

NATIONAL DRUG REGISTER OF UGANDA HUMAN MEDICINES MARCH 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
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,1.0 X2.0X5.0X2.0 ML AMPOULE	7/1/2013
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
9	NDA/MAL/HDP/0031	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFTATIME-SB 1.5	CEFTRIAXONE +SULBACTAM	1000MG+500 MG	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/0041	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECIM	CIMETIDINE	200MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2013

11	NDA/MAL/HDP/0045	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL CAPLETS	PARACETAMO L	500MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2007
12	NDA/MAL/HDP/0051	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL ACUPHASE	ZUCLOPENTH IXOL ACETATE	50MG/ML	H. LUNDBECK A/S - OTTILIAVEJ 9,2500 VALBY	DENMARK	PARENTERA L ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	7/1/2015
13	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

14	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	PARENTERA L RETARD AMPOULES	1.0X1.0 ML AMPOULE	7/1/2015
15	NDA/MAL/HDP/0054	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	FUNGOAL	CLOTRIMAZOL E	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
16	NDA/MAL/HDP/0055	H.LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL DEPOT	ZUCLOPENTH IXOL DECANOATE	200MG/ML	H. LUNDBECK A/S ,,- OTTILIAVEJ 9, DK- 2500, VALBY- COPENHAGEN	DENMARK	PARENTERA L ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	7/1/2015

17	NDA/MAL/HDP/0056	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR QPS	DICLOFENAC	4%W/V	TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA-382728, GUJARAT, INDIA TROIKAA PHARMACEUTICALS LTD-BLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST.	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	7/1/2015
18	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
19	NDA/MAL/HDP/0059	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	VAGIBACT CREAM	CLINDAMYCIN PHOSPHATE	2%W/W	NABIQASIM INDUSTRIES (PVT) LTDV-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI-PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE + 1 APPLICATOR	7/1/2006

20	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,	SWITZERLAND ITALY	PARENTERA L ORDINARY PRE-FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION	7/1/2015
21	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
22	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,	SWITZERLAND	PARENTERA L ORDINARY CARTRIDGES	1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION	7/1/2015

23	NDA/MAL/HDP/0069	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATI N	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
24	NDA/MAL/HDP/0070	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATI N	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
25	NDA/MAL/HDP/0073	NAARI LTD	PHARMA VILLE LIMITED	FASILE-ONE	LEVONORGEST REL TABLETS BP	1.5MG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16, 55- 57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	7/1/2013

26	NDA/MAL/HDP/0077	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	X-SONE	DEXAMETHASONE SODIUM PHOSPHATE	0.1 % W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	7/1/2015
27	NDA/MAL/HDP/0079	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	REVOKE 72	LEVONORGESTREL	750MCG	MYLAN LABORATORIES LIMITED...PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	7/1/2014
28	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	2.7MG+0.52MG+0.58MG+0.30MG+20MG PER 200ML, 6.75MG+1.30MG+1.45MG+0.75MG+20MG PER 500ML SACHET, 13.5MG+2.60MG+2.90MG+1.50MG+20MG	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

29	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
30	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
31	NDA/MAL/HDP/0101	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTETRA CAPSULES	TETRACYCLINE HYDROCHLORIDE	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE	7/1/1998

32	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
33	NDA/MAL/HDP/0103	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	ATOREM 20	ATORVASTATI N	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
34	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

35	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,1.0X5 00.0 TABLET CONTAINER,1. 0X100.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER	7/1/1998
36	NDA/MAL/HDP/0107	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ASUNRA	DEFERASIROX	400MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERTRASS E	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER	7/1/2015
37	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

38	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
39	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 SCHAFFHAUSERTRASS E 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
40	NDA/MAL/HDP/0114	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY 4	MONTELUKAS T 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

41	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
42	NDA/MAL/HDP/0117	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 1.5G	CEFUROXIME SODIUM	1.5G	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205 SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL + 1 AMPOULE OF WFI	7/1/2013
43	NDA/MAL/HDP/0118	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 750MG	CEFUROXIME SODIUM	750MG	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205 SANCE LABORATORIES PVT LTD-VI/51B, P.B. NO.2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL + 1 AMPOULE WFI	7/1/2013

44	NDA/MAL/HDP/0119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+ CHLORPHENIR AMINE MALEATE+PAR ACETAMOL+P SEUDOEPHED RINE	30MG+4MG+4 00MG+30MG	DAWA LIMITED - BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2013
45	NDA/MAL/HDP/0121	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	BETA HEALTH CARE INTERNATIONAL LIMITED/-PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	TANZANIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2015
46	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2015

47	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
48	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
49	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

50	NDA/MAL/HDP/0135	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	HEMOVIT SYRUP	IRON + FOLIC ACID + PYRIDOXINE + CYANOCOBAL AMIN + ZINC	200MG + 1.5MG + 0.5MG + 50 MCG + 2.33MG	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD SHELYS PHAMACEUTICALS LTD .-NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2013
51	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
52	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 SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/1998

53	NDA/MAL/HDP/0152	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	RYCARDON 150	IRBESARTAN	150MG	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	
54	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	
55	NDA/MAL/HDP/0155	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ASTHATOR 10	MONTELUKAS T 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

56	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
57	NDA/MAL/HDP/0162	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETH ORPHAN 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
58	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

59	NDA/MAL/HDP/0164	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENPRESS	PROPRANOLOL	40MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2014
60	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
61	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

62	NDA/MAL/HDP/0167	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TOLANZ 10	OLANZAPINE ORODISPERSIB LE TABLETS	10MG	TORRENT PHARMACEUTICALS LTD .,-AHMEDABAD- MEHSANA HIGHWAY, TALUKA- KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRA TING TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
63	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
64	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

65	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
66	NDA/MAL/HDP/0186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+ BENZYDAMINE +CATALKONIUM CHLORIDE	1.5%W/V+0.1 5%W/V+0.041 3%W/V	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE	7/1/2014
67	NDA/MAL/HDP/0187	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON TABLET	TRANEXAMIC ACID	500 MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2014

68	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2013
69	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
70	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

71	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 ADMINISTR ATION CFC- FREE METERED- DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	7/1/2015
72	NDA/MAL/HDP/0204	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY	DOLUTEGRAVI R 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
73	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

74	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	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	7/10/2013
75	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
76	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

77	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 SUSPENSION S	1.0X120.0 ML BOTTLE	7/1/2012
78	NDA/MAL/HDP/0217	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	PALETHET	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	PARENTERA L ORDINARY I M AMPOULES	2.0X3.0X1.0 ML AMPOULE	7/1/2014
79	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

80	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
81	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
82	NDA/MAL/HDP/0233	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	CEFIMED 400	CEFIXIME TRIHYDRATE	400MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOUS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	7/1/2014

83	NDA/MAL/HDP/0234	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	CEFIMED 200	CEFIXIME TRIHYDRATE	200MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X8.0 TABLET BLISTER,1.0X2. 0X5.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2014
84	NDA/MAL/HDP/0235	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	7/1/2014
85	NDA/MAL/HDP/0239	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 140	ARTEMETHER + LUMEFANTRIN E	20 MG+ 120 MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X3.0 TABLET BLISTER,1.0X1 8.0 TABLET BLISTER,1.0X2 4.0 TABLET BLISTER,1.0X6. 0 TABLET BLISTER,1.0X2. 0X6.0 TABLET BLISTER	7/1/2014

86	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
87	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
88	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

89	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
90	NDA/MAL/HDP/0252	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VAST-40	ATORVASTATI N	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
91	NDA/MAL/HDP/0253	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TENLOW-5	AMLODIPINE BESYLATE	5MG	LINCO N PHARMACEUTICALS LIMITED-TRIMUL ESTATE KHATRAJ KALOL GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

92	NDA/MAL/HDP/0254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARA TE	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
93	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(WORKSH OP 406 AND 407)	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	7/1/2001
94	NDA/MAL/HDP/0269	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMISTAT-8	ONDANSETRO N	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

95	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,1.0X1 0.0 TABLET BLISTER	7/1/2001
96	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 KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X10.0 ML AMPOULE,1.0 X24.0X10.0 ML AMPOULE,1.0 X5.0 ML VIAL (10 DOSES)	7/1/2001
97	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

98	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
99	NDA/MAL/HDP/0278	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMA ZINE TABLETS B.P 100MG	CHLORPROMA ZINE HYDROCHLORI DE	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,1 0.0X10.0 TABLET BLISTER	7/1/1998
100	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2013

101	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
102	NDA/MAL/HDP/0290	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	NATOA	MEBENDAZOL E	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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/1997
103	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

104	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
105	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 SUSPENSION S/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	7/1/2013
106	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

107	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
108	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
109	NDA/MAL/HDP/0311	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	FENTANYL	FENTANYL CITRATE	50MCG/ML	MARTINDALE PHARMACEUTICAL LIMITED -BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2013

110	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2013
111	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,RM3 844	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2013
112	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

113	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
114	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
115	NDA/MAL/HDP/0322	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2009

116	NDA/MAL/HDP/0326	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	OSTEBON	CALCIUM + COLECALCIFER OL	250MG + 125 IU	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X200.0 ML BOTTLE	7/1/2014
117	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2014
118	NDA/MAL/HDP/0331	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVOKILZ 500	LEVOFLOXACI N	500MG	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 TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2014

119	NDA/MAL/HDP/0333	KOPRAN LIMITED	TATA UGANDA LIMITED	CLAVAMYN-625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG +125MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA-KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2014
120	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
121	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

122	NDA/MAL/HDP/0339	IND-SWIFT	PLANET PHARMACEUTICALS UGANDA LTD	SWAZI *250	AZITHROMYCI N	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
123	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
124	NDA/MAL/HDP/0341	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 40	TELMISARTAN + HYDROCHLOR OTHIAZIDE	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

125	NDA/MAL/HDP/0342	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	TELSWIFT- H 80	TELMISARTAN + HYDROCHLOR OTHIAZIDE	80MG + 12.5MG	IND SWIFT LTD- GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,3.0X1 0.0 TABLET BLISTER	7/1/2014
126	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
127	NDA/MAL/HDP/0348	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA	BETAMETHAS ONE SODIUM PHOSPHATE	0.1%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMI C DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	7/1/2015

