451	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN 75 SR	DICLOFENAC SODIUM	75 MG	ACINO PHARMA AG-DORNACHERSTRASSE 114, CH-4147 AESCH	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2004

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948	NDA/MAL/HDP/2452	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELADED 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	7/1/2007
949	NDA/MAL/HDP/2460	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS 2MG	BENZHEXOL HCL	2MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	7/1/2000
950	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+90.0 MG+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	7/1/1997

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951	NDA/MAL/HDP/2467	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NOKLOT	CLOPIDOGREL	75MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2003
952	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	7/1/2011
953	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	7/1/2010

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954	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	7/1/2001
955	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	7/1/2003
956	NDA/MAL/HDP/2478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMOL+DICL OFENAC	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	7/1/2005

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957	NDA/MAL/HDP/2479	SANCE LABORATORIES PVT LTD	DELMAN 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	7/1/2012
958	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	7/1/2004
959	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	7/1/2007

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960	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	7/1/1997
961	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	7/1/2008
962	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	7/1/2011

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963	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2007
964	NDA/MAL/HDP/2508	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	HYOSCINE	HYOSCINE	20MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2011
965	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	7/1/1997

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966	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	7/1/2013
967	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	7/1/2009
968	NDA/MAL/HDP/2513	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMETHYLPENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1997

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969	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	
970	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	7/1/2005
971	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	7/1/1997

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972	NDA/MAL/HDP/2524	MEDLEY PHARMACEUTICAL S 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 AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005
973	NDA/MAL/HDP/2525	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	7/1/1998
974	NDA/MAL/HDP/2526	REGAL PHARMACEUTICALS 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	7/1/2009

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975	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	7/1/1997
976	NDA/MAL/HDP/2552	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CAROFIT	VITAMIN C/ VITAMIN A/ ZINC SULPHATE	150MG/10MG /75MG	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	7/1/2005
977	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	7/1/2003

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978	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	7/1/2005
979	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	7/1/1998
980	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	7/1/1999

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981	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	7/1/2005
982	NDA/MAL/HDP/2565	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE,1.0X5.0X2.0 ML AMPOULE	7/1/2001
983	NDA/MAL/HDP/2567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACIN	500MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA 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	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997

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984	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	7/1/1997
985	NDA/MAL/HDP/2570	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	AMOXAPEN 250 CAPSULES	AMOXYCILLIN	250MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,100.0X10.0 CAPSULE BLISTER	7/1/1997
986	NDA/MAL/HDP/2571	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 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 LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	7/1/2010

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987	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, 1.0X100.0X10.0 TABLET BLISTER, 1.0X50.0X2.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	7/1/1997
988	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 - -	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	7/1/1998
989	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	7/1/2005

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990	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2009
991	NDA/MAL/HDP/2597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	RUBIEPHARM ARZNEIMITTEL GMHH - GERMANY BENE- ARZNEIMITTEL GMBH- HERTERICHSTR. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	7/1/2005
992	NDA/MAL/HDP/2600	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE-OD	CLARITHROMYCIN(EX TENTED 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	7/1/2008

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993	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	7/1/2010
994	NDA/MAL/HDP/2603	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	VIRADAY	TENOFOVIR + EMTRICITABINE + EFAVIRENZ	300 MG + 200 MG + 600 MG	CIPLA LTD .-PLOT NO. S-103 TO S-105, S-107 TO S-112, L-147 TO L-1147-1, VERNA ELECTRONIC CITY GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2011
995	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	7/1/2000

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996	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	7/1/2009
997	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	7/1/2004
998	NDA/MAL/HDP/2641	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	7/1/2014

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999	NDA/MAL/HDP/2642	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	7/1/2009
1000	NDA/MAL/HDP/2645	SANCE LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	7/1/2010
1001	NDA/MAL/HDP/2647	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	IBUPROFEN DENK 400MG	IBUPROFEN	400MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 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	7/1/2005

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1002	NDA/MAL/HDP/2648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	RUBIEPHARM ARZNEIMITTEL GMBH - GERMANY BENE- ARZNEIMITTEL GMBH- HERTERICHSTR. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP	7/1/2005
1003	NDA/MAL/HDP/2650	DENK PHARMA	BENLE CONSULT LIMITED	VIT-B-DENK	THIAMINE HCL + PYRIDOXINE HCL	100MG + 200MG	DENK PHARMA GMBH & CO.-PRINZREGENTENSTR. 79, 81675 MÜNCHEN, GÖLLSTR. 1, 84529 TITTMONING, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CARTON,1.0X10.0X10. 0 TABLET BLISTER	7/1/2005
1004	NDA/MAL/HDP/2651	REGAL PHARMACEUTICALS 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	7/1/1997

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1005	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	7/1/2006
1006	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2008
1007	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	7/1/2005

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1008	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	7/1/2011
1009	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	7/1/2004
1010	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	7/1/2006

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1011	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	7/1/2007
1012	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	7/1/2005
1013	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	7/1/2011

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1014	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	7/1/2011
1015	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	7/1/2012
1016	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	7/1/1997

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1017	NDA/MAL/HDP/2699	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 12.5	CARVEDILOL	12.5 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2005
1018	NDA/MAL/HDP/2702	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 2	GLIMEPIRIDE	2MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2004
1019	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	7/1/2007

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1020	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	7/1/1997
1021	NDA/MAL/HDP/2708	MACK BROWN PHARMACEUTICAL S 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,1.0X2.0X5 0.0 TABLET BLISTER	7/1/2000
1022	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	7/1/1997

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1023	NDA/MAL/HDP/2712	NEON LABORATORIES 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.OX20.0 ML VIAL	7/1/2014
1024	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.OX1.OX60.0 TABLET CONTAINER	7/1/2008
1025	NDA/MAL/HDP/2717	CENTAUR PHARMACEUTICAL S 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.OX3.5 G TUBE	7/1/2000

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1026	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	7/1/2007
1027	NDA/MAL/HDP/2720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACILLIN	125MG/5ML+ 125MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X80.0 ML BOTTLE	7/1/2007
1028	NDA/MAL/HDP/2721	MACK BROWN PHARMECEUTICAL S 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	7/1/2007

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1029	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	7/1/2007
1030	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	7/1/2009
1031	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	7/1/2001

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1032	NDA/MAL/HDP/2739	REGAL PHARMACEUTICALS 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	7/1/2001
1033	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	7/1/2005
1034	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	7/1/2015

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1035	NDA/MAL/HDP/2746	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH & CO. KG- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER	7/1/2000
1036	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	7/1/2009
1037	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,1.0X50.0X1.0X1.0X3.0 TABLET BLISTER	7/1/2016

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1038	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	7/1/2010
1039	NDA/MAL/HDP/2760	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELATED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+DE XTROMETHORPHAN+ 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	7/1/1997
1040	NDA/MAL/HDP/2761	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	TRIFLUOPERAZINE	TRIFLUOPERAZINE HYDROCHLORIDE	5MG	REMEDICA LTD-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE, 3056 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X 10.0 TABLET BLISTER	7/1/2010

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1041	NDA/MAL/HDP/2763	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	CANDISTAT	CLOTRIMAZOLE	100MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	VAGINAL SUPPOSITORIES	1.0X2.0X3.0 PESSARY STRIP	7/1/1997
1042	NDA/MAL/HDP/2773	REGAL PHARMACEUTICALS 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	7/1/2004
1043	NDA/MAL/HDP/2774	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	BACTIFLOX NEO 500	CIPROFLOXACIN	500MG	ACINO PHARMA AG.-DORNACHERSTRASSE 114, CH-4147 AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2005

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1044	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	7/1/2016
1045	NDA/MAL/HDP/2779	BROOKES PHARMACEUTICAL LABORATORIES LTD	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	
1046	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	7/1/2011

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1047	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	7/1/2006
1048	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	11/19/2017
1049	NDA/MAL/HDP/2796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN 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	7/1/2001

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1050	NDA/MAL/HDP/2800	NOVO NORDISK	STAR PHARMACEUTICALS LTD	ACTRAPID HM PENFILL	HUMAN INSULIN	100 I.U./ML	NOVO NORDISK PHARMA- NOVO ALLE NOVO NORDISK PRODUCTION SAS- 45 AVENUE D'ALLORÉANS, 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	1.0X1.5 ML PREFILLED PEN,1.0X3.0 ML PREFILLED PEN	7/1/1997
1051	NDA/MAL/HDP/2802	CENTAUR PHARMACEUTICAL S 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	7/1/2005
1052	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/1997

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1053	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 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X3.0 TABLET BLISTER,1.0X20.0X6.0 TABLET BLISTER,1.0X25.0X3.0 TABLET BLISTER,1.0X25.0X6.0 TABLET BLISTER	7/1/2011
1054	NDA/MAL/HDP/2811	REGAL PHARMACEUTICALS 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	7/1/2001
1055	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.	NETHERLANDS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2005

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1056	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	7/1/1997
1057	NDA/MAL/HDP/2816	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-100 TABLETS	ATENOLOL	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997
1058	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	7/1/2011

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1059	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	7/1/1997
1060	NDA/MAL/HDP/2835	LINCOLN PHARMACEUTICAL S 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	7/1/2011
1061	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	7/1/2010

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1062	NDA/MAL/HDP/2848	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROGENTA OINTMENT	BETAMETHASONE /GENTAMICIN SULPHATE	0.5MG/G+1.0 MG/G	SCHERING-PLOUGH LABONV-INDUSTRIE PARK 30, B-220 HEIST-OP-DEN- BERG, BELGIUM	CANADA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	7/1/2001
1063	NDA/MAL/HDP/2850	MEDICAL UNION PHARMACEUTICAL S	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	7/1/2007
1064	NDA/MAL/HDP/2868	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR 50	LOSARTAN POTASSIUM	50MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X7.0 TABLET BLISTER	7/1/2003

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1065	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)	7/1/2010
1066	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	7/1/2001
1067	NDA/MAL/HDP/2878	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOCIN CREAM	GENTAMYCIN SULPHATE	0.1%W/W	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2000

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1068	NDA/MAL/HDP/2879	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLIN-200	OFLOXACIN	200MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,10.0X1.0X10.0 TABLET BLISTER	7/1/2004
1069	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	7/1/2010
1070	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,1.0X24.0X28.0 TABLET BLISTER	7/1/2005

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1071	NDA/MAL/HDP/2891	MACLEODS PHARMACEUTICAL S 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	7/1/2006
1072	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	7/1/2009
1073	NDA/MAL/HDP/2894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO- 10TH OF RAMADAN CITY- FIRST INDUSTRIAL AREA - EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE	7/1/2005

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1074	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	7/1/2005
1075	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	7/1/2006
1076	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	7/1/2005

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1077	NDA/MAL/HDP/2902	MACLEODS PHARMACEUTICAL S 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	7/1/2005
1078	NDA/MAL/HDP/2903	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	ABACAVIR SULPHATE TABLETS	ABACAVIR SULFATE	300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	7/1/2009
1079	NDA/MAL/HDP/2905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+EPHE DRINE HYDROCHLORIDE+DIP HENHYDRAMINE HYDROCHLORIDE+DE XTROMETHORPHAN	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	7/1/2007

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1080	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	7/1/2013
1081	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	7/1/2010
1082	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	7/1/2009

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1083	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	7/1/2010
1084	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	7/1/1997
1085	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	7/1/1997

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1086	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	7/1/2011
1087	NDA/MAL/HDP/2920	CENTAUR PHARMACEUTICAL S 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	7/1/2001
1088	NDA/MAL/HDP/2940	CENTAUR PHARMACEUTICAL S 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	7/1/2005

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1089	NDA/MAL/HDP/2941	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 20	ATORVASTATIN	20MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X7.0 TABLET BLISTER	7/1/2005
1090	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	7/1/2005
1091	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	7/1/2005

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1092	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	7/1/1998
1093	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,1.0X10.0X 10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X250.0 BLISTER CARTON	7/1/1998
1094	NDA/MAL/HDP/2948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORIDE	850MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X15.0 TABLET BLISTER	7/1/2007

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1095	NDA/MAL/HDP/2951	BLISS GVS PHARMA LIMITED	DELMAR 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	7/1/2007
1096	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	7/1/2007
1097	NDA/MAL/HDP/2957	MEDI PHARM 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	7/1/2009

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1098	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	7/1/1997
1099	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	7/1/2010
1100	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	TABLET BLISTER, TABLET BLISTER	7/1/2014

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1101	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	7/1/2000
1102	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	7/1/2004
1103	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	7/1/1997

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1104	NDA/MAL/HDP/2980	BLISS GVS PHARMA LIMITED	DELMAR 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	7/1/2007
1105	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	7/1/2004
1106	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X4.0 CAPSULE BLISTER	7/1/2004

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1107	NDA/MAL/HDP/2985	SANOFI 410 THALES	SURGIPHARM (U) 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	7/1/2004
1108	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	7/1/2004
1109	NDA/MAL/HDP/2995	GITTOES PHARMACEUTICAL S 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	NULL

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1110	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	7/1/2017
1111	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 AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1112	NDA/MAL/HDP/3003	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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	7/1/2007

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1113	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	7/1/1997
1114	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	7/1/2009
1115	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	7/1/1998

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1116	NDA/MAL/HDP/3013	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2007
1117	NDA/MAL/HDP/3015	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA-50 TABLETS	SILDENAFIL	50MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0X4.0 TABLET BLISTER	7/1/2001
1118	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	7/1/2008

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1119	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	7/1/2008
1120	NDA/MAL/HDP/3021	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2012
1121	NDA/MAL/HDP/3023	GITTOES PHARMACEUTICAL S 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	7/1/2007

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1122	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2008
1123	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	7/1/2007
1124	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	7/1/2008

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1125	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	7/1/2007
1126	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	7/1/2007
1127	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	7/1/2007

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1128	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	7/1/2007
1129	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,1.0X10.0X 10.0 CAPSULE BLISTER	7/1/2007
1130	NDA/MAL/HDP/3044	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PIRICAM-20 CAPSULES	PIROXICAM	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,2.0X10.0 CAPSULE BLISTER	7/1/1997

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1131	NDA/MAL/HDP/3046	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	7/1/2009
1132	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	7/1/2007
1133	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	7/1/2005

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1134	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	7/1/2007
1135	NDA/MAL/HDP/3058	SANOFI-AVENTIS	SURGIPHARM (U) LIMITED	XATRAL LP 10MG	ALFUZOSIN	10MG	SANOFI WINTHROP INDUSTRIE,-30-36, AVENUE GUSTAVEEIFFEL BP 27166 - 37071 TOURS CEDEX 2	FRANCE	ORAL SOLID ORDINARY COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008
1136	NDA/MAL/HDP/3060	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	KETOS TABLET	KETOCONAZOLE USP	200 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	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10. 0 TABLET BLISTER	7/7/2007

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1137	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2007
1138	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	7/1/2007
1139	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	7/1/2007

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1140	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	7/1/2007
1141	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,1.0X100.0 X10.0 TABLET BLISTER,1.0X10.0X10. 0 TABLET BLISTER	7/1/1998
1142	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	7/1/1997

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1143	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	7/1/2007
1144	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	7/1/2008
1145	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	7/1/2010

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1146	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	7/1/2007
1147	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	7/1/2007
1148	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, ALJUBAIIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	7/1/2004

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1149	NDA/MAL/HDP/3091	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ONDI	ONDANSETRON	2MG/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	7/1/2013
1150	NDA/MAL/HDP/3092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG/12.5 MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHAZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRASSE 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	7/1/2015
1151	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	7/1/2007

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1152	NDA/MAL/HDP/3098	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOSEDIN	LORATADINE	5MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2004
1153	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	7/1/2007
1154	NDA/MAL/HDP/3101	DAWA LIMITED	SUPER MEDIC LTD	DACOLD SYRUP	PARACETAMOL + PSEUDOEPHEDRINE HCL + CHLORPHENIRAMINE MALEATE	120MG/5ML+ 10MG/5ML+2 MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2010

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1155	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	7/1/2007
1156	NDA/MAL/HDP/3105	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DEPIN-E RETARD	NIFEDIPINE	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/1997
1157	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/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/1997

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1158	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	7/1/2010
1159	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 BLISTER,1.0X1.0X12.0	7/1/2011
1160	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	7/1/2002

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1161	NDA/MAL/HDP/3123	BLISS GVS PHARMA LIMITED	DELMAR 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	7/1/2007
1162	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	7/1/2009
1163	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	7/1/2004

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1164	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	7/1/2007
1165	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	7/1/2009
1166	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	7/1/2007

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1167	NDA/MAL/HDP/3144	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL 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	7/1/2007
1168	NDA/MAL/HDP/3147	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 40/12.5	TELMISARTAN/HYDRO CHLOROTHIAZIDE	40MG/12.5M G	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	7/1/2009
1169	NDA/MAL/HDP/3155	MEDREICH PLC	SURGIPHARM (U) LIMITED	BIOFERON	FERRIC AMMONIUM CITRATE + CYANOCOBALAMIN + FOLIC ACID	200MG/5ML + 10MG/5ML + 750MCG/5ML	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096 MEDREICH LTD (UNIT III) -SURVEY 4/3 AVALAHALI ANJANAPURA POST OFF KARNAKATA BANGALORE 560 062	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2007

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1170	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	7/1/2008
1171	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	7/1/2012
1172	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	7/1/2006

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1173	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	7/1/2012
1174	NDA/MAL/HDP/3176	AFRICURE PHARMACEUTICAL S (INDIA) PRIVATE LIMITED	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,1.0X10.0X 10.0 CAPSULE BLISTER	7/1/2005
1175	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	7/1/1997

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1176	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	7/1/2005
1177	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	7/1/2013
1178	NDA/MAL/HDP/3180	MJ BIOPHARM PVT LTD	VITACARE LIMITED	LOFIN 500	METFORMIN HYDROCHLORIDE	500MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2008

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1179	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	7/1/2013
1180	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	7/1/2000
1181	NDA/MAL/HDP/3198	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-125	PHENOXYMETHYL PENICILLIN POTASSIUM	125MG/ML	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/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	7/1/2011

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1182	NDA/MAL/HDP/3199	MERCK SHARP & DOHME BV.	SURGIPHARM (U) LIMITED	ISENTRESS	RALTEGRAVIR	400MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD - ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD XUNQIAE LINHAI ZHIJIANG	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	7/1/2011
1183	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	7/1/1997
1184	NDA/MAL/HDP/3203	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	TETANUS ANTITOXIN	TETANUS ANTITOXIN	1500 I.U	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X1.0 ML AMPOULE (1 DOSE AMPOULE)	7/1/2013

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1185	NDA/MAL/HDP/3204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	RELKER GEL	ALUMINIUM HYDROXIDE/MAGNESI UM HYDROXIDE/DIMETHI CONE/LIQUORICE	6G+80MG+10 0MG+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	7/1/2000
1186	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	7/1/2010
1187	NDA/MAL/HDP/3208	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRFOL 1%	PROPOFOL	1%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0X20.0 ML VIAL,1.0X10.0X50.0 ML VIAL	7/1/2010

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1188	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,1.0X10.0X10. 0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2005
1189	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	7/1/2010
1190	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	7/1/2009

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1191	NDA/MAL/HDP/3219	GITTOES PHARMACEUTICAL S 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	7/1/1998
1192	NDA/MAL/HDP/3221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASONE/NE OMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	7/1/1999
1193	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: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	7/1/1997

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1194	NDA/MAL/HDP/3225	LINCOLN PHARMACEUTICAL S 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	7/1/2010
1195	NDA/MAL/HDP/3223	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	7/1/1997
1196	NDA/MAL/HDP/3237	LINCOLN PHARMACEUTICAL S 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	7/1/2008

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1197	NDA/MAL/HDP/3241	LINCOLN PHARMACEUTICAL S 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	7/1/2008
1198	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	7/1/2013
1199	NDA/MAL/HDP/3246	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2000

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1200	NDA/MAL/HDP/3248	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	RUMAFEN GEL 10%	IBUPROFEN	10%W/W	ATCO LABS (PVT) LTD-B18 S.I.T.E KARACHI, PAKISTAN	PAKISTAN	ORAL TOPICAL UNIT DOSE GELS/SOLS	1.0X30.0 G TUBE	7/1/2005
1201	NDA/MAL/HDP/3249	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2004
1202	NDA/MAL/HDP/3252	GALENTIC PHARMA LTD	VITACARE LIMITED	PYLOOCAIN	BETAMETHASONE + PHENYLEPHRINE + LIDOCAINE	0.5 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	7/1/2005

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1203	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	7/1/2011
1204	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	7/1/1997
1205	NDA/MAL/HDP/3261	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	300MG+200M G+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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2008

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1206	NDA/MAL/HDP/3263	REGAL PHARMACEUTICALS 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	7/1/2009
1207	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	7/1/1997
1208	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	7/1/2001

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1209	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	7/1/1997
1210	NDA/MAL/HDP/3275	LINCOLN PHARMACEUTICAL S 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	7/1/2010
1211	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	7/1/1997

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1212	NDA/MAL/HDP/3282	MACK BROWN PHARMECEUTICAL S PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRINE HCL + CHLORPHENIRAMINE MALEATE + DEXTROMETHORPHA N	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	7/1/2009
1213	NDA/MAL/HDP/3284	LABORATORY&ALLI ED 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	7/1/1997
1214	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1997

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1215	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	7/1/2009
1216	NDA/MAL/HDP/3288	REGAL PHARMACEUTICAL S LTD	REGAL PHARMA (U) LTD	DELATED CHESTY COUGHS SYRUP	DIPHENHYDRAMINE HCL BP+AMMONIUM CHLORIDE BP+SODIUM CITRATE BP+MENTHOL BP	14MG+135MG +57MG+1.1M G/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	7/1/1997
1217	NDA/MAL/HDP/3289	GLENMARK PHARMACEUTICAL 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	7/1/1999

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1218	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.OX15.0 G TUBE	7/1/2003
1219	NDA/MAL/HDP/3292	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+SO DIUM CITRATE+MENTHOL	7MG+28.5MG +0.55MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.OX100.0 ML BOTTLE,1.OX60.0 ML BOTTLE	7/1/1997
1220	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.OX10.OX10.0 CAPSULE BLISTER	7/1/2004

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1221	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	7/1/2008
1222	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	7/1/2011
1223	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	7/1/2011

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1224	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	7/1/2003
1225	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	7/1/2009
1226	NDA/MAL/HDP/3304	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN	CEFALEXIN MONOHYDRATE	250MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2007

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1227	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	7/1/2002
1228	NDA/MAL/HDP/3312	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TIDOMET FORTE	CO-CARELDOPA	25MG/250MG	TORRENT PHARMACEUTICAL LTD- AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2004
1229	NDA/MAL/HDP/3314	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	SILVEREX	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	10MG/G+10M G/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	7/1/2004

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1230	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	NULL
1231	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998
1232	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	7/1/2005

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1233	NDA/MAL/HDP/3321	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOLIN-GM	CLOBETASOL+GENTA MICIN+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	7/1/2008
1234	NDA/MAL/HDP/3328	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN	1 MU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) 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	7/1/2001
1235	NDA/MAL/HDP/3331	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	BETOPTIC	BETAXOLOL	0.5%W/V	ALCON COUVREUR NV- RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	7/1/1997

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1236	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	7/1/2009
1237	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	7/1/2005
1238	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	7/1/2008

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1239	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	7/1/1997
1240	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	7/1/1997
1241	NDA/MAL/HDP/3347	REGAL PHARMACEUTICALS 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	7/1/1997

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1242	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	7/1/2007
1243	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	7/1/1997
1244	NDA/MAL/HDP/3356	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL-100 CAPSULES	CELECOXIB	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	7/1/2001

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1245	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	7/1/2008
1246	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	7/1/2011
1247	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	7/1/2008

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1248	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	7/1/2000
1249	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	7/1/1998
1250	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	7/1/2008

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1251	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	7/1/2005
1252	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	7/1/2005
1253	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	NULL

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1254	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,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/2011
1255	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	7/1/2011
1256	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	7/1/2011

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1257	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	7/1/2010
1258	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2010
1259	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	7/1/2007

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1260	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	7/1/2007
1261	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	7/1/2009
1262	NDA/MAL/HDP/3390	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ALUGEL	ALUMINIUM HYDROXIDEL / MAGNESIUM TRISLICATE	120MG/250M G	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	7/1/1997

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1263	NDA/MAL/HDP/3391	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER	7/1/2017
1264	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	7/1/1997
1265	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	7/1/2013

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1266	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	GERMANY	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE, 1.0X20.0 G TUBE	7/1/1997
1267	NDA/MAL/HDP/3405	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL BABY AND INFANT 120MG/5ML	PARACETAMOL	120MG/5ML	FARMACLAIR -440 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2008
1268	NDA/MAL/HDP/3406	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	MICRONEMA	NYSTATIN ORAL SUSPENSION, SODIUM CITRATE + SODIUM LAURYL SULPHATE + GLYCERIN	26,450MG/10 ML+75MG/10 ML+ 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	7/1/2005

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1269	NDA/MAL/HDP/3409	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARITYNE	LORATADINE	10MG	SCHERING PLOUGH LABO N.V.,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	NULL	ORAL SOLID ORDINARY TABLETS	3.0X10.0 TABLET BLISTER	7/1/2000
1270	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 SCHAFFHAUSERTRASSE 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	7/1/2007
1271	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	7/1/2004

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1272	NDA/MAL/HDP/3426	REGAL PHARMACEUTICALS 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	7/1/1997
1273	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	7/1/2016
1274	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	7/1/1997

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1275	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	7/1/2000
1276	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	7/1/2010
1277	NDA/MAL/HDP/3449	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAZONE 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,1.0X10.0X1.0X10.0 ML VIAL	7/1/2008

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1278	NDA/MAL/HDP/3450	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMADOL 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	7/1/2009
1279	NDA/MAL/HDP/3451	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL CAPSULES (THANE)	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	1.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X1000. 0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER	7/1/1998
1280	NDA/MAL/HDP/3453	MJ BIOPHARM PVT LTD	VITACARE LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	25MG/ML	M.J BIOPHARM PVT LTD- TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X10.0 ML AMPOULE	7/1/2014

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1281	NDA/MAL/HDP/3456	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGAVALEX 150MG	PREGABALIN	150MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	7/1/2013
1282	NDA/MAL/HDP/3458	REGAL PHARMACEUTICALS 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	7/1/1997
1283	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	7/1/1997

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1284	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	7/1/2007
1285	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	7/1/2008
1286	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	7/1/2007

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1287	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	7/1/2008
1288	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	7/1/2015
1289	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	7/1/2008

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1290	NDA/MAL/HDP/3473	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE	CEFTRIAXONE	1G	SHANDONG P.R & INJECT CARE PARENTERALS PVT LTD-PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI-396195,GUJARAT,INDIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0X1.0 G VIAL	7/1/2011
1291	NDA/MAL/HDP/3474	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125MG/5ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2008
1292	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	7/1/2010

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1293	NDA/MAL/HDP/3482	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLOX-250	CLOXACILLIN	250MG	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NOS 63, 67 & 87, JAWAHAR CO- OP. INDUSTRIAL STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2011
1294	NDA/MAL/HDP/3483	JOHNSON&JOHNS ON 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	7/1/2007
1295	NDA/MAL/HDP/3485	CIRON DRUGS & PHARMACEUTICAL S 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	7/1/2007

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1296	NDA/MAL/HDP/3490	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	LAXOLAC SYRUP	LACTULOSE	67G/100ML	MEDICAL UNION PHARMACEUTICALS LTD- ABU SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	7/1/2003
1297	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	7/1/1997
1298	NDA/MAL/HDP/3494	FERRER INTERNATIONAL, S.A.	LABOREX UGANDA LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINO BUTYRIC 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	7/1/2015

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1299	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	7/1/2009
1300	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	7/1/2014
1301	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	7/1/2010

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1302	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	7/1/2015
1303	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	7/1/2015
1304	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	7/1/1997

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1305	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 (WITHOUT AMFM LOGO)	7/1/2007
1306	NDA/MAL/HDP/3516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHENYPHENIDYL 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	7/1/1998
1307	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	7/1/2013

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1308	NDA/MAL/HDP/3519	STRIDES SHASUN LIMITED	DELMAR 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	7/1/2010
1309	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, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G BOTTLE, 1.0X10.0 G BOTTLE	7/1/2010
1310	NDA/MAL/HDP/3522	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) 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	NULL

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1311	NDA/MAL/HDP/3525	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCCLIN	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,1.0X100.0 X10.0 CAPSULE BLISTER	7/1/1998
1312	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	7/1/2009
1313	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	7/1/2007

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1314	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	7/1/2005
1315	NDA/MAL/HDP/3543	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DROX 250	CEFADROXIL	250 MG	AUROBINDO PHARMA LTD (UNIT VI) ,-SURVEY NOS. 329/39 & 329/47,CHITKUL VILLAGE,PATANCHERU MANDAL, MEDAK DISTRICT PIN CODE 502307, ANDHRA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2008
1316	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	7/1/2000

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1317	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	7/1/2013
1318	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	7/1/2008
1319	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	7/1/2009

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1320	NDA/MAL/HDP/3549	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIRAMINE MALEATE+PSEUDO EPHEDRINE HCL+GUAIPHENISIN+ MENTHOL	1.0MG+15.0MG+50.0MG+0.5 MG / 5ML	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2007
1321	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.2/103/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	7/1/2009
1322	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	7/1/2007

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1323	NDA/MAL/HDP/3558	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	SEROFLO-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	7/1/2009
1324	NDA/MAL/HDP/3561	GITTOES PHARMACEUTICAL S 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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998
1325	NDA/MAL/HDP/3563	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	LEVOLIFE	LEVOFLOXACIN	500MG/100M L	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1326	NDA/MAL/HDP/3566	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	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	7/1/2008
1327	NDA/MAL/HDP/3569	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CARBADAC-200	CARBAMAZEPINE	200MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/1997
1328	NDA/MAL/HDP/3574	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOOZ 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT I- PLOT3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAP USA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2007