128	NDA/MAL/HDP/0349	SWISS PARENTERALS PVT LTD	SHREEJI CARE LIMITED	CLAXY 1.2 G	COAMOXICLA V	1.2G	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.2 G VIAL	7/1/2013
129	NDA/MAL/HDP/0350	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CETIREN	CETIRIZINE HYDROCHLORI DE	10MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2015
130	NDA/MAL/HDP/0351	MANKIND PHARM LTD	TATA UGANDA LIMITED	DEPREGDINA	LEVONORGEST REL	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

131	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
132	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 INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2015
133	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

134	NDA/MAL/HDP/0358	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	STREPTOCIN	STREPTOMYCIN SULPHATE	1GM	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY IM VIALS	1.0X1.0 G VIAL	7/1/2014
135	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
136	NDA/MAL/HDP/0362	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	BUPI	BUPIVACAINE	5 MG/ML	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	7/1/2015

137	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
138	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
139	NDA/MAL/HDP/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2010

140	NDA/MAL/HDP/0372	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEZYNCET	LEVOCETIRIZIN E	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
141	NDA/MAL/HDP/0373	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	TEMELIN	CETIRIZINE HYDROCHLORI DE	10MG	MEDOCHEMIE 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
142	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

143	NDA/MAL/HDP/0376	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-D	AMLODIPINE + HYDROCHLOR OTHIAZIDE	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
144	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
145	NDA/MAL/HDP/0382	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	KETAMINE FRESENIUS	KETAMINE HYDROCHLORI DE	50MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERA L ORDINARY VIALS	1.0X10.0X10.0 ML VIAL	7/1/2014

146	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	PARENTERA L ORDINARY INFUSION BAGS	1.0X500.0 ML BAG	7/1/2014
147	NDA/MAL/HDP/0386	EMCURE PHARMACEUTICALS 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	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	7/1/2014
148	NDA/MAL/HDP/0388	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP,1.0X250 .0 CAPSULE CONTAINER,1. 0X1000.0 CAPSULE CONTAINER,1. 0X500.0 CAPSULE CONTAINER,1. 0X100.0X10.0 CAPSULE	7/1/1997

149	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
150	NDA/MAL/HDP/0397	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-LT	AMLODIPINE + LOSARTAN POTASSIUM	2.5 MG + 50 MG	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0X10.0 TABLET BLISTER	7/1/2013
151	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

152	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
153	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
154	NDA/MAL/HDP/0407	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	NEOROF	PROPOFOL	1%W/V	NEON LABORATORIES LTD - PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	7/1/2013

155	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
156	NDA/MAL/HDP/0409	NEON LABORATORIES LTD.	NORVIK ENTERPRISES LIMITED	TYDE-S*	CHLORAMPHE NICOL 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
157	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

158	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
159	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
160	NDA/MAL/HDP/0415	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRAMINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SODIUM CITRATE+MENTHOL	14.03MG+138MG+57.03MG+0.90MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997

161	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
162	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
163	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

164	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,1.0X1 00.0X10.0 CAPSULE BLISTER	7/1/2013
165	NDA/MAL/HDP/0424	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMA ZINE TABLETS B.P 25MG	CHLORPROMA ZINE	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,1 0.0X10.0 TABLET BLISTER	7/1/1998
166	NDA/MAL/HDP/0427	MICRO LABS LTD	LABOREX UGANDA LIMITED	AMLOZAAR -H	LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOR OTHIAZIDE	50MG + 5MG + 12.5MG	MICRO LABS LTD ...- 57, SIPCOT INDUSTRIAL COMPLEX, HOSUR- 635126, TAMIIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2015

167	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
168	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
169	NDA/MAL/HDP/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC +PARACETAMOL	100MG+500MG	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP- 462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X15.0X10.0 TABLET BLISTER	7/1/2013

170	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
171	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
172	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

173	NDA/MAL/HDP/0437	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL NEONATAL FRESENIUS	NALOXONE HYDROCHLORI DE	0.02MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2014
174	NDA/MAL/HDP/0439	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL FRESENIUS 0.4MG/1ML	NALOXONE HYDROCHLORI DE	0.4MG/1ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2015
175	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

176	NDA/MAL/HDP/0444	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	NEOSTIGMINE METHYLSUIPH ATE FRESENIUS	NEOSTIGMINE METHYLSULPH ATE	2.5MG\ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2015
177	NDA/MAL/HDP/0449	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD GRANULES	CYANOCOBAL AMIN	5MCG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C- 4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X10.0X5.0 G SACHET	7/1/2013 0:00
178	NDA/MAL/HDP/0453	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD LIQUID	AMINO ACIDS + MULTIVITAMI NS	MULTI INGREDIENTS	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C- 4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	7/1/2013 0:00

179	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
180	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
181	NDA/MAL/HDP/0460	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE	7/1/2009

182	NDA/MAL/HDP/0463	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TOPHEN	PHENYTOIN	100MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 00.0 CAPSULE CONTAINER,1. 0X100.0X10.0 CAPSULE BLISTER	7/1/2011
183	NDA/MAL/HDP/0467	DAWA PHARMACEUTICALS LIMITED	SUPER MEDIC LTD	CURAMOL PLUS	PARACETAMO L/CAFFEINE	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
184	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	DENMARK	PARENTERA L ORDINARY DRY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	7/1/2014

185	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	DENMARK	PARENTERA L ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	7/1/2014
186	NDA/MAL/HDP/0472	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	BCG VACCINE (FREEZE DRIED)	BCG VACCINE(FREE ZE DRIED)	1.33*100000 C.F.U/0.1ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 ML VIAL,1.0X0.5 ML VIAL	7/1/2015
187	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

188	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
189	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
190	NDA/MAL/HDP/0483	FOUNTIL LIFE SCIENCES PVT LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID TABLETS	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE+ MAGNESIUM TRISILICATE + SIMETICONE	200MG + 250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET STRIP	7/1/2013 0:00

191	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
192	NDA/MAL/HDP/0491	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EYE DROPS	CHLORAMPHE NICOL	0.5% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL	7/1/2013
193	NDA/MAL/HDP/0497	LABORATORY&ALLIED 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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2014

194	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	SLOVENIA AUSTRIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	7/1/2014
195	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
196	NDA/MAL/HDP/0506	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	OPTA-ATROPINE EYE DROPS	ATROPINE SULPHATE	1%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0x10.0 ML VIAL	7/1/2001

197	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
198	NDA/MAL/HDP/0518	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CYCLOREN	ACICLOVIR	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2006
199	NDA/MAL/HDP/0521	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PAN 40	PANTOPRAZO LE 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

200	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
201	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
202	NDA/MAL/HDP/0531	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	ENDERM-GM	CLOBETASOL PROPIONATE + GENTAMYCIN + MICONAZOLE NITRATE	0.05%W/W + 0.10%W/W + 2.0%W/W	LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	

203	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
204	NDA/MAL/HDP/0540	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	HYDRICORT	HYDROCORTISONE SODIUM SUCCINATE	100MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	7/1/2014
205	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

206	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
207	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
208	NDA/MAL/HDP/0544	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

209	NDA/MAL/HDP/0547	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MISO-KARE	MISOPROSTOL	200MCG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16 &55- 57, SECTOR-5, IIE, PANTNAGAR, RUDRAPUR-263153, DIST. U.S. NAGAR, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER (COMBIPACK), 1.0X3.0X4.0 TABLET BLISTER	7/1/2013
210	NDA/MAL/HDP/0548	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAS T	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
211	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,1.0X1 000.0 TABLET CONTAINER	7/1/2014

212	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
213	NDA/MAL/HDP/0558	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGENTA EYE DROPS	GENTAMICIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML VIAL	7/1/2014
214	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

215	NDA/MAL/HDP/0563	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	EZO 40	ESOMEPRAZO LE 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
216	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,GUJR AT,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	7/1/2013
217	NDA/MAL/HDP/0568	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUOXIREN	FLUOXETINE	20MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2013

218	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
219	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
220	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

221	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
222	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
223	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

224	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
225	NDA/MAL/HDP/0580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDIENT	MULTINGREDIENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.- PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/1997
226	NDA/MAL/HDP/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC +PARACETAMOL+SERRATIO PEPTIDASE	100MG + 500MG + 15MG	ARISTO PHARMACEUTICALS PVT LTD-VILLAGE: MAKHNUMAJRA P.O. BHUD BADDI DISTRIC: SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2015

227	NDA/MAL/HDP/0584	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 1	GLIMEPIRIDE+ PIOGLITAZONE +METFORMIN HYDROCHLORI DE	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2014
228	NDA/MAL/HDP/0587	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADIGREL	CLOPIDOGREL	75MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
229	NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLON E ACETATE	1%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMI C SUSPENSION S	1.0X5.0 ML BOTTLE	7/1/2013

230	NDA/MAL/HDP/0589	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 2	GLIMEPIRIDE+ PIOGLITAZONE +METFORMIN HYDROCHLORI DE	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2014
231	NDA/MAL/HDP/0592	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCHROM E	CROMOLYN SODIUM	2%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMI C LIQUIDS	1.0X10.0 ML CONTAINER	7/1/2013
232	NDA/MAL/HDP/0593	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PANTOP-D	PANTOPRAZO LE SODIUM SESQUIHYDRA TE + DOMPERIDON E 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,1.0X3.0 X10.0 CAPSULE STRIP	7/1/2014

233	NDA/MAL/HDP/0595	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ORNOF	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2015
234	NDA/MAL/HDP/0596	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN /HYDROCHLO ROTHIAZIDE	40MG/12.5M G	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	1/7/2011
235	NDA/MAL/HDP/0598	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LIPICURE-20	ATORVASTATI N	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2003

236	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,1.0X1 0.0 TABLET BLISTER	7/1/2013
237	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
238	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,1.0X2 00.0 ML BOTTLE	7/1/1999

239	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
240	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
241	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

242	NDA/MAL/HDP/0610	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PYLOR KIT	LANSOPRAZOL E DELAYED RELEASE + CLARITHROMY CIN+ TINIDAZOLE	30MG + 250MG + 500MG	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X7.0X1.0X6 .0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	
243	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
244	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/1998