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1329	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	7/1/2007
1330	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	7/1/2005
1331	NDA/MAL/HDP/3580	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	7/1/2008

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1332	NDA/MAL/HDP/3581	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOOZ 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT I-PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAP USA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2007
1333	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 NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	7/1/2008
1334	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	7/1/2004

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1335	NDA/MAL/HDP/3591	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	ARTESIANE 80MG/ML	ARTEMETHER	80MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE	7/1/1998
1336	NDA/MAL/HDP/3597	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	ARTESIANE 20 PAEDIATRIC	ARTEMETHER	20MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2001
1337	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	7/1/2005

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1338	NDA/MAL/HDP/3600	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTEMISINI N + 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	7/1/2008
1339	NDA/MAL/HDP/3606	STRIDES ARCOLAB LTD	DELMAN ENTERPRISES LIMITED	CELLTRIAxon	CEFTRIAxONE	1G	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA. SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2010
1340	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	7/1/2004

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1341	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	7/1/1998
1342	NDA/MAL/HDP/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL 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	7/1/2010
1343	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	7/1/2011

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1344	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	7/1/2013
1345	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	7/1/2008
1346	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	7/1/2011

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1347	NDA/MAL/HDP/3619	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CAPTOPRIL DENK - 25	CAPTOPRIL	25MG	DENK PHARMA, GOLLSTR.,- 1-D-845 529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	7/1/2000
1348	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	7/1/2004
1349	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/SY RUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	7/1/2007

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1350	NDA/MAL/HDP/3626	CADILA HEALTH CARE 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	7/1/1997
1351	NDA/MAL/HDP/3628	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 55	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	7/1/2001
1352	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	7/1/2009

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1353	NDA/MAL/HDP/3631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008
1354	NDA/MAL/HDP/3634	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPLUS	PARACETAMOL+DEXTROROMETHORPHAN 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	7/1/2008
1355	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	7/1/2011

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1356	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	7/1/1997
1357	NDA/MAL/HDP/3639	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL ADVANCE	PARACETAMOL	500MG	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X11.0X10.0 TABLET BLISTER,1.0X10.0X10. 0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	7/1/2010
1358	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	7/1/2009

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1359	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	7/1/2007
1360	NDA/MAL/HDP/3647	GITTOES PHARMACEUTICAL S 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	7/1/2008
1361	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	7/1/2009

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1362	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	7/1/1997
1363	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	7/1/1997
1364	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 LOGO)	7/1/2008

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1365	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	7/1/2009
1366	NDA/MAL/HDP/3663	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 10	AMLODIPINE BESYLATE	10MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER	7/1/2003
1367	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	7/1/2011

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1368	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	7/1/2008
1369	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/SY RUPS/DROPS	1.0X70.0 ML BOTTLE, 1.0X140.0 ML BOTTLE	7/1/1998
1370	NDA/MAL/HDP/3669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO-TRIMOXAZOLE	SULFAMETHOXAZOLE /TRIMETHOPRIM	200MG/40MG	MEDICAMEN BIOTECH LTD - -SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	7/1/2014

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1371	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	7/1/2000
1372	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	7/1/2003
1373	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	7/1/2008

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1374	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	7/1/2010
1375	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	7/1/1997
1376	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	7/1/2008

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1377	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	7/1/2000
1378	NDA/MAL/HDP/3685	GALPHAR LABORATORIES LTD	AIVEEN (U) LIMITED	ODICEF	CEFTRIAXONE	1G	INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195 ALKEM LABORATORIES LIMITED.- VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT- SOLAN, (HP), INDIA-173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2013
1379	NDA/MAL/HDP/3686	ACINO PHARMA AG -	GOODMAN INTERNATIONAL LTD	NEURORUBINE TM - FORTE 20 FILM- COATED TABLETS	MULTIVITAMIN	MULTINGREDI ENT	ACINO PHARMA AG (FORMER MEPHA LLC)- DORNACHERSTRASSE 114 P.O BOX 445 CH4147, AESCH/BL ACINO PHARMA AG-BIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/1997

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1380	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	7/1/2010
1381	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 + 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	7/1/2013
1382	NDA/MAL/HDP/3692	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	COTRIM 120	CO-TRIMOXAZOLE	120MG	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,1.0X1000.0 TABLET CONTAINER	7/1/2011

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1383	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	7/1/2002
1384	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1997
1385	NDA/MAL/HDP/3699	GLOBAL NAPI PHARMACEUTICAL S	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	7/1/2005

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1386	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	7/1/2005
1387	NDA/MAL/HDP/3703	REGAL PHARMACEUTICALS 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	7/1/2014
1388	NDA/MAL/HDP/3704	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA 100	SILDENAFIL	100MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0X4.0 TABLET BLISTER	7/1/2002

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1389	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	7/1/2005
1390	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	7/1/2010
1391	NDA/MAL/HDP/3708	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL M	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG+500MG	HANDOK INC-78, DAEPUNGSANDAN-RO, DAESO-MYEON, EUMSEONG-GUN, CHUNGCHEONGBUK-DO, KOREA	SOUTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2015

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1392	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	7/1/2010
1393	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	7/1/1997
1394	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	7/1/2013

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1395	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	7/1/2010
1396	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	7/1/2001
1397	NDA/MAL/HDP/3717	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEFTRIAZONE SODIUM	CEFTRIAZONE 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	7/1/2011

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1398	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/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	7/7/1997
1399	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	7/1/2015
1400	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	7/1/2007

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1401	NDA/MAL/HDP/3728	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH & CO. KG-- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER + 1 * 10 SAMPLE	7/1/1998
1402	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	7/1/2008
1403	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	7/1/2001

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1404	NDA/MAL/HDP/3732	REGAL PHARMACEUTICALS 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	7/1/2003
1405	NDA/MAL/HDP/3736	BLISS GVS PHARMA LIMITED	DELMAN 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	7/1/2007
1406	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	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009

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1407	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	7/1/2010
1408	NDA/MAL/HDP/3739	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ALDREN	ALENDRONATE	70MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	7/1/2011
1409	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	7/1/2006

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1410	NDA/MAL/HDP/3743	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 3.125	CARVEDILOL	3.125 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/2006
1411	NDA/MAL/HDP/3744	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHALAC SOLUTION	LACTULOSE	67G/100ML	ABBOTT BIOLOGICALS B.V - ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE,1.0X10.0X15.0 ML BOTTLE	7/1/2001
1412	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	7/1/2008

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1413	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	7/1/2011
1414	NDA/MAL/HDP/3748	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOSPIRIN	ACETYL SALICYLIC ACID	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	1.0X1000.0 TABLET CONTAINER	7/1/2010
1415	NDA/MAL/HDP/3752	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PAINOTAB 200	PARACETAMOL/CAFFEINE	500MG+65MG	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	7/1/2003

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1416	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	7/1/2006
1417	NDA/MAL/HDP/3754	CENTAUR PHARMACEUTICAL S 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	7/1/2006
1418	NDA/MAL/HDP/3757	REGAL PHARMACEUTICALS 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	7/1/1997

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1419	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	7/1/1997
1420	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	7/1/1998
1421	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	7/1/1999

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1422	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	7/1/2009
1423	NDA/MAL/HDP/3770	AMOUN PHARMACEUTICAL S 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	7/1/2005
1424	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	7/1/2005

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1425	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,1.0X100.0 X10.0 TABLET BLISTER,1.0X10.0X10. 0 TABLET BLISTER	7/1/2005
1426	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	7/1/2004
1427	NDA/MAL/HDP/3781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTEL	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	7/1/2014

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1428	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	7/1/1997
1429	NDA/MAL/HDP/3784	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPUIM	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	7/1/2011
1430	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	7/1/2004

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1431	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	7/1/2005
1432	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	7/1/2005
1433	NDA/MAL/HDP/3792	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING 228.5	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	200MG+28.5MG	MEDREICH LIMITED UNIT 1-12TH MILE, OLD MADRAS ROAD, VIRGONAGAR, BANGLORE-560049	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	7/1/2007

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1434	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	7/1/2005
1435	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	7/1/2004
1436	NDA/MAL/HDP/3801	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/2002

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1437	NDA/MAL/HDP/3802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDROCHLORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	7/1/2005
1438	NDA/MAL/HDP/3803	BLISS GVS PHARMA LIMITED	DELMAN 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	7/1/2007
1439	NDA/MAL/HDP/3804	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBINE IM	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100MG+1MG	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	7/1/1997

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1440	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	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2008
1441	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	7/1/2006
1442	NDA/MAL/HDP/3809	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID DAY & NIGHT	PARACETAMOL+CHLO RPHENIRAMINE MALEATE+PHENYLEP RINE 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	7/1/2006

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1443	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	7/1/1997
1444	NDA/MAL/HDP/3813	MACK BROWN PHARMACEUTICAL S 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	7/1/1997
1445	NDA/MAL/HDP/3814	MARTINDALE PHARMACEUTICAL S 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	7/1/1997

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1446	NDA/MAL/HDP/3825	UNI MEDICO LAB	ROYAL PHARMA 2011 LIMITED	UMOXIL 250	AMOXICILLIN	250MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2015
1447	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	7/1/2005
1448	NDA/MAL/HDP/3829	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	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	7/1/2006

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1449	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	7/1/2007
1450	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	7/1/2000
1451	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	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	7/1/1997

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1452	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	7/1/1998
1453	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 INDUSTRIES-PLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER	7/1/2006
1454	NDA/MAL/HDP/3840	MACK BROWN PHARMECEUTICAL S 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	7/1/2000

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1455	NDA/MAL/HDP/3843	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK	AZITHROMYCIN	250MG	WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0 CAPSULE BLISTER	7/1/1998
1456	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	7/1/1997
1457	NDA/MAL/HDP/3845	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL 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	7/1/2011

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1458	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	7/1/2005
1459	NDA/MAL/HDP/3848	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK	AZITHROMYCIN	200MG/5ML	WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	7/1/1998
1460	NDA/MAL/HDP/3850	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHAZI DE	50MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2009

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1461	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	7/1/2003
1462	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	7/1/2009
1463	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	7/1/2008

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1464	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	7/1/1997
1465	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	7/1/2006
1466	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	7/1/2010

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1467	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	7/1/2005
1468	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	7/1/2009
1469	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	7/1/1997

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1470	NDA/MAL/HDP/3883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLATE SODIUM	360MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRASSE 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	7/1/2006
1471	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	7/1/2004
1472	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	7/1/2007

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1473	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	7/1/2007
1474	NDA/MAL/HDP/3892	MACK BROWN PHARMECEUTICAL S 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	7/1/1997
1475	NDA/MAL/HDP/3893	GITTOES PHARMACEUTICAL S 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	7/1/2008

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1476	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	7/1/2010
1477	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	7/1/2010
1478	NDA/MAL/HDP/3899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDATE + 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	7/1/2013

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1479	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	7/1/2011
1480	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	7/1/2012
1481	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	7/1/2010

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1482	NDA/MAL/HDP/3916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRAMIDE HYDROCHLORIDE INJECTION	METOCLOPRAMIDE HYDROCHLORIDE	5MG/ML	KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJIAKOU CITY, HEBEI PROVINCE 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,1.0X10.0X10.0X2.0 ML AMPOULE	
1483	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	7/1/2011
1484	NDA/MAL/HDP/3924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMOL+PSEU DOEPHEDRINE HYDROCHLORIDE+TRI POLIDINE HYDROCHLORIDE	300MG+36MG +1.5MG	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	7/1/1997

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1485	NDA/MAL/HDP/3925	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CALCIUM GLUCONATE INJECTION	CALCIUM GLUCONATE	10 %W/V	NINGBO DAHONGYING PHARMACEUTICALS-N0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	7/1/2009
1486	NDA/MAL/HDP/3926	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	MIFUPEN TABLETS	ACETYSALICYLIC ACID + CAFFEINE	350 MG + 50 MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET STRIP	7/1/1997
1487	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 MAHALLESİ İHLA VADİSİ SOKAK, NO.2, 34912 KURTKOY, İSTANBUL - TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	7/1/2014

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1488	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	7/1/2008
1489	NDA/MAL/HDP/3933	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD- AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	7/1/2001
1490	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	7/1/2011

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1491	NDA/MAL/HDP/3947	INTAS PHARMACEUTICALS 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	7/1/2008
1492	NDA/MAL/HDP/3948	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	50MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	7/1/2009
1493	NDA/MAL/HDP/3949	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION			REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/1997

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1494	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	7/1/2014
1495	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	7/1/2004
1496	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	7/1/2008

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1497	NDA/MAL/HDP/3963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS URUNLERI TURKEY-YENISEHIR MAHALLESİ, IHLARA VADİSİ SOKAK, NO. 2, TR 34912, PENDİK, İSTANBUL, TURKEY.	UNITED STATES	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,2.0X1.0X24.0 TABLET BLISTER,2.0X1.0X18.0 TABLET BLISTER,1.0X36.0X6.0 TABLET BLISTER	7/1/2009
1498	NDA/MAL/HDP/3965	EMCURE PHARMACEUTICALS 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	7/1/2004
1499	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/SY- RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2011

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1500	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/GRAN ULES	1.0X6.5 G SACHET	7/1/2002
1501	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/1997
1502	NDA/MAL/HDP/3972	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FERTOMID-50	CLOMIPHENE	50MG	CIPLA LTD-VERNA INDIA ESTATES 403722 GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2007

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1503	NDA/MAL/HDP/3977	CHINOIN PHARMACEUTICALS AND CHEMICAL WORKS, CO. LTD	SURGIPHARM (U) LIMITED	NO-SPA 40MG	DROTAVERINE HYDROCHLORIDE	40MG	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO.LTD-H-2112, VERESEGYHAZ, LEVAI U.S.HUNGARY	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	7/1/1998
1504	NDA/MAL/HDP/3983	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMOL/CAFF EINE 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,1.0X50.0X2.0 TABLET BLISTER	7/1/2008
1505	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	7/1/2008

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1506	NDA/MAL/HDP/3987	REGAL PHARMACEUTICALS 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	7/1/1997
1507	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	7/1/2008
1508	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	7/1/1997

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1509	NDA/MAL/HDP/3996	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2007
1510	NDA/MAL/HDP/3998	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN+BROM HEXINE HYDROCHLORIDE +LEVOMENTHOL	1.25MG/5ML+ 50MG//5ML+4 MG/5ML+2.5 MG/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	7/1/2008
1511	NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENARIMINE MALEATE/DEXAMETH ASONE	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	7/1/2008

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1512	NDA/MAL/HDP/4001	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD PLUS SYRUP	PARACETAMOL+PHEN- YLEPHRINE+CHLORPH- ENIRAMINE+SODIUM CITRATE	125MG/5ML+ 2.5MG/5ML+1 MG/5ML+60M G /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	7/1/2008
1513	NDA/MAL/HDP/4002	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCID	ALUMINIUM HYDROXIDE+MAGNES- IUM 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	7/1/2007
1514	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	7/1/2005

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1515	NDA/MAL/HDP/4007	SANOFI PASTEUR	LABOREX UGANDA LIMITED	SHANCHOL CHOLERA VACCINE	V.CHOLERA STRAINS-01 INABA FORMALDEHYDE KILLED +01 OGAWA HEAT KILLED + 01 OGAWA FORMALDEHYDE KILLED + 01 INABA HEAT KILLED + 0139 FORMALDEHYDE KILLED	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACC HARIDE (LPS)	SHANTHA BIOTECHNICS LTD -SURVEY NO. 274, ATHVELLI VILLAGE, MEDCHAL MANDAL – 501401, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X1.5 ML VIAL (1 DOSE)	7/1/2016
1516	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	7/1/1997
1517	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	7/1/2004

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1518	NDA/MAL/HDP/4015	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TAMBAC 50	CEFPODOXIME PROXETIL	50MG/5ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE, 1.0X1.0X100.0 ML BOTTLE	7/1/2005
1519	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	7/1/2007
1520	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	7/1/2007

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1521	NDA/MAL/HDP/4023	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST LINCTUS	CHLORPHENIRAMINE +DEXTROMETHORPHAN+METHANOL	2MG+10MG+1.5MG	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997
1522	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	7/1/2007
1523	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	7/1/2007

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1524	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	7/1/2010
1525	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	7/1/2012
1526	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	7/1/2011

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1527	NDA/MAL/HDP/4049	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVODAY 500	LEVOFLOXACIN HEMIHYDRATE	500MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X5.0 TABLET BLISTER,1.0X20.0X5.0 TABLET BLISTER,1.0X6.0X2.0X 5.0 TABLET BLISTER	7/1/2004
1528	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	7/1/2006
1529	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,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10 .0 CAPSULE BLISTER	7/1/2011

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1530	NDA/MAL/HDP/4060	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/DEXAM ETHASONE	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	7/1/1997
1531	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,1.0X3.0X1 0.0 TABLET BLISTER	7/1/2006
1532	NDA/MAL/HDP/4064	GITTOES PHARMACEUTICAL S 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	7/1/2010

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1533	NDA/MAL/HDP/4067	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-50 TABLETS	ATENOLOL	50MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/1997
1534	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	7/1/2001
1535	NDA/MAL/HDP/4075	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	CHERICOF COUGH FORMULAR	CHLORPHENIRAMINE/ DEXTROMETHORPHAN HBR/PHENYLEPHRINE HCL	2MG/10MG/5 MG	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	7/1/2015

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1536	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, ALJUBAHA	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2009
1537	NDA/MAL/HDP/4085	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINACEF	CEFUROXIME SODIUM	750MG	GLAXO WELLCOME - VERONA ITALY	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	7/1/1997
1538	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	7/1/2008

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1539	NDA/MAL/HDP/4094	STRIDES SHASUN LIMITED	DELMAR 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	7/1/2007
1540	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	7/1/2007
1541	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	7/1/1997

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1542	NDA/MAL/HDP/4098	STRIDES SHASUN LIMITED	DELMAR ENTERPRISES LIMITED	EFAVIRENZ TABLETS	EFAVIRENZ	600MG	STRIDES SHASUN LTD-NO. 36/7, SURAGAJAKKHANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BANGALORE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2007
1543	NDA/MAL/HDP/4099	GLENMARK PHARMACEUTICAL 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	7/1/2007
1544	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	7/1/2007

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1545	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	7/1/2015
1546	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 8CCID 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)	7/1/2016
1547	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	

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1548	NDA/MAL/HDP/4113	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTIN 10	EBASTINE	10 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	7/1/2005
1549	NDA/MAL/HDP/4114	REGAL PHARMACEUTICALS 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	7/1/1997
1550	NDA/MAL/HDP/4115	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	PREDILONE	PREDNISOLONE	5.0 MG	REGAL PHARMACEUTICALS 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	7/1/2007

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1551	NDA/MAL/HDP/4118	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	OCUREST-AH	PHENYLEPHRINE HYDROCHLORIDE+NA PHAZOLINE HYDROCHLORIDE+CH LORPHRENIRAMINE 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	7/1/2005
1552	NDA/MAL/HDP/4127	SANOFI 410 THALES	SURGIPHARM (U) 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	7/1/1998
1553	NDA/MAL/HDP/4130	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	KEFSTAR-250	CEFUROXIME AXETIL	250MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET STRIP,1.0X10.0 TABLET BLISTER	7/1/2005

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1554	NDA/MAL/HDP/4132	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL 200	CELECOXIB	200MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2001
1555	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	7/1/2013
1556	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	7/1/2011

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1557	NDA/MAL/HDP/4147	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	NIFEDI-DENK 20 RETARD	NIFEDIPINE	20MG	DENK PHARMA GMBH & CO. KG- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529	GERMANY	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2000
1558	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	7/1/1998
1559	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	7/1/1997

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1560	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 REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2001
1561	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	7/1/2008
1562	NDA/MAL/HDP/4170	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC	TRAMADOL HYDROCHLORIDE	50MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2000

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1563	NDA/MAL/HDP/4171	MACK BROWN PHARMECEUTICAL S PVT LTD	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	7/1/2005
1564	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	7/1/2009
1565	NDA/MAL/HDP/4182	CENTAUR PHARMACEUTICAL S 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	7/1/2007

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1566	NDA/MAL/HDP/4183	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORPROMAZINE	CHLORPROMAZINE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2011
1567	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	7/1/1997
1568	NDA/MAL/HDP/4188	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRAZ	PRAZQUANTEL	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	7/1/2013

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1569	NDA/MAL/HDP/4241	GITTOES PHARMACEUTICAL S 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	7/1/2011
1570	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 ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D 68305 MANNHEIM GERMANY	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL	7/1/2016
1571	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	7/1/2013

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1572	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	7/1/2014
1573	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	7/1/2016
1574	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	7/1/2013

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1575	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 ROCHE DIAGNOSTICS GMBH- SANDHOFER STRASSE 116 D 68305 MANNHEIM GERMANY	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL	7/1/2016
1576	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	7/1/2010
1577	NDA/MAL/HDP/4291	GITTOES PHARMACEUTICAL S LIMITED	GITTOES PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN 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	7/1/2008

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1578	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	7/1/2016
1579	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	7/1/2009
1580	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) MAHABOBNAGAR 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	7/1/2010

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1581	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	7/1/2016
1582	NDA/MAL/HDP/4315	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	DESLORA-DENK 5	DESLORATIDINE	5MG	DENK PHARMA GMBH & CO.KG -GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016
1583	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 &CO.KG--PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER	7/1/2011

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1584	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	7/1/2009
1585	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	7/1/2010
1586	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	7/1/2016

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1587	NDA/MAL/HDP/4331	STEDMAN PHARMACEUTICAL S 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	7/1/2010
1588	NDA/MAL/HDP/4334	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	LOSAR-DENK 50	LOSARTAN	50MG	DENK PHARMA GMBH & CO.-PRINZREGENTENSTR. 79, 81675 MÜNCHEN, GÖLLSTR. 1, 84529 TITTMONING, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2011
1589	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	7/1/2009

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1590	NDA/MAL/HDP/4339	GLAXOSMITHKLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE 125 EVOHALER	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG/125M CG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.OX120.0 METERED DOSE CANNISTER	7/1/2007
1591	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.OX100.0 ML BOTTLE	7/1/1997
1592	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.OX5.0X2.0 ML AMPOULE	7/1/1997

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1593	NDA/MAL/HDP/4358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGISTICS 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	7/1/2016
1594	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	7/1/2009
1595	NDA/MAL/HDP/4362	MACLEODS PHARMACEUTICAL S 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	7/1/2016

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1596	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	7/1/2009
1597	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,1.0X100.0 X10.0 CAPSULE BLISTER	7/1/2004
1598	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	7/1/2010

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1599	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,BORG SAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	7/1/1997
1600	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,1.0X1.0X6.0X 20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER	7/1/2010
1601	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE	7/1/1998

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1602	NDA/MAL/HDP/4383	ZEE PHARMACEUTICAL S LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	THE MADRAS PHARMACEUTICALS-137- B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHEN NAL INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2016
1603	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	7/1/2016
1604	NDA/MAL/HDP/4389	PHARMACARE LTD	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	600MG	JANSSEN ORTHO LLC.-- STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	7/1/2011

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1605	NDA/MAL/HDP/4390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHENICOL	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	7/1/2016
1606	NDA/MAL/HDP/4392	IND SWIFT LTD	PLANET PHARMACEUTICALS 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	7/1/2003
1607	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	7/1/2007

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1608	NDA/MAL/HDP/4398	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9 % W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	7/1/1997
1609	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,1.0X100.0X10 .3 G SACHET	7/1/1997
1610	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	7/1/2014

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1611	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.OX6.0 TABLET STRIP	7/1/2014
1612	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.OX1.0 VIAL CARTON	7/1/2016
1613	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.OX4.0 TABLET BLISTER	7/1/2011

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1614	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	7/1/2016
1615	NDA/MAL/HDP/4408	REGAL PHARMACEUTICALS 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	7/1/1997
1616	NDA/MAL/HDP/4411	ASTRA ZENECA	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	7/1/2010

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1617	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)	7/1/2011
1618	NDA/MAL/HDP/4415	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 50MG TABLETS	DICLOFENAC POTASSIUM	50MG	NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY NOVARTIS--URUNLERI INSTABUL TURKEY	ITALY	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	7/1/1997
1619	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	7/1/2014

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1620	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	7/1/2010
1621	NDA/MAL/HDP/4468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	AUROBINDOPHARMA LIMITED,-UNIT VII, SEZ APIIC, PLOT NO.SI SURVEY NO'S 425, 434,435 & 458 GREEN INDUSTRIAL PARK, POLEPALLY VILLAGEJEDCHERTA MANDAL, MAHABOBNAGAR DISTRICT, ANDRA PRADESH, INDIA. AUROBINDO UNIT XV-PLOT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016
1622	NDA/MAL/HDP/4483	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/1997

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1623	NDA/MAL/HDP/4519	ARISTO PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 5	AMLODIPINE BESILATE	5MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X 3.0X10.0 TABLET BLISTER	7/1/2007
1624	NDA/MAL/HDP/4522	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 2.5	AMLODIPINE BESILATE	2.5 MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X 3.0X10.0 TABLET BLISTER	7/1/2007
1625	NDA/MAL/HDP/4523	ARISTO PHARMACEUTICAL S PVT LTD	NORVIK ENTERPRISES LIMITED	BIGOMET SR 500	METFORMIN HYDROCHLORIDE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEP PRADESH	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008

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1626	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	7/1/2008
1627	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	7/1/2011
1628	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	7/1/2008

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1629	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	7/1/2008
1630	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	7/1/2008
1631	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	7/1/2008

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1632	NDA/MAL/HDP/4534	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	LORYTEC 10	LORATADINE	10MG	DELOBIS 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	7/1/2007
1633	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	7/1/2004
1634	NDA/MAL/HDP/4540	DELOBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIPROLOX 500	CIPROFLOXACIN	500MG	DELOBIS 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	7/1/2008

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1635	NDA/MAL/HDP/4542	DELORBIS PHARMACEUTICAL S 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	7/1/2008
1636	NDA/MAL/HDP/4543	SANOFI-AVENTIS	SURGIPHARM (U) LIMITED	RHINATHIOL 5%	CARBOCISTEINE	5%W/V	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	7/1/2015
1637	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	7/1/2000

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1638	NDA/MAL/HDP/4545	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2010
1639	NDA/MAL/HDP/4550	SANOFI AVENTIS FRANCE	SURGIPHARM (U) LIMITED	RHINATHIOL 2%	CARBOCISTEINE	20MG/ML	UNITHER LIQUID MANUFACTURING INDUSTRIE -COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770 A. NATTERMANN & CIE GMBH.- NATTERMANNALLEE 1 ,50829 COLOGNE, GERMANY	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	7/1/2001
1640	NDA/MAL/HDP/4553	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	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	7/1/2011

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1641	NDA/MAL/HDP/4556	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250MG + 125MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTD- VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	7/1/2005
1642	NDA/MAL/HDP/4558	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	IFICIPRO 500	CIPROFLOXACIN	500MG	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-- 304-308 ,GIDC , PANOLI 394116	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005
1643	NDA/MAL/HDP/4568	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	INDCHEMIE HEALTH SPECIALITIES PVT. LTD- VILLAGE-THANA, BADDI, DIST. SOLAN, HIMACHAL PRADESH-173 205.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	7/1/2005

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1644	NDA/MAL/HDP/4575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASONE+GE NTAMICIN	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.OX5.0 ML BOTTLE	7/1/2010
1645	NDA/MAL/HDP/4579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 500 IV VIALS	CEFTRIAXONE	500MG	LABESFAL LABORATORIOS ALMIRO, S.A ,.-ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.OX500.0 MG VIAL + 1*5 ML WFI AMPOULE	7/1/2005
1646	NDA/MAL/HDP/4588	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	FLUCAN 200	FLUCONAZOLE	200MG	LINCOLN PHARMACEUTICAL LIMITED- TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.OX10.0X1.0 TABLET BLISTER	7/1/2011

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1647	NDA/MAL/HDP/4589	FEROZSONS LABORATORIES LTD	HARLEYS UGANDA LIMITED	LEFOXICIN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	FEROZSONS LABORATORIES LTD-AMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2013
1648	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	7/1/2009
1649	NDA/MAL/HDP/4592	LINCOLN PHARMACEUTICAL S 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	7/1/2008

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1650	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	7/1/2011
1651	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, 1.0X25.0X4.0 TABLET BLISTER	7/1/1997
1652	NDA/MAL/HDP/4595	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS 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, 1.0X3.0X10.0 TABLET BLISTER	7/1/2010

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1653	NDA/MAL/HDP/4598	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS 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	7/1/2011
1654	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	7/1/2000
1655	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	7/1/2005

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1656	NDA/MAL/HDP/4605	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTROMETHOR PHAN 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	7/1/2009
1657	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	7/1/2013
1658	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	7/1/2011

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1659	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	7/1/2006
1660	NDA/MAL/HDP/4615	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 150	NILOTONIB HYDROCHLORIDE MONOHYDRATE	150MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSRERTRASSE CH- 4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	7/1/2014
1661	NDA/MAL/HDP/4617	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN	10MG	IPR PHARMACEUTICALS INC,-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2010

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1662	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	7/1/2009
1663	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	7/1/2007
1664	NDA/MAL/HDP/4621	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 6.25	CARVEDILOL	6.25MG	CADILA HEALTHCARE LTD-- PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA 403401	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	7/1/2006