245	NDA/MAL/HDP/0617	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	SILVEX	SILVER SULFADIAZINE + CHLORHEXIDINE	1%W/W + 0.2%W/W	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2014
246	NDA/MAL/HDP/0619	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D10	GLUCOSE	10%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	7/1/2013
247	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

248	NDA/MAL/HDP/0626	KPI INDUSTRIES(1996) LTD	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
249	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,1.0X2.0 X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2015
250	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

251	NDA/MAL/HDP/0633	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIPROCIN	CIPROFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL,1.0X5.0 ML VIAL	7/1/2013
252	NDA/MAL/HDP/0634	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	TRISOLIV	ANDROGRAPHOLIDES/TRICHOLOLINE 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
253	NDA/MAL/HDP/0635	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-AMIN	AMINOPHYLLINE	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	7/1/2009

254	NDA/MAL/HDP/0637	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ZUDICORT	FUSIDIC ACID + BETAMETHAS ONE 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
255	NDA/MAL/HDP/0638	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABLLO-5 EYE DROPS	TIMOLOL MALEATE	0.5% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	7/1/2013
256	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

257	NDA/MAL/HDP/0643	NAARI LTD	PHARMA VILLE LIMITED	MISOPRO	MISOPROSTOL	200MCG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16, 55-57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	ARGENTINA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER,25.0X1.0X4.0 TABLET BLISTER	7/1/2013
258	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
259	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

260	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
261	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) MAHABOONNAGAR 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
262	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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER	7/1/2013

263	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
264	NDA/MAL/HDP/0668	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TELI 40	TELMISARTAN	40MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
265	NDA/MAL/HDP/0669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXEL FUNGICORT CREAM	MICONAZOLE NITRATE + HYDROCORTIS ONE	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

266	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
267	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,1.0X1 00.0X10.0 TABLET BLISTER	7/1/2013
268	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER	7/1/2013

269	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
270	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
271	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

272	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,1.0X1 00.0X10.0 CAPSULE BLISTER	7/1/2013
273	NDA/MAL/HDP/0681	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ELAXIM 40	TENECTEPLAS E (RECOMBINAN T TISSUE PLASMINOGE N ACTIVATOR)	40MG/VIAL	GENNOVA BIOPHARMACEUTIC ALS LIMITED-BLOCK 1, PLOT NO. P-1 AND P-2, ITBT PARK, PHASE II, MIDC, HINJAWADI, PUNE - 411057	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X40.0 MG VIAL , 1*8 ML VIAL OF WFI	7/1/2013
274	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	PARENTERA L RETARD I M AMPOULES	1.0X5.0X4.0 ML AMPOULE	7/1/2015

275	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
276	NDA/MAL/HDP/0688	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	HBB	HYOSCINE BUTYLBROMID E	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
277	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

278	NDA/MAL/HDP/0690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHEASE CREAM	BECLOMETHA SONE DIPROPRIONA TE + PHENYLEPHRI NE HCL + LIGNOCAINE HCL + CHLOROCRES OL	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
279	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
280	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,1.0X1 000.0 CAPSULE CONTAINER	7/1/2015

281	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,1.0X1 000.0 CAPSULE CONTAINER	7/1/2014
282	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,1.0X1 0.0X10.0 TABLET CARTON	7/1/2013
283	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

284	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
285	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
286	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

287	NDA/MAL/HDP/0703	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	DICLODAY GEL	DICLOFENAC DIETHYLAMIN E+ 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
288	NDA/MAL/HDP/0704	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	M-FLOX	MOXIFLOXACI N HYDROCHLORI DE	400MG	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- UNIT II & III BADDI THE NALAGARH DIST	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X 1.0X5.0 TABLET BLISTER	7/1/2013
289	NDA/MAL/HDP/0705	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ACICLOVIR	ACICLOVIR	5%W/W	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	7/1/2011

290	NDA/MAL/HDP/0706	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 5	ROSUVASTATI N	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
291	NDA/MAL/HDP/0710	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 20	ROSUVASTATI N	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
292	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 SUSPENSION S	1.0X20.0 ML BOTTLE	7/1/1997

293	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
294	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
295	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

296	NDA/MAL/HDP/0718	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-2	GLIMEPIRIDE+ METFORMIN HYDROCHLORI DE	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
297	NDA/MAL/HDP/0719	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 4000	RECOMBINAN T HUMAN ERYTHROPOIE TIN	4000 I.U	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X0.4 ML PRE- FILLED SYRINGE	7/1/2011
298	NDA/MAL/HDP/0720	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 400 DROPS	COLECALCIFER OL	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

299	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
300	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
301	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

302	NDA/MAL/HDP/0727	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELL ADONA DRY EXTRACT+THY MOL+MENTH OL	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
303	NDA/MAL/HDP/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUIN E 25/67.5	ARTESUNATE+ AMODIAQUIN E	25MG+67.5MG	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	7/1/2013
304	NDA/MAL/HDP/0731	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUIN E 50/135	ARTESUNATE + AMODIAQUIN E	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

305	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
306	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
307	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

308	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
309	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
310	NDA/MAL/HDP/0741	MEDOCHEMIE LTD	LABOREX UGANDA 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

311	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
312	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
313	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

314	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
315	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
316	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	1.0X500.0 MG VIAL	7/1/2014

317	NDA/MAL/HDP/0754	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TORAS DENK 10	TORASEMIDE	10MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2015
318	NDA/MAL/HDP/0756	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 100	TOLPERISONE	100MG	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	7/1/2014
319	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	1.0X10.0X10.0 TABLET BLISTER	7/1/2014

320	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
321	NDA/MAL/HDP/0768	FDC LTD	AIVEEN (U) LIMITED	PYRIMON EYE DROP	DEXAMETHAS ONE/CHLORA MPHENICOL	1%W/V + 0.1%W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/1999
322	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

323	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	1.0X3.0X1.0X1 0.0 TABLET BLISTER	7/1/2012
324	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
325	NDA/MAL/HDP/0776	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL TABLETS	PARACETAMO L 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,1.0X1 000.0 TABLET CONTAINER	7/1/1999

326	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
327	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,1.0X5.0X4.0 TABLET BLISTER	7/1/2013
328	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

329	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
330	NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGYDEX	TOBRAMYCIN/ DEXAMETHAS ONE	3MG+1MG/M L	REMINGTON PHARMACEUTICALS (PVT) LTD-18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/2014
331	NDA/MAL/HDP/0795	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMET HYL PENICILLIN POTASSIUM	250MG	MILAN LABORATORIES (INDIA) PVT LTD .- PLOTS 63,67,87,35,36,64,6 5, 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

332	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
333	NDA/MAL/HDP/0798	HETERO LABS LTD	AIVEEN (U) LIMITED	AMLOSIN 10	AMLODIPINE BESILATE	10MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2013
334	NDA/MAL/HDP/0802	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE HCT 5MG/ 160MG/12.5M G	AMLODIPINE + VALSARTAN + HYDROCHLOR OTHIAZIDE	5MG+ 160MG+ 12.5MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSERTRA SSE 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

335	NDA/MAL/HDP/0808	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	ISOFLURANE	ISOFLURANE	250ML	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATION S	1.0X250.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2005
336	NDA/MAL/HDP/0811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
337	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

338	NDA/MAL/HDP/0820	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FIXIME 400MG	CEFIXIME	400MG	NKUNZI PHARMACEUTICALS- 259 DAVIDSON ROAD, WADEVILLEGERMIST ON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER,1.0X1. 0 TABLET BLISTER,1.0X1. 0X10.0 TABLET BLISTER	7/1/2015
339	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
340	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	PARENTERA L ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL,1.0X100. 0X0.5 G VIAL,1.0X10.0 X0.5 G VIAL	7/1/2014

341	NDA/MAL/HDP/0823	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAP TABLETS	TRAMADOL HCL + PARACETAMOL	37.5MG+325 MG	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
342	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
343	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

344	NDA/MAL/HDP/0830	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 25 MCG	LEVOTHYROXI NE 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
345	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,1.0X1 000.0 CAPSULE CONTAINER	7/1/2013
346	NDA/MAL/HDP/0832	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 100MCG	LEVOTHYROXI NE	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

347	NDA/MAL/HDP/0834	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMI-6	DOXYLAMINE SUCCINATE & PYRIDOXINE HYDROCHLORI DE	10MG + 10MG	LINCOLN PHARMACEUTICALS LIMITED.-TRIMUL ESTATE NEAR KHATRAJ CHOKADI KHATRAJ 382721 GHANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X10.0X1.0X 10.0 TABLET BLISTER	7/1/2013
348	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,1.0X1 000.0 TABLET CONTAINER	7/1/2013
349	NDA/MAL/HDP/0836	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CALBONE-500	CALCIUM CARBONATE + COLECALCIFER OL	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	1.0X3.0X1.0X1 0.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2012

350	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
351	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
352	NDA/MAL/HDP/0843	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	COXERIN	CYCLOSERINE	250MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	7/1/2013

353	NDA/MAL/HDP/0845	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	OLEVO-500	LEVOFLOXACIN	500 MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X5.0X1.0X10.0 TABLET BLISTER	7/1/2013
354	NDA/MAL/HDP/0846	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MOXIMAC	MOXIFLOXACIN	400MG	MACLEODS PHARMACEUTICALS LTD--PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER	7/1/2014
355	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

356	NDA/MAL/HDP/0850	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LCT KIT	LANSOPRAZOL E + CLARITHROMY CIN + 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
357	NDA/MAL/HDP/0853	RANBAXY LABORATORIES LTD GOA	STAR PHARMACEUTICALS LTD	BRUSTAN GEL	IBUPROFEN + LEVOMENTHO L	5% W/W+ 3%W/W	RANBAXY LABORATORIES LTD GOA-NO.2 MADKAI INDUSTRIAL ESTATE GOA 403 404	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 G CONTAINER	7/1/2012
358	NDA/MAL/HDP/0854	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-50	BECLOMETAS ONE	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 ADMINISTR ATION METERED- DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	7/1/2013

359	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,1.0X1 0.0 TABLET BLISTER	7/1/2013
360	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
361	NDA/MAL/HDP/0858	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA SWEDEN OPERATIONS- ASTRAZENECA SWEDEN OPERATIONS SE-151 85 SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2001

362	NDA/MAL/HDP/0864	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	PANTIN-40	PANTOPRAZO LE SODIUM	40 MG	HETERO LABS LIMITED UNIT V- APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALL Y 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
363	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X300.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2013
364	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	PARENTERA L ORDINARY VIALS	1.0X2.0X6.0X2 .0 ML VIAL	7/1/2013

365	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	PARENTERA L ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2013
366	NDA/MAL/HDP/0870	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENAD IONE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED-THOL, DIST. MEHSANA-382728, GUJARAT,INDIA	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2010
367	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 AHMEDABAD 382213 GUJARATI NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2009

368	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
369	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 SUSPENSION S	1.0X1.0X170.0 ML BOTTLE	7/1/2007
370	NDA/MAL/HDP/0879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBES FORTE FILM COATED TABLETS	THIAMINE + PYRIDOXINE + CYANOCOBAL AMIN	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

371	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
372	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
373	NDA/MAL/HDP/0889	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	7/1/2012

374	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
375	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
376	NDA/MAL/HDP/0897	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 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

377	NDA/MAL/HDP/0899	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE	CEFTRIAZONE	1G	INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML VIAL WFI	7/1/2013
378	NDA/MAL/HDP/0902	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPINE SR	NIFEDIPINE	20MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2013
379	NDA/MAL/HDP/0906	VIRCHOW HEALTHCARE PVT LTD	LEGIT MEDEQ 2007 LIMITED	IONSIL	SILVER NITRATE	0.2%W/W	VIRCHOW BIOTECH PVT, -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	7/1/2015

380	NDA/MAL/HDP/0911	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HEALACE	RECOMBINAN T 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
381	NDA/MAL/HDP/0914	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	OSTEOTIDE	TERIPARATIDE [RECOMBINAN T HUMAN PARATHYROID HORMONE (1- 34)] INJECTION	250MCG/ML	VIRCHOW BIOTECH PVT LTD -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH	INDIA	PARENTERA L ORDINARY VIALS	1.0X3.0 ML VIAL,1.0X3.0 ML PREFILLED PEN	7/1/2015
382	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

383	NDA/MAL/HDP/0920	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPIROXY 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
384	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, 1.0X2.0 X10.0 TABLET STRIP	7/1/2004
385	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

386	NDA/MAL/HDP/0929	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DUOQUIN	DIHYDROARTE MISININ + PIPERAQUINE PHOSPHATE	40MG +320MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X9.0 TABLET BLISTER,10.0X1.0X8.0 TABLET BLISTER	7/1/2012
387	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
388	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

389	NDA/MAL/HDP/0939	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	ARH	ALPHA -BETA ARTEETHER	150MG /2ML	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE	7/1/2012
390	NDA/MAL/HDP/0940	FEROZSON'S LABORATORIES LTD	HARLEYS UGANDA LIMITED	ESOMEGA 40MG	ESOMEPRAZOLE AS MAGNESSIUM TRIHYDRATE PELLETS	40MG	FEROZSON'S LABORATORIES LTD- AMANGARH- NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER	7/1/2013
391	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

392	NDA/MAL/HDP/0942	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	ARH FORTE	ALPHA -BETA ARTEETHER	225MG/ 3ML	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X3.0 ML AMPOULE	7/1/2012
393	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
394	NDA/MAL/HDP/0952	NEON LABORATORIES LTD.	NORVIK ENTERPRISES LIMITED	EFFECTAL	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

395	NDA/MAL/HDP/0953	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	CIZCAN	CISPLATIN	10MG/10ML	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	7/1/2013
396	NDA/MAL/HDP/0954	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	50MG/20ML	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL RETARD OTHER VIALS	1.0X20.0 ML VIAL	7/1/2013
397	NDA/MAL/HDP/0957	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	LYRED SYRUP	VITAMINE A + VITAMINE E ACETATE + ASCORBIC ACID + SELENIUM + ZINC	2500 IU + 10 IU + 50MG + 35MCG + 3MG	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	7/1/2012

398	NDA/MAL/HDP/0959	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DISPERSIBLE 20/120	ARTEMETHER + LUMEFANTRIN E	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,1.0X3 0.0X6.0 TABLET BLISTER,1.0X3 0.0X12.0 TABLET BLISTER	7/1/2013
399	NDA/MAL/HDP/0963	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD	ARTESUNATE+ AMODIAQUIN E	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
400	NDA/MAL/HDP/0964	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 25 / 67.5	ARTESUNATE + AMODIAQUIN E	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

401	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
402	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
403	NDA/MAL/HDP/0988	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CADITOR 20	ATORVASTATI N	20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013

404	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
405	NDA/MAL/HDP/0995	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	FLUCOMOL	PARACETAMOL + PHENYLEPHRINE HCL + DEXTROMETHORPHAN HBR + CHLORPHENIRAMINE MALEATE	250MG + 5MG + 10MG + 2MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	
406	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

407	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
408	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,1.0 X5.0X2.5 ML AMPOULE	7/1/2012
409	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

410	NDA/MAL/HDP/1006	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRIPRIDE-2	GLIMEPIRIDE + PIOGLITAZONE + METFORMIN	2MG+15MG+5 00MG	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
411	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
412	NDA/MAL/HDP/1009	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY 0.5%	BUPIVACAINE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERA L ORDINARY VIALS	1.0X20.0 ML VIAL	7/1/2012

413	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
414	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	PARENTERA L ORDINARY OTHER VIALS	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	7/1/2013
415	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	7/1/2013

416	NDA/MAL/HDP/1017	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYCLOX	AMPICILLIN/C LOXACILLIN	125MG/125MG	ELYS CHEMICAL INDUSTRIES LIMITED- ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2015
417	NDA/MAL/HDP/1018	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM CHLOR	CHLORAMPHE NICOL	250MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.- PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,1 000.0 CAPSULE CONTAINER,2 50.0 CAPSULE CONTAINER,5 00.0 CAPSULE CONTAINER,1. 0X10.0 CAPSULE CONTAINER	7/1/1997
418	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	1.0X10.0X1.0X 12.0 TABLET BLISTER	7/1/2012

419	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
420	NDA/MAL/HDP/1030	LABORATORIOS SALVAT SA	LABOREX UGANDA LIMITED	MALACUR	DIHYDROARTE MISININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	ELDER PHARMACEUTICALS LTD -PLOT NO. C- 11/1, INDUSTRIAL AREA, SELAQUI, DEHRADUN-248197, UTTRAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X12.0 TABLET BLISTER	7/1/2014
421	NDA/MAL/HDP/1031	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOXIFLOX	MOXIFLOXACI N	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

422	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
423	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
424	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

425	NDA/MAL/HDP/1042	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 80/12.5	TELMISARTAN +HYDROCHLO ROTHIAZIDE	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,1.0X3.0 X10.0 TABLET STRIP	7/1/2013
426	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
427	NDA/MAL/HDP/1047	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 180MG	FEXOFENADIN E	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

428	NDA/MAL/HDP/1048	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 120MG	FEXOFENADIN E	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
429	NDA/MAL/HDP/1049	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVATE	BETAMETHAS ONE 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
430	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER,10.0X 10.0 TABLET BLISTER	7/1/2013

431	NDA/MAL/HDP/1052	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	MICLOGEN	MICONAZOLE NITRATE+CLO BETASOLE PROPIONATE+ GENTAMICIN SULPHATE	2.0%W/W+0.0 5%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
432	NDA/MAL/HDP/1053	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .- PLOTS 63,67,87,35,36,64,6 5, 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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2013
433	NDA/MAL/HDP/1054	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-250	AZITHROMYCI N	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

434	NDA/MAL/HDP/1056	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVATE-N OINTMENT	BETAMETHAS ONE + 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
435	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
436	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2013

437	NDA/MAL/HDP/1065	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM-5	DIAZEPAM	5MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	7/1/2007
438	NDA/MAL/HDP/1067	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PARACETAMOL	200MG+250MG/10ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2010
439	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	1.0X10.0X10.0 X1.0 ML AMPOULE	7/1/2014

440	NDA/MAL/HDP/1071	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/25MG	VALSARTAN + HYDROCHLOR OTHIAZIDE	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
441	NDA/MAL/HDP/1072	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 80/12.5MG	VALSARTAN + HYDROCHLOR OTHIAZIDE	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
442	NDA/MAL/HDP/1076	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST 4MG	MONTELUKAS T 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

443	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
444	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
445	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

446	NDA/MAL/HDP/1082	DAWA LIMITED	SUPER MEDIC LTD	DACOF PAEDIATRIC	DIPHENHYDRA MINE HYDROCHLORI DE + 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
447	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
448	NDA/MAL/HDP/1084	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIR AMINE MALEATE	4MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2013

449	NDA/MAL/HDP/1085	AGIO PHARMACEUTICALS 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
450	NDA/MAL/HDP/1086	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	SYNOGEN TABLETS	DIACEREIN + METHYL SULPHONYL METHANE + GLUCOSAMIN E 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
451	NDA/MAL/HDP/1087	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCYCLINE	TETRACYCLINE	3%W/W	AGOG PHARMA LTD.- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/2013

452	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	PARENTERA L ORDINARY DRY VIALS	1.0X750.0 MG VIAL	7/1/2015
453	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2013
454	NDA/MAL/HDP/1095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R- 635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2012

455	NDA/MAL/HDP/1099	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	MOMATE F CREAM	FUSIDIC ACID+MOMET ASONE 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
456	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
457	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

458	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
459	NDA/MAL/HDP/1107	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDN A) (PAEDIATRIC))	HEPATITIS B VACCINE(RDN A)	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
460	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

461	NDA/MAL/HDP/1111	DAWA LIMITED	SUPER MEDIC LTD	FAST-ACT GEL	DICLOFENAC DIETHYLAMIN E + 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
462	NDA/MAL/HDP/1113	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID- YELLOW	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X400.0 ML BOTTLE,1.0X1 60.0 ML BOTTLE	7/1/1997
463	NDA/MAL/HDP/1114	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/ METHYL SALICYLATE/M ENTHOL/CAPS ICUM 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

464	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	OPHTHALMI C OINTMENTS	1.0X20.0X3.5 G TUBE	7/1/2013
465	NDA/MAL/HDP/1123	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPAR	PARACETAMO L	500 MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 00.0 TABLET CONTAINER	7/1/2012
466	NDA/MAL/HDP/1124	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO SCRUB	CHLORHEXIDI NE 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