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1665	NDA/MAL/HDP/4626	ACINO PHARMA AG -	GOODMAN INTERNATIONAL LTD	GASEC-20	OMEPRAZOLE	20MG	ACINO PHARMA AG - DORNACHERSTRASSE, 114, 4147, AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BOTTLE	7/1/2005
1666	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	7/1/1997
1667	NDA/MAL/HDP/4634	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	LOSAR-DENK 100	LOSARTAN	100MG	DENK PHARMA GMBH & CO.-PRINZREGENTENSTR. 79, 81675 MÜNCHEN, GÖLLSTR. 1, 84529 TITTMONING, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2011

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1668	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	7/1/2009
1669	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	7/1/2013
1670	NDA/MAL/HDP/4645	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	20MG	IPR PHARMACEUTICALS INC.-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2010

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1671	NDA/MAL/HDP/4646	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	LEFLOCIN	LEVOFLOXACIN	5MG/ML	YURIA-PHARM, LTD.-18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE.	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X150.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	7/1/2013
1672	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	7/1/2010
1673	NDA/MAL/HDP/4652	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII TETANUS TOXOID VACCINE	TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	Â%¥ 5 LF (Â%¥ 40 IU) ON Â%¥ 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)	7/1/1997

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1674	NDA/MAL/HDP/4661	YURIA PHARM LTD-UKRAINE	PHARMA VILLE LIMITED	FLUCONAZOLE-UF	FLUCONAZOLE	2MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	7/1/2013
1675	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	7/1/2014
1676	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	7/1/2009

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1677	NDA/MAL/HDP/4680	SANCE LABORATORIES PVT LTD	DELMAN 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	7/1/2011
1678	NDA/MAL/HDP/4697	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	SANBE CLANEKSI	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	PT SANBE FARMA-JI LEUGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X6.0 VIAL CARTON	7/1/2011
1679	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	7/1/1997

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1680	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	7/1/1998
1681	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	NULL
1682	NDA/MAL/HDP/4714	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEPHOXIN 250MG/5ML	CEPHALEXIN	250MG/5ML	PHARCO-B INTERNATIONAL PHARMACEUTICALS-BORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE	7/1/1998

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1683	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	7/1/2011
1684	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	7/1/2011
1685	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	7/1/2011

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1686	NDA/MAL/HDP/4723	REGAL PHARMACEUTICALS 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	7/1/1997
1687	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	7/1/1997
1688	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	7/1/1997

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1689	NDA/MAL/HDP/4727	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	MELONAX	MELOXICAM	15MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2010
1690	NDA/MAL/HDP/4728	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	ADRENALINE	ADRENALINE	1MG/ML	M.J BIOPHARM PVT LTD- TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE	7/1/2014
1691	NDA/MAL/HDP/4738	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	CILOXAN	CIPROFLOXACIN	0.3%W/V	ALCON -ALCON COUVREUR NV B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/1997

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1692	NDA/MAL/HDP/4739	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	MERO	MEROPENEM	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	7/1/2011
1693	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	7/1/2013
1694	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	7/1/2013

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1695	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	7/1/2014
1696	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	7/1/2011
1697	NDA/MAL/HDP/4748	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE+SIMET HICONE	720MG+25MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER	7/1/2006

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1698	NDA/MAL/HDP/4751	GITTOES PHARMACEUTICAL S 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,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/2009
1699	NDA/MAL/HDP/4757	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	METFORMIN-DENK 500	METFORMIN	500MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	7/1/1998
1700	NDA/MAL/HDP/4758	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	METFORMIN DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	7/1/2011

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1701	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	7/1/2001
1702	NDA/MAL/HDP/4768	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	METHACHLOR EYE DROPS	DEXAMETHASONE/CH LORAMPHENICOL	1MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/1999
1703	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,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/2009

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1704	NDA/MAL/HDP/4774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+RIBOTLAVINE+PYRIDOXINE HCL+NICOTINAMIDE+ZINC	150MG+0.5MG+50MG+2MG+2MG+1MG+10MG+25MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER	7/1/2014
1705	NDA/MAL/HDP/4778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CURISAFE	CEFADROXIL MONOHYDRATE	125MG/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 DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2000
1706	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	7/1/1997

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1707	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	7/1/1997
1708	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	7/1/2012
1709	NDA/MAL/HDP/4799	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITROLIN SOLUTION	CETRIMIDE+LIDOCAIN E	25MG+3MG	PHARCO PHARMACEUTICALS LTD- KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL TOPICAL LIQUIDS	1.0X120.0 ML BOTTLE	7/1/1998

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1710	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	7/1/2009
1711	NDA/MAL/HDP/4805	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOFEN	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 FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/2000
1712	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,1.0X100.0 X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2009

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1713	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	7/1/2011
1714	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	NULL
1715	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,1.0X10.0X 10.0 TABLET BLISTER,1.0X100.0X10 .0 TABLET BLISTER	7/1/2009

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1716	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	7/1/2001
1717	NDA/MAL/HDP/4813	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL TABLETS (THANE)	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	1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X1000. 0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER	7/1/1998
1718	NDA/MAL/HDP/4814	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	METLIFE	METRONIDAZOLE	500MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1719	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	7/1/2014
1720	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	7/1/1997
1721	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	7/1/1998

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1722	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	7/1/2009
1723	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	7/1/1997
1724	NDA/MAL/HDP/4834	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICALS LIMITED	FINAGEN	FINASTERIDE	5MG	AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELENGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2004

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1725	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,1.0X100.0X10 .0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/2009
1726	NDA/MAL/HDP/4839	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOCAINE+HY DROCORTISONE+ALLA NTOIN	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	7/1/2007
1727	NDA/MAL/HDP/4845	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ANTIDEP	IMIPRAMINE	25MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VI LL.MANAKPUR,TEH.NALAG ARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/1997

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1728	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	7/1/2014
1729	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	7/1/2000
1730	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	7/1/2001

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1731	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	7/1/2003
1732	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	7/1/2003
1733	NDA/MAL/HDP/4867	CENTAUR PHARMACEUTICAL S 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	7/1/2003

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1734	NDA/MAL/HDP/4868	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCANIR	FLUCONAZOLE	2MG/ML	ACULIFE HEALTHCARE PVT LTD-VILLAGE SACHANA, TALUKA, VIRAMGAM, DIST. AHMEDABAD 382150, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2011
1735	NDA/MAL/HDP/4872	DAWA LIMITED	SUPER MEDIC LTD	MICLOCIN CREAM	MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICIN	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	7/1/2013
1736	NDA/MAL/HDP/4874	SANOI-AVENTIS	SURGIPHARM (U) LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOI WINTHROP INDUSTRIE-180 RUE JEAN JAURE'S BP 94702, MAISONS-ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0X0.6 ML PRE- FILLED SYRINGE	7/1/2009

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1737	NDA/MAL/HDP/4876	SANOFI-AVENTIS	SURGIPHARM (U) LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE-180 RUE JEAN JAURE'S BP 94702, MAISONS-ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X2.0X0.8 ML PRE-FILLED SYRINGE	7/1/2009
1738	NDA/MAL/HDP/4877	SANOFI-AVENTIS	SURGIPHARM (U) LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE-180 RUE JEAN JAURE'S BP 94702, MAISONS-ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X2.0X0.4 ML PRE-FILLED SYRINGE	7/1/2009
1739	NDA/MAL/HDP/4878	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	FLUCOLIFE	FLUCONAZOLE	200MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1740	NDA/MAL/HDP/4879	SANOFI-AVENTIS	SURGIPHARM (U) LIMITED	CLEXANE	ENOXAPARIN SODIUM	100MG/ML	SANOFI WINTHROP INDUSTRIE--180 RUE JEAN JUARES BP 4094702 MAISON ALFORT CEDEX	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X2.0X0.2 ML PRE-FILLED SYRINGE	7/1/2009
1741	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	7/1/2014
1742	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	7/1/1997

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1743	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	7/1/1999
1744	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	7/1/1997
1745	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	7/1/1997

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1746	NDA/MAL/HDP/4903	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+DRIED ALUMINIUM HYDROXIDE+PEPPER MINT 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2008
1747	NDA/MAL/HDP/4904	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30	INSULIN HUMAN	100 I.U./ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	7/1/1997
1748	NDA/MAL/HDP/4908	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD	DENMARK	PARENTERAL ORDINARY CARTRIDGES	1.0X1.5 ML CARTRIDGE,1.0X5.0X3 .0 ML CARTRIDGE	7/1/1997

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1749	NDA/MAL/HDP/4909	AXA PARENTERALS LTD	VITACARE LIMITED	AXAGYL	METRONIDAZOLE	0.5%W/V	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.OX100.0 ML BOTTLE	7/1/2015
1750	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.OX10.0 TABLET BLISTER	7/1/2008
1751	NDA/MAL/HDP/4917	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIMETHI CONE	400MG/5ML+ 400MG/5ML+ 40MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.OX120.0 ML BOTTLE	7/1/2010

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1752	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 MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2008
1753	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	7/1/2011
1754	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	7/1/1999

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1755	NDA/MAL/HDP/4924	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MULTIVIT TABLET	MULTIVITAMIN	MULTI- INGREDIENT	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	7/1/2001
1756	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/1997
1757	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	7/1/2009

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1758	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	7/1/1997
1759	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	7/1/1997
1760	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	7/1/1997

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1761	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	7/1/2005
1762	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	7/1/2006
1763	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	7/1/1997

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1764	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	7/1/1999
1765	NDA/MAL/HDP/4949	JOHNSON&JOHNS ON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETHORPHA N 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	7/1/1997
1766	NDA/MAL/HDP/4951	JOHNSON&JOHNS ON 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	7/1/1997

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1767	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	7/1/1997
1768	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	7/1/2009
1769	NDA/MAL/HDP/4955	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	COMPOUND SODIUM LACTATE INFU.	COMPOUND SODIUM LACTATE	MULTI-INGREDIENT	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/1997

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1770	NDA/MAL/HDP/4956	UNIQUE PHARMACEUTICAL S 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	7/1/2010
1771	NDA/MAL/HDP/4957	GLENMARK PHARMACEUTICALS 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	7/1/2004
1772	NDA/MAL/HDP/4958	TROIKAA PHARMACEUTICAL S 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	7/1/2011

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1773	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	7/1/2011
1774	NDA/MAL/HDP/4962	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	BETAD	BETAMETHASONE DIPROPIONATE	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	7/1/2010
1775	NDA/MAL/HDP/4964	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENAMINE+P HENYLEPHRINE+PARA CETAMOL	IMG+5MG+16 0MG	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	7/1/2011

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1776	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	7/1/2001
1777	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,1.0X50.0X1.0 X6.0 TABLET BLISTER	7/1/2010
1778	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	7/1/2008

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1779	NDA/MAL/HDP/4969	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) 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	7/1/2001
1780	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	7/1/1997
1781	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	7/1/2001

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1782	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	7/1/2014
1783	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	7/1/1998
1784	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	7/1/2015

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1785	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	7/1/2010
1786	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	7/1/1998
1787	NDA/MAL/HDP/4984	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CALNIF RETARD	NIFEDIPINE	20 MG	CADILA PHARMACEUTICALS LIMITED-1389,TRASAD ROAD, DHOLKA-382 225, AHMEDABAD GUJARAT STATE,INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/1998

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1788	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	7/1/2010
1789	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	7/1/2007
1790	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	7/1/2000

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1791	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	7/1/1997
1792	NDA/MAL/HDP/5005	MACK BROWN PHARMECEUTICALS PVT LTD	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	7/1/2010
1793	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	7/1/1997

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1794	NDA/MAL/HDP/5015	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP 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	7/1/1997
1795	NDA/MAL/HDP/5017	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP SYRUP	PARACETAMOL+PRO METHAZINE HYDROCHLORIDE+CODEINE PHOSPHATE+PSEUDOPHEDRINE HYDROCHLORIDE	120MG+6.5MG+5MG+25MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997
1796	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	7/1/1997

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1797	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	7/1/2011
1798	NDA/MAL/HDP/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTREL+FE RROUS FUMARATE	0.03MG+0.15 MG+75MG	BAYER PHARMA AG BERLIN BAYER PHARMA AG -13353 BERLIN GERMANY BAYER WEIMAR GMBH UND CO. KG,-WEIMAR DEBEREINERSTRASSE 20, 99427 WEIMAR GERMANY	FRANCE GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X100.0X28.0 TABLET BLISTER	7/1/2011
1799	NDA/MAL/HDP/5028	THE MENTHOLATUM COMPANY LTD TWY	HARLEYS UGANDA LIMITED	DEEP HEAT SPRAY	MULTI-INGREDIENT	MULTI- INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,- 1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	7/1/1997

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1800	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	7/1/1997
1801	NDA/MAL/HDP/5032	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELATED 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	7/1/2004
1802	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	7/1/2014

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1803	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	7/1/2002
1804	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	7/1/1997
1805	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	7/1/1998

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1806	NDA/MAL/HDP/5043	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHASONE/NE- OMYCIN/POLYMYXIN B	0.1%W/W+35 001.U/ML+600 01.U/ML	ALCON COUVREUR NV- RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/1997
1807	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	7/1/1997
1808	NDA/MAL/HDP/5051	CADILA HEALTHCARE LIMITED SARKHEJ	ABACUS PHARMA (AFRICA) LIMITED	DERIHALER	SALBUTAMOL	100CMG/DOS E	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	7/1/2005

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1809	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	7/1/1997
1810	NDA/MAL/HDP/5059	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	SURGIPHARM (U) LIMITED	MAALOX PLUS SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIMETHI CONE	200MG+175MG+25MG/5ML	WINTHROP PHARMACEUTICALS (PTY) LTD.-PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETORIA-PRIVATE BAG X516,SILVERTON,0127,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X350.0 ML BOTTLE,1.0X150.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE	7/1/1997
1811	NDA/MAL/HDP/5062	ICARE PHARMA LIMITED	AIVEEN (U) LIMITED	MANNILIFE	MANNITOL	20MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1812	NDA/MAL/HDP/5064	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	MANNITOL INFUSION	MANNITOL	20%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2011
1813	NDA/MAL/HDP/5065	N.V. ORGANON	SURGIPHARM (U) LIMITED	MARVELON	DESOGESTREL/ETHIN YLESTRADIOL	150MG/30MG	N.V. ORGANON-KLOOSTERSTRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X100.0X1.0X28.0 TABLET BLISTER	7/1/2015
1814	NDA/MAL/HDP/5066	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE SODIUM PHOSPHATE	4MG/ML	M.J. BIOPHARM PVT. LTD-L-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	7/1/2015

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1815	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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2010
1816	NDA/MAL/HDP/5070	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-60	ENOXAPARIN SODIUM	60MG/0.6ML	EMCURE PHARMACEUTICALS LTD - PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	7/1/2009
1817	NDA/MAL/HDP/5071	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-40	ENOXAPARIN SODIUM	40MG/0.4ML	EMCURE PHARMACEUTICALS LTD - PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	7/1/2009

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1818	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	7/1/1997
1819	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	7/1/2006
1820	NDA/MAL/HDP/5080	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	LOBAK	DICLOFENAC/PARACETAMOL/CHLORZOXAZONE	50MG/325MG /250MG	GENO PHARMACEUTICALS LTD--PHARMACEUTICAL COMPLEX, TIVIM INDUSTRIAL ESTATE, P.O. KARASWADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2011

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1821	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	7/1/1998
1822	NDA/MAL/HDP/5092	MICRO LABS LTD 92 SIPCOT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE	GLIMEPIRIDE	2MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2011
1823	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	7/1/2011

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1824	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	7/1/2013
1825	NDA/MAL/HDP/5096	ATCO LABORATORIES LTD	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	7/1/2003
1826	NDA/MAL/HDP/5097	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	GLUCOLIFE	GLUCOSE	50%W/V	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1827	NDA/MAL/HDP/5098	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIARIV	DI-iodo HYDROXYQUINOLINE/ PHTHALYL SULPHATHIAZOLE/ HOMATROPINE / STREPTOMYCIN	125MG/ 150MG/ 1MG/ 100MG	RIVA PHARMA FREE ZONE- NASR CITY CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2011
1828	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	7/1/2005
1829	NDA/MAL/HDP/5100	LINCOLN PHARMACEUTICAL S LTD	METRO PHARMACEUTICALS LIMITED	L-GENTA	GENTAMICIN	0.3%W/V	LINCOLN PHARMACEUTICALS LTD-- TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	7/1/2005

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1830	NDA/MAL/HDP/5102	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 500MG	METFORMIN	500MG	MERCK SANTÉ-2, RUE DU PRESOIR 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	1/7/2010
1831	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	7/1/2010
1832	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 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	7/1/2014

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1833	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	7/1/2003
1834	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	7/1/2011
1835	NDA/MAL/HDP/5110	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	GLUCOSE INFUSION BP	DEXTROSE	5%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE	7/1/1997

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1836	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	7/1/1998
1837	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	7/1/2000
1838	NDA/MAL/HDP/5117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMEDIES-UNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	7/1/2011

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1839	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	7/1/1999
1840	NDA/MAL/HDP/5122	CENTAUR PHARMACEUTICALS 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	7/1/2007
1841	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 TYPE I+INACTIVATED POLIO VIRUS TYPE	MIN 30 I.U.+MIN 40 I.U.+25MG+25MG+8MG+10MG,40DU+8DU+32DU+10MG	GLAXOSMITHKLINE BIOLOGICALS-S.A RUE DE L'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)	7/1/2013

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1842	NDA/MAL/HDP/5125	MACK BROWN PHARMECEUTICAL S 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	7/1/1998
1843	NDA/MAL/HDP/5127	UNIQUE PHARMACEUTICAL S LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN INJECTION	DICLOFENAC SODIUM	25MG/ML	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)-- 304-308 ,GIDC , PANOLI 394116	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X3.0 ML AMPOULE,1.0X5.0X3. 0 ML AMPOULE	7/1/1997
1844	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	7/1/2009

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1845	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	7/1/2006
1846	NDA/MAL/HDP/5131	NOVO NORDISK	STAR PHARMACEUTICALS LTD	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	7/1/1997
1847	NDA/MAL/HDP/5132	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	KETROZOL 200 TABLETS	KETOCONAZOLE	200MG	REMEDICA LIMITED,- LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997

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1848	NDA/MAL/HDP/5133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66MG/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.	7/1/2015
1849	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	7/1/1997
1850	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	7/1/2010

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1851	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	7/1/1997
1852	NDA/MAL/HDP/5137	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	KETOREN	KETOCONAZOLE	200MG	RENE INDUSTRIES LTD- PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2010
1853	NDA/MAL/HDP/5139	NOVO NORDISK	STAR PHARMACEUTICALS LTD	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X1.5 ML CARTRIDGE,1.0X3.0 ML CARTRIDGE	7/1/1997

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1854	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	7/1/1997
1855	NDA/MAL/HDP/5141	MACK BROWN PHARMECEUTICAL S 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	7/1/2003
1856	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	7/1/1997

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1857	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	7/1/2011
1858	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	7/1/2011
1859	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	7/1/2011

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1860	NDA/MAL/HDP/5148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	BETANASE TABLETS	GLIBENCLAMIDE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X3.0X 10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X2.0X5 0.0 TABLET BLISTER	7/1/1997
1861	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	60.0 ML BOTTLE	7/1/2003
1862	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	7/1/1997

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1863	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	7/1/1997
1864	NDA/MAL/HDP/5157	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL N	BETAMETHASONE+NE OMYCIN 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	7/1/1997
1865	NDA/MAL/HDP/5164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BROMHEX INE HYDROCHLORIDE+GU AIFENESIN+MENTHOL	1MG+2MG+50 MG+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	7/1/2010

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1866	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	7/1/2003
1867	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	7/1/2004
1868	NDA/MAL/HDP/5167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMOL	400MG + 300MG	SUN PHARMACEUTICALS IND. LTD-B-2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA-403404, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/1998

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1869	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	7/1/2000
1870	NDA/MAL/HDP/5171	TROIKAA PHARMACEUTICAL S 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	7/1/2011
1871	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	7/1/1997

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1872	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	7/1/2013
1873	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	7/1/2007
1874	NDA/MAL/HDP/5180	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (PAEDIATRIC)	EPHEDRINE HYDROCHLORIDE	5MG/ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	7/1/1997

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1875	NDA/MAL/HDP/5182	REGAL PHARMACEUTICALS 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	7/1/1997
1876	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	7/1/2000
1877	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	7/1/2000

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1878	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	7/1/2014
1879	NDA/MAL/HDP/5187	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	HEALIT SKIN OINTMENT	BACITRACIN+POLYMYXIN B SO4+NEOMYCIN+LIDOCaine	500UNITS+500 0UNITS+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	7/1/2007
1880	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	7/1/2009

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1881	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	7/1/1998
1882	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	7/1/1997
1883	NDA/MAL/HDP/5205	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-VENT	SALBUTAMOL	4MG	KAMPALA PHARMACEUTICALS INDUSTRIES-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	7/1/1997

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1884	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	7/1/2013
1885	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	7/1/2009
1886	NDA/MAL/HDP/5214	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMET	METRONIDAZOLE	500MG/100M L	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010

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1887	NDA/MAL/HDP/5221	GITTOES PHARMACEUTICAL S 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	7/1/2006
1888	NDA/MAL/HDP/5222	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EMTRICITABINE+TE NOFOVIR DF	EMTRICITABINE/TENO FOVIR	200MG/300M G	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	7/7/2008
1889	NDA/MAL/HDP/5224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EMTRICITABINE+TE NOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE/TENO FOVIR DISOPROXIL FUMERATE	200MG/300M G	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	7/1/2009

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1890	NDA/MAL/HDP/5226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABINE+TE NOFOVIR DISOPROXIL FUMERATE	EMTRICITABINE+TEN OFOVIR 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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2013
1891	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	7/1/2009
1892	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	7/1/2005

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1893	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	7/1/2006
1894	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	7/1/1997
1895	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	7/1/1997

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1896	NDA/MAL/HDP/5237	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	EUROCIP	CIPROFLOXACIN	200MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010
1897	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	7/1/2013
1898	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	7/1/2013

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1899	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	7/1/1997
1900	NDA/MAL/HDP/5249	EMCURE PHARMACEUTICAL S LTD	HARLEYS UGANDA LIMITED	ENCIFER	IRON SUCROSE	100MG/5ML	EMCURE PHARMACEUTICALS LTD - PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057 SAMRUDH PHARMACEUTICALS PVT LIMITED-J-174 AND J-168, M.I.D.C., TARAPUR, BOISAR, THANE, 401506, MAHARASHTRA, INDIA	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	7/1/2013
1901	NDA/MAL/HDP/5250	PHARCO PHARMACEUTICAL S	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	7/1/1998

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1902	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	7/1/1997
1903	NDA/MAL/HDP/5253	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOZOL SUSPENSION	BENZOYL METRONIDAZOLE	200MG/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	1.0X120.0 ML BOTTLE	7/1/1998
1904	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/GRAN ULES	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	7/1/2000

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1905	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	7/1/2001
1906	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	7/1/1997
1907	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	7/1/1997

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1908	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.OX30.0 MG TUBE	7/1/2001
1909	NDA/MAL/HDP/5269	INTAS, PHARMACEUTICAL S 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.OX3.OX10.0 TABLET BLISTER	7/1/2010
1910	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/SY RUPS/DROPS	1.OX100.0 ML BOTTLE	7/1/1997

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1911	NDA/MAL/HDP/5272	GITTOES PHARMACEUTICAL S 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	7/1/2011
1912	NDA/MAL/HDP/5274	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ECOZOLE	ECONAZOLE	150MG	BLISS GVS PHARMA LTD- PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	VAGINAL TABLETS	1.0X3.0 PESSARY STRIP	7/1/2008
1913	NDA/MAL/HDP/5277	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	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 CONTAINER	7/1/2011

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1914	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	7/1/2011
1915	NDA/MAL/HDP/5281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ+EMTRICI TABINE+TENOFVIR DISOPROXIL	EFAVIRENZ + EMTRICITABINE + TENOFVIR 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	7/1/2015
1916	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	7/1/2014

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1917	NDA/MAL/HDP/5283	REGAL PHARMACEUTICALS 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	7/1/2001
1918	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	7/1/2015
1919	NDA/MAL/HDP/5288	REGAL PHARMACEUTICALS 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	7/1/1997

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1920	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	7/1/2000
1921	NDA/MAL/HDP/5291	REGAL PHARMACEUTICALS 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	7/1/1997
1922	NDA/MAL/HDP/5292	LINCOLN PHARMACEUTICAL S 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	7/1/2011

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1923	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	7/1/2000
1924	NDA/MAL/HDP/5295	LABORATORY&ALLI ED 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,1.0X10.0X 10.0 CAPSULE BLISTER	7/1/2000
1925	NDA/MAL/HDP/5298	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	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	7/1/1997

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1926	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	7/1/2014
1927	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	7/1/2015
1928	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	7/1/2014

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1929	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2008
1930	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	7/1/2005
1931	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	7/1/2001

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1932	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	7/1/2009
1933	NDA/MAL/HDP/5317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FORMULA	TERBUTALINE SULPHATE+BROMHEX INE HYDROCHLORIDE+GU AIFENESIN+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	7/1/2003
1934	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	7/1/2009

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1935	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,1.0X10.0X 10.0 CAPSULE BLISTER,1.0X100.0X10 .0 CAPSULE BLISTER	7/1/2010
1936	NDA/MAL/HDP/5323	STEDMAN PHARMACEUTICAL S 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	7/1/2010
1937	NDA/MAL/HDP/5330	STEDMAN PHARMACEUTICAL S 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	7/1/2011

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1938	NDA/MAL/HDP/5333	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	IBUFEN	IBUPROFEN	200MG	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES 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,1.0X10.0X 10.0 TABLET BLISTER	7/1/1997
1939	NDA/MAL/HDP/5341	LABORATORY&ALLI ED 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	7/1/1997
1940	NDA/MAL/HDP/5343	PHARCO PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFORAN 1GM	CEFOTAXIME SODIUM	1GM	PHARCO B INTERNATIONAL: - KILO 31 ALEXANDRIA CAIRO DESERT ROAD ARAB REPUBLIC OF EGYPT, P.O. BOX 12 SIDI GABER ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1X5ML AMPOULE OF WFI	7/1/2000

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1941	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	7/1/2014
1942	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	7/1/2014
1943	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	7/1/2005

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1944	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	7/1/2005
1945	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	7/1/1997
1946	NDA/MAL/HDP/5358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	GUAIFENESIN+AMMO NIUM CHLORIDE+CHLORPHE NIRAMINE+SODIUM CITRATE	80MG+100MG +2MG+44MG	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	7/1/1997

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1947	NDA/MAL/HDP/5361	MACK BROWN PHARMECEUTICAL S PVT LTD	SHURIK LTD	CALFIC	MULTI-INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD - ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.OX100.0 ML BOTTLE	7/1/1997
1948	NDA/MAL/HDP/5362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELD-CESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.OX14.0 TABLET STRIP	7/1/2001
1949	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.OX2.OX14.0 TABLET BLISTER	7/1/1997

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1950	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, ALJUBAHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE, 1.0X30.0 ML BOTTLE	7/1/2007
1951	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, 1.0X10.0X10.0 TABLET BLISTER	7/1/2005
1952	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	7/1/2001

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1953	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	7/1/2008
1954	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	7/1/2008
1955	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	7/1/2001

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1956	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	7/1/2011
1957	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 BLISTER 1.0X30.0X18.	7/1/2011
1958	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	7/1/2008

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1959	NDA/MAL/HDP/5392	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRATE	10MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2008
1960	NDA/MAL/HDP/5393	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2008
1961	NDA/MAL/HDP/5395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005

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1962	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	7/1/1999
1963	NDA/MAL/HDP/5404	INTAS, PHARMACEUTICAL S 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	7/1/2013
1964	NDA/MAL/HDP/5405	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OLANDUS 10	OLANZAPINE	10MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005

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1965	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	7/1/2007
1966	NDA/MAL/HDP/5409	LINCON PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS LIMITED	MINTO GEL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	150 MG + 150 MG + 25 MG	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 SUSPENSIONS	1.0X180.0 ML BOTTLE	7/1/2012
1967	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 ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2009

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1968	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	7/1/2007
1969	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	7/1/2009
1970	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	7/1/2005

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1971	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	7/1/2007
1972	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	7/1/2005
1973	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,1.0X100.0 X10.0 TABLET BLISTER	7/1/2005

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1974	NDA/MAL/HDP/5423	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	600MG/300MG/300MG	HETERO DRUGS LTD-UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055 HETERO LABS LTD. UNIT (V) .-S.NO.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	7/1/2013
1975	NDA/MAL/HDP/5427	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRCIP	CIPROFLOXACIN	200MG/100MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010
1976	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	7/1/2006

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1977	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	7/1/2015
1978	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	7/1/2008
1979	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	7/1/2013

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1980	NDA/MAL/HDP/5444	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS TABLETS	DES Loratidine	5MG	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	7/1/2001
1981	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,1.0X10.0X10. 0 TABLET BLISTER	7/1/2012
1982	NDA/MAL/HDP/5453	PHARCO PHARMACEUTICAL S LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 250MG/5ML	AMOXICILLIN	250MG/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 DRY SUSPENSIONS/SY RUPS/DROPS	1.0X10.0 ML BOTTLE	7/1/1998

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1983	NDA/MAL/HDP/5456	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 125MG/5ML	AMOXICILLIN	125MG/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 DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998
1984	NDA/MAL/HDP/5460	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE+AMODI AQUINE	50MG+135MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI 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	7/1/2011
1985	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 BLISTER,1.0X1.0X6.0	7/1/2007

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1986	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	7/1/1997
1987	NDA/MAL/HDP/5469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY I V VIALS	1.0X50.0 ML VIAL	7/1/2009
1988	NDA/MAL/HDP/5471	MICRO LABS LTD	LABOREX UGANDA LIMITED	AVAS 40	ATORVASTATIN	40MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