467	NDA/MAL/HDP/1128	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BTC KIT	FLUCONAZOLE + AZITHROMYCI N + SECNIDAZOLE	150MG + 1G + 1G	LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COMBINATI ON PACK TABLETS	1.0X4.0 TABLET BLISTER	7/1/2013
468	NDA/MAL/HDP/1130	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	KLARO-500	CLARITHROMY CIN 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	1.0X10.0X1.0X 10.0 TABLET BLISTER	7/1/2012
469	NDA/MAL/HDP/1132	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-CALZ	CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFER OL	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

470	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
471	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,1.0X6 0.0 ML BOTTLE	7/1/2013
472	NDA/MAL/HDP/1139	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVATE	BETAMETHAS ONE	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

473	NDA/MAL/HDP/1140	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVATE-N	BETAMETHAS ONE+NEOMYC IN 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
474	NDA/MAL/HDP/1141	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	CALBONE	CALCIUM CARBONATE + COLECALCIFER OL	250MG+125M G/5ML	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2012
475	NDA/MAL/HDP/1142	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CANDIZOL	CLOTRIMAZOL E	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

476	NDA/MAL/HDP/1143	LINCOLN P'CAL'S 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
477	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
478	NDA/MAL/HDP/1149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	UNIVERSAL CORPORATION LTD...- PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2015

479	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	PARENTERA L ORDINARY DRY VIALS	1.0X30.0 ML VIAL	7/1/2012
480	NDA/MAL/HDP/1155	TRIVENI FORMULATIONS LIMITED	SUPER MEDIC LTD	DOXYCYCLINE	DOXYCYCLINE	100 MG	TRIVENI FORMULATION LTD- PLOT NO.52,53,54,63,62,6 4, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2012
481	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

482	NDA/MAL/HDP/1160	DAFRA PHARMA LTD	MULTIPHAR UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + CLAVULANIC ACID	875MG+125M G	BILIM PHARMACEUTICALS-- CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0 TABLET BLISTER	7/1/2011
483	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
484	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

485	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
486	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	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2010
487	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

488	NDA/MAL/HDP/1169	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	NEBI 5	NEBIVOLOL HYDROCHLORI DE	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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X3. 0X3.0X10.0 TABLET BLISTER	7/1/2013
489	NDA/MAL/HDP/1170	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO MEGANEURO N	METHYLCOBA LAMIN	500MCG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	PARENTERA L ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE	7/1/2013
490	NDA/MAL/HDP/1172	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	LIDOCAINE HYDROCHLORI DE	LIDOCAINE HYDROCHLORI DE	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N- 118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDI A.	INDIA	PARENTERA L ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	7/1/2010

491	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
492	NDA/MAL/HDP/1179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONA DOTROPIN ALFA	250MCG/0.5M L	MERCK SERONO SA- 1170 AUBONNE(SWITZERL AND) MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.7002 6 MODUGNO (BA).ITALY	SWITZERLAND	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X1.0 REFILLED SYRINGE CARTON	7/1/2015
493	NDA/MAL/HDP/1182	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ASTHATOR 5	MONTELUKAS T 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

494	NDA/MAL/HDP/1184	DAWA LIMITED	SUPER MEDIC LTD	DACOF MUCOLYTIC	SALBUTAMOL + BROMHEXINE + GUAIPHENESI N + 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
495	NDA/MAL/HDP/1185	DAWA LIMITED	SUPER MEDIC LTD	DACOF DRY	DIPHENHYDRA MINE + DEXTROMETH ORPHAN + 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
496	NDA/MAL/HDP/1186	DAWA LIMITED	SUPER MEDIC LTD	DACOF EXPECTORANT	DIPHENHYDRA MINE HYDROCHLORI DE + 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

497	NDA/MAL/HDP/1188	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	GMYCIN-80	GENTAMYCIN SULPHATE	80MG/2ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	
498	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	1.0X10.0X10.0 X3.0 ML AMPOULE	7/1/2013
499	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

500	NDA/MAL/HDP/1195	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	ALTRINE	CETIRIZINE	5MG/5ML	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	7/1/2013
501	NDA/MAL/HDP/1196	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	ACNESOL	TRETINOIN	0.05%W/W	UNIVERSAL CORPORATION LTD.-PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	7/1/2012
502	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2008

503	NDA/MAL/HDP/1206	THE METHOLATUM CO. LTD	HARLEYS UGANDA LIMITED	DEEP RELIEF	IBUPROFEN + MENTHOL	5%W/W + 3% W/W	THE MENTHOLATUM CO. LTD. -1 REDWOOD AVE PEEL PARK CAMPUS EAST KILBRIDE	UNITED KINGDOM	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X50.0 G CONTAINER,1.0X15.0 G CONTAINER,1.0X30.0 G CONTAINER	7/1/2013
504	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
505	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

506	NDA/MAL/HDP/1211	ASTRA ZENECA	MACNAUGHTON LIMITED	BRILINTA	TICAGRELOR	90MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	7/1/2011
507	NDA/MAL/HDP/1212	GUILIN PHARMACEUTICALS 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	1.0X6.0X1.0 ML AMPOULE	7/1/2011
508	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

509	NDA/MAL/HDP/1215	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE+NEOMYCIN SULPHATE+NY STATIN	500MG+65,000I.U+100,000I.U	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X10.0 TABLET BLISTER	7/1/2013
510	NDA/MAL/HDP/1219	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTSTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2014
511	NDA/MAL/HDP/1220	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BLISTER	7/1/2008

512	NDA/MAL/HDP/1223	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	7/1/1997
513	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
514	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

515	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	
516	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
517	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

518	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
519	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
520	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

521	NDA/MAL/HDP/1247	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROCIP	CYPROHEPTA DINE	4MG	AGOG PHARMA LTD.- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X1 0.0 TABLET BLISTER	7/1/2012
522	NDA/MAL/HDP/1250	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	STRIMOL EXTRA	PARACETAMO L+CAFFEINE	500MG+30MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHAN LI INDLAWADICROSS ANEKAL TALUK BANYALURE-562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	7/1/2014
523	NDA/MAL/HDP/1252	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHAMACEAUTICALS PVT LTD-VILL ISSAPUR P.O DAPPAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	7/1/2013

524	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
525	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
526	NDA/MAL/HDP/1264	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	OCUCYCLINE EYE OINTMENT	TETRACYCLINE HYDROCHLORIDE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE,1.0X3.5 G TUBE	7/1/2000

527	NDA/MAL/HDP/1265	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COMBIPLEX	VITAMIN B1 + VITAMIN B2 + NICOTINAMID E + VITAMIN B6	1.0 MG + 1.0 MG + 15 MG + 0.5 MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2008
528	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
529	NDA/MAL/HDP/1278	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTE MESININ + 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,1.0X2 5.0X1.0X9.0 TABLET BLISTER	7/1/2013

530	NDA/MAL/HDP/1282	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	LOSABERG	LOSARTAN POTASSIUM	50MG	THE MADRAS PHARMACEUTICALS. .-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2016
531	NDA/MAL/HDP/1285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X750.0 MG VIAL	7/1/2012
532	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2014

533	NDA/MAL/HDP/1288	PHARCO PHARMACEUTICALS	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
534	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
535	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	PARENTERA L ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100. 0 ML VIAL	7/1/2012

536	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
537	NDA/MAL/HDP/1295	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR	ALBENDAZOLE	200MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	7/1/1997
538	NDA/MAL/HDP/1299	SANCE LABORATORIES PVT LTD	DELMAW 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,1.0X50.0 X1.0 VIAL CARTON	7/1/2012

539	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/1997
540	NDA/MAL/HDP/1303	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FIBRAL	FINOFIBRATE	200MG	MICRO LABS LTD --57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER	7/1/2013
541	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

542	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
543	NDA/MAL/HDP/1312	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM- 2.5	DIAZEPAM	2.5MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITOR IES	1.0X5.0 SUPPOSITORY BLISTER	7/1/2007
544	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

545	NDA/MAL/HDP/1324	SHIJIAZHUANG AOSUO INTERNATIONAL TRADE CO. 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
546	NDA/MAL/HDP/1325	MACLEODS PHARMACEUTICALS 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
547	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

548	NDA/MAL/HDP/1331	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N OINTMENT	BETAMETHAS ONE 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
549	NDA/MAL/HDP/1334	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	30MG	MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H- 13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X3 0.0 CAPSULE CONTAINER	7/1/2016
550	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

551	NDA/MAL/HDP/1336	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	45MG	MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H- 13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER, CAPSULE CONTAINER	7/1/2015
552	NDA/MAL/HDP/1341	AUROLAB	SWASTIK PHARMACEUTICAL LTD	G-FLOX	GATIFLOXACIN SESQUIHYDRA TE	0.3%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMI C LIQUIDS	1.0X5.0 ML VIAL	7/1/2016
553	NDA/MAL/HDP/1343	MICRO LABS LTD	PHARMA VILLE LIMITED	PRAZQUANTE L	PRAZQUANTE L	600MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126 MICRO LABS LIMITED, BOMMASANDRA (ML07),-PLOT 121- 124, IV PHASE KIADB, BOMMASANDRA IND. AREA, JIGNI LINK ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	

554	NDA/MAL/HDP/1345	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SWICH-200	CEFPODOXIME	200MG	ALKEM LABORATORIES LTD- VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	7/1/2010
555	NDA/MAL/HDP/1347	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	7/1/2010
556	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 ,INDIA-382721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2009

557	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
558	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
559	NDA/MAL/HDP/1353	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	KITPYLO - C	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMY CIN	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

560	NDA/MAL/HDP/1355	PIRAMAL HEALTHCARE LTD	MEDIWORLD PHARMA AFRICA LTD	SEVOFLURANE	SEVOFLURANE	100% V/V	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT, ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	7/1/2010
561	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
562	NDA/MAL/HDP/1361	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	FALCI CARE	ARTESUNATE	120MG	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL 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

563	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
564	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
565	NDA/MAL/HDP/1367	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2013