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1989	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	7/1/2007
1990	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	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	7/1/2012
1991	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	7/1/2005

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1992	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 BESTEIRO PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI	7/1/2002
1993	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	7/1/2010
1994	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	7/1/1997

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1995	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	7/1/2010
1996	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 SHANGHAI 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	7/1/2011
1997	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	7/1/2009

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1998	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	7/1/2008
1999	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	7/1/2001
2000	NDA/MAL/HDP/5496	ASTRA ZENECA	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	7/1/2010

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2001	NDA/MAL/HDP/5497	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXPEN	BENZYL PENICILLIN	1MU	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	7/1/2011
2002	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	7/1/2011
2003	NDA/MAL/HDP/5619	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	RABELOX 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	7/1/2006

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2004	NDA/MAL/HDP/5644	GITTOES PHARMACEUTICAL S 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	7/1/2001
2005	NDA/MAL/HDP/5648	KARNATAKA ANTIBIOTICS & PHARMACEUTICAL S 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	7/1/2010
2006	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	3/28/2019

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2007	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	7/1/2016
2008	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	3/28/2019
2009	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,1.0X10.0X10. 0 CAPSULE BLISTER,1.0X1000.0 CAPSULE JAR	7/1/2017

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2010	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	7/1/2017
2011	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	7/1/2017
2012	NDA/MAL/HDP/6046	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACYCLOVIR	ACYCLOVIR	200MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017

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2013	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	7/1/2017
2014	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	7/1/2009
2015	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	7/1/2017

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2016	NDA/MAL/HDP/6059	RESONANT PHARMACEUTICAL S 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	7/1/2017
2017	NDA/MAL/HDP/6060	NOVARTIS ACCESS	SURGIPHARM (U) LIMITED	SALBUTAMOL	SALBUTAMOL	100MCG	AEROPHARM GMBH...- RUDOLSTADT ALLEMAGNE	GERMANY	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X200.0 METERED DOSE CONTAINER	7/1/2017
2018	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	7/1/2017

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2019	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	7/1/2017
2020	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	7/1/2017
2021	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	7/1/2017

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2022	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	7/1/2017
2023	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	7/1/2017
2024	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	7/1/2017

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2025	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 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
2026	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	7/1/2017
2027	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	7/1/2017

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2028	NDA/MAL/HDP/6082	EXPHAR SA	SURGIPHARM (U) LIMITED	CROMSOL	SODIUM CROMOGLYCAT	2%W/V	AHLCONPARENTALS (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	7/1/2017
2029	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	7/1/2017
2030	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	7/1/2017

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2031	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	7/1/2017
2032	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 NAACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE	7/1/2017
2033	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	7/1/2017

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2034	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	7/1/2017
2035	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	7/1/2017
2036	NDA/MAL/HDP/6104	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	FUROSEMIDE	FUROSEMIDE	10MG/ML	PSYCHOTROPICS INDIA LTD- PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE	7/1/2017

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2037	NDA/MAL/HDP/6105	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPIIL 200	AZITHROMYCIN	200MG/5ML	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	7/1/2017
2038	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	7/1/2005
2039	NDA/MAL/HDP/6115	I-CARE PHARMA LTD	SUPER MEDIC LTD- MBARARA	TIZOL	TINIDAZOLE	500MG	MEDICO REMEDIES PVT LTD.,-8 & 9 DEWAN AND SONS, UDYOG NAGAR, PALGHAR, DIST. THANE- 401404, MAHARSHITRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET STRIP	7/1/1997

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2040	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	7/1/2017
2041	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	7/1/2017
2042	NDA/MAL/HDP/6121	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	DEXIREN	DEXKETOPROFEN TROMETAMOL	25MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2017

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2043	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	7/1/2016
2044	NDA/MAL/HDP/6127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	7/1/2016
2045	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 GLAXOSMITHKLINE PHARMACEUTICALS SA- GRUNWALDZKA 189 STREET, 60-322 POZNANA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2016

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2046	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	7/1/2016
2047	NDA/MAL/HDP/6136	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 120	ETORICOXIB	120MG	CADILA HEALTHCARE LIMITED -PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016
2048	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	

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2049	NDA/MAL/HDP/6138	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 60	ETORICOXIB	60MG	CADILA HEALTH CARE LIMITED -PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016
2050	NDA/MAL/HDP/6142	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCARB	ACTIVATED CHARCOAL	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	1.0X100.0 TABLET BOTTLE,1.0X10.0X10.0 TABLET BLISTER	7/1/2016
2051	NDA/MAL/HDP/6143	MARCYRL PHARMACEUTICAL INDUSTRIES	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	7/1/2016

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2052	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	7/1/2016
2053	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,1.0X10.0X10.0 TABLET BLISTER	7/1/2016
2054	NDA/MAL/HDP/6161	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	DICLAC	DICLOFENAC SODIUM	150MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE-ALLEE	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016

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2055	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	1/7/2016
2056	NDA/MAL/HDP/6169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	7/1/2016
2057	NDA/MAL/HDP/6171	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	SUXAMETHONIUM CHLORIDE	SUXAMETHONIUM CHLORIDE	50MG/ML	ROTEXMEDICA GMBH ARZNEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY DRY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2016

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2058	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	7/1/2016
2059	NDA/MAL/HDP/6174	ROTEXMEDICA GMBH ARZNEIMITTELWE RK	GITTOES PHARMACEUTICALS LIMITED	FLUPHENAZINE DECANOATE INJECTION USP 25MG/ML	FLUPHENAZINE DECANOATE	25MG/ML	ROTEXMEDICA GMBH ARZEMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2016
2060	NDA/MAL/HDP/6179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON-DENK 4MG ODT	ONDANSETRON	4MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	7/1/2016

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2061	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	7/1/2016
2062	NDA/MAL/HDP/6185	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	DOLOFORTE DENK	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2016
2063	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	7/1/2016

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2064	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	7/1/2016
2065	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	7/1/2016
2066	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+POTASSIUM CHLORIDE,ANHYDRO	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	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	7/1/2015

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2067	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-BOUR CITY, KALYUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	7/1/2016
2068	NDA/MAL/HDP/6193	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	CEFTRIAZONE SANDOZ	CEFTRIAZONE SODIUM	1G	SANDOZ GMBH- BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2016
2069	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	7/1/2016

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2070	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	7/1/2016
2071	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	7/1/2016
2072	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)	INDIA	VAGINAL TABLETS	1.0X14.0 PESSARY STRIP	7/1/2016

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2073	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	7/1/2016
2074	NDA/MAL/HDP/6205	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACICLOVIR	ACICLOVIR	400MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016
2075	NDA/MAL/HDP/6211	EXPHAR SA	SURGIPHARM (U) LIMITED	CLOFAINS	PARACETAMOL/DICL OFENAC 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	7/1/2016

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2076	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)	7/1/2016
2077	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	7/1/2016
2078	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	7/1/2016

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2079	NDA/MAL/HDP/6227	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ISONIAZID	ISONIAZID	300MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2016
2080	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	7/1/2016
2081	NDA/MAL/HDP/6230	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2016

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2082	NDA/MAL/HDP/6231	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	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	7/1/2016
2083	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)	7/1/2016
2084	NDA/MAL/HDP/6234	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	D-ARTEPP DISPERSIBLE	DIHYDROARTEMISININE/ 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	7/1/2016

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2085	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	7/1/2016
2086	NDA/MAL/HDP/6236	MOONLINK PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL ADVANCE	PARACETAMOL + IBUPROFEN + CAFFEINE	325 MG + 400 MG + 40 MG	FREDUN PHARMACEUTICALS LTD-VEOOR PALGHAR (E) 401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X40.0X2.0X10.0 CAPSULE BLISTER	7/1/2016
2087	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	7/1/2016

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2088	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	7/1/2016
2089	NDA/MAL/HDP/6239	BLISS GVS PHARMA LIMITED	DELMAR 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 NAACL + 1*1 ML OF 5%W/V SODIUM BICARBONATE	7/1/2016
2090	NDA/MAL/HDP/6241	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	CLOPIDOGREL NORVATIS ACCESS	CLOPIDOGREL	75MG	SANDOZ PVT LTD- PLOT NO. 8-A/2 & 8-B TTC INDUSTRIAL AREA LARWE BLOCK VILLAGE DIGHE NAVI MUMBAI 400 708 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2016

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2091	NDA/MAL/HDP/6242	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	STAR PHARMACEUTICALS LTD	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	7/1/2016
2092	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	7/1/2016
2093	NDA/MAL/HDP/6244	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2016

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2094	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	7/1/2016
2095	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	7/1/2016
2096	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	7/1/2016

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2097	NDA/MAL/HDP/6251	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TORGABALIN 75	PREGABALIN	75MG	TORRENT PHARMACEUTICAL LTD- AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2016
2098	NDA/MAL/HDP/6257	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	EDURANT	RILPIVIRINE	25MG	JANSSEN CILAG S.P.A-VIA C.JANSSEN, BORGIO	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2016
2099	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	7/1/2016

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2100	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	7/1/2016
2101	NDA/MAL/HDP/6270	MACLEODS PHARMACEUTICAL S 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	7/1/2017
2102	NDA/MAL/HDP/6275	SEV PHARMACEUTICAL S LIMITED	SEV PHARMACEUTICALS LIMITED	BENZYL BENZOATE APPLICATION BP	BENZYL BENZOATE	25%W/V	SEV PHARMACEUTICALS LTD, -PLOT 100 MASAKA ROAD ,NALUKOLONGO KAMPALA,UGANDA.	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	

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2103	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	1/25/2019
2104	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	11/7/2018
2105	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	11/7/2018

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2106	NDA/MAL/HDP/6284	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PAEDIATRIC PARACETAMOL ORAL SOLUTION	PARACETAMOL	120MG/5ML	CIPLA LTD INDORE -PLOT NO. 9 AND 10, INDORE SPECIAL ECONOMIC ZONE, PHASE -II, PITHAMPUR, DISTRICT DHAR, 454 775, MADHYA PRADESH - INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	11/7/2018
2107	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	11/7/2018
2108	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)	1/25/2019

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2109	NDA/MAL/HDP/6288	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFIX-100 DS	CEFIXIME TRIHYDRATE	100MG/5ML	THEON PHARMACEUTICALS LIMITED.- VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	12/17/2018
2110	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	12/17/2018
2111	NDA/MAL/HDP/6293	MACLEODS PHARMACEUTICAL S 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	12/17/2018

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2112	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	1/4/2019
2113	NDA/MAL/HDP/6295	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	LIRAPYN 75MG	PREGABALIN	75MG	RANBAXY LABORATORIES LTD-PAONTA SAHIB, DISTRICT – SIRMOUR, HIRMACHAL	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	7/1/2017
2114	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	1/31/2018

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2115	NDA/MAL/HDP/6304	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	UNOSURE 72	LEVONORGESTREL	1.5MG	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0 TABLET BLISTER	3/28/2019
2116	NDA/MAL/HDP/6314	YELURI FORMULATIONS PVT LTD	ESCORTS PHARMACEUTICALS LIMITED	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	5/30/2018
2117	NDA/MAL/HDP/6316	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	OSMOLAX	LACTULOSE	3.40G/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)- SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	7/25/2018

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2118	NDA/MAL/HDP/6322	CACHET PHARMACEUTICAL S PVT LIMITED	ASTRA PHARMA (U) LIMITED	ACINET 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	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, 1.0X2.0X7.0 TABLET BLISTER	3/28/2018
2119	NDA/MAL/HDP/6323	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MOXAM 400	MOXIFLOXACIN	400MG	ALKEM LABS LTD.-VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/28/2019
2120	NDA/MAL/HDP/6333	BHARAT BIOTECH INTERNATIONAL LIMITED	PILLAR PHARMA LIMITED	REVAC-B+®	HEPATITIS B SURFACE ANTIGEN (HBSAG)	20MCG/ML	BHARAT BIOTECH INTERNATIONAL LTD- GENOME VALLEY, SHAMEERPET MANDAL, RANGAREDDY, TELANGANA STATE-500078 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.5 ML VIAL, 1.0X1.0X1.0 ML VIAL, 1.0X1.0X10.0 ML VIAL	3/28/2019

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2121	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	3/28/2019
2122	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	3/28/2019
2123	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	5/30/2018

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2124	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	1/31/2018
2125	NDA/MAL/HDP/6341	MACLEODS PHARMACEUTICALS 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	1/31/2018
2126	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	5/30/2018

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2127	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	3/28/2019
2128	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	9/26/2018
2129	NDA/MAL/HDP/6345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 600MG VAIL	AMOXYCILLIN SODIUM/ CLAVULANATE POTASSIUM	500MG/100M G	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/25/2018

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2130	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	3/28/2019
2131	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	9/26/2018
2132	NDA/MAL/HDP/6350	MEGA LIFESCINCES 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	3/28/2019

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2133	NDA/MAL/HDP/6351	GETZ PHARMA PVT LTD	MU PHARMA CO - SMC LIMITED	FEXET	FEXOFENADINE	120MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	9/29/2021
2134	NDA/MAL/HDP/6352	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	OMIPIN-20	OMEPRAZOLE	20MG	BRAWN LABORATORIES LTD -13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	3/28/2019
2135	NDA/MAL/HDP/6353	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVIR/LA MIVUDINE/TENOFO VIR DISOPROXIL FUMARATE TABLETS 50MG/300MG/300 MG	DOLUTEGRAVIR+LAMI VUDINE+TENOFIVIR 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	12/11/2019

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2136	NDA/MAL/HDP/6354	EXPHAR SA.	SURGIPHARM (U) LIMITED	TIMOSOL ®	TIMOLOL MALEATE	0.5%W/V	AHLCONPARENTALS (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	7/1/2017
2137	NDA/MAL/HDP/6357	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NUCOXIA 90	ETORICOXIB	90MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/28/2019
2138	NDA/MAL/HDP/6358	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 20	ROSUVASTATIN CALCIUM	20MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	3/28/2019

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2139	NDA/MAL/HDP/6359	CCL PHARMACEUTICALS (PVT.) LTD.	HARLEYS UGANDA LIMITED	NEO-KLAR 250MG	CLARITHROMYCIN	250MG	CCL PHARMACEUTICALS (PVT) LTD -62 INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE-54770, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/28/2019
2140	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	7/1/2017
2141	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	3/28/2019

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2142	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	1/31/2018
2143	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	3/28/2018
2144	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	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	2/6/2019

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2145	NDA/MAL/HDP/6380	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 1200MG VIAL	AMOXICILLIN + CLAVULANIC ACID	1000MG+120 MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	7/25/2018
2146	NDA/MAL/HDP/6381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTA CONAZOLE 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	3/28/2019
2147	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, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017

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2148	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	7/25/2018
2149	NDA/MAL/HDP/6386	STEDMAN PHARMACEUTICAL S 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	5/30/2018
2150	NDA/MAL/HDP/6390	MACLEODS PHARMACEUTICAL S 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	2/6/2019

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2151	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	5/30/2018
2152	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	5/29/2019
2153	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	5/29/2019

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2154	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	7/1/2017
2155	NDA/MAL/HDP/6397	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	INDOSUPP 100	INDOMETHACIN	100 MG	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	7/1/2017
2156	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	7/1/2017

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2157	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,NAVSAR I 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	7/1/2017
2158	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	7/1/2017
2159	NDA/MAL/HDP/6405	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	CLOPRAZ	CLOPIDOGREL BISULFATE	75MG	ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017

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2160	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 CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X25.0X30.0 ML VIAL	2/6/2019
2161	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	11/29/2017
2162	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	5/29/2019

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2163	NDA/MAL/HDP/6412	PHARCO PHARMACEUTICAL S 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	7/1/2017
2164	NDA/MAL/HDP/6413	BHARAT BIOTECH INTERNATIONAL LIMITED	REDDYS PHARMA LIMITED	ROTAVAC	ROTAVIRUS 116E BULK, LIVE ATTENUATED	NLT 10 ⁵ .0 FFU / 0.5ML	BHARAT BIOTECH INTERNATIONAL LTD- GENOME VALLEY, SHAMEERPET MANDAL, RANGAREDDY, TELANGANA STATE-500078 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X1.0X0.5 ML VIAL,1.0X1.0X2.5 ML VIAL,1.0X1.0X5.0 ML VIAL	5/29/2019
2165	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	5/29/2019

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2166	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	5/29/2019
2167	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	9/26/2018
2168	NDA/MAL/HDP/6424	GLENMARK PHARMACEUTICAL S 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	3/27/2019

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2169	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, 1.0X30.0X1.0X12.0 TABLET BLISTER	3/27/2019
2170	NDA/MAL/HDP/6431	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2171	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	3/27/2019

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2172	NDA/MAL/HDP/6433	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2173	NDA/MAL/HDP/6435	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2174	NDA/MAL/HDP/6436	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	MOXAF	MOXIFLOXACIN HYDROCHLORIDE	400 MG	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	7/1/2017

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2175	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	11/29/2017
2176	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	3/27/2019
2177	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	7/1/2017

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2178	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	3/28/2018
2179	NDA/MAL/HDP/6442	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 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	7/1/2018
2180	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	3/27/2019

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2181	NDA/MAL/HDP/6447	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2182	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	7/25/2018
2183	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	3/27/2019

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2184	NDA/MAL/HDP/6453	LINCOLN PHARMACEUTICAL S 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	3/27/2019
2185	NDA/MAL/HDP/6454	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	2/6/2019
2186	NDA/MAL/HDP/6455	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017

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2187	NDA/MAL/HDP/6458	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO	RIVAROXABAN	10 MG	LIPTIS EGYPT 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	3/27/2019
2188	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	3/27/2019
2189	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	9/26/2018

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2190	NDA/MAL/HDP/6465	MACLEODS PHARMACEUTICAL S 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	7/1/2017
2191	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	5/30/2018
2192	NDA/MAL/HDP/6472	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MOXICLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	250MG + 125MG	MEDOCHÉMIE 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	2/4/2019

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2193	NDA/MAL/HDP/6478	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	RANTAG INJECTION	RANITIDINE HYDROCHLORIDE	50MG/2ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	7/25/2018
2194	NDA/MAL/HDP/6481	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	MOXAL PLUS CHEWABLE TABLETS	DRIED ALUMINIUM HYDROXIDE GEL+MAGNESIUM HYDROXIDE+SIMETHI CONE	200MG+200MG+25MG	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	7/1/2017
2195	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	3/27/2019

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2196	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.OX750.0 MG VIAL	1/31/2018
2197	NDA/MAL/HDP/6488	GUILIN PHARMACEUTICAL CO.LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PARACETAMOL INJECTION	PARACETAMOL	300MG/2ML	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY AMPOULES	1.OX10.0X10.0X2.0 ML AMPOULE	5/30/2018
2198	NDA/MAL/HDP/6489	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL-SF	SALBUTAMOL+BROM HEXINE HYDROCHLORIDE+GU AIFENESIN	2MG+4MG+10 0MG/10ML	GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.OX100.0 ML BOTTLE	7/1/2017

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2199	NDA/MAL/HDP/6491	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAMIN	75MG+750MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	3/28/2018
2200	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	7/25/2018
2201	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	5/29/2019

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2202	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	5/29/2019
2203	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	11/29/2017
2204	NDA/MAL/HDP/6504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CAPXCEL	CAPECITABINE	500MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	5/29/2019

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2205	NDA/MAL/HDP/6506	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	ACTITOP	ETOPOSIDE	50MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X8.0 CAPSULE BOTTLE	5/29/2019
2206	NDA/MAL/HDP/6508	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	XALIPAT-100	OXALIPLATIN	100 MG/ 50ML (2MG/ML)	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	5/29/2019
2207	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	5/29/2019

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2208	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 CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	5/29/2019
2209	NDA/MAL/HDP/6512	AXA PARENTERALS LTD	VITACARE LIMITED	AXACIP	CIPROFLOXACIN	200MG/100ML	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	1/31/2018
2210	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	5/29/2019

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2211	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	5/29/2019
2212	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	7/1/2017
2213	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	3/28/2019

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2214	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	7/1/2017
2215	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	3/28/2019
2216	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	3/28/2019

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2217	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	3/28/2019
2218	NDA/MAL/HDP/6529	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	PRAZIQUANTEL TABLETS 600 MG	PRAZIQUANTEL	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	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0X10.0 TABLET BLISTER	3/28/2018
2219	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	3/28/2018

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2220	NDA/MAL/HDP/6537	EXPHAR SA	SURGIPHARM (U) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTALS (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	1/31/2018
2221	NDA/MAL/HDP/6542	PINNACLE LIFE SCIENCE PVT. LTD.	ABACUS PHARMA (AFRICA) LIMITED	GESIC ADL	IBUPROFEN	400MG	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	3/28/2019
2222	NDA/MAL/HDP/6544	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	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	3/28/2018

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2223	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	3/29/2019
2224	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	3/29/2019
2225	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	7/1/2017

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2226	NDA/MAL/HDP/6548	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIROPAIN GEL	DICLOFENAC DIETHYLAMINE BP	1%W/W	CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	7/1/2017
2227	NDA/MAL/HDP/6550	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	REDCEPHIN	CEFTRIAZONE	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	3/27/2019
2228	NDA/MAL/HDP/6551	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN FOR CHILDREN SUGAR FREE	IBUPROFEN	100MG/5ML	RECKITT BENCKISER HEALTHCARE LTD, HULL- DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	3/29/2019

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2229	NDA/MAL/HDP/6552	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	NUROFEN	IBUPROFEN + LYSINE	342MG	RECKITT BENCKISER HEALTHCARE LTD, HULL- DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	3/29/2019
2230	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	3/28/2019
2231	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	4/1/2019

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2232	NDA/MAL/HDP/6555	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DERMIRIV OC	OFLOXACIN + ORNIDAZOLE + TERBINAFINE HYDROCHLORIDE + CLOBETASOL PROPIONATE	0.75%W/W + 2.0%W/W + 1.0%W/W + 0.05%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	8/28/2019
2233	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	3/29/2019
2234	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	3/28/2019

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2235	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	1/31/2018
2236	NDA/MAL/HDP/6562	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	ATROPINE EYE DROP BP 1 %W/V	ATROPINE SULPHATE	1%W/V	SWISS PARENTERALS PVT LTD ..-809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	3/28/2019
2237	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	3/28/2019

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2238	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	3/28/2019
2239	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 INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	3/28/2019
2240	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	7/1/2017

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2241	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	3/28/2019
2242	NDA/MAL/HDP/6572	NTICALS LTD.	VITACARE LIMITED	METOMAC 50	METOPROLOL SUCCINATE	50MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/4/2018
2243	NDA/MAL/HDP/6578	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) 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	8/28/2019

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2244	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	8/28/2019
2245	NDA/MAL/HDP/6582	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL 10	BISOPROLOL FUMARATE	10 MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER	8/28/2019
2246	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	5/29/2019

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2247	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	5/29/2019
2248	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	5/29/2019
2249	NDA/MAL/HDP/6590	NABIQASIM INDUSTRIES (PVT) LTD.	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	5/29/2019

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2250	NDA/MAL/HDP/6592	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ZINAXIME 500	CEFUROXIME AXETIL	500MG	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	2/4/2019
2251	NDA/MAL/HDP/6593	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	TRANSIC	TRANEXAMIC ACID	500MG	NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	5/29/2019
2252	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	2/4/2019

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2253	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	3/27/2019
2254	NDA/MAL/HDP/6601	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	FEXET	FEXOFENADINE	180MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER	9/29/2021
2255	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	3/27/2019

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2256	NDA/MAL/HDP/6607	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RANI	RANITIDINE HYDROCHLORIDE	150MG	PHARCO PHARMACEUTICAL IND. LTD-KM 31, ALEX, CAIRO DESERT AMRIYA, ALEXANDRA	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRAN ULES	1.0X6.0X5.4 G SACHET	5/29/2019
2257	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	5/29/2019
2258	NDA/MAL/HDP/6610	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND	ONDANSETRON 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,1.0X4.0X4. 0 ML AMPOULE	7/1/2017

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2259	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	7/1/2008
2260	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	7/1/2017
2261	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	7/1/2009

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2262	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	7/1/2016
2263	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	7/1/2016
2264	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	7/1/2011

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2265	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 INDUSTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND-247667	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016
2266	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) TEMPELHOFFER 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)	7/1/2016
2267	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, THAILAND	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	7/1/1997

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2268	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	7/1/1997
2269	NDA/MAL/HDP/6629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+HYDROC HLOROTHIAZIDE	5MG+25MG	BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION)- TEMPELHOFFER 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	7/1/2016
2270	NDA/MAL/HDP/6630	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZOLE	20MG	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 AUROBINDO UNIT XV-PLOT NO. 17 A. E.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016

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2271	NDA/MAL/HDP/6631	GITTOES PHARMACEUTICAL S 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	7/1/2016
2272	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	7/1/2006
2273	NDA/MAL/HDP/6633	SHELYS PHARMACEUTICAL S LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	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,1.0X12.0X1.0 X2.0X10.0 CAPSULE BLISTER	7/1/2010

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2274	NDA/MAL/HDP/6638	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS 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	7/1/2016
2275	NDA/MAL/HDP/6640	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (40/12.5)	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	7/1/2017
2276	NDA/MAL/HDP/6641	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) 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	7/1/2016

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2277	NDA/MAL/HDP/6645	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (80/12.5)	TELMISARTAN + HYDROCHLOROTHIAZIDE	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	7/1/2017
2278	NDA/MAL/HDP/6648	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	DEXAMETHASONE 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	7/1/2016
2279	NDA/MAL/HDP/6650	INDUS LIFE SCIENCES PVT LIMITED	NORVIK ENTERPRISES LIMITED	INTRIAX-S-1	CEFTRIAXONE SODIUM+SULBACTAM SODIUM	1G+0.5G	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT- 686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2016

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2280	NDA/MAL/HDP/6651	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CYCLOVEER	ACICLOVIR	5%W/W	KREMOINT PHARMA PVT LTD-B-8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	7/1/2016
2281	NDA/MAL/HDP/6652	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE +TENOFVIR DISOPROXIL FUMARATE	LAMIVUDINE+TENOFVIR 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	7/1/2017
2282	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	7/1/2016

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2283	NDA/MAL/HDP/6658	MSN LABORATORIES LTD	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	7/1/2017
2284	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	7/1/2013
2285	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	7/1/2016

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2286	NDA/MAL/HDP/6665	REGAL PHARMACEUTICALS 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	7/1/1997
2287	NDA/MAL/HDP/6666	MSN LABORATORIES LTD	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	7/1/2017
2288	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	7/1/2016

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2289	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	7/1/2016
2290	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	7/1/2016
2291	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	7/1/2016

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2292	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	
2293	NDA/MAL/HDP/6685	NEON LABORATORIES 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	7/1/2014
2294	NDA/MAL/HDP/6689	DAWA LIMITED	SUPER MEDIC LTD	EFLARON	METRONIDAZOLE	200MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/1997

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2295	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	7/1/2016
2296	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	7/1/2016
2297	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	7/1/2016

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2298	NDA/MAL/HDP/6696	CCL PHARMACEUTICALS (PVT.)LTD.	HARLEYS UGANDA LIMITED	GABLIN	PREGABALIN	75MG	CCL PHARMACEUTICALS (PVT) LTD -62 INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE-54770, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	3/28/2019
2299	NDA/MAL/HDP/6700	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2009
2300	NDA/MAL/HDP/6705	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2010

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2301	NDA/MAL/HDP/6706	CACHET PHARMACEUTICAL S PVT LTD	ASTRA PHARMA (U) 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	7/1/2009
2302	NDA/MAL/HDP/6712	CACHET PHARMACEUTICAL S PVT LTD	ASTRA PHARMA (U) 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	7/1/2011
2303	NDA/MAL/HDP/6713	CACHET PHARMACEUTICAL S PVT LTD	ASTRA PHARMA (U) 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	7/1/2009

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2304	NDA/MAL/HDP/6715	CACHET PHARMACEUTICAL S PVT LTD	ASTRA PHARMA (U) 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	7/1/2009
2305	NDA/MAL/HDP/6717	CACHET PHARMACEUTICAL S PVT LTD	ASTRA PHARMA (U) 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	7/1/2011
2306	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	7/1/2016

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2307	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	7/1/2000
2308	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	7/1/2010
2309	NDA/MAL/HDP/6731	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	PIPTAZO 4.5G	PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	4G+0.5G	SANDOZ GMBH-BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 ML VIAL	7/1/2016

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2310	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	7/1/2010
2311	NDA/MAL/HDP/6734	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2009
2312	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	7/1/2016

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2313	NDA/MAL/HDP/6738	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SEEBRI BREEZHALER	GLYCOPYRRONIUM BROMIDE	50MCG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X1.0 CANNISTER CARTON + 30 CAPSULE BLISTER	7/1/2016
2314	NDA/MAL/HDP/6741	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ULTIBRO BREEZHALER	INDACATEROL MALEATE+GLYCOPYR RONIUM BROMIDE	110MCG+50M CG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X30.0 CAPSULE BLISTER	7/1/2016
2315	NDA/MAL/HDP/6744	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	CEFTRIAXONE FOR INJECTION	CEFTRIAXONE	1G	M.J.BIOPHARM PVT LTD-L-7 MIDC INDUSTRIAL AREA TALOYA NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2004

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2316	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	7/1/2005
2317	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,1.0X10.0X 10.0 TABLET BLISTER	7/1/2000
2318	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. BASAVIAH 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	7/1/2016

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2319	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 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2016
2320	NDA/MAL/HDP/6764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	IZRA 40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	UNICHEM LABORATORIES LTD-UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0 TABLET STRIP	7/1/2016
2321	NDA/MAL/HDP/6765	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	7/1/2010

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2322	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	7/1/2016
2323	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	7/1/2016
2324	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	7/1/2007

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2325	NDA/MAL/HDP/6774	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FLEMIN EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE +AMMONIUM CHLORIDE	12.5MG+130MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2008
2326	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	7/1/2010
2327	NDA/MAL/HDP/6777	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID	FUSIDIC ACID	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	7/1/2016

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2328	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	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2016
2329	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	7/1/2007
2330	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	7/1/2008

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2331	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	7/1/2008
2332	NDA/MAL/HDP/6788	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ROYAL VIT G	MULTI-INGREDIENTS	MULTI-INGREDIENTS	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)- 1ST INDUSTRIAL ZONE, S" OF OCTOBER CITY, EGYPT. PO. BOX 43, OCTOBER CITY. POSTAL CODE NO.12566	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	7/1/2005
2333	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	7/1/2016

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2334	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	01-07-20
2335	NDA/MAL/HDP/6792	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	400MG	JANSSEN ORTHO LLC.-- STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER	7/1/2017
2336	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 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2017

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2337	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	7/1/2016
2338	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	7/1/1997
2339	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	01-07-05

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2340	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'MONOPHOS PHORYL LIPID A(MPL)	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'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	7/1/2007
2341	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	7/1/2016
2342	NDA/MAL/HDP/6818	SANOPI PASTEUR	LABOREX UGANDA LIMITED	IMOVAX POLIO	POLIO VIRUS; (MAHONEY) TYPE 1- INACTIVE + (MEF-1) TYPE 2- INACTIVE + (SAUKETT) TYPE 3- INACTIVE	40 D + 8D + 32 D ANTIGEN UNITS/ 0.5ML	SANOPI PASTEUR-MÉRIEUX 69280 MARCY L'ÉTOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	7/1/2016

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2343	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	7/1/2016
2344	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	7/1/2016
2345	NDA/MAL/HDP/6826	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINC SULFATE	ZINC SULFATE	20MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016

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2346	NDA/MAL/HDP/6833	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ON.SENTRON-DENK 8MG ODT	ONDANSETRON	8MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	7/1/2016
2347	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	7/1/2009
2348	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	7/1/2017

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2349	NDA/MAL/HDP/6857	BRAWN LABORATORIES LTD	TATA UGANDA 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	11/29/2017
2350	NDA/MAL/HDP/6859	BRAWN LABORATORIES LTD	TATA UGANDA 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	9/26/2018
2351	NDA/MAL/HDP/6862	BRAWN LABORATORIES LTD	TATA UGANDA 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, 1.0X10.0 G TUBE	7/1/2017

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2352	NDA/MAL/HDP/6865	BRAWN LABORATORIES LTD	TATA UGANDA 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	11/29/2017
2353	NDA/MAL/HDP/6870	BRAWN LABORATORIES LTD	TATA UGANDA 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	11/29/2017
2354	NDA/MAL/HDP/6871	BRAWN LABORATORIES LTD	TATA UGANDA 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	9/26/2018

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2355	NDA/MAL/HDP/6872	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2356	NDA/MAL/HDP/6873	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	ROXITHIN TABLETS	ROXITHROMYCIN	150MG	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	9/26/2018
2357	NDA/MAL/HDP/6874	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017

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2358	NDA/MAL/HDP/6875	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRUMOX-250 CAPSULES	AMOXICILLIN TRIHYDRATE	250MG	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	7/1/2017
2359	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	7/1/2006
2360	NDA/MAL/HDP/6898	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	5000I.U/0.3ML	ROCHE DIAGNOSTICS GMBH MANNHEIM-SANDHOFER STRABE 116, 68305, MANNHEIM	GERMANY	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X1.0X0.3 ML PRE- FILLED SYRINGE	5/29/2019

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2361	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	5/29/2019
2362	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	5/29/2019
2363	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	8/28/2019

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2364	NDA/MAL/HDP/6911	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	SCABION	CROTAMITON + SULPHUR	10 G + 2 G	ATCO LABS LTD,-B-18, S.I.T.E, KARACHI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	
2365	NDA/MAL/HDP/6912	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 5	ROSUVASTATIN CALCIUM	5 MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	8/28/2019
2366	NDA/MAL/HDP/6913	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 10	ROSUVASTATIN CALCIUM	10 MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	8/28/2019

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2367	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	8/28/2019
2368	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, 1.0X25.0X3.0 TABLET BLISTER	3/27/2019
2369	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	1/25/2019

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2370	NDA/MAL/HDP/6921	B & O PHARM ZAC	PHILLIPS PHARMACEUTICALS (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	7/1/2017
2371	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, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	1/25/2019
2372	NDA/MAL/HDP/6923	MACLEODS PHARMACEUTICAL S 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,1.0X25.0X3.0 TABLET BLISTER	3/27/2019

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2373	NDA/MAL/HDP/6924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PARACE TAMOL+CHLORZOXAZ ONE	50MG+325MG +250MG	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	1/31/2018
2374	NDA/MAL/HDP/6927	CRATUS PHARMA PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN MR	ACECLOFENAC BP+TIZANIDINE HYDROCHLORIDE USP+PARACETAMOL BP	100MG+2MG+ 500MG	SAI MIRRA INNOPHARM PVT LIMITED -288&299, SIDCO ESTATE AMBTTUR, CHENNAI 600098	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	5/29/2019
2375	NDA/MAL/HDP/6929	MSN LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	RANCV1000	RANOLAZINE	1000MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/27/2019

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2376	NDA/MAL/HDP/6930	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	TAPAL 50	TAPENTADOL	50MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/27/2019
2377	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	8/28/2019
2378	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	7/25/2018

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2379	NDA/MAL/HDP/6934	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	ANASTROZOLE 1 MG	ANASTROZOLE	1MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE- ALLEE 1, 39179 BARLEBEN,	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
2380	NDA/MAL/HDP/6935	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	SIMVASTATIN 40 MG	SIMVASTATIN	40MG	SANDOZ GRUP SAGLIK .- GEBZE 2 GOSB IHSAN DEDE CAD. 900. SOK 41480 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2017
2381	NDA/MAL/HDP/6939	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	TAPAL 100	TAPENTADOL	100MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/27/2019

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2382	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	11/7/2018
2383	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	11/7/2018
2384	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	5/29/2019

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2385	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	5/29/2019
2386	NDA/MAL/HDP/6946	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	FEVERAL	PARACETAMOL	10MG/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	5/29/2019
2387	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	7/1/2017

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2388	NDA/MAL/HDP/6949	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	MEGA FER	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	5/29/2019
2389	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	5/29/2019
2390	NDA/MAL/HDP/6955	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SEVOTROY 250	SEVOFLURANE	250	TROIKAA PHARMACEUTICALS LIMITED..-THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	5/29/2019

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2391	NDA/MAL/HDP/6956	TROIKAA PHARMACEUTICAL S 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	5/29/2019
2392	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	5/29/2019
2393	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	5/29/2019

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2394	NDA/MAL/HDP/6959	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	XAAR	PREGABALIN	100MG	WILSHIRE LABORATORIES (PVT) LTD-124/1 INDUSTRIAL AREA, KOT LAKHPAT LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X5.0 CAPSULE BLISTER	5/29/2019
2395	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	5/29/2019
2396	NDA/MAL/HDP/6966	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	TAMOXIFEN	TAMOXIFEN CITRATE	20MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	5/29/2019

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2397	NDA/MAL/HDP/6968	F.HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	MABTHERA® SC 1400MG	RITUXIMAB	1400MG/13.4 ML	F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBSSTANDORT KAISERAUGST, 4303 KAIERAUGST	SWITZERLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X13.4 ML VIAL	8/28/2019
2398	NDA/MAL/HDP/6971	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	MONTIRIV-10	MONTELUKAST SODIUM	10 MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	8/28/2019
2399	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	11/27/2019

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2400	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	7/1/2017
2401	NDA/MAL/HDP/6977	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CLINDARIV	CLINDAMYCIN PHOSPHATE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	8/28/2019
2402	NDA/MAL/HDP/6979	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TERBIRIV	TERBINAFINE HYDROCHLORIDE	1.0%W/W	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	8/28/2019

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2403	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	8/28/2019
2404	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	8/28/2019
2405	NDA/MAL/HDP/6984	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VIREXIM-400	CEFIXIME TRIHYDRATE	400 MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	8/28/2019

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2406	NDA/MAL/HDP/6985	MEDLEY PHARMACEUTICAL S 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	7/1/2017
2407	NDA/MAL/HDP/6986	MEDLEY PHARMACEUTICAL S 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	7/1/2017
2408	NDA/MAL/HDP/6987	MEDLEY PHARMACEUTICAL S 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	7/1/2017

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2409	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	11/27/2019
2410	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	5/29/2019
2411	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	5/29/2019

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2412	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	5/29/2019
2413	NDA/MAL/HDP/6993	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AZIRIV-500	AZITHROMYCIN (AS DIHYDRATE)	500MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	5/29/2019
2414	NDA/MAL/HDP/6999	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	NYSTATIN ORAL SUSPENSION	NYSTATIN	100000 UNITS/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE	1/31/2018

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2415	NDA/MAL/HDP/7000	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CIRAB	RABEPRAZOLE SODIUM	20 MG/VIAL	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119, N-113 MIDC TARAPUR BOISAR DIST. THANE 401506 MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL	3/28/2019
2416	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X120.0 CAPSULE BOTTLE	9/6/2019
2417	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	12/3/2018

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2418	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	1/31/2018
2419	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	8/28/2019
2420	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	9/2/2019

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2421	NDA/MAL/HDP/7007	MSN LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	EPNONE 50	EPLERENONE	50MG	MSN LABORATORIES PRIVATE LIMITED - -PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT, TELANGANA 502325, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	1/25/2019
2422	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	8/28/2019
2423	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	3/27/2019

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2424	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	1/31/2018
2425	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	11/29/2017
2426	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	11/29/2017

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2427	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	1/31/2018
2428	NDA/MAL/HDP/7018	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	125MG + 125MG	LABORATORY & ALLIED LTD -PLOT 209/10349 OFF MOMBASA ROAD	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	8/28/2019
2429	NDA/MAL/HDP/7019	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	SULFAMETHOXAZOLE + TRIMETHOPRIM	200MG + 40MG / 5ML	LABORATORY & ALLIED LTD -PLOT 209/10349 OFF MOMBASA ROAD	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE	8/28/2019

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2430	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	8/28/2019
2431	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	11/29/2017
2432	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	7/1/2017

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2433	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, 1.0X20.0X10.0 ML BOTTLE	3/28/2018
2434	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	11/29/2017
2435	NDA/MAL/HDP/7029	ZIM LABORATORIES LTD	REDDYS PHARMA LIMITED	LIPIZAR 20	ATORVASTATIN CALCIUM (TRIHYDRATE)	20MG	ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/28/2018

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2436	NDA/MAL/HDP/7044	MEDLEY PHARMACEUTICAL S 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	8/28/2019
2437	NDA/MAL/HDP/7046	GULF PHARMACEUTICAL INDUSTRIES(JULPH AR).	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	7/1/2017
2438	NDA/MAL/HDP/7047	GULF PHARMACEUTICAL INDUSTRIES(JULPH AR).	OMASI MED LIMITED	XEMADERM 0.1% 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	7/1/2017

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2439	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+0.25 MG+1MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)- AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/2017
2440	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	7/1/2017
2441	NDA/MAL/HDP/7066	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	8/28/2019

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2442	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	8/28/2019
2443	NDA/MAL/HDP/7068	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	FENSUPP-25	DICLOFENAC SODIUM	25MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	8/28/2019
2444	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	7/25/2018

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2445	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	7/25/2018
2446	NDA/MAL/HDP/7077	CIPLA LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FORACORT-400	FORMETEROL 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	7/25/2018
2447	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	8/28/2019

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2448	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	8/28/2019
2449	NDA/MAL/HDP/7086	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYLIN 75	PREGABALIN	75MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER	3/28/2019
2450	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	5/30/2018

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2451	NDA/MAL/HDP/7089	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ES-LOPROT	ESOMEPRAZOLE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	8/28/2019
2452	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	11/29/2017
2453	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 VIALS	1.0X10.0 ML VIAL	8/28/2019

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2454	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	8/28/2019
2455	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,1.0X25.0X4.0 CAPLET STRIP	11/27/2019
2456	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	7/1/2017

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2457	NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC+PARA CETAMOL+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	1/31/2018
2458	NDA/MAL/HDP/7100	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART 80/480MG	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	STRIDES SHASUN LIMITED- NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106	INDIA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X6.0 SACHET CARTON	7/25/2018
2459	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	7/1/2016

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2460	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	7/1/2016
2461	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	11/27/2019
2462	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	5/30/2018

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2463	NDA/MAL/HDP/7105	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) 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	7/1/2017
2464	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	7/1/2016
2465	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	3/27/2019

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2466	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	11/27/2019
2467	NDA/MAL/HDP/7110	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHA N + 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	11/27/2019
2468	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	8/28/2019

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2469	NDA/MAL/HDP/7113	HETERO DRUGS LTD	AIVEEN (U) LIMITED	RILAST 500	RITUXIMAB	500MG/50ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	8/28/2019
2470	NDA/MAL/HDP/7114	HETERO DRUGS LTD	AIVEEN (U) LIMITED	RILAST 100	RITUXIMAB	100MG/10ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	8/28/2019
2471	NDA/MAL/HDP/7115	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	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	11/7/2018

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2472	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	11/27/2019
2473	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	11/27/2019
2474	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	11/27/2019

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2475	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	11/27/2019
2476	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	11/27/2019
2477	NDA/MAL/HDP/7121	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ATERISE-100	ATENOLOL	100MG	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	8/29/2019

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2478	NDA/MAL/HDP/7122	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ATERISE-50	ATENOLOL	50MG	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	8/29/2019
2479	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. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER	7/1/2017
2480	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	2/4/2019

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2481	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, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	11/7/2018
2482	NDA/MAL/HDP/7128	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	COTRIKANT-960	TRIMETHOPRIM+SULF AMETHOXAZOLE	800MG+160M G	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	9/26/2018
2483	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2017

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2484	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	11/7/2018
2485	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 + DIPHENHYDRAMINE HYDROCHLORIDE	DAY TABLET: 325MG + 30MG + 4.5MG NIGHT TABLET : 500MG + 30MG + 25MG	LIPTIS EGYPT 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)	2/4/2019
2486	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	7/25/2018

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2487	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	5/30/2018
2488	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, 1.0X10.0X10.0 TABLET STRIP	7/25/2018
2489	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	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	5/30/2018

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2490	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	5/30/2018
2491	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	2/4/2019
2492	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	11/29/2017

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2493	NDA/MAL/HDP/7159	SQUARE PHARMACEUTICAL S LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.050%	OXYMETAZOLINE HYDROCHLORIDE	0.050W/V%	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	8/29/2019
2494	NDA/MAL/HDP/7161	SQUARE PHARMACEUTICAL S LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.025%	OXYMETAZOLINE HYDROCHLORIDE	0.025W/V%	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	8/29/2019
2495	NDA/MAL/HDP/7162	ACG PHARMAPACK PVT. LTD	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	7/1/2017

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2496	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 INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	8/29/2019
2497	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 INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	8/29/2019
2498	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	8/29/2019

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2499	NDA/MAL/HDP/7169	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	PHYTON 2.25G	PIPERACILLIN + TAZOBACTAM	2.0G + 0.25G	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 + 1X20ML WFI AMPOULE	8/29/2019
2500	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	8/29/2019
2501	NDA/MAL/HDP/7179	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AVONZA	TENOFOVIR DISOPROXIL FUMARATE+LAMIVUDINE+EFAVIRENZ	300MG+300MG+400MG	MYLAN LABORATORIES LIMITED, -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	11/7/2018

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2502	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	8/29/2019
2503	NDA/MAL/HDP/7182	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	SUNFLAM	MELOXICAM	7.5G	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	8/29/2019
2504	NDA/MAL/HDP/7183	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LEVOSUN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	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,1.0X10.0 TABLET BLISTER	8/29/2019

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2505	NDA/MAL/HDP/7184	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	EVOKE TABLETS	SILDENAFIL	50MG	LABORATORY & ALLIED LTD -PLOT 209/10349 OFF MOMBASA ROAD	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	5/29/2019
2506	NDA/MAL/HDP/7190	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	TRIPSUN-25	AMITRIPTYLINE HYDROCHLORIDE	25MG	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	8/29/2019
2507	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	2/6/2019

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2508	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	5/29/2019
2509	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	5/29/2019
2510	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 + PROLINE + SERINE + TAURINE +	[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] +	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)	2/4/2019

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2511	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	8/29/2019
2512	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	1/2/2019
2513	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 + PROLINE + SERINE + TAURINE +	"[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] +	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)	2/4/2019

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2514	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, 1.0X50.0X1.0 DOSE VIAL + 1ML DILUENT	8/29/2019
2515	NDA/MAL/HDP/7202	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VILDAGLIPTIN	VILDAGLIPTIN	50MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRASSE 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	7/1/2017
2516	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 + PROLINE + SERINE + TAURINE +	[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	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)	2/4/2019

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2517	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 + PROLINE + SERINE + TAURINE +	[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%] +	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)	2/4/2019
2518	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 + METHIONINE +	[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	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)	2/4/2019
2519	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	3/28/2019

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2520	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 + METHIONINE +	[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] +	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)	2/4/2019
2521	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	7/25/2018
2522	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	11/29/2017

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2523	NDA/MAL/HDP/7219	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAXONE	1G	THEON PHARMACEUTICALS LTD.-VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	11/29/2017
2524	NDA/MAL/HDP/7222	SAMRUDH PHARMACEUTICAL S PVT. 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)	11/27/2019
2525	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	11/27/2019

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2526	NDA/MAL/HDP/7225	MACLEODS PHARMACEUTICAL S 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	11/27/2019
2527	NDA/MAL/HDP/7228	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	AMOXICILLIN 250MG DISPERSIBLE TABLETS	AMOXICILLIN TRIHYDRATE	250 MG	SANDOZ GMBH BIOCHEMISTRASSE 10-6250 KUNDL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10 .0 TABLET BLISTER	7/1/2017
2528	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	11/29/2017

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2529	NDA/MAL/HDP/7237	STEDMAN PHARMACEUTICAL S 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	11/27/2019
2530	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	3/28/2018
2531	NDA/MAL/HDP/7239	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	GAVISCON PEPPERMINT LIQUID	SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	500MG + 267MG + 160MG	RECKITT BENCKISER HEALTHCARE LTD, HULL- DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X12.0X10.0 ML SACHET,1.0X200.0 ML BOTTLE	5/29/2019

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2532	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	RECKITT BENCKISER HEALTHCARE LTD, HULL-DAMSON LANE, HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X8.0 TABLET BLISTER	5/29/2019
2533	NDA/MAL/HDP/7241	EXPHAR SA.	SURGIPHARM (U) LIMITED	GENTASOL	GENTAMICIN SULFATE	0.3%W/V	AHLCON PARENTERAL (I) LTD.-SP-918,BHLWADI (RAJ) INDIA M.LIC.: RAJ 2002	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	11/29/2017
2534	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	11/27/2019

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2535	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	2/4/2019
2536	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	11/27/2019
2537	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	7/25/2018

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2538	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	7/25/2018
2539	NDA/MAL/HDP/7250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR SODIUM, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM +LAMIVUDINE +TENFOVIR 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	11/29/2019
2540	NDA/MAL/HDP/7251	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROXYUREA	HYDROXYCARBAMIDE	500MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	11/27/2019

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2541	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	11/27/2019
2542	NDA/MAL/HDP/7256	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG KIT	AMOXICILLIN + CLARITHROMYCIN + ESOMEPRAZOLE	1000MG + 500MG + 20MG	MICRO LABS LIMITED ,,-92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET STRIP (2+2+2)	11/27/2019
2543	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	7/1/2017

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2544	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	1/31/2018
2545	NDA/MAL/HDP/7259	FERRER INTERNATIONAL, S.A.	LABOREX 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	11/27/2019
2546	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	11/27/2019

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2547	NDA/MAL/HDP/7264	PHARCO PHARMACEUTICAL S	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE+SIMET HICONE	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	7/1/2017
2548	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	11/27/2019
2549	NDA/MAL/HDP/7269	EXPHAR SA.	SURGIPHARM (U) LIMITED	FEBRILEX SYRUP	PARACETAMOL+DEXT ROMETORPHAN HYDROBROMIDE+CHL ORPHENAMINE 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	7/1/2017

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2550	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 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	
2551	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	11/27/2019
2552	NDA/MAL/HDP/7274	SURGIPHARM (U) 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	7/1/2017

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2553	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	11/27/2019
2554	NDA/MAL/HDP/7284	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATIN CALCIUM	10MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/25/2018
2555	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	7/1/2017

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2556	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	7/1/2017
2557	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	1/31/2017
2558	NDA/MAL/HDP/7292	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUPLUS SUSPENSION	IBUPROFEN+.PARACE TAMOL	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	11/27/2019

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2559	NDA/MAL/HDP/7293	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	ALRINAST	DESLOTRADINE	5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	11/29/2017
2560	NDA/MAL/HDP/7296	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	2/6/2019
2561	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	11/29/2017

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2562	NDA/MAL/HDP/7302	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ACRETIN 0.025%	TRETINOIN	0.025%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	11/27/2019
2563	NDA/MAL/HDP/7303	AXA PARENTERALS LTD	VITACARE LIMITED	AXATOL-20	MANNITOL	20%W/V	AXA PARENTERALS LTD- PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE- 247667, DIST. HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	2/6/2019
2564	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	5/29/2019

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2565	NDA/MAL/HDP/7310	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	ACRETIN 0.05%	TRETINOIN	0.05%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	11/27/2019
2566	NDA/MAL/HDP/7315	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AROXICAM 7.5	MELOXICAM	7.5MG	AUROBINDO PHARMA LTD, UNIT III -SURVEY NO. 313, 314 BACHUPALLY (VILLAGE) QUTHUBULLAPUR (MANDAL) RR DISTRICT HYDERABAD ANDHRA PRADESH 500090	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019
2567	NDA/MAL/HDP/7317	CACHET PHARMACEUTICAL S PVT LIMITED	ASTRA PHARMA (U) 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	11/27/2019

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2568	NDA/MAL/HDP/7318	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	2/4/2019
2569	NDA/MAL/HDP/7319	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.-ESENBOĞA MERKEZ MAH CUBUK CAD NO.31 CUBUK ANKARA - TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER	1/31/2018
2570	NDA/MAL/HDP/7325	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.	BUFFALO HEALTH CARE LTD	DALMAN AQ NASAL SPRAY	FLUTICASON PROPIONATE	0.05%W/V	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş. --ESENBOĞA MERKEZ MAH. ÇUBUK CADDESİ NO: 31 06760 ANKARA - TURKEY	TURKEY	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE	7/25/2018

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2571	NDA/MAL/HDP/7329	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+CHL ORZOAZONE	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	3/28/2018
2572	NDA/MAL/HDP/7332	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.	BUFFALO HEALTH CARE LTD	DIVATOR 20MG FILM TABLET	ATORVASTATIN	20MG	DROGSAN İLAÇLARI SAN VE TİC. A.Ş.-ESENBOGA MERKEZ MAH. CUBUK CAD. NO. 31 CUBUK/ANKAEA- TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/29/2019
2573	NDA/MAL/HDP/7337	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 150	DARUNAVIR	150MG	JANSSEN ORTHO LLC.-- STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X240.0 TABLET BOTTLE	7/1/2017

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2574	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	12/5/2019
2575	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	5/30/2018
2576	NDA/MAL/HDP/7340	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HIFEN -200	IBUPROFEN	200MG	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	11/28/2019

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2577	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	7/1/2017
2578	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	11/28/2019
2579	NDA/MAL/HDP/7344	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	HEPANIR	HEPARIN SODIUM	1000IU/ML	ACULIFE HEALTH CARE, FORMALLY NIRMA(HEALTHCARE DIVISION)-VILLAGE: SACHANA, TALUKA: VIRAMGAM DISTRICT: AHMEDABAD-382150 GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	11/29/2017

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2580	NDA/MAL/HDP/7345	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	11/28/2019
2581	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	11/29/2017
2582	NDA/MAL/HDP/7351	TWENTY FIRST CENTURY PHARMACEUTICAL S 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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2017

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2583	NDA/MAL/HDP/7352	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	DOLOMOL PAEDIATRIC DROPS	PARACETAMOL	100 MG/ML	LINCOLN PHARMACEUTICALS LTD-- 11 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	1/7/2019
2584	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 MERCK SANTÉ S.A.S.-2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE	GERMANY	ORAL SOLID RETARD TABLETS	1.0X6.0X15.0 TABLET BLISTER	3/28/2018
2585	NDA/MAL/HDP/7354	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	OSMOTICARE	SODIUM CHLORIDE	0.9%W/V	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, 1.0X250.0 ML BOTTLE, 1.0X500.0 ML BOTTLE	11/28/2019

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2586	NDA/MAL/HDP/7355	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN SUSPENSION	ARTEMETHER+LUMEFANTRINE	180MG+1080 MG	AJANTA PHARMA LIMITED.- B-41516, MIDC INDUSTRIAL AREA, PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	1/31/2018
2587	NDA/MAL/HDP/7357	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	1/31/2018
2588	NDA/MAL/HDP/7359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	AARON PHARMACEUTICALS 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	7/1/2017

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2589	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	RECKITT BENCKISER HEALTHCARE LTD, HULL- DAMSON LANE, HULL, HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X150.0 ML BOTTLE, 1.0X300.0 ML BOTTLE, 1.0X12.0X10.0 ML SACHET	11/28/2019
2590	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	11/28/2019
2591	NDA/MAL/HDP/7363	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	AARON PHARMACEUTICALS 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	7/1/2017

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2592	NDA/MAL/HDP/7364	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACIN HYDROCHLORIDE	400MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER	7/1/2017
2593	NDA/MAL/HDP/7365	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	DOLOACT MR	PARACETAMOL+ DICLOFENAC POTASSIUM+CHLORZOXAZONE	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	7/1/2017
2594	NDA/MAL/HDP/7366	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL 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	7/1/2017

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2595	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	7/1/2017
2596	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	7/1/2017
2597	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	7/1/2017

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2598	NDA/MAL/HDP/7375	INTAS PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	FOLISURGE 75	FOLLITROPIN ALFA	75IU/0.12 ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)-PLOT NO. 423/P/A, SARKHEJ-BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.12 ML PRE-FILLED SYRINGE	11/28/2019
2599	NDA/MAL/HDP/7377	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX DS	AMOXICILLIN TRIHYDRATE	125MG/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	7/1/2017
2600	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	3/28/2018

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2601	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	7/1/2017
2602	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	7/1/2017
2603	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	11/28/2019

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2604	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	1/25/2019
2605	NDA/MAL/HDP/7394	AXA PARENTERALS LTD	VITACARE LIMITED	AXADEX (D50%)	GLUCOSE ANHYDROUS	50%W/V	AXA PARENTERALS LTD- PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE- 247667, DIST. HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	11/28/2019
2606	NDA/MAL/HDP/7395	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	ACE KIT	MIFEPRISTONE + MISOPROSTOL	200MG + 20MCG	ACME FORMULATION PVT LTD -ROPAR ROAD, NALAGARH DISTT. SOLAN HP-174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER	12/5/2019

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2607	NDA/MAL/HDP/7396	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	HARVONI	SOFOSBUVIR+LEDIPAS VIR	400 MG+90 MG	PATHEON INC- MISSISSAUGA, ON L5N 7K9 CANADA	CANADA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE	7/1/2017
2608	NDA/MAL/HDP/7403	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE /LAMIVUDINE DISPERSIBLE TABLETS 60MG/30MG	ABACAVIR SULFATE / LAMIVUDINE	60 MG /30 MG	MYLAN LABORATORIES LTD -F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2016
2609	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), MAHABOONNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/28/2019

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2610	NDA/MAL/HDP/7408	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	ZIFLAM 100	ACECLOFENAC	100MG	ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/28/2019
2611	NDA/MAL/HDP/7413	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) 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	11/28/2019
2612	NDA/MAL/HDP/7414	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	RIBOREA	HYDROXYUREA	500MG	KHANDELWAL LABORATORIES PVT. LTD-B-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	11/28/2019

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2613	NDA/MAL/HDP/7415	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MAMOFEN-20	TAMOXIFEN CITRATE	20MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	11/28/2019
2614	NDA/MAL/HDP/7417	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	SARTEL-40	TELMISARTAN	40MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD, SELAQUI, DEHRADUN- 248197, UTTARKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/28/2019
2615	NDA/MAL/HDP/7418	INTAS PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	FOLISURGE 1200	FOLLITROPIN ALFA	1200 IU/1.92ML	INTAS PHARMACEUTICALS LTD (BIOPHARMA DIVISION)-PLOT NO. 423/P/A, SARKHEJ-BAVLA HIGHWAY, MORAIYA, TALUKA SANAND, AHMEDABAD- 382213, GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.92 ML VIAL	11/28/2019

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2616	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	7/1/2017
2617	NDA/MAL/HDP/7423	BEIJING FANXING GUANGDIAN MEDICAL TREATMENT EQUIPMENT CO.,LTD	ABACUS PARENTERAL DRUGS LIMITED	TENLOW-10	AMLODIPINE BESYLATE	10MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016
2618	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	7/1/2017

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2619	NDA/MAL/HDP/7425	AUROCHEM LABORATORIES(I) PVT LTD	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	11/28/2019
2620	NDA/MAL/HDP/7426	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	11/28/2019
2621	NDA/MAL/HDP/7429	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI 1000	CEFTRIAXONE SODIUM	1G	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	1.0X50.0X1.0 G VIAL,1.0X1.0 G VIAL	11/28/2019

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2622	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	9/26/2018
2623	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	11/28/2019
2624	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	11/28/2019