566	NDA/MAL/HDP/1368	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE	7/1/2010
567	NDA/MAL/HDP/1370	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	NEUTRAL	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE,1.0X7.5 ML AMPOULE	
568	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/100ML	AXA PARENTERALS LTD-KISHNPUR, JAMALPUR ROORKEE 247677	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2014

569	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0 ML AMPOULE	7/1/2014
570	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 DISINTEGRA TING TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2013
571	NDA/MAL/HDP/1387	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	LAN-30	LANSOPRAZOL E	30MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0X1 0.0 CAPSULE STRIP	7/1/2004

572	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
573	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
574	NDA/MAL/HDP/1393	SANCE LABORATORIES PVT LTD	DELMAR 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

575	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	PARENTERA L ORDINARY DRY VIALS	1.0X15.0 ML VIAL	7/1/2010
576	NDA/MAL/HDP/1395	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZO LE	40MG/5ML	ASTRA ZENECA-- KVARNBERGAGATAN 12, SE-151 SODERTALIJE	SWEDEN	PARENTERA L ORDINARY VIALS	1.0X1.0X5.0 ML VIAL,1.0X10.0 X5.0 ML VIAL	7/1/2010
577	NDA/MAL/HDP/1397	ASTRA ZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA SWEDEN OPERATIONS- ASTRAZENECA SWEDEN OPERATIONS SE-151 85 SODERTALIJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2001

578	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 ADMINISTR ATION CFC- FREE METERED- DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	7/1/2010
579	NDA/MAL/HDP/1400	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 500	METFORMIN HYDROCHLORI DE	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
580	NDA/MAL/HDP/1402	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 1000	METFORMIN HYDROCHLORI DE	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

581	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2014
582	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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X15.0 ML BOTTLE	7/1/2007
583	NDA/MAL/HDP/1411	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIRAMINE	4MG	LEBEN LAB PVT LTD- L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X20.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2011

584	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,MOGA DISHU 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
585	NDA/MAL/HDP/1415	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND	CANDESARTAN	32MG	ASTRA ZENECA SWEDEN OPERATIONS-TABLET PRODUCTION SE-15185, GARTUNAVAGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2011
586	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

587	NDA/MAL/HDP/1418	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	AMINOPHYLLI NE TABLETS	AMINOPHYLLI NE	100MG	NEM LABORATORIES PVT LTD-PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2011
588	NDA/MAL/HDP/1419	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 10	LISINOPRIL	10MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2005
589	NDA/MAL/HDP/1422	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	STAMIN	CETIRIZINE DIHYDROCHLO RIDE	10MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	

590	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
591	NDA/MAL/HDP/1425	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	L-TRIM	COTRIMOXAZ OLE	240MG/5ML	LEBEN LABORATORIES PVT. LTD-L-4, PHASE –III, M.I.D.C,	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE,1.0X1. 0X100.0 ML BOTTLE	7/1/2007
592	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,1.0X2 8.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2011

593	NDA/MAL/HDP/1433	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORISTERAT	NORETHISTER ONE 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
594	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
595	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

596	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	PARENTERA L ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	7/1/2003
597	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
598	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

599	NDA/MAL/HDP/1449	SHAIGAN PHARMACEUTICALS (PVT) LTD	HARLEYS UGANDA LIMITED	ZEPAR SUSPENSION	ALBENDAZOLE	200MG/5ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSION S	1.0X10.0 ML BOTTLE	7/1/2000
600	NDA/MAL/HDP/1450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMM ONIUM	1%W/V	GSK CONSUMER HEALTH SA-GSK CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, NYON, 1260, SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X50.0 G TUBE	7/1/1997
601	NDA/MAL/HDP/1451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRA SSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERA L ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	7/1/1997

602	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
603	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
604	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

605	NDA/MAL/HDP/1460	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PARIN E	ENOXAPARIN	80MG	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X10.0X2.0X 0.8 ML PRE-FILLED SYRINGE	7/1/2009
606	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
607	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

608	NDA/MAL/HDP/1468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID 20	OMEPRAZOLE	20MG	S KANT HEALTHCARE LTD- PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA EAST AFRICAN (INDIA)	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	7/1/1998
609	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
610	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

611	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
612	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	PARENTERA L ORDINARY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF SOLVENT IN PRE-FILLED SYRINGE,1.0X1 0.0X10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	7/1/1997
613	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

614	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
615	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, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	7/1/1998
616	NDA/MAL/HDP/1493	AUROBINDO PHARMA LTD UNIT VII	GITTOES PHARMACEUTICALS LIMITED	KOACT 1000	AMOXICILLIN/CLAVULANATE POTASSIUM	875MG/125MG	AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELEGANA (STATE)	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X5.0 TABLET BLISTER	7/1/2007

617	NDA/MAL/HDP/1494	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	PEITEL 0.25%	PREDNICARBA TE	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
618	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
619	NDA/MAL/HDP/1497	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE CREAM	BETAMETHAS ONE 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

620	NDA/MAL/HDP/1499	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZI NE	PROMETHAZI NE HYDROCHLORI DE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	7/1/2005
621	NDA/MAL/HDP/1500	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ATRIPLA	EFAVIRENZ+E MTRICITABINE + 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
622	NDA/MAL/HDP/1503	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT CREAM	HYDROCORTIS ONE+CINCHO CAINE	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

623	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 ADMINISTR ATION CFC- FREE METERED- DOSE INHALER	1.0X1.0 CANNISTER CARTON	7/1/2007
624	NDA/MAL/HDP/1506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 2000	RECOMBINAN T HUMAN ERYTHROPOIE TIN	2000 IU	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	7/1/2011
625	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 SUSPENSION S	1.0X10.0 ML BOTTLE	7/1/2009

626	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2007
627	NDA/MAL/HDP/1514	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	100MG	JOHNSON & JOHNSON (PTY) LTD- 241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X6.0 TABLET BLISTER	7/1/1997
628	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

629	NDA/MAL/HDP/1517	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	VEST MENTAMU BALM	COMPOUND METHYLSALIC YLATE	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
630	NDA/MAL/HDP/1523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2007
631	NDA/MAL/HDP/1524	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	125 MG / 5 ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2008

632	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 SUSPENSION S	1.0X10.0 ML BOTTLE	7/1/2007
633	NDA/MAL/HDP/1526	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMI DE + AMINO BUTYRI C ACID + AMINO HYDROXYBUT YRIC 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
634	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

635	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
636	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
637	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

638	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
639	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
640	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

641	NDA/MAL/HDP/1546	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LANPRO	LANSOPRAZOL E	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	1.0X5.0X2.0X1 0.0 CAPSULE BLISTER	7/1/1999
642	NDA/MAL/HDP/1549	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	PREDNICOL EYE DROPS	PREDNISOLON E/CHLORAMP HENICOL	5MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD- 117 ALLAM	PAKISTAN	OPHTHALMI C DROPS	1.0X10.0 ML VIAL	7/1/1999
643	NDA/MAL/HDP/1551	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CALOSHELL- 500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2004

644	NDA/MAL/HDP/1553	EMCURE PHARMACEUTICALS 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
645	NDA/MAL/HDP/1554	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CETIRIZINE	CETIRIZINE DIHYDROCHLO RIDE	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
646	NDA/MAL/HDP/1555	GALENTIC PHARMA LTD	VITACARE LIMITED	GALSCRUB	CHLORHEXIDI NE	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

647	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
648	NDA/MAL/HDP/1557	GLAXOSMITHKLINE	UNITED HEALTHCARE DISTRIBUTORS LTD	SYNFLORIX VACCINE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V, 14,23F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPTHERIA TOXOID CARRIER	1MCG+3MCG+13MCG+8MCG+5MCG+0.5MG	GLAXOSMITHKLINE BIOLOGICALS-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),1.0X10.0X0.5 ML VIAL (1 DOSE)	7/1/2010
649	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,1.0X100.0 TABLET CONTAINER,1.0X100.0X1.0X10.0 TABLET BLISTER	7/1/2003

650	NDA/MAL/HDP/1561	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	NEOVAG	NYSTATIN	10000IU	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJ ARAT, INDIA	INDIA	VAGINAL TABLETS	1.0X14.0 PESSARY STRIP	7/1/2004
651	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997
652	NDA/MAL/HDP/1571	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	RHOCLONE	MONOCLONAL ANTI-D IMMUNOGLO BULIN	300MCG	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X2.0 ML VIAL (1 DOSE VIAL)	7/1/2013

653	NDA/MAL/HDP/1572	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	ROSUVAS 20	ROSUVASTATI N	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
654	NDA/MAL/HDP/1574	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AMTAS-5	AMLODIPINE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X2.0X7.0 TABLET BLISTER,10.0X 10.0 TABLET BLISTER	7/1/2003
655	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	7/1/2011

656	NDA/MAL/HDP/1581	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PANTOTAB	PANTOPRAZO LE	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
657	NDA/MAL/HDP/1582	LINCON PHARMCUETICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CEEPRO-500	CIPROFLOXACI N	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
658	NDA/MAL/HDP/1585	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	UDIHEP FORTE	URSODEOXYC HOLIC 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

659	NDA/MAL/HDP/1589	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SI METHICONE	40MG+200MG +250MG/5ML	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE,1.0X1 70.0 ML BOTTLE	7/1/1997
660	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
661	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

662	NDA/MAL/HDP/1605	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ASPIRIN TABLETS	ACETYL SALICYLIC ACID	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	7/1/2001
663	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
664	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,1.0X3 0.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2011

665	NDA/MAL/HDP/1627	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID-V GEL	CLOTRIMAZOL E	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
666	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
667	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 SUSPENSION S	1.0X240.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2007

668	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF WFI	7/1/2005
669	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	PARENTERA L ORDINARY VIALS	1.0X1.0 G VIAL	7/1/1997
670	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

671	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	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
672	NDA/MAL/HDP/1642	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	EUCHLOR-1000	CHLORAMPHENICOL SODIUM SUCCINATE 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
673	NDA/MAL/HDP/1646	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE+DILOXANIDE	200MG+250MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU 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

674	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
675	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 ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2009
676	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

677	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET STRIP	7/1/2005
678	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
679	NDA/MAL/HDP/1663	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-PINK	ALUMINIUM HYDROXIDE/M AGNESIUM TRISILICATE	400MG+400M G/50ML	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X400.0 ML BOTTLE,1.0X1 60.0 ML BOTTLE	7/1/2003