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2625	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	11/28/2019
2626	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	11/29/2017
2627	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	11/28/2019

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2628	NDA/MAL/HDP/7443	DAWA LIMITED-	SUPER MEDIC LTD	GOUTSTAT 40	FEBUXOSTAT	40MG	DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	11/28/2019
2629	NDA/MAL/HDP/7445	DAWA LIMITED-	SUPER MEDIC LTD	GOUTSTAT 80	FEBUXOSTAT	80MG	DAWA LIMITED-16633-00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	11/28/2019
2630	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	11/28/2019

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2631	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	11/29/2017
2632	NDA/MAL/HDP/7449	SURGIPHARM (U) LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ TENOFOVIR DF 300/300MG	LAMIVUDINE+TENOF OVIR 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	1/31/2018
2633	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	11/29/2017

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2634	NDA/MAL/HDP/7451	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	MYTHRO 500	AZITHROMYCIN DIHYDRATE	500MG	AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	11/28/2019
2635	NDA/MAL/HDP/7452	OCHOA LABORATORIES	SUPER MEDIC LTD	XTRADERM CREAM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	0.64 MG/1 G + 0.1 MG/1 G + 10 MG/1 G	AUROCHEM LABORATORIES LTD -PLOT 08 PALGHAR 401404 MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE, 1.0X15.0 G TUBE, 1.0X10.0 G TUBE	11/29/2017
2636	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 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	11/28/2019

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2637	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	11/28/2019
2638	NDA/MAL/HDP/7458	HETERO DRUGS LTD	AIVEEN (U) LIMITED	DERISE™25	DARBEPOETIN ALFA	25MCG/0.42ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.42 ML PRE- FILLED SYRINGE (SINGLE DOSE)	11/28/2019
2639	NDA/MAL/HDP/7459	HETERO DRUGS LTD	AIVEEN (U) LIMITED	DERISE™40	DARBEPOETIN ALFA	40MCG/0.4ML	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	PARENTERAL RETARD PRE- FILLED SYRINGES	1.0X0.2 ML PRE- FILLED SYRINGE	11/28/2019

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2640	NDA/MAL/HDP/7461	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	WOMAZOL	ANASTROZOLE	1MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	5/29/2019
2641	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	8/28/2019
2642	NDA/MAL/HDP/7465	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	P-ALAXIN TS	DIHYDROARTEMISINI N + 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	11/28/2019

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2643	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	8/28/2019
2644	NDA/MAL/HDP/7468	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	GYNO PLUS	METRONIDAZOLE + MICONAZOLE NITRATE	100MG + 100MG	AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	VAGINAL TABLETS	1.0X1.0X10.0 TABLET BLISTER	11/28/2019
2645	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	7/25/2018

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2646	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	11/28/2019
2647	NDA/MAL/HDP/7475	UNI MEDICO LAB	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	7/1/2015
2648	NDA/MAL/HDP/7476	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	AKRIDOL 12.5	CARVEDILOL	12.5 MG	AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019

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2649	NDA/MAL/HDP/7478	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	SIMVASTATIN 20 MG FILM-COATED TABLETS	SIMVASTATIN	20MG	SANDOZ GRUP SAGLIK - GEBZE 2 GOSB IHSAN DEDE CAD. 900. SOK 41480 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
2650	NDA/MAL/HDP/7479	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ALLTERA 50	LOPINAVIR + RITONAVIR	40MG + 10MG / SACHET	MYLAN LABORATORIES LTD .-F/4 & F/12, MALEGAON MIDC, SINNAR, NASHIK-422 113, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X120.0 SACHET CARTON	11/27/2019
2651	NDA/MAL/HDP/7481	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	INTAGRA 100	SILDENAFIL CIRATE	100MG	INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER	7/1/2017

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2652	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	11/27/2019
2653	NDA/MAL/HDP/7484	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 10/20	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	10MG + 20MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019
2654	NDA/MAL/HDP/7485	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 5/10	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	5MG + 10MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019

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2655	NDA/MAL/HDP/7486	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 5/20	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	5MG + 20MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET CARTON	11/27/2019
2656	NDA/MAL/HDP/7487	ATCO LABORATORIES LTD	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	11/27/2019
2657	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	7/1/2017

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2658	NDA/MAL/HDP/7489	MACLEODS PHARMACEUTICAL S LTD	VITACARE LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR + LAMIVUDINE + TENOFIVIR 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.	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	11/27/2019
2659	NDA/MAL/HDP/7490	INTAS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES LIMITED	INTAGRA 50	SILDENAFIL CITRATE	50MG	INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	7/1/2017
2660	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	7/1/2017

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2661	NDA/MAL/HDP/7492	LINCOLN PHARMACEUTICAL S 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	8/28/2019
2662	NDA/MAL/HDP/7494	LINCON PHARMCUETICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE TABLET	CYPROHEPTADINE HYDROCHLORIDE	4MG	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	5/29/2019
2663	NDA/MAL/HDP/7500	RESONANT PHARMACEUTICAL S	SHREEJI CARE LIMITED	DICLOZONE MR TABLETS	DICLOFENAC POTASSIUM + PARACETAMOL + CHLORZOXAZONE	50 MG + 325 MG + 250 MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019

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2664	NDA/MAL/HDP/7504	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	IMATINATE 400	IMATINIB MESYLATE	400MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	9/26/2018
2665	NDA/MAL/HDP/7505	DEV LIFE CORPORATION	PLANET PHARMACEUTICALS UGANDA LTD	EPIRYTE 300	SODIUM VALPOATE	300 MG	SWISS GARNIER LIFE SCIENCES-21-23 INDUSTRIAL AREA, MEHATPUR, UNA DIST., HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP, 1.0X100.0 TABLET BOTTLE	11/27/2019
2666	NDA/MAL/HDP/7506	DEV LIFE CORPORATION	PLANET PHARMACEUTICALS UGANDA LTD	EPIRYTE 500	SODIUM VALPOATE	500 MG	SWISS GARNIER LIFE SCIENCES-21-23 INDUSTRIAL AREA, MEHATPUR, UNA DIST., HIMACHAL PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X100.0 TABLET BOTTLE, 1.0X10.0X10. 0 TABLET STRIP, 1.0X3.0X10.0 TABLET BLISTER	11/27/2019

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2667	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 MMAN, JORDAN	JORDAN	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	5/29/2019
2668	NDA/MAL/HDP/7517	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI CARE LIMITED	LEVOCET-M	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019
2669	NDA/MAL/HDP/7518	RESONANT PHARMACEUTICALS	SHREEJI CARE LIMITED	LEVOCET-M SUSPENSION	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	2.5MG / 5ML + 4MG / 5ML	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	11/27/2019

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2670	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	11/27/2019
2671	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	3/28/2019
2672	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	7/1/2017

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2673	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	11/27/2019
2674	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	11/27/2019
2675	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	11/27/2019

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2676	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	11/27/2019
2677	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	11/27/2019
2678	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	11/27/2019

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2679	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), MAHABOONAGAR, 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	11/7/2018
2680	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	8/28/2019
2681	NDA/MAL/HDP/7536	PLANET PHARMACEUTICAL S 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	7/1/2017

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2682	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	11/29/2017
2683	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	11/27/2019
2684	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	11/29/2017

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2685	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	11/29/2017
2686	NDA/MAL/HDP/7594	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROCHLOROTHIAZIDE 25MG TABLETS	HYDROCHLOROTHIAZIDE	25MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE-ALLEE 1, 39179 BARLEBEN,	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER	7/1/2017
2687	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	11/27/2019

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2688	NDA/MAL/HDP/7596	INTERNATIONAL ORGANIZATION FOR MIGRATION	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PEGASET 150	PREGABALIN	150 MG	CORONA REMEDIES PVT LTD.-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	11/27/2019
2689	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	11/27/2019
2690	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	11/27/2019

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2691	NDA/MAL/HDP/7610	ATCO LABORATORIES LTD	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	11/27/2019
2692	NDA/MAL/HDP/7611	FERRING GMBH	MACNAUGHTON LIMITED	PABAL	CARBETOCIN	100MCG/ML	FERRING GMBH.-11, WITTLAND	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	7/1/2017
2693	NDA/MAL/HDP/7614	PLANET PHARMACEUTICAL S 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	11/27/2019

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2694	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)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X2.0X7.0 TABLET BLISTER	11/26/2019
2695	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	3/28/2018
2696	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	7/25/2018

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2697	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	7/1/2017
2698	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	7/1/2017
2699	NDA/MAL/HDP/7635	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 10MG FILM-COATED TABLETS	BISOPROLOL FUMARATE	10MG	LEK S.A.-95 - 010 STRYKÓW, PODLPIE 16, POLAND SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE- ALLEE	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER	7/1/2017

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2700	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	7/1/2017
2701	NDA/MAL/HDP/7663	SURGIPHARM (U) 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	7/1/2017
2702	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	7/1/2017

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2703	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	7/1/2017
2704	NDA/MAL/HDP/7683	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DESLOTRADINE	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	7/1/2017
2705	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	7/1/2017

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2706	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	7/1/2017
2707	NDA/MAL/HDP/7706	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	CACEF 200	CEFPODOXIME PROXETIL	200MG	ALKEM LABORATORIES LIMITED -VILLAGE- THANA BADDI, YEH NALAGAR, DISTRICT SOLAN, HIMACHAL PRADESH INDIA 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	7/1/2017
2708	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	7/1/2017

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2709	NDA/MAL/HDP/7710	MYLAN LABS LTD	KIMSY MEDS LTD	FLUCONAZOLE	FLUCONAZOLE	50MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2017
2710	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	
2711	NDA/MAL/HDP/7716	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DESLOTRATIDINE	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	11/29/2017

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2712	NDA/MAL/HDP/7722	SANOFI-AVENTIS KENYA	SURGIPHARM (U) LIMITED	MAALOX MINT FLAVORING	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE	175MG + 200MG/ 5ML	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X355.0 ML BOTTLE,1.0X250.0 ML BOTTLE	7/1/2017
2713	NDA/MAL/HDP/7724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU]	75 IU + 75 IU/ 4ML VIAL	FERRING (PTY) LTD- WITTLAND II 24146 KIEL	GERMANY	PARENTERAL ORDINARY DRY VIALS	10.0X4.0 ML VIAL 10*1ML CLEAR COLOURLESS GLASS AMPOULES CONTAINING 9.0MG/ML OF NACL	7/1/2017
2714	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	7/1/2017

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2715	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	7/1/2017
2716	NDA/MAL/HDP/7728	NORVATIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	LINEX	LACTOBACILLUS ACIDOPHILUS + BIFIDOBACTERIUM INFANTIS + ENTEROCOCCUS FAECIUM	1.2 * 10 TO POWER 7 COLONY FORMING UNITS OF VIABLE LACTIC ACID BACTERIA SPECIES	LEK PHARMACEUTICALS- D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE BLISTER	7/1/2017
2717	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	7/1/2017

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2718	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	7/1/2017
2719	NDA/MAL/HDP/7784	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	LORATOL	LORATADINE	5MG/5ML	NOBEL ILAC DUZCE- SANAYIINVE TICARET A.S SANCARLAR 81100 DUZCE	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2017
2720	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	7/1/2009

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2721	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	7/1/2016
2722	NDA/MAL/HDP/7906	AXA PARENTERALS LTD	VITACARE LIMITED	IVMOL	PARACETAMOL	10MG/ML	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2016
2723	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	7/1/2017

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2724	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	7/1/2017
2725	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	7/1/2017
2726	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	7/1/2017

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2727	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	7/1/2011
2728	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	7/1/2011
2729	NDA/MAL/HDP/8032	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR SULFATE/LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	CIPLA LTD-A-33 & A-37/2/2 MIDC PATALGANGA 410220	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2011

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2730	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	7/1/2007
2731	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	7/1/1997
2732	NDA/MAL/HDP/8078	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 100/270	ARTESUNATE + AMODIAQUINE	100 MG + 270 MG	AJANTA PHARMA LTD .-B- 4//5/6, MIDC INDUSTRIALAREA, PAITHAN- 431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X6.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	7/1/2011

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2733	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	7/1/2007
2734	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,1.0X100.0 X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER	7/1/1997
2735	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,1.0X10.0X 10.0 CAPSULE BLISTER	7/1/1997

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2736	NDA/MAL/HDP/8093	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ ZIDOVUDINE/ NEVIRAPINE TABLETS 150MG/300MG/200 MG	ZIDOVUDINE + LAMIVUDINE + NEVIRAPINE	300MG + 150MG + 200MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED (CIPLAQCIL)-PLOT 1-7, 1ST RING ROAD, LUZIRA INDUSTRIAL PARK	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2010
2737	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 & CO.KG-- PRINZREGENTSTR.79.8167 5 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2016
2738	NDA/MAL/HDP/8096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYL PENICILLIN 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, 1.0X100.0X2.4 VIAL CARTON, 1.0X10.0X2.4 VIAL CARTON	7/1/2011

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2739	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	7/1/2017
2740	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	7/1/2017
2741	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	7/1/2017

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2742	NDA/MAL/HDP/8113	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	7/1/2016
2743	NDA/MAL/HDP/8114	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS 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	7/1/2016
2744	NDA/MAL/HDP/8115	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	MACLEODS PHARMACEUTICALS LTD.- PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2017

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2745	NDA/MAL/HDP/8116	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	EMTRICITABINE + TENOFVIR 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	7/1/2013
2746	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	7/1/2013
2747	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	7/1/2017

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2748	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	7/1/2011
2749	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	7/1/2016
2750	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	7/1/2017

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2751	NDA/MAL/HDP/8140	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	FUROSEMIDE	FUROSEMIDE	40MG	SANDOZ PVT LTD.--MIDC IND, AREA KALWE BLOCK VILLAGE DIGHE NAVI MUMBAI 400708	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER	7/1/2017
2752	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	7/1/2017
2753	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 RUHRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	7/1/2013

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2754	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	7/1/2016
2755	NDA/MAL/HDP/8145	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR 10	MONTELUKAST SODIUM	10MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2017
2756	NDA/MAL/HDP/8146	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 4	MONTELUKAST SODIUM	4MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2017

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2757	NDA/MAL/HDP/8147	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 5	MONTELUKAST SODIUM	5 MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2017
2758	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	5/30/2018
2759	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	7/1/2017

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2760	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,1.0X10.0X 10.0 TABLET STRIP	7/1/2005
2761	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	7/1/2017
2762	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	7/1/2013

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2763	NDA/MAL/HDP/8155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	SMG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	7/1/2017
2764	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 IU (≥ 4.0 IU)+12.5MCG+11MCG	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHERR (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)	7/1/2014
2765	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	7/1/2016

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2766	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 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2017
2767	NDA/MAL/HDP/8160	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+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	7/1/2017
2768	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	7/1/2017

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2769	NDA/MAL/HDP/8170	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+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	7/1/2017
2770	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	7/1/2016
2771	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,1.0X10.0X10.0 TABLET BLISTER	7/1/2005

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2772	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	7/1/2005
2773	NDA/MAL/HDP/8194	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	SOLODEX-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,1.0X24.0X 28.0 TABLET BLISTER	7/1/2005
2774	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	7/1/2005

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2775	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	7/1/2017
2776	NDA/MAL/HDP/8198	MEDLEY PHARMACEUTICAL S 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	7/1/1999
2777	NDA/MAL/HDP/8199	MEDLEY PHARMACEUTICAL S 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	7/1/2000

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2778	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	7/1/2017
2779	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,1.0X10.0X10.0 TABLET BLISTER,1.0X24.0X28.0 TABLET BLISTER	7/1/2017
2780	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	7/1/2017

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2781	NDA/MAL/HDP/8206	BRAWN LABORATORIES LTD	TATA UGANDA 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	7/1/2017
2782	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	7/1/2017
2783	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	7/1/2010

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2784	NDA/MAL/HDP/8212	FDC LTD	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	7/1/1998
2785	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	7/1/2001
2786	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	7/1/2017

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2787	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.OX5.0 G TUBE	7/1/2017
2788	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.OX60.0 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	7/1/2017
2789	NDA/MAL/HDP/8228	AFRICURE PHARMACEUTICAL S (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.OX10.0X10.0 TABLET BLISTER	7/1/2017

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2790	NDA/MAL/HDP/8231	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ANASTROZOLE DENK	ANASTROZOLE	1MG	HAUPT PHARMA GMBH & CO KG- SCHLEEBRUGGENKAMP 15, 48159 MUNSTER, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
2791	NDA/MAL/HDP/8232	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MOMATE	MOMETASONE FUROATE MONOHYDRATE	50MCG/ SPRAY	GLENMARK PHARMACEUTICALS LTD- VILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X120.0 METERED DOSE BOTTLE	7/1/2017
2792	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	7/1/2017

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2793	NDA/MAL/HDP/8238	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	METROSUPP 500	METRONIDAZOLE	500MG	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	7/1/2017
2794	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	7/1/2017
2795	NDA/MAL/HDP/8248	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) 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	7/1/2017

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2796	NDA/MAL/HDP/8250	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM DT	ARTEMETHER+LUMEF ANTRINE	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	7/1/2017
2797	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 FRESENIUS KABI DEUTSCHLAND GMBH- FRESENIUSSTRASSE 1, D- 61169, FRIEDBERG	AUSTRIA GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL,1.0X10.0X100.0 ML VIAL	7/1/2017
2798	NDA/MAL/HDP/8253	REYOUNG PHARMACEUTICAL CO LTD	ROYAL PHARMA 2011 LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	25MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	10.0X10.0X3.0 ML AMPOULE	7/1/2017

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2799	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	7/1/2017
2800	NDA/MAL/HDP/8264	CACHET PHARMA PVT LTD	ASTRA PHARMA (U) 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	7/1/2017
2801	NDA/MAL/HDP/8279	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	GENTACIN	GENTAMICIN SULPHATE	80MG/2ML	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	1.0X2.0X6.0X2.0 ML AMPOULE IN BLISTERS	7/1/2013

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2802	NDA/MAL/HDP/8293	NAARI LTD	PHARMA VILLE LIMITED	DIVABO	MIFEPRISTONE + MISOPROSTOL	200MG+200M CG	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 COMBINATION PACK TABLETS	1.0X1.0 TABLET BLISTER + 1.0X4.0 TABLETS OF MISOPROSTOL	8/28/2019
2803	NDA/MAL/HDP/8299	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	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	7/1/2007
2804	NDA/MAL/HDP/8300	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	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	7/1/2007

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2805	NDA/MAL/HDP/8308	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	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	7/1/2008
2806	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	11/29/2017
2807	NDA/MAL/HDP/8315	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 75	DARUNAVIR	75MG	JANSSEN ORTHO LLC.-- STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X480.0 TABLET BOTTLE	7/1/2017

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2808	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	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE, 1.0X90.0 TABLET BOTTLE	5/30/2018
2809	NDA/MAL/HDP/8318	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	B-CANE HEAVY	BUPIVACAINE HYDROCHLORIDE BP	5 MG/ML	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0 ML AMPOULE	11/29/2017
2810	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	11/29/2017

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2811	NDA/MAL/HDP/8321	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROSTAR- 200 CAPSULES	PROGESTERONE	200 MG	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER	1/31/2018
2812	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	11/29/2017
2813	NDA/MAL/HDP/8324	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) 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	11/29/2017

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2814	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 (EMBOSSSED WITH "GOU NOT FOR SALE" & NON-EMBOSSSED)	11/29/2017
2815	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	11/29/2017
2816	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	11/29/2017

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2817	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	1/31/2018
2818	NDA/MAL/HDP/8340	MACLEODS PHARMACEUTICAL S 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	11/29/2017
2819	NDA/MAL/HDP/8341	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR+COBICI STAT+EMTRICISTABIN E+TENOFIVIR 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	1/31/2018

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2820	NDA/MAL/HDP/8343	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE)	325MG+675M G	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	11/28/2019
2821	NDA/MAL/HDP/8344	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CELZA DRY SYRUP	CEFUROXIME AXETIL USP	125 MG/5 ML	ALKEM LABS LTD.-VILLAGE THANA, BADDI, THE NALAGARH, DIST SOLAN (HP) 173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X50.0 ML BOTTLE	11/29/2017
2822	NDA/MAL/HDP/8345	CACHET PHARMACEUTICAL S PRIVATE LIMITED	ASTRA PHARMA (U) 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	11/29/2017

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2823	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	11/29/2017
2824	NDA/MAL/HDP/8348	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5MG	IRBESARTAN + HYDROCHLOROTHIAZIDE	300MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	11/29/2017
2825	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	5/30/2018

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2826	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	11/26/2019
2827	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	11/29/2017
2828	NDA/MAL/HDP/8354	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZORUXA	ZOLEDRONIC ACID	5MG/100ML	GLAND PHARMA LIMITED 143-148-D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	11/29/2017

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2829	NDA/MAL/HDP/8355	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ONECLAPZ 75	CLOPIDOGREL	75MG	AUROBINDO PHARMA LTD-- UNIT VII SEZ PLOT S1 SPECIAL ECONOMIC ZONE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/29/2017
2830	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	11/29/2017
2831	NDA/MAL/HDP/8392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5MG	IRBESARTAN + HYDROCHLOROTHIAZIDE	150MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	11/29/2017

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2832	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,1.0X3.0X2 8.0 TABLET BLISTER,1.0X24.0X28. 0 TABLET BLISTER	11/29/2017
2833	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,1.0X3.0X2 8.0 TABLET BLISTER	11/29/2017
2834	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	11/29/2017

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2835	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	11/29/2017
2836	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	11/29/2017
2837	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,1.0X100.0X 2.0 ML AMPOULE	

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2838	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	7/1/2017
2839	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	7/1/2009
2840	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	1/31/2018

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2841	NDA/MAL/HDP/8476	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AURODANZ 8	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG	AUROBINDO PHARMA LTD-- UNIT-III SURVEY NO. 313 & 314, BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT TELANGANA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	1/31/2018
2842	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	1.0X3.0 ML CARTRIDGE	1/31/2018
2843	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	1/31/2018

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2844	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	1/31/2018
2845	NDA/MAL/HDP/8485	CACHET PHARMACEUTICAL S PVT LIMITED	ASTRA PHARMA (U) 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	1/31/2018
2846	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	1/31/2018

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2847	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,1.0X5.0X2.0 ML AMPOULE	1/31/2018
2848	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	1/31/2018
2849	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	FRANCE	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON	1/31/2018

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2850	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	1/31/2018
2851	NDA/MAL/HDP/8495	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) 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	1/31/2018
2852	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	1/31/2018

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2853	NDA/MAL/HDP/8498	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	OMASI MED LIMITED	TRIAZONE 0.5G	CEFTRIAZONE	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	1/31/2018
2854	NDA/MAL/HDP/8502	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING	AMOXICILLIN + POTASSIUM CLAVULANATE	400MG/5ML + 57MG/5ML	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE	7/1/2009
2855	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	11/29/2017

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2856	NDA/MAL/HDP/8522	PLANET PHARMACEUTICAL S UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	DAYPENAM	MEROPENEM	500MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	7/1/2017
2857	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	11/26/2019
2858	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/SY RUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	3/28/2018

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2859	NDA/MAL/HDP/8642	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORAFAST	DESLOTRADINE	2.5MG/5ML	EGYPHAR-INDUSTRIAL ZONE (A), PARTS NO. 9 & 10, BLOCK 13026 – EL OBOUR CITY, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	1/13/2020
2860	NDA/MAL/HDP/8643	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	BLISS INDAS LIFESCENCE 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	3/28/2018
2861	NDA/MAL/HDP/8644	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	3/28/2018

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2862	NDA/MAL/HDP/8645	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MODAZAR	LOSARTAN + HYDROCHLOROTHIAZIDE	100MG + 25MG	EGYPHAR-INDUSTRIAL ZONE (A), PARTS NO. 9 & 10, BLOCK 13026 – EL OBOUR CITY, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X4.0 TABLET STRIP	1/13/2020
2863	NDA/MAL/HDP/8647	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZISROCIN	AZITHROMYCIN DIHYDRATE	100MG/5ML	EGYPHAR-INDUSTRIAL ZONE (A), PARTS NO. 9 & 10, BLOCK 13026 – EL OBOUR CITY, EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	1/13/2020
2864	NDA/MAL/HDP/8649	INJECTCARE PARENTERALS PVT. LTD	MATRIX (U) LTD	CEFCARE	CEFTRIAXONE SODIUM	1G	INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	1/31/2018

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2865	NDA/MAL/HDP/8650	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	CEFDIA 400MG	CEFIXIME TRIHYDRATE	400MG	NOBEL İLAÇ SAN. VE TİC. A.Ş.-81100 SANCARLAR, DÜZCE- TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER,1.0X2.0X1.0X 5.0 TABLET BLISTER	3/28/2018
2866	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 MERCK SANTÉ S.A.S.-2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE	GERMANY	ORAL SOLID RETARD TABLETS	1.0X4.0X15.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER	3/28/2018
2867	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	3/28/2018

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2868	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	3/28/2018
2869	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 MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	3/28/2018
2870	NDA/MAL/HDP/8665	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) 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	3/28/2018

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2871	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	5/30/2018
2872	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	5/30/2018
2873	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	5/30/2018

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2874	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	5/30/2018
2875	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	5/30/2018
2876	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	7/1/2018

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2877	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	5/30/2018
2878	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	5/30/2018
2879	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	7/1/2010

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2880	NDA/MAL/HDP/8778	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF-250	CEFUROXIME AXETIL	250MG	ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	11/26/2019
2881	NDA/MAL/HDP/8779	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	STATINOR 20	ROSUVASTATIN	20MG	HETERO LABS LIMITED UNIT V-TSIC 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	5/29/2019
2882	NDA/MAL/HDP/8780	HETERO DRUGS LTD	AIVEEN (U) LIMITED	STATINOR 10	ROSUVASTATIN CALCIUM	10 MG	HETERO LABS LIMITED UNIT V-TSIC 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	3/27/2019

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2883	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	11/26/2019
2884	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)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	11/26/2019
2885	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	11/26/2019

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2886	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/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	11/26/2019
2887	NDA/MAL/HDP/8786	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM	CEFIXIME TRIHYDRATE	100MG	ASSOCIATED BIOTECH-KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	11/26/2019
2888	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	11/26/2019

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2889	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	11/26/2019
2890	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	11/26/2019
2891	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	5/30/2018

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2892	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	5/30/2018
2893	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	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	5/30/2018
2894	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	5/30/2018

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2895	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	5/30/2018
2896	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	5/30/2018
2897	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	5/30/2018

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2898	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	5/30/2018
2899	NDA/MAL/HDP/8829	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE M/S. ANNORA PHARMA PRIVATE LIMITED-SY. NO. 261, ANNARAM VILLAGE, GUMMADIDALA MANDAL	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X180.0 TABLET BOTTLE	12/20/2018
2900	NDA/MAL/HDP/8830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOROTHAZI DE	300MG + 12.5MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/26/2019

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2901	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	11/26/2019
2902	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	11/7/2018
2903	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	11/26/2019

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2904	NDA/MAL/HDP/8839	MACK BROWN PHARMECEUTICAL S PVT LTD	SHURIK LTD	HEALTH RICH	FERRIC AMMONIUM CITRATE + FOLIC ACID + VITAMIN B1 HCL + VITAMIN B6 HCL + NICOTINAMIDE + VITAMIN B12	900MG + 10MG + 20MG + 40MG + 200MG + 360MG /5ML	TORQUE PHARMACEUTICALS PVT LTD -VILL. ISSAPUR, P.O. DAPPAR, PUNJAB-140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	11/26/2019
2905	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	11/7/2018
2906	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	11/26/2019

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2907	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	7/25/2018
2908	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	7/25/2018
2909	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	7/25/2018

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2910	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	7/25/2018
2911	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	7/25/2018
2912	NDA/MAL/HDP/8920	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERONE	90MG/APPLICATOR	FLEET LABORATORIES LTD -- 94 RICKMANSWORTH ROAD, WATFORD, HERT, WD18 7JJ, UNITED KINGDOM	UNITED KINGDOM	VAGINAL GELS AND SOLS	1.0X1.0X15.0 POUCH CARTON	7/25/2018

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2913	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 VIII S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/25/2018
2914	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 SHAPORJI 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	7/25/2018
2915	NDA/MAL/HDP/8929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESELLSCHA FT 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	7/1/2018

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2916	NDA/MAL/HDP/8933	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	Q-TIB	SULFAMETHOXAZOLE + TRIMETHOPRIM + ISONIAZID + PYRIDOXINE HYDROCHLORIDE	800MG + 160MG + 300MG +25MG	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	7/25/2018
2917	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	7/25/2018
2918	NDA/MAL/HDP/8936	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD- PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	7/25/2018

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2919	NDA/MAL/HDP/8939	FREDUN PHARMACEUTICAL S 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) DIST: THANE – 401 404 - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER	7/25/2018
2920	NDA/MAL/HDP/8940	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	RABIZA 20MG	RABEPRAZOLE SODIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/25/2018
2921	NDA/MAL/HDP/8941	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	LIVERCOL 20MG	ROSUVASTATIN CALCIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/25/2018

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2922	NDA/MAL/HDP/8943	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT 150/12.5	IRBESARTAN + HYDROCHLOROTHAZIDE	150MG + 12.5MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/26/2019
2923	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	7/25/2018
2924	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	7/25/2018

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2925	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	7/25/2018
2926	NDA/MAL/HDP/8948	GULF PHARMACEUTICAL INDUSTRIES(JULPH AR).	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/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	7/25/2018
2927	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	7/1/2018

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2928	NDA/MAL/HDP/8952	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFLEX -500	CEFALEXIN MONOHYDRATE	500 MG	THEON PHARMACEUTICALS LIMITED.- VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/25/2018
2929	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	7/25/2018
2930	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	7/25/2018