680	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,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10. 0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER,1. 0X10.0X10.0 CAPSULE BLISTER	7/1/1998
681	NDA/MAL/HDP/1669	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL 2	GLIMEPIRIDE	2MG	AVENTIS PHARMA- AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	
682	NDA/MAL/HDP/1670	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	AMARYL 4	GLIMIPIRIDE	4MG	AVENTIS PHARMA- AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	

683	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
684	NDA/MAL/HDP/1675	MERCK SHARP & DOHME BV	SURGIPHARM (U) LIMITED	GARDASIL	QUADRIVALENT HUMAN PAPILLOMAVIRUS RECOMBINANT VACCINE (TYPES 6, 11, 16, 18)	(20MCG+40MCG+40MCG+20MCG)/0.5ML	MERK & CO. INC-SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE),1.0X10.0X0.5 ML VIAL (1 DOSE)	7/1/2007
685	NDA/MAL/HDP/1676	KOPRAN LIMITED	TATA UGANDA LIMITED	CLOXIN-250	CLOXACILLIN	250MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	7/1/1997

686	NDA/MAL/HDP/1680	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	H-CORT	HYDROCORTIS ONE	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
687	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,1.0X1 0.0X1.0X10.0 TABLET BLISTER	7/1/2005
688	NDA/MAL/HDP/1685	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL	KETOCONAZO LE	200MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJ ARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2005

689	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
690	NDA/MAL/HDP/1690	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLO RIDE	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
691	NDA/MAL/HDP/1691	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZITHRORIV	AZITHROMYCI N	500MG	RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER	7/1/2011

692	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 SUSPENSION S/SYRUPS/D ROPS	1.0X50.0 ML BOTTLE	7/1/2007
693	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
694	NDA/MAL/HDP/1697	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLO RIDE	10MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2005

695	NDA/MAL/HDP/1701	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FORMIN	METFORMIN HYDROCHLORI DE	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
696	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
697	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

698	NDA/MAL/HDP/1707	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	FEBRICOL TABLETS	PARACETAMOL / PSEUDOEPHEDRINE / CHLORPHENIRAMINE	500MG / 30MG / 2MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BLD -1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER	7/1/1997
699	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
700	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

701	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,1.0X1 000.0 CAPSULE CONTAINER	7/1/1997
702	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER,1.0X1. 0X6.0 TABLET BLISTER,1.0X1. 0X24.0 TABLET BLISTER,1.0X3 0.0X12.0 TABLET BLISTER,1.0X1. 0X12.0 TABLET BLISTER,1.0X3 0.0X18.0	7/1/2007
703	NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHENIRAMINE+DEXTROMETHORPHAN+BROMHEXINE	50MG+2MG+5MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA SHELYS PHARMACEUTICALS LTD,-NEW	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	7/1/2011

704	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
705	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
706	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

707	NDA/MAL/HDP/1724	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACTUATION	GLAXO OPERATIONS UK LTD---HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X120.0 METERED DOSE CANNISTER	7/1/2009
708	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
709	NDA/MAL/HDP/1728	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DELISPRIN 75MG	ASPIRIN	75MG	ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0X14.0 TABLET STRIP	7/1/2007

710	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
711	NDA/MAL/HDP/1731	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-S OINTMENT	BETAMETHAS ONE VALERATE + SALICYLIC ACID	0.05%W/W + 3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/1997
712	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

713	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,IRUHUL AM,PSOT,SATYAVED U MANDAL,CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0 TABLET CONTAINER,2 50.0 TABLET CONTAINER,5 00.0 TABLET CONTAINER,1 00.0 TABLET CONTAINER,1 000.0 TABLET CONTAINER	7/1/1997
714	NDA/MAL/HDP/1736	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	KLERIMED	CLARITHROMY CIN	500MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2009
715	NDA/MAL/HDP/1738	ALCON PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TEARS NATURELE II	NATURAL TEARS	15ML	ALCON COUVREUR NV-RIJKSWEWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMI C DROPS	1.0X15.0 ML BOTTLE	7/1/1997

716	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
717	NDA/MAL/HDP/1741	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEOPRED-P	PREDNISOLON E 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	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005
718	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	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005

719	NDA/MAL/HDP/1748	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-500	AZITHROMYCI N	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
720	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2005
721	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	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005

722	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	OPHTHALMI C DROPS	1.0X5.0 ML AMPOULE	7/1/2005
723	NDA/MAL/HDP/1753	PHARMATEC PAKISTAN PVT LTD	HEALTHCARE LTD.	FLU-GONE-P. PLUS SYRUP	PARACETAMO L + PSEUDOEPHE DRINE HCL + CHLORPHENIR AMINE MALEATE	120MG/5ML + 15MG/5ML + 1MG/5ML	PHARMATEC PKISTAN (PVT) LTD-D - 86 / A S.I.T.E KARACHI, PAKISTAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	7/1/2013
724	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	OPHTHALMI C DROPS	1.0X1.0X5.0 ML VIAL	7/1/2005

725	NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICROM 2%	SODIUM CROMOGLYCA TE	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005
726	NDA/MAL/HDP/1758	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICORT	PREDNISOLON E ACETATE	0.12%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005
727	NDA/MAL/HDP/1760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHA SONE	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

728	NDA/MAL/HDP/1761	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ATAZOR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	EMCURE PHARMACEUTICALS LTD .-PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2014
729	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	OPHTHALMI C DROPS	1.0X1.0X10.0 ML VIAL	7/1/2005
730	NDA/MAL/HDP/1763	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	ASPIRIN TABLETS BP	ACETYL SALICYLIC ACID	300MG	LABORATORY & ALLIED LTD.-PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X5 00.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER	7/1/1997

731	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
732	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
733	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

734	NDA/MAL/HDP/1767	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PROSTETROL	ALFUZOSIN HYDROCHLORI DE	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
735	NDA/MAL/HDP/1768	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 2MG	REMIFENTANI L	2MG	GLAXOSMITHKLINE MANUFACTURING SPA ,,-STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	ITALY	PARENTERA L ORDINARY DRY VIALS	1.0X5.0 VIAL CARTON	7/1/1999
736	NDA/MAL/HDP/1769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERA L ORDINARY VIALS	1.0X10.0X0.5 ML VIAL (1 DOSE),1.0X25. 0X0.5 ML VIAL (1 DOSE)	7/1/1997

737	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
738	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
739	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

740	NDA/MAL/HDP/1778	PHARCO PHARMACEUTICALS	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
741	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,1.0X4 50.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	7/1/2006
742	NDA/MAL/HDP/1780	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM SUSPENSION	CO- TRIMOXAZOLE	240MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE	7/1/2000

743	NDA/MAL/HDP/1781	ASTRAZENECA	MACNAUGHTON LIMITED	ARIMIDEX	ANASTROZOLE	1MG	ASTRAZENECA PHARMACEUTICALS LP-NEWARK, DELAWARE	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2000
744	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
745	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

746	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
747	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, MOGA DISHU 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
748	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, 1 0.0X10.0 TABLET BLISTER	7/1/2001

749	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
750	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
751	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 MAHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X1.0X6.0 TABLET BLISTER	7/1/2006

752	NDA/MAL/HDP/1797	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	AMPICILLIN+C LOXACILLIN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X500. 0 MG VIAL	7/1/2010
753	NDA/MAL/HDP/1798	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	CARDITAS RETARD	NIFEDIPINE	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997
754	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

755	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
756	NDA/MAL/HDP/1801	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN PESSARIES	CLOTRIMAZOL E	100MG	LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	7/1/1997
757	NDA/MAL/HDP/1803	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG	ESOMEPRAZO LE	40MG	ASTRAZENECA AB.- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X1 4.0 TABLET CARTON,1.0X2 8.0 TABLET CARTON	7/1/2001

758	NDA/MAL/HDP/1804	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL	LISINOPRIL	5MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD- MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2001
759	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 SUSPENSION S/SYRUPS/D ROPS	1.0X8.0 ML BOTTLE	7/1/1997
760	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. 0X10.0X10.0 TABLET BLISTER	7/1/2004

761	NDA/MAL/HDP/1810	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRI	TRIFLUOPERAZ INE	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,1.0X1 000.0 TABLET CONTAINER	7/1/2010
762	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X6 0.0 TABLET BOTTLE	7/1/2001
763	NDA/MAL/HDP/1812	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN TABLETS	QUININE SULPHATE	300MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2001

764	NDA/MAL/HDP/1813	DAWA LIMITED	SUPER MEDIC LTD	MOXAFORTE	AMOXICILLIN + FLUCLOXACILLIN	125 MG + 125MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2014
765	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
766	NDA/MAL/HDP/1816	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	DRESS UP CREAM	NEOMYCIN SULPHATE	0.5%W/W	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	7/1/1998

767	NDA/MAL/HDP/1821	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL 500 TABLETS	MEFENAMIC ACID	500MG	BLUE CROSS LABORATORIES LTD- L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/1997
768	NDA/MAL/HDP/1822	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	EPHEDRINE	EPHEDRINE HYDROCHLORI DE	30MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2005
769	NDA/MAL/HDP/1825	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMO L+CHLORPHEN IRAMINE MALEATE+PSE UDOEPHEDRI NE HYDROCHLORI DE	120MG+2MG+ 15MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2005

770	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
771	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
772	NDA/MAL/HDP/1841	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL CREAM	CLOTRIMAZOLE	1%W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2000

773	NDA/MAL/HDP/1842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUIN E 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
774	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
775	NDA/MAL/HDP/1844	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHO XAZOLE / TRIMETHOPRI M	SULFAMETHO XAZOLE / TRIMETHOPRI M	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,1.0X1 000.0 TABLET CONTAINER	7/1/2011

776	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 SUSPENSION S	1.0X170.0 ML BOTTLE	7/1/2013
777	NDA/MAL/HDP/1847	MICRO LABS	MALIX PHARMA (U) LIMITED	MOXILEB-250 CAPSULE	AMOXICILLIN	250MG	LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE –III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER	7/1/2007
778	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