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2931	NDA/MAL/HDP/9051	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	SULFAMETHOXAZOLE/ TRIMETHOPRIM TABLETS USP	SULFAMETHOXAZOLE + TRIMETHOPRIM	400MG + 80MG	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	1.0X1.0X10.0 TABLET BLISTER	9/26/2018
2932	NDA/MAL/HDP/9052	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	SULFAMETHOXAZOLE/ TRIMETHOPRIM TABLETS USP	SULFAMETHOXAZOLE + TRIMETHOPRIM	800MG + 160MG	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	1.0X1.0X10.0 TABLET BLISTER	9/26/2018
2933	NDA/MAL/HDP/9053	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	MABTHERA® 100MG/10ML	RITUXIMAB	100MG/10ML	ROCHE DIAGNOSTICS GMBH MANNHEIM-- SANDHOFFER STRASSE 116 - 68305 MANNHEIM GERMANY.	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X2.0X10.0 ML VIAL	9/26/2018

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2934	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	9/26/2018
2935	NDA/MAL/HDP/9057	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	PHILLIPS PHARMACEUTICALS (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, 1.0X6.0X25.0 TABLET BLISTER	9/26/2018
2936	NDA/MAL/HDP/9058	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	PHILLIPS PHARMACEUTICALS (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, 1.0X3.0X25.0 TABLET BLISTER	9/26/2018

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2937	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/SY RUPS/DROPS	1.0X10.0 ML BOTTLE	9/26/2018
2938	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	9/26/2018
2939	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	9/26/2018

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2940	NDA/MAL/HDP/9064	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOMOX-250	AMOXICILLIN TRIHYDRATE	250 MG	THEON PHARMACEUTICALS LIMITED.- VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	9/26/2018
2941	NDA/MAL/HDP/9065	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFLEX -250	CEFALEXIN MONOHYDRATE	250 MG	THEON PHARMACEUTICALS LIMITED.- VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	9/26/2018
2942	NDA/MAL/HDP/9066	THEON PHARMACEUTICAL S LTD	AIVEEN (U) LIMITED	THEOFIX-200	CEFEXIME TRIHYDRATE	200 MG	THEON PHARMACEUTICALS LIMITED.- VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/26/2018

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2943	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	11/28/2019
2944	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	11/26/2019
2945	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	11/26/2019

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2946	NDA/MAL/HDP/9138	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	L-THROX 50	LEVOTHYROXINE SODIUM	50MCG	CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE	11/26/2019
2947	NDA/MAL/HDP/9139	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	L THROX 100	LEVOTHYROXINE SODIUM	100MCG	CORONA REMEDIES PVT. LTD-VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE	11/26/2019
2948	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	11/26/2019

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2949	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	11/26/2019
2950	NDA/MAL/HDP/9142	THEON PHARMACEUTICALS LIMITED	AIVEEN (U) LIMITED	THEOFIX -50 DS	CEFIXIME TRIHYDRATE	50MG/5ML	THEON PHARMACEUTICALS LTD ,-VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	11/26/2019
2951	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,1.0X24.0X28.0 TABLET BLISTER,1.0X1000.0 TABLET BOTTLE	11/27/2019

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2952	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)	11/27/2019
2953	NDA/MAL/HDP/9165	BLISS GVS PHARMA LIMITED	DELMAN 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	11/27/2019
2954	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	1/10/2020

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2955	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	1/10/2020
2956	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	1/13/2020
2957	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	1/13/2020

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2958	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	1/13/2020
2959	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	1/13/2020
2960	NDA/MAL/HDP/9178	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	LORADE	LORATIDINE,LORATIDI NE	10MG,10MG	PROFARMA SH.A-MYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	1/13/2020

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2961	NDA/MAL/HDP/9190	SAKAR HEALTHCARE LIMITED	TATA UGANDA LIMITED	RABEKAR			SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHMABAD 382213 GUJARATI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE	9/28/2020
2962	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/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	9/28/2020
2963	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	9/28/2020

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2964	NDA/MAL/HDP/9194	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC	AMOXICILLIN TRIHYDRATE + 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	9/28/2020
2965	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	9/28/2020
2966	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	9/28/2020

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2967	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	9/28/2020
2968	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	9/28/2020
2969	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/GRAN ULES	1.0X15.0 G SACHET	9/28/2020

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2970	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	9/28/2020
2971	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	9/28/2020
2972	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	9/28/2020

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2973	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	9/28/2020
2974	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	9/28/2020
2975	NDA/MAL/HDP/9205	SYNOKEM PHARMACEUTICAL S 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	9/28/2020

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2976	NDA/MAL/HDP/9207	STRIDES SHASUN LIMITED	DELMAR 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	9/28/2020
2977	NDA/MAL/HDP/9209	STRIDES SHASUN LIMITED	DELMAR 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	9/28/2020
2978	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	9/28/2020

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2979	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	9/28/2020
2980	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	9/28/2020
2981	NDA/MAL/HDP/9213	STRIDES SHASUN LIMITED	DELMAR 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	9/28/2020

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2982	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	9/28/2020
2983	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	9/28/2020
2984	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	9/28/2020

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2985	NDA/MAL/HDP/9219	TROIKAA PHARMACEUTICAL S 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	9/28/2020
2986	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	9/28/2020
2987	NDA/MAL/HDP/9226	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZURIG 80	FEBUXOSTAT	80MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	9/25/2020

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2988	NDA/MAL/HDP/9230	LINCOLN P'CAL'S LTD	ABACUS PHARMA (AFRICA) LIMITED	PERILIN	PERILIN	5 MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE	9/28/2020
2989	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	9/28/2020
2990	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	9/25/2020

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2991	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	9/25/2020
2992	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	9/25/2020
2993	NDA/MAL/HDP/9243	M.J BIOPHARM PVT LTD	VITACARE LIMITED	ZYPANE-150	PREGABALIN	150 MG	M.J BIOPHARM PVT LTD,-L- 7, MIDC INDUSTRIAL AREA, TALOJA, NAVI MUMBAI- 410208, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY COMBINATION PACK COATED TABLETS	1.0X3.0X10.0 CAPSULE BLISTER	9/28/2020

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2994	NDA/MAL/HDP/9244	M.J BIOPHARM PVT LTD	VITACARE LIMITED	ZYPANE-300	PREGABALIN	300 MG	M.J BIOPHARM PVT LTD,-L-7, MIDC INDUSTRIAL AREA, TALOJA, NAVI MUMBAI-410208, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 TABLET BLISTER	9/28/2020
2995	NDA/MAL/HDP/9246	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	CLAMOXIN	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDOPHARM PVT LIMITED- NO. 50 KAYARAMBEDU VILLAGE, GUDUVANCHERY-603202	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	2/19/2021
2996	NDA/MAL/HDP/9247	LUKAS LAB LTD	PLUTO PHARMACEUTICALS LIMITED	VAGIRISK	CLINDAMYCIN PHOSPHATE + CLOTRIMAZOLE	100 MG + 100 MG	OLIVE HEALTHCARE, UNIT 1-197/2 ATHIAWAD, DABHEL VILLAGE, NANI DAMAN 396210 UT	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 SUPPOSITORY BLISTER	4/8/2021

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2997	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	9/28/2020
2998	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	9/28/2020
2999	NDA/MAL/HDP/9250	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MONTEER	AMLODIPINE BESYLATE + ATORVASTATIN CALCIUM	5 MG + 10 MG	UNITED PHARMACEUTICALS MANUFACTURING LTD CO- AL- RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	9/28/2020

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3000	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	9/28/2020
3001	NDA/MAL/HDP/9252	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	FLUCO-BKRS	FLUCONAZOLE	0.2% 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	9/25/2020
3002	NDA/MAL/HDP/9253	MSD (PTY) LTD	SURGIPHARM (U) LIMITED	ERVEBO	EBOLA ZAIRE VACCINE (RVSVΔG-ZEBOV-GP, LIVE ATTENUATED)	72MILLION PFU/ML	MSD SITE-BURGWEDEL BIOTECH GMBH-IM LANGEN FELDE 5, 30938 BURGWEDEL BIORELIANCE CORPORATION-9900 BLACKWELL ROAD, ROCKVILLE, MARYLAND 20850-3349 BIORELIANCE CORPORATION-9610 MEDICAL CENTER DRIVE, ROCKVILLE, MARYLAND 20850-3349	GERMANY UNITED STATES	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON	9/28/2020

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3003	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	9/28/2020
3004	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	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X60.0 TABLET CONTAINER	9/28/2020
3005	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	9/28/2020

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3006	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	9/28/2020
3007	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	9/28/2020
3008	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	9/28/2020

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3009	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	9/28/2020
3010	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	9/28/2020
3011	NDA/MAL/HDP/9291	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	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	9/28/2020

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3012	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	9/28/2020
3013	NDA/MAL/HDP/9296	BLISS GVS PHARMA LIMITED	DELMAN 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	9/25/2020
3014	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	9/28/2020

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3015	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	9/28/2020
3016	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	9/28/2020
3017	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	9/25/2020

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3018	NDA/MAL/HDP/9316	ATCO LABORATORIES LTD	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	9/25/2020
3019	NDA/MAL/HDP/9317	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FEPAR	ALBENDAZOLE	200 MG/5 ML	AL FAZAL PHARMA INDUSTRIES (PVT) LTD- PLOT 20,21,22, DEFENSE INDUSTRIAL ZONE LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE	9/25/2020
3020	NDA/MAL/HDP/9318	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FLOTIZOL	CLOTRIMAZOLE	1%W/W	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	9/25/2020

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3021	NDA/MAL/HDP/9322	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50 MG + 300 MG + 300 MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, RING ROAD, LUZIRA INDUSTRIAL PARK - UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	9/25/2020
3022	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	9/25/2020
3023	NDA/MAL/HDP/9327	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	OXICIN-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	9/25/2020

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3024	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	10/26/2020
3025	NDA/MAL/HDP/9348	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PARACETAMOL - PHARCO B INTERNATIONAL	PARACETAMOL	1G/100ML	PHARCO-B INTERNATIONAL PHARMACEUTICALS-BORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL	12/22/2020
3026	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	12/22/2020

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3027	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,1.0X30.0X2.0 X6.0 TABLET BLISTER	12/22/2020
3028	NDA/MAL/HDP/9356	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS	DESLOTRADINE	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	12/22/2020
3029	NDA/MAL/HDP/9357	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL H 5/6.25	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	5 MG + 6.25 MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/22/2020

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3030	NDA/MAL/HDP/9361	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PEGASET 75	PREGABALIN	75MG	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, MAHABOON NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	12/22/2020
3031	NDA/MAL/HDP/9363	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER 40/240	ARTEMETHER + LUMEFANTRINE	40 MG + 240 MG	OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER, 1.0X30.0X6.0 TABLET BLISTER, 1.0X30.0X1.0 X6.0 TABLET BLISTER	12/22/2020
3032	NDA/MAL/HDP/9365	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 100	BEVACIZUMAB	100MG/4ML	HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOONNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	12/22/2020

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3033	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	12/18/2020
3034	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	1.0X1.0X5.0 ML VIAL	12/18/2020
3035	NDA/MAL/HDP/9368	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 400	BEVACIZUMAB	400MG/16ML	HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIC- FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	12/22/2020

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3036	NDA/MAL/HDP/9373	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ATORKEY 10	ATORVASTATIN CALCIUM TRIHYDRATE	10MG	AUROBINDO UNIT XV-PLOT NO. 17 A, E. BONANGI (VILLAGE), JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM DIST, ANDHRA PRADESH -531021 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/22/2020
3037	NDA/MAL/HDP/9375	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ATORKEY 20	ATORVASTATIN CALCIUM TRIHYDRATE	20MG	AUROBINDO UNIT XV-PLOT NO. 17 A, E. BONANGI (VILLAGE), JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM DIST, ANDHRA PRADESH -531021 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/22/2020
3038	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	12/18/2020

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3039	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	12/18/2020
3040	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	12/18/2020
3041	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	12/18/2020

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3042	NDA/MAL/HDP/9385	BRAWN LABORATORIES LTD	TATA UGANDA 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	12/18/2020
3043	NDA/MAL/HDP/9386	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	PROXYVON PLUS	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5 MG + 325 MG	WOCKHARDT LIMITED- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	12/18/2020
3044	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	12/22/2020

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3045	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	12/22/2020
3046	NDA/MAL/HDP/9399	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFZIM	CEFTAZIDIME PENTAHYDRATE	1G	PHARCO-B INTERNATIONAL PHARMACEUTICALS-BORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + (2*5ML WFI)	12/22/2020
3047	NDA/MAL/HDP/9400	PHARCO B INTERNATIONAL,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFAZONE 1 G	CEFOPERAZONE	1G	PHARCO-B INTERNATIONAL PHARMACEUTICALS-BORG EL-ARAB 3D INDUSTRIAL ZONE, BLOCK 18 AREA, 10, 11, ALEXANDRIA EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + (1*5 ML WFI)	12/22/2020

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3048	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, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	12/22/2020
3049	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	12/18/2020
3050	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	12/18/2020

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3051	NDA/MAL/HDP/9427	SANOFI AVENTIS KENYA LTD	LABOREX UGANDA LIMITED	SHANIPV	CONCENTRATED TRIVALENT OF INACTIVATED POLIOMYELITIS VIRUS; TYPE 1 (MAHONEY) + TYPE 2 (MEF-1) + TYPE 3 (SAUKETT)	40 DU + 8 DU + 32 DU/DOSE	SHANTHA BIOTECHNICS LTD-SURVEY NO. 274, ATHVELLI VILLAGE MEDCHAL MANDAL RANGWA REDDY DISTRICT, ANDRA PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0X1.0X5.0 DOSE VIAL	12/18/2020
3052	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	12/18/2020
3053	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	12/18/2020

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3054	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	12/22/2020
3055	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	12/22/2020
3056	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	12/22/2020

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3057	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	12/22/2020
3058	NDA/MAL/HDP/9452	BRAWN LABORATORIES LTD	TATA UGANDA 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	12/22/2020
3059	NDA/MAL/HDP/9453	BRAWN LABORATORIES LTD	TATA UGANDA 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	12/22/2020

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3060	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	2/3/2021
3061	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	2/3/2021
3062	NDA/MAL/HDP/9480	TROIKAA PHARMACEUTICAL S LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PHLEBOTROY QPS	HEPARIN SODIUM	1000 IU/ML	TROIKAA PHARMACEUTICALS LIMITED..-THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X5.0 ML VIAL	12/22/2020

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3063	NDA/MAL/HDP/9481	BKRS PHARMA PVT. LTD.	VEERAM HEALTHCARE (U) LIMITED	OFLO-BKRS	OFLOXACIN	0.2% 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	12/18/2020
3064	NDA/MAL/HDP/9491	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	DOMNET 10	DOMPERIDONE MALEATE	10 MG	ZIM LABS LTD.-B 21/22, MIDC AREA, KALMESHWAR 441501, DIST-NAGPUR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	3/4/2021
3065	NDA/MAL/HDP/9492	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	TEMOZOL 100	TEMOZOLOMIDE	100 MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE CONTAINER	3/4/2021

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3066	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	3/4/2021
3067	NDA/MAL/HDP/9495	MANEESH EXPORTS (EOU)	PLANET PHARMACEUTICALS UGANDA LTD	BOOSTIM-625	AMOXICILLIN TRIHYDRATE + DILUTED POTASSIUM CLAVULANATE	500 MG + 125 MG	MANEESH EXPORTS (EOU)- PLOT D-16/7, TTC INDUSTRIAL AREA, MIDC TURBHE, NAVI MUMBAI – 400 703, DIST. THANE, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	3/4/2021
3068	NDA/MAL/HDP/9500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRADIOL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED-PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BLISTER	3/4/2021

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3069	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	3/4/2021
3070	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	3/4/2021
3071	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	3/4/2021

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3072	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	3/4/2021
3073	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	3/4/2021
3074	NDA/MAL/HDP/9508	ACME FORMULATION PVT. LTD.	PLANET PHARMACEUTICALS UGANDA LTD	PLAN 2	LEVONORGESTREL	0.75 MG	ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X1.0X2.0 TABLET BLISTER	3/4/2021

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3075	NDA/MAL/HDP/9509	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOBIDERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + TOLNAFTATE + IODOCHLORHYDROXY QUINOLINE	(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	3/4/2021
3076	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	3/4/2021
3077	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	3/4/2021

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3078	NDA/MAL/HDP/9512	INDASI LIFESCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	INDART- 120	ARTESUNATE	120 MG/VIAL	BLISS INDASI LIFESCIENCE PRIVATE LIMITED-PLOT NO. 73 TO 76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN- 396 210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 12 ML SODIUM PHOSPHATE VIAL	3/4/2021
3079	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	3/4/2021
3080	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	3/4/2021

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3081	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	3/4/2021
3082	NDA/MAL/HDP/9516	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FORTYMOX	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	ORCHIDIA PHARMACEUTICAL INDUSTRIES-AL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML CONTAINER	3/4/2021
3083	NDA/MAL/HDP/9517	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEVXAL	NEPAFENAC	0.1% W/V	ORCHIDIA PHARMACEUTICAL INDUSTRIES-AL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML CONTAINER	3/4/2021

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3084	NDA/MAL/HDP/9523	KOTRA PHARMA (M) SDN. BHD	ABACUS PHARMA (AFRICA) LIMITED	CEFACLOX-125	CEFACLOX MONOHYDRATE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD, -NO. 1, 2 & 3, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA.	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	3/4/2021
3085	NDA/MAL/HDP/9524	STRIDES PHARMA SCIENCE LIMITED	DELMAR 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	3/4/2021
3086	NDA/MAL/HDP/9525	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	PHILLIPS PHARMACEUTICALS (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	3/4/2021

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3087	NDA/MAL/HDP/9526	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	PHILLIPS PHARMACEUTICALS (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	3/4/2021
3088	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	3/4/2021
3089	NDA/MAL/HDP/9530	PFIZER LABORATORIES	LABOREX UGANDA LIMITED	ZAVICEFTA	CEFTAZIDIME PENTAHYDRATE + AVIBACTAM SODIUM	(2G +0.5 G)/VIAL	GLAXOSMITHKLINE MANUFACTURING S.P.A- VIA A.FLEMING,2-37135 VERONA-ITALY	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X20.0 ML VIAL	3/4/2021

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3090	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	3/4/2021
3091	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	3/4/2021
3092	NDA/MAL/HDP/9535	ARISTO PHARMACEUTICAL S 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	3/4/2021

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3093	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	3/4/2021
3094	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	3/4/2021
3095	NDA/MAL/HDP/9539	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	D-TAIL	DOCETAXEL TRIHYDRATE	20 MG/VIAL	KHANDELWAL LABORATORIES PVT. LTD-B-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X20.0 MG VIAL + 1*1*1.5 ML DILUENT	3/4/2021

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3096	NDA/MAL/HDP/9540	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TENGLYN	TENELIGLIPTIN HEMIPENTAHYDROBROMIDE HYDRATE	20MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/4/2021
3097	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/4/2021
3098	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/4/2021

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3099	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	3/4/2021
3100	NDA/MAL/HDP/9544	TIL HEALTHCARE PVT.LTD.	ESCORTS PHARMACEUTICALS LIMITED	OFLOCARE-200	OFLOXACIN	200MG	TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R- 5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/4/2021
3101	NDA/MAL/HDP/9545	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VIATUFF 100	SILDENAFIL CITRATE	100MG	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 FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	3/4/2021

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3102	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	3/4/2021
3103	NDA/MAL/HDP/9547	TWENTY FIRST CENTURY PHARMACEUTICAL S PVT LIMITED-	SWASTIK PHARMACEUTICAL LTD	TRYCLOR 125 DS	CEFACTOR	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD-UNIT II, KHABRA NO.282, NALHERI DEHVIRAN, NALHERA ANANTPOR, PUHANA- IQBALPUR ROAD, ROORKEE- 247688. HARIDWAR DIST (UTTARAKHAND)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	3/4/2021
3104	NDA/MAL/HDP/9548	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	DICLAC 75 LP	DICLOFENAC SODIUM	75MG	SALUTAS PHARMA GMBH- OTTO-VON-GUERICKE ALLEE-1, 39179 BARLEBEN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	3/4/2021

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3105	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	3/4/2021
3106	NDA/MAL/HDP/9555	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRAMADOL DENK 200MG RETARD	TRAMADOL HYDROCHLORIDE	200 MG	GRUNENTHAL GMBH- ZIEGLERSTR. 6, 52078 AACHEN - GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/5/2021
3107	NDA/MAL/HDP/9556	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRAMADOL DENK 100MG RETARD	TRAMADOL HYDROCHLORIDE	100 MG	GRUNENTHAL GMBH- ZIEGLERSTR. 6, 52078 AACHEN - GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/5/2021

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3108	NDA/MAL/HDP/9557	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIACTIN	CYPROHEPTADINE HYDROCHLORIDE	2 MG/5 ML	MEDIPHARM INDUSTRIES (E.A.) LTD-PLOT 65 KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	3/4/2021
3109	NDA/MAL/HDP/9572	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	TELMA 80H PLUS	TELMISARTAN + HYDROCHLOROTHIAZIDE	80MG + 25MG	GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. 2, PHASE-II, PHARMA ZONE, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST. DHAR (M.P), PINCODE: 454775	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	5/4/2021
3110	NDA/MAL/HDP/9573	OCTOBER PHARMA	ABACUS PHARMA (AFRICA) LIMITED	MONOMAK 40	ISOSORBIDE -5- NITRATE	40 MG	OCTOBER PHARMA-1ST INDUSTRIAL ZONE, STREET 25 PLOT 190, 6TH OCTOBER CITY CAIRO, ARAB REPUBLIC OF EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	6/3/2021

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3111	NDA/MAL/HDP/9576	SAVA HEALTHCARE LIMITED -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUTIAIR 0.05%	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	6/3/2021
3112	NDA/MAL/HDP/9584	WALLACE PHARMACEUTICALS PVT. LTD	SURGIPHARM (U) LIMITED	ZN20	ZINC GLUCONATE	20 MG/5 ML	WALLACE PHARMACEUTICALS PVT LTD-BHATIAN, NALAGARH, DIST. SOLAN HP 174101	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	6/4/2021
3113	NDA/MAL/HDP/9585	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	TACROVATE	TACROLIMUS	0.03% W/W	AUROCHEM LABS (I) PVT LTD-PLOT 08, PTICE LTD PALGHAR 401404	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE	6/3/2021

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3114	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	6/3/2021
3115	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	6/4/2021
3116	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	6/3/2021

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3117	NDA/MAL/HDP/9589	MACLEODS PHARMACEUTICAL S LTD	NORVIK ENTERPRISES 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	6/4/2021
3118	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	6/3/2021
3119	NDA/MAL/HDP/9591	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITIZ-500	AZITHROMYCIN DIHYDRATE	500 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	1.0X1.0X3.0 TABLET BLISTER	6/4/2021

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3120	NDA/MAL/HDP/9592	JAMJOOM PHARMACEUTICAL S COMPANY	MU PHARMA CO - SMC LIMITED	XOLA	DORZOLAMIDE HYDROCHLORIDE	22.25 MG/ML	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML BOTTLE	6/4/2021
3121	NDA/MAL/HDP/9593	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO 50	LOSARTAN POTASSIUM	50 MG	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	6/4/2021
3122	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	6/3/2021

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3123	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	6/3/2021
3124	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	6/3/2021
3125	NDA/MAL/HDP/9599	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	VORICONA-DENK 200MG	VORICONAZOLE	200 MG	ACTAVIS LTD-BLB015-016, BULEBEL INDUSTRIAL ESTATE, ZEJTUN ZTN3000	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/3/2021

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3126	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	6/3/2021
3127	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	6/3/2021
3128	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	6/3/2021

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3129	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	6/3/2021
3130	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	INDIA	PARENTERAL ORDINARY OTHER INFUSIONS	1.0X5.0X20.0 ML VIAL	6/3/2021
3131	NDA/MAL/HDP/9608	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	ACTITOP	ETOPOSIDE	20 MG/ML	KHANDELWAL LABORATORIES PVT. LTD-B-1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	6/3/2021

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3132	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	6/3/2021
3133	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 INDUSTRIAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	6/3/2021
3134	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	6/3/2021

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3135	NDA/MAL/HDP/9616	ZIM LABORATORIES LTD	ESCORTS PHARMACEUTICALS LTD - WILSON ROAD	NEUROZEL	GABAPENTIN	300 MG	ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 TABLET BLISTER	6/3/2021
3136	NDA/MAL/HDP/9617	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TROYMIDATE	ETOMIDATE	2 MG/ML	TROIKAA PHARMACEUTICALS LIMITED,,C-1, SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN-248197, UTTARAKHAND	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X1.0X10.0 ML VIAL	6/3/2021
3137	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, TELEGANA	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	6/3/2021

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3138	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	6/3/2021
3139	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,1.0X2.0X21.8 G SACHET COMBIPACK	6/3/2021
3140	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, UPPSALA, SE-751 74	SWEDEN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE	6/3/2021

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3141	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	6/3/2021
3142	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 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	6/3/2021
3143	NDA/MAL/HDP/9625	ACME FORMULATION PVT. LTD.	POPULATION SERVICES INTERNATIONAL - UGANDA	AVERTISO	MISOPROSTOL	200 MCG	ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER	6/3/2021

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3144	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	6/3/2021
3145	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	6/3/2021
3146	NDA/MAL/HDP/9628	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	AMPLIFY 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	6/3/2021

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3147	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	6/3/2021
3148	NDA/MAL/HDP/9630	NEOMI PHARMACEUTICAL S PVT LTD -	ROYAL PHARMA 2011 LIMITED	ROXONE 2G	CEFTRIAXONE SODIUM	2G/VIAL	M/S ZEISS PHARMACEUTICALS PVT LTD,, -PLOT 72, EPIP PHASE 1, JHARMAJRI BADDI, DIST: SOLAN HP-INDIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	6/3/2021
3149	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	6/3/2021

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3150	NDA/MAL/HDP/9632	AGIO PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	CANISON VAGINAL 100	CLOTRIMAZOLE	100 MG	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE-411026, MAHARASHTRA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	6/3/2021
3151	NDA/MAL/HDP/9633	AGIO PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	AGILAX	LACTULOSE SOLUTION	3.35G/5ML	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE-411026, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	6/3/2021
3152	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	6/3/2021

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3153	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	6/3/2021
3154	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	6/3/2021
3155	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	6/3/2021

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3156	NDA/MAL/HDP/9639	ZOTA HEALTHCARE LTD	HARLEYS UGANDA LIMITED	ZOMEPR-ES-40	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40 MG	ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/3/2021
3157	NDA/MAL/HDP/9641	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PRILIGY 60 MG	DAPOXETINE HYDROCHLORIDE	60 MG	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES SRL-VIA CAMPO DI PILE 67100 L'AQUILA (AQ)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	6/3/2021
3158	NDA/MAL/HDP/9642	GLENMARK PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLOMIL	AMOROLFINE HYDROCHLORIDE	5% W/V	GLENMARK PHARMACEUTICALS LTD.- PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X2.5 ML VIAL + 1*12, ISOPROPYL ALCOHOL 70% SWAB SACHETS	6/3/2021

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3159	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	6/4/2021
3160	NDA/MAL/HDP/9648	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO - SMC LIMITED	FUSIBACT CREAM	FUSIDIC ACID	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	1.0X1.0X15.0 G TUBE	6/4/2021
3161	NDA/MAL/HDP/9649	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO 100	LOSARTAN POTASSIUM	100MG	AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/4/2021

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3162	NDA/MAL/HDP/9650	AGIO PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	SILVEX PLUS CREAM	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	1 % W/W + 0.2 % W/W	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE-411026, MAHARASHTRA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	6/4/2021
3163	NDA/MAL/HDP/9651	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANTOCYN	OXYTOCIN	10 IU/ML	PT SANBE FARMA UNIT 3.-JL INDUSTRI CIMAEME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	6/4/2021
3164	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	6/4/2021

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3165	NDA/MAL/HDP/9653	LABORATE PHARMACEUTICAL S 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	6/4/2021
3166	NDA/MAL/HDP/9654	THEON PHARMACEUTICAL S LIMITED	AIVEEN (U) LIMITED	THEOTAX-1G	CEFOTAXIME SODIUM	1 G/VIAL	THEON PHARMACEUTICALS LTD ,-VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	6/4/2021
3167	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 FRESENIUS KABI DEUTSCHLAND GMBH- FRESENIUSSTRASSE 1, D- 61169, FRIEDBERG	GERMANY SOUTH AFRICA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BAG	6/4/2021

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3168	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	6/4/2021
3169	NDA/MAL/HDP/9664	TAKEDA (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	XEFO RAPID	LORNOXICAM	8 MG	TAKEDA GMBH, PLANT ORANIENBURG-PLANT ORANIENBURG, LEHNITZSTRASSE 70-98, DE - 16515, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	6/4/2021
3170	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	6/4/2021

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3171	NDA/MAL/HDP/9666	SCOTT-EDIL PHARMACIA LTD.,	ESCORTS PHARMACEUTICALS LIMITED	VOLIGESIC-GEL	DICLOFENAC DIETHYLAMINE	1.0 % W/W	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	6/4/2021
3172	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	6/4/2021
3173	NDA/MAL/HDP/9669	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOCOLD	PARACETAMOL + CHLORPHENAMINE MALEATE + PHENYLEPHRINE HYDROCHLORIDE	500 MG + 2 MG + 5 MG	ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	6/4/2021

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3174	NDA/MAL/HDP/9670	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	CDGREL-75	CLOPIDOGREL BISULFATE	75MG	ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN-394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/4/2021
3175	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	6/4/2021
3176	NDA/MAL/HDP/9672	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NASO B12	METHYLCOBALAMIN	250 MCG/ACTUATION	TROIKAA PHARMACEUTICALS LIMITED..-THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X2.3 ML BOTTLE	6/4/2021

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3177	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	6/4/2021
3178	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	6/4/2021
3179	NDA/MAL/HDP/9675	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OD-TAM 0.4	TAMSULOSIN HYDROCHLORIDE	0.4 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), TSIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE: 509302.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	6/4/2021

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3180	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	6/4/2021
3181	NDA/MAL/HDP/9677	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 200 MG / 100 ML	DOXORUBICIN HYDROCHLORIDE	200 MG / 100 ML	EBEWE PHARMA GES.M.B.H. NFG.KG- MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML VIAL	6/4/2021
3182	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	6/4/2021

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3183	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	6/4/2021
3184	NDA/MAL/HDP/9681	SYNOKEM PHARMACEUTICAL S LIMITED	ROYAL PHARMA 2011 LIMITED	MISSROL-200	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LIMITED -PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,10.0X1.0X10.0 TABLET BLISTER	6/23/2021
3185	NDA/MAL/HDP/9682	SYNOKEM PHARMACEUTICAL S 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	6/23/2021

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3186	NDA/MAL/HDP/9683	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	CAPTOGLO	CAPTOPRIL	25 MG	GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT-394230,GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	6/23/2021
3187	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	7/2/2021
3188	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	SOUTH KOREA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER	7/2/2021

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3189	NDA/MAL/HDP/9696	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	QUINFER	QUININE SULPHATE	300MG	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,1.0X500.0 TABLET CONTAINER,1.0X1000. 0 TABLET CONTAINER	7/26/2021
3190	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	9/13/2021
3191	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	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0 TABLET BLISTER	9/15/2021

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3192	NDA/MAL/HDP/9714	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ROVISTA	ROSUVASTATIN	20MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	9/29/2021
3193	NDA/MAL/HDP/9715	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ROVISTA	ROSUVASTATIN	10MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	9/29/2021
3194	NDA/MAL/HDP/9716	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LIPIGET	ATORVASTATIN	20MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	9/29/2021

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3195	NDA/MAL/HDP/9717	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ESOME	ESOMEPRAZOLE	40MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	9/29/2021
3196	NDA/MAL/HDP/9718	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	RISEK 20	OMEPRAZOLE	20MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER, 1.0X10.0X10.0 CAPSULE BLISTER	9/29/2021
3197	NDA/MAL/HDP/9719	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ESOME	ESOMEPRAZOLE	20MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	9/29/2021

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3198	NDA/MAL/HDP/9720	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	RISEK 40	OMEPRAZOLE	40MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	9/29/2021
3199	NDA/MAL/HDP/9721	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	4MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY GRANULES	1.0X14.0 SACHET CARTON	9/29/2021
3200	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	10/12/2021

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3201	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	10/12/2021
3202	NDA/MAL/HDP/9724	AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD	ROYAL PHARMA 2011 LIMITED	METFORMIN TABLETS BP 500 MG	METFORMIN HYDROCHLORIDE	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	10/12/2021
3203	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	10/12/2021

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3204	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	10/12/2021
3205	NDA/MAL/HDP/9727	Y.S.P. INDUSTRIES (M) SDN. BHD.	ROYAL PHARMA 2011 LIMITED	CLARIMYCIN	CLARITHROMYCIN	500MG	Y.S.P INDUSTRIES (M) SDN BHN.-LOT 3,5 & 7, JALAN P/7, SECTION 13	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	10/12/2021
3206	NDA/MAL/HDP/9728	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ATONL 100	ATENOLOL	100MG	ENCORE HEALTHCARE PVT LTD-D-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	10/12/2021

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3207	NDA/MAL/HDP/9729	ENCORE HEALTHCARE PVT. LTD.	REDDYS PHARMA LIMITED	ATONL 50	ATENOLOL	50MG	ENCORE HEALTHCARE PVT LTD-D-5, MIDC AREA, PAITHAN- 431148, DIST. AURANGABAD, MAHARASHTRA - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	10/12/2021
3208	NDA/MAL/HDP/9730	RUSAN PHARMA LTD	NORVIK ENTERPRISES LIMITED	ADDTREX 50MG	NALTREXONE HYDROCHLORIDE	50 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	1.0X4.0X7.0 TABLET BLISTER, 1.0X5.0X10.0 TABLET BLISTER, 1.0X3.0X10.0 TABLET BLISTER	10/12/2021
3209	NDA/MAL/HDP/9731	MICRO LABS LIMITED	LABOREX 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	10/12/2021

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3210	NDA/MAL/HDP/9732	ZIM LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	AZITO 250	AZITHROMYCIN DIHYDRATE	250MG	ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	10/12/2021
3211	NDA/MAL/HDP/9733	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS 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	10/12/2021
3212	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	10/11/2021

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3213	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]	10/12/2021
3214	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	10/11/2021
3215	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	10/11/2021

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3216	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	10/11/2021
3217	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	10/11/2021
3218	NDA/MAL/HDP/9750	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO 15 MG	RIVAROXABAN	15MG	LIPTIS EGYPT 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	10/11/2021

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3219	NDA/MAL/HDP/9751	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO 20 MG	RIVAROXABAN	20MG	LIPTIS EGYPT 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	10/11/2021
3220	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 EGYPT 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	10/11/2021
3221	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 EGYPT 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	10/11/2021

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3222	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	10/11/2021
3223	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	10/12/2021
3224	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	10/12/2021

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3225	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	10/12/2021
3226	NDA/MAL/HDP/9758	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SKUDEXA	TRAMADOL HYDROCHLORIDE + DEXKETOPROFEN	75MG + 25MG	MENARINI - VON HEYDEN GMBH-LEIPZIGER STRABE 7-13, 01097 DRESDEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	10/12/2021
3227	NDA/MAL/HDP/9759	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	EZITA	EZETIMIBE	10MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	9/29/2021

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3228	NDA/MAL/HDP/9760	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANT	CANDESARTAN	16MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	9/29/2021
3229	NDA/MAL/HDP/9761	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	AMLO	AMLODIPINE BESILATE	10MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/29/2021
3230	NDA/MAL/HDP/9762	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANTEC	CANDESARTAN CILEXETIL + HYDROCHLOROTHIAZIDE	16MG + 12.5MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	9/29/2021

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3231	NDA/MAL/HDP/9763	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DPIRIV 40/320 TABLET	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	10/12/2021
3232	NDA/MAL/HDP/9764	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DPIRIV 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	10/12/2021
3233	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	10/11/2021

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3234	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	10/11/2021
3235	NDA/MAL/HDP/9767	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	PREZEL 75	PREGABALIN	75MG	IND-SWIFT LIMITED „- PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	10/12/2021
3236	NDA/MAL/HDP/9768	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	MALAREST	QUININE DIHYDROCHLORIDE	600MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	FRANCE	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	10/11/2021

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3237	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	10/11/2021
3238	NDA/MAL/HDP/9770	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO-H 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	100MG + 12.5MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/11/2021
3239	NDA/MAL/HDP/9771	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO-H 50/12.5	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/11/2021

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3240	NDA/MAL/HDP/9772	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO-H 100/25	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	100MG + 25MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/11/2021
3241	NDA/MAL/HDP/9773	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	LOPERAGLOBE	LOPERAMIDE HYDROCHLORIDE	2MG	GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT-394230,GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	10/11/2021
3242	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	10/11/2021

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3243	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	10/11/2021
3244	NDA/MAL/HDP/9776	PLEX LIFE PROVIDER	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	10/11/2021
3245	NDA/MAL/HDP/9777	PLEX LIFE PROVIDER	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	10/11/2021

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3246	NDA/MAL/HDP/9778	PLEX LIFE PROVIDER	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	10/11/2021
3247	NDA/MAL/HDP/9779	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	EYLEA			BAYER AG, BERLIN- MULLERSTRABE 178, 13353 BERLIN - GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	10/11/2021
3248	NDA/MAL/HDP/9780	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE DS 125	CLARITHROMYCIN	125 MG/5 ML	IND-SWIFT LIMITED ,,- PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA- 184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	10/12/2021

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3249	NDA/MAL/HDP/9781	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE DS 250	CLARITHROMYCIN	250 MG/5 ML	IND-SWIFT LIMITED ,,- PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	10/12/2021
3250	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, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	10/12/2021
3251	NDA/MAL/HDP/9783	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	TRAVOLOL	TRAVOPROST + TIMOLOL MALEATE	(0.04 MG + 6.83 MG)/ ML	WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	10/12/2021

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3252	NDA/MAL/HDP/9784	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	BRINZOL	BRINZOLAMIDE + TIMOLOL	(10.0 MG + 5.0 MG)/ML	WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	10/12/2021
3253	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	10/12/2021
3254	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	10/12/2021

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3255	NDA/MAL/HDP/9787	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	SURE-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	10/12/2021
3256	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	10/12/2021
3257	NDA/MAL/HDP/9789	AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD	ROYAL PHARMA 2011 LIMITED	NALIDIXIC ACID TABLETS BP 500 MG	NALIDIXIC ACID	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	10/12/2021

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3258	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	10/12/2021
3259	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	10/12/2021
3260	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	10/12/2021

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3261	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	10/12/2021
3262	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	10/12/2021
3263	NDA/MAL/HDP/9795	INOSAN BIOPHARMA, S.A.	LABOREX UGANDA LIMITED	INOSERP	POLYVALENT F(AB') ₂ IMMUNOGLOBULIN FRAGMENTS (EQUINE) - SNAKE ANTIVENOM	1000MG/VIAL	VETERIA LABS S.A. (INOSAN BIOPHARMA S.A.)- LUCERNA, PLOT NO.7.COL - JUAREZ CP 06600,DEL CUAUHTEMOC MEXICO D.F, MEXICO	MEXICO	PARENTERAL RETARD DRY VIALS	1.0X1.0 VIAL PACK	10/12/2021

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3264	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	10/12/2021
3265	NDA/MAL/HDP/9797	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	TRAMASURE-100	TRAMADOL HYDROCHLORIDE	100 MG/2ML	MANKIND PHARMA LTD.- VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X4.0X2.0 ML AMPOULE	10/12/2021
3266	NDA/MAL/HDP/9798	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OZOLAMIDE	DORZOLAMIDE HYDROCHLORIDE	22.26 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 BOTTLE	10/12/2021

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3267	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	10/12/2021
3268	NDA/MAL/HDP/9800	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYDALIS 10	TADALAFIL	10MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	10/12/2021
3269	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	10/12/2021

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3270	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	10/12/2021
3271	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	10/12/2021
3272	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	10/11/2021

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3273	NDA/MAL/HDP/9805	INTERNATIONAL PARTNERSHIP FOR MICROBICIDES (IPM) SOUTH AFRICA NPC INDUSTRIES COMPANY	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DAPIRING	DAPIVIRINE	25MG/RING	QPHARMA AB- AGNESLUNDSVAGEN 27, MALMO, 21215 - SWEDEN	SWEDEN	VAGINAL OTHER SPECIAL FORMS	1.0X1.0X52.0 MG RING	10/12/2021
3274	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	10/11/2021
3275	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	1.0X12.0X10.0 ML PRE-FILLED SYRINGE	10/11/2021

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3276	NDA/MAL/HDP/9808	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LIPIGET	ATORVASTATIN	10MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	9/29/2021
3277	NDA/MAL/HDP/9809	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	REVENTA	ALENDRONATE SODIUM	70MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	9/29/2021
3278	NDA/MAL/HDP/9810	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAST SODIUM	4MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X1.0X7.0X2.0 TABLET BLISTER	9/29/2021

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3279	NDA/MAL/HDP/9811	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	GETRYL	GLIMEPIRIDE	2MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0X10.0 TABLET BLISTER	9/29/2021
3280	NDA/MAL/HDP/9812	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	GETRYL	GLIMEPIRIDE	3MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0X10.0 TABLET BLISTER	9/29/2021
3281	NDA/MAL/HDP/9813	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	GETRYL	GLIMEPIRIDE	1MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0X10.0 TABLET BLISTER	9/29/2021

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3282	NDA/MAL/HDP/9814	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ZOLID	PIOGLITAZONE	15MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	9/29/2021
3283	NDA/MAL/HDP/9815	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	ADVANT	CANDESARTAN	8MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/29/2021
3284	NDA/MAL/HDP/9816	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	AMLO	AMLODIPINE	5MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/29/2021

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3285	NDA/MAL/HDP/9817	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LARINEX	DES Loratidine	5MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	9/29/2021
3286	NDA/MAL/HDP/9818	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC / MISOPROSTOL	75MG/200MG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/29/2021
3287	NDA/MAL/HDP/9819	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	CYTOPAN	DICLOFENAC SODIUM + MISOPROSTOL	50MG + 200MCG	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	9/29/2021

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3288	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	10/11/2021
3289	NDA/MAL/HDP/9821	JERUSALEM PHARMACEUTICAL S CO. LIMITED	GAMA PHARMACEUTICALS (U) LIMITED	FRINASE NASAL SPRAY	FLUTICASONE PROPIONATE	50 MCG/0.1 ML (ONE ACTUATION)	JERUSALEM PHARMACEUTICALS CO. LTD-AL-BIREH RAMALLAH INDUSTRIAL ZONE, AL- BIREH NABLUS ROAD, P.O. BOX: 3570 PALESTINE	PALESTINE	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X120.0 DOSE CONTAINER	10/11/2021
3290	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	10/11/2021

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3291	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	10/11/2021
3292	NDA/MAL/HDP/9824	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	AVADEX	DEXAMETHASONE SODIUM PHOSPHATE	1 MG/ML	WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	10/11/2021
3293	NDA/MAL/HDP/9825	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	AVALOL	TIMOLOL MALEATE	0.5%W/V	WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	10/11/2021

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3294	NDA/MAL/HDP/9826	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	DEXA NP	DEXAMETHASONE + NEOMYCIN SULPHATE + POLYMYXIN B SULPHATE	(1.0 MG + 3.5 MG + 6000 IU)/ML	WORLD MEDICINE ILAC SAN VE TIC A.S.-15 TEMMUZ MAHALLESİ, CAMI YOLU CADDESİ, NO: 50 K:4 WM PLAZA, GÜNEŞİL-BAGCILAR/İSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	10/11/2021
3295	NDA/MAL/HDP/9827	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CAPEMAX 500	CAPECITABINE	500MG	INTAS PHARMACEUTICALS LTD.-PLOT NO. 457, 458, VILLAGE: MATODA, TAL. SANAND, AHMEDABAD, GUJARAT, 382210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	10/11/2021
3296	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	10/11/2021

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3297	NDA/MAL/HDP/9829	RENATA LIMITED	MARIE STOPES UGANDA LIMITED	WELL-PLAN			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	10/11/2021
3298	NDA/MAL/HDP/9830	GLOBELA PHARMA PVT. LTD.	ROYAL PHARMA 2011 LIMITED	DICLOGLOBE	DICLOFENAC SODIUM	50MG	GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT- 394230,GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	10/11/2021
3299	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	10/11/2021

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3300	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	10/11/2021
3301	NDA/MAL/HDP/9834	ABACUS PARENTERAL DRUGS LTD (APDL)	ABACUS PARENTERAL DRUGS LIMITED	TFEN	KETOTIFEN FUMARATE	0.025%W/V	ABACUS PARENTERAL DRUGS LTD (APDL)-PLOT 114, BLOCK 191, KINGA - MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	12/16/2021
3302	NDA/MAL/HDP/9835	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	METAPROMIDE	METOCLOPRAMIDE HYDROCHLORIDE	10 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	12/16/2021

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3303	NDA/MAL/HDP/9837	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AURODANZ 4	ONDANSETRON HYDROCHLORIDE	4MG	AUROBINDO PHARMA LIMITED UNIT 3-PLOT NO. 313, 314, BACHUPALLY, RR DIST. 500090	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	12/16/2021
3304	NDA/MAL/HDP/9838	AGIO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AZIAGIO 100	AZITHROMYCIN DIHYDRATE	100MG/5ML	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE-411026, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	12/16/2021
3305	NDA/MAL/HDP/9839	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVIR AND LAMIVUDINE TABLETS 50 MG / 300 MG	DOLUTEGRAVIR SODIUM + LAMIVUDINE	50 MG + 300 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	1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET CONTAINER	12/16/2021

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3306	NDA/MAL/HDP/9840	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	SANDOZ® CAPECITABINE 150MG	CAPECITABINE	150MG	HETERO LABS LIMITED (UNIT VI)-APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301 SALUTAS PHARMA GMBH-OTTO-VON- GUERICKE ALLEE-1, 39179 BARLEBEN	AUSTRIA INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	12/16/2021
3307	NDA/MAL/HDP/9841	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	SANDOZ® CAPECITABINE 500MG	CAPECITABINE	500MG	HETERO LABS LIMITED (UNIT VI)-APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301 SALUTAS PHARMA GMBH-OTTO-VON- GUERICKE ALLEE-1, 39179 BARLEBEN	GERMANY INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	12/16/2021
3308	NDA/MAL/HDP/9842	LABORATOIRE AGUETTANT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ADRENALINE AGUETTANT	ADRENALINE TARTRATE	1MG/10ML	LABORATOIRE AGUETTANT- 1 RUE ALEXANDER FLEMING 69007, LYON - FRANCE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X10.0 ML SYRINGE	12/16/2021

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3309	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	12/16/2021
3310	NDA/MAL/HDP/9844	RUSAN PHARMA LTD	NORVIK ENTERPRISES LIMITED	FENSTUD	FENTANYL CITRATE	100MCG/2ML	RUSAN PHARMA LTD- KHASRA NO. 122MI, CENTRAL HOPE TOWN, BEHIND PHARMA CITY, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X10.0 ML AMPOULE	12/16/2021
3311	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	12/16/2021

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3312	NDA/MAL/HDP/9846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	400MG + 320MG	GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT-394230,GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X9.0 TABLET BLISTER	12/16/2021
3313	NDA/MAL/HDP/9847	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICALS (U) LIMITED	PROCTOHEAL NEW® SUPPOSITORIES	LIDOCAINE HYDROCHLORIDE + FLUOCINOLONE ACETONIDE	40.0 MG + 0.1MG	DAR AL DAWA-NA'UR – PRINCE HASHEM BIN AL-HUSSEIN STREET P.O. BOX 9364 AMMAN 11191 JORDAN	JORDAN	SUPPOSITORIES	1.0X2.0X10.0 SUPPOSITORY BLISTER	12/16/2021
3314	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	12/16/2021

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3315	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), TSIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0X0.8 ML SYRINGE	12/16/2021
3316	NDA/MAL/HDP/9850	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZEDGRA 50	SILDENAFIL CITRATE	50 MG	ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY STATION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	12/16/2021
3317	NDA/MAL/HDP/9851	INJECTCARE PARENTERALS PVT. LTD	REDDYS PHARMA LIMITED	INJZATHINE	BENZATHINE BENZYL PENICILLIN	2400000 IU/VIAL	INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X2.0 G VIAL	12/16/2021

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3318	NDA/MAL/HDP/9852	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	IRNIZET 500	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	500MG/25ML	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	1.0X1.0X25.0 ML VIAL	12/16/2021
3319	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	12/16/2021
3320	NDA/MAL/HDP/9856	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM DISPERSIBLE	ARTEMETHER + LUMEFANTRINE	20MG +120MG	S KANT HEALTHCARE LIMITED-1802 – 1805, G.I.D.C., PHASE III, VAPI - 396195 GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X6.0 TABLET BLISTER	12/16/2021

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3321	NDA/MAL/HDP/9857	SQUARE PHARMACEUTICAL S LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	ANLEPTIC	CARBAMAZEPINE	100 MG/5 ML	SQUARE PHARMACEUTICALS LTD.- SQUARE ROAD SALGARIA PABNA	BANGLADESH	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	12/16/2021
3322	NDA/MAL/HDP/9858	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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	12/16/2021
3323	NDA/MAL/HDP/9859	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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	12/16/2021

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3324	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	12/16/2021
3325	NDA/MAL/HDP/9861	MEDICAMEN ORGANICS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	FERROUS SULFATE + FOLIC ACID TABLETS	FERROUS SULFATE + FOLIC ACID	200 MG + 0.4 MG	MEDICAMEN ORGANICS LIMITED-PLOT NO. 60, SECTOR -6A, IIE, SIDCUL, RANIPUR, HARIDWAR-249403 (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X5.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	12/16/2021
3326	NDA/MAL/HDP/9862	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	DERMASOL-N CREAM	CLOBETASOL PROPIONATE + NEOMYCIN SULFATE + NYSTATIN	(0.5 MG + 5 MG + 100,000 UNITS)/ GRAM	SQUARE PHARMACEUTICALS LTD.- SQUARE ROAD SALGARIA PABNA	BANGLADESH	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	12/16/2021

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3327	NDA/MAL/HDP/9864	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 400 MG / 300 MG / 300 MG	EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	400MG+300MG+300MG	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	1.0X90.0 TABLET BOTTLE, 1.0X30.0 TABLET BOTTLE	12/21/2021
3328	NDA/MAL/HDP/9865	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	PINFOL	FOLIC ACID	5MG	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	12/21/2021
3329	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)-PRIORITY STREET, WARE, SG12 ODJ	SPAIN UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	12/21/2021

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3330	NDA/MAL/HDP/9867	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.	ASTRA PHARMA (U) LIMITED	CEFTRIAZONE	CEFTRIAZONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD- NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	12/21/2021
3331	NDA/MAL/HDP/9868	PHARMA BAVARIA INTERNACIONAL PORTUGAL	GOODMAN INTERNATIONAL LTD	CADEN 6MG/2ML	ADENOSINE	6MG/2ML	GETZ PHARMA (PVT) LIMITED-29, 30, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI-74900	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0X6.0X2.0 ML VIAL	12/21/2021
3332	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	12/21/2021

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3333	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	12/21/2021
3334	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	12/21/2021
3335	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	12/21/2021

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3336	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	12/21/2021
3337	NDA/MAL/HDP/9874	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OCTANATE 500 IU	HUMAN COAGULATION FACTOR VIII	500IU PER VIAL	OCTAPHARMA DESSAU GMBH-OTTO-REUTER-STR.3 06847 DESSAU, ROSSLAU	GERMANY SWEDEN	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 I.U VIAL + 1*5ML APOULE OF WATER FOR INJECTION + 1 SYRINGE + 1 TRANSFER SET + 1 INFUSION SET + 2 ALCOHOL SWABS	12/21/2021
3338	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		12/21/2021

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3339	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	12/21/2021
3340	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, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	12/21/2021
3341	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, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X2.5 ML BOTTLE	12/21/2021

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3342	NDA/MAL/HDP/9879	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	AMILAB-500	AMIKACIN SULFATE	500MG/2 ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL	12/21/2021
3343	NDA/MAL/HDP/9880	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	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	12/21/2021
3344	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	12/21/2021

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3345	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	12/21/2021
3346	NDA/MAL/HDP/9884	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	FOLILAB	FOLIC ACID,	5MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/21/2021
3347	NDA/MAL/HDP/9885	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BECLOCORT	BECLOMETHASONE DIPROPIONATE	50MCG/METE RED DOSE	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	NASAL TOPICAL METERED-DOSE LIQUIDS	1.0X1.0X30.0 ML BOTTLE	12/21/2021

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3348	NDA/MAL/HDP/9887	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	FOLIC ACID 5 MG TABLETS	FOLIC ACID	5MG	AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/21/2021
3349	NDA/MAL/HDP/9888	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	GLOMET 200	METRONIDAZOLE	200MG	GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT-394230,GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	12/21/2021
3350	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	12/21/2021

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3351	NDA/MAL/HDP/9893	SUPREME PHARMA HEALTHCARE PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-BROLEX	AMBROXOL HYDROCHLORIDE + SALBUTAMOL SULFATE + GUAIFENESIN	30MG+2MG+50MG/5ML	SAI MIRRA INNOPHARM PVT LIMITED -288&299, SIDCO ESTATE AMBTUR, CHENNAI 600098	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	12/11/2021
3352	NDA/MAL/HDP/9894	R.N. LABORATORIES PVT LTD	NORVIK ENTERPRISES LIMITED	IODOSHIELD 10 %	POVIDONE -IODINE	10%W/V	R.N. LABORATORIES PVT. LIMITED-PLOT NO. 1 & 86 DIAMOND PARK, SURSEZ, SACHIN, SURAT, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE	12/30/2021
3353	NDA/MAL/HDP/9895	R.N. LABORATORIES PVT LTD	NORVIK ENTERPRISES LIMITED	BACTOSHIELD 4% SOAP SOLUTION	CHLORHEXIDINE GLUCONATE	4%W/V	R.N. LABORATORIES PVT. LIMITED-PLOT NO. 1 & 86 DIAMOND PARK, SURSEZ, SACHIN, SURAT, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	12/30/2021

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3354	NDA/MAL/HDP/9896	R.N. LABORATORIES PVT LTD	NORVIK ENTERPRISES LIMITED	BACTOSHIELD 5%	CHLORHEXIDINE GLUCONATE	5%W/V	R.N. LABORATORIES PVT. LIMITED-PLOT NO. 1 & 86 DIAMOND PARK, SURSEZ, SACHIN, SURAT, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	12/30/2021
3355	NDA/MAL/HDP/9897	MEDOPHARM	PLANET PHARMACEUTICALS UGANDA LTD	CO-TRIMOXAZOLE TABLETS BP	TRIMETHOPRIM + SULPHAMETHOXAZOLE	400MG + 80MG	MEDOPHARM PVT LTD. -50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	12/11/2021
3356	NDA/MAL/HDP/9899	MEDICAL UNION PHARMACEUTICAL S.	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	12/11/2021

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3357	NDA/MAL/HDP/9900	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	TELMA 20	TELMISARTAN	20MG	GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. S - 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA	NULL	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	12/11/2021
3358	NDA/MAL/HDP/9901	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	LOS ANGIO-H	LOSARTAN POTASSIUM + HYDROCHLOROTHAZIDE	50MG + 12.5MG	ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHVAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	12/11/2021
3359	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	12/21/2021

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3360	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	12/11/2021
3361	NDA/MAL/HDP/9904	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLEDOMOX 228.5 DT	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200 MG + 28.5 MG	MEDOPHARM PVT LTD. -50, KAYARAMBEDU VILLAGE, GUDUVANCHERY VILLAGE, 603 203	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X2.0X10.0 TABLET STRIP	12/11/2021
3362	NDA/MAL/HDP/9905	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL H 10/6.25	BISOPROLOL FUMARATE + HYDROCHLOROTHIAZIDE	10MG +6.25 MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021

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3363	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	12/11/2021
3364	NDA/MAL/HDP/9907	ZEN PHARMA (P) LTD.	EUROPA HEALTHCARE (U) LTD	ONDAZEN	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG/4ML	ZEN PHARMA PVT LTD- 75/1, GIDC. VAPI-396 195 GUJARAT,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE	12/11/2021
3365	NDA/MAL/HDP/9908	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ABISART HCTZ 150/12.5	IRBESARTAN + HYDROCHLOROTHIAZIDE	150 MG +12.5 MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021

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3366	NDA/MAL/HDP/9909	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ABISART HCTZ 300/12.5	IRBESARTAN + HYDROCHLOROTHAZIDE	300 MG +12.5 MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021
3367	NDA/MAL/HDP/9910	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ABISART HCTZ 300/25	IRBESARTAN + HYDROCHLOROTHAZIDE	300 MG+25 MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021
3368	NDA/MAL/HDP/9911	THE UNITED PHARMACEUTICAL S MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BISOPROLOL® 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	12/11/2021

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3369	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	12/11/2021
3370	NDA/MAL/HDP/9914	SQUARE PHARMACEUTICALS LTD.	GAMA PHARMACEUTICALS (U) LIMITED	MUCOSPEL	BROMHEXINE HYDROCHLORIDE	4MG/5ML	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	12/11/2021
3371	NDA/MAL/HDP/9915	ZIM LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	TELCARD 80 H	TELMISARTAN + HYDROCHLOROTHIAZIDE	80 MG + 12.5 MG	ZIM LABORATORIES LIMITED-B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021

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3372	NDA/MAL/HDP/9916	SYREN HEALTHCARE	ROYAL PHARMA 2011 LIMITED	ROFLOXIN 200	OFLOXACIN	200MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/11/2021
3373	NDA/MAL/HDP/9917	SYREN HEALTHCARE	ROYAL PHARMA 2011 LIMITED	ROFLOXIN 400	OFLOXACIN	400MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	12/11/2021
3374	NDA/MAL/HDP/9918	GLENMARK PHARMACEUTICAL S LTD	STAR PHARMACEUTICALS LTD	POWERCORT	CLOBETASOL PROPIONATE	0.05% W/W	GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE, 1.0X1.0X30.0 G TUBE	12/11/2021

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3375	NDA/MAL/HDP/9919	TAKEDA PHARMA A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NINLARO 4MG	IXAZOMIB	4MG	HAUPT PHARMA AMAREG GMBH-DONAUSTAUFER STRASSE 378, 93055 REGENSBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X1.0 CAPSULE BLISTER	12/30/2021
3376	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	12/11/2021
3377	NDA/MAL/HDP/9921	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	SONATEC MOUTHWASH MENTHOL BREEZE	CETYLPYRIDINIUM CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTD -PLOT NO. 7879/18, OFF BABA DOGO ROAD, RUARAKA - NAIROBI	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	12/30/2021

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3378	NDA/MAL/HDP/9922	CIPLA LTD.	QUALITY CHEMICALS LTD	PALONOSETRON HYDROCHLORIDE INJECTION	PALONOSETRON HYDROCHLORIDE	0.25MG/5ML	CIPLA LTD-M-61, M-62 & M-63, VERNA INDUSTRIAL ESTATE VERNA GOA,INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	12/11/2021