779	NDA/MAL/HDP/1849	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIFIN	CIPROFLOXACIN	0.2%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2011
780	NDA/MAL/HDP/1850	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	400MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER	7/1/2010
781	NDA/MAL/HDP/1851	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CAPSIFENAC GEL	CAPSAICIN + DICLOFENAC + LEVOMENTHOL + METHYL SALICYLATE	0.438 G + 0.335 G + 0.135 G + 0.918 G	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE, 1.0X1.0X10.0 G TUBE	7/1/2011 0:00

782	NDA/MAL/HDP/1853	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS ORAL SOLUTION	DESLOTATADINE	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
783	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
784	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

785	NDA/MAL/HDP/1861	GUILIN PHARMACEUTICALS CO LTD	TRIDEM PHARMA UGANDA LIMITED	SULFAMETHO XAZOLE / TRIMETHOPRI M	SULFAMETHO XAZOLE / TRIMETHOPRI M	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,1.0X1 000.0 TABLET CONTAINER	7/1/2011
786	NDA/MAL/HDP/1863	AMOUN PHARMACEUTICALS 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
787	NDA/MAL/HDP/1864	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	PATANOL	OLOPATADINE HYDROCHLORI DE	0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMI C DROPS	1.0X5.0 ML VIAL	7/1/2009

788	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
789	NDA/MAL/HDP/1879	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMET HYL 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
790	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

791	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,LAKHA BAVAD,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
792	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
793	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	7/1/1997

794	NDA/MAL/HDP/1889	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PRED SOL	PREDNISOLON E	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,1.0X1 0.0 TABLET	7/1/1997
795	NDA/MAL/HDP/1891	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LEVOMAC 500	LEVOFLOXACI N	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
796	NDA/MAL/HDP/1892	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LEVOMAC 250	LEVOFLOXACI N	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

797	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER	7/1/2007
798	NDA/MAL/HDP/1898	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	ZAPACID - 30	LANSOPRAZOL E	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
799	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,1.0X1 0.0X10.0 CAPSULE STRIP	7/1/2007

800	NDA/MAL/HDP/1901	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL	IBUPROFEN + PARACETAMO L	100MG + 162.5 MG /5ML	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2013
801	NDA/MAL/HDP/1902	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMODIUM	LOPERAMIDE HYDROCHLORI DE	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
802	NDA/MAL/HDP/1911	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CODEINE PHOSPHATE TABLETS BP 30	CODEINE PHOSPHATE	30MG	COSMOS LIMITED - RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/1998

803	NDA/MAL/HDP/1912	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM	ALBENDAZOLE	200MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	7/1/2008
804	NDA/MAL/HDP/1914	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CHLORPHENIR AMINE	CHLORPHENIR AMINE	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
805	NDA/MAL/HDP/1919	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDIDERM CREAM	BECLOMETAS ONE/CLOTRIM AZOLE/GENTA MYCIN	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

806	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
807	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	
808	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, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X10.0 TABLET BLISTER	7/1/2013

809	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
810	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
811	NDA/MAL/HDP/1934	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHENICOL	125MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2001

812	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
813	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
814	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

815	NDA/MAL/HDP/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOC IV	RABEPRAZOLE	20MG/VIAL	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERA L ORDINARY VIALS	1.0X5.0 ML VIAL	7/1/2005
816	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
817	NDA/MAL/HDP/1943	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 2.6	NITROGLYCERI N (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

818	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
819	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	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	7/1/1998
820	NDA/MAL/HDP/1949	MACLEODS PHARMACEUTICALS LTDS LTD	VITACARE LIMITED	TRENAXA 500	TRANEXAMIC ACID	500MG	MACLEODS PHARMACEUTICALS - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X6.0 TABLET BLISTER	7/1/2011

821	NDA/MAL/HDP/1951	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	CLOPI 75	CLOPIDOGREL	75MG	MACLEODS PHARMACEUTICALS - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP,3.0X10. 0 TABLET STRIP	7/1/2006
822	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,1.0X1.0 X10.0 TABLET STRIP	7/1/2011
823	NDA/MAL/HDP/1956	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	MILOXY	AMOXYCILLIN	250MG	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NOS 63, 67 & 87, JAWAHAR CO- OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER	7/1/2006

824	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2005
825	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, 1.0X10.0X10.0 TABLET BLISTER	7/1/2005
826	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

827	NDA/MAL/HDP/1962	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	NIMBEX	CISATRACURIUM MESYLATE	2MG/ML	GLAXOSMITHKLINE S.P.A -STRADA PROVINCIALE ASOLANA 9	ITALY	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL,1.0X2.5 ML VIAL	7/1/1997
828	NDA/MAL/HDP/1963	MILAN LABORATORIES 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 ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X35.0 G TUBE	7/1/2006
829	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 ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2007

830	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
831	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
832	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1998

833	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
834	NDA/MAL/HDP/1975	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BET-CODERMIN	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
835	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

836	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
837	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
838	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

839	NDA/MAL/HDP/1990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTD-- UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205 UNICHEM LABORATORIES LTD-- -C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X 2.0 TABLET BLISTER	7/1/2005
840	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,1.0X1 000.0 TABLET JAR (WITH STATEMENT "FOR HOSPITAL USE ONLY".)	7/1/2011
841	NDA/MAL/HDP/1999	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPI NE	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

842	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	1.0X2.0X5.0X1 0.0 TABLET BLISTER	7/1/2000
843	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
844	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

845	NDA/MAL/HDP/2008	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- CREAM	CLOTRIMAZOL E + BECLOMETAS ONE DIPROPRIONA TE 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
846	NDA/MAL/HDP/2009	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCI N	200MG/5ML	COSMOS LTD.- RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X15.0 ML BOTTLE,1.0X3 0.0 ML BOTTLE	7/1/2010
847	NDA/MAL/HDP/2012	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- LOTION	CLOTRIMAZOL E + BECLOMETHA SONE DIPROPIONAT E	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

848	NDA/MAL/HDP/2014	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	CANI-MAKS	CLOTRIMAZOL E	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
849	NDA/MAL/HDP/2016	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID CREAM	CLOTRIMAZOL E	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/2000
850	NDA/MAL/HDP/2018	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	ORAXIN SYRUP	CYPROHEPTA DINE+TRICHOL INE CITRATE	2MG+275MG	CENTAUR PHARMACEUTICALS LTD,--KARASWADA MAPUSA GOA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/1997

851	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
852	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,1.0X1 000.0 TABLET CONTAINER,1. 0X500.0 TABLET CONTAINER,1. 0X100.0 TABLET CONTAINER,1. 0X250.0 TABLET	7/1/1997
853	NDA/MAL/HDP/2021	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGVIT ZINC	MULTIVITAMI N/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

854	NDA/MAL/HDP/2022	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TORACTIN	CYPROHEPTA DINE	2MG/5ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/1997
855	NDA/MAL/HDP/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZO LE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2004
856	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,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/1997

857	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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2009
858	NDA/MAL/HDP/2027	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/12.5MG	VALSARTAN + HYDROCHLOR OTHIAZIDE	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
859	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. 0X10.0X10.0 TABLET BLISTER	7/1/2004

860	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
861	NDA/MAL/HDP/2035	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NEOSIDAR	SULPHADOXIN E + PYRIMETHAMI NE	500MG + 25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X5 0.0X3.0 TABLET BLISTER	7/1/2004
862	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	PARENTERA L ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X 3.0 ML CARTRIDGE	7/1/1998

863	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	7/1/2006
864	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
865	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

866	NDA/MAL/HDP/2045	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	BUPICAN	BUPIVACAINE	0.5% W/V	CLARIS INJECTABLES LIMITED--- CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	
867	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
868	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

869	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,1.0X1.0 X10.0 TABLET BLISTER	7/1/2005
870	NDA/MAL/HDP/2053	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-5	AMLODIPINE BESILATE	5MG	EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2005
871	NDA/MAL/HDP/2055	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	120MG	GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERA L 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

872	NDA/MAL/HDP/2056	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	BRO-ZEDEX	TERBUTALINE SULPHATE +BROMHEXIN E HYDROCHLORI DE+GUAIPHEN ESIN+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
873	NDA/MAL/HDP/2058	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	QUININE SULPHATE	QUININE SULPHATE	300MG	MACLEODS PHARMACEUTICALS - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2006
874	NDA/MAL/HDP/2062	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN PAEDIATRIC SYRUP	DEXTROMETH ORPHAN HYDROBROMI DE BP + CHLORPHENIR AMINE MALEATE BP + AMMONIUM CHLORIDE BP + PSEUDOEPHE DRINE HYDROCHLORI	(5MG + 2MG + 50MG + 10MG)/ 5ML	BETA HEALTHCARE INTERNATIONAL LTD -PLOT NO LR 209/6534 MOGADISHU ROAD SHELYS PHAMACEUTICALS LTD .-NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	7/1/2006

875	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
876	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
877	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

878	NDA/MAL/HDP/2068	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	DOMADOL	TRAMADOL HYDROCHLORI DE	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
879	NDA/MAL/HDP/2069	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SK DERM	BETAMETHAS ONE + CLOTRIMOXAZ OLE + 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
880	NDA/MAL/HDP/2070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGEST REL	52MG	BAYER OY- PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERA L RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON	7/1/2009

881	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2000
882	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML AMPOULE OF STERILE WATER FOR INJECTION,1.0 X10.0 DOSE VIAL + 5ML AMPOULE OF STERILE WATER FOR INJECTION	7/1/1997
883	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1998

884	NDA/MAL/HDP/2075	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRED	PREDNISOLON E	5MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1 0.0X10.0 TABLET BLISTER	7/1/2006
885	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER	7/1/2006
886	NDA/MAL/HDP/2077	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORI DE	30MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2007

887	NDA/MAL/HDP/2083	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BEVAC	PURIFIED HEPATITIS B SURFACE ANTIGEN	20MCG	BIOLOGICAL E LTD- PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERA L ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 DOSE VIAL),1.0X24.0 X10.0 ML VIAL (10 DOSE VIAL)	7/1/2015
888	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
889	NDA/MAL/HDP/2090	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CIPROREN	CIPROFLOXACI N	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

890	NDA/MAL/HDP/2091	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CAMSTON	CLOTRIMAZOL E	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
891	NDA/MAL/HDP/2093	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TRIGAN-D TABLET	PARACETAMO L + DICYCLOMINE	500MG + 20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP	7/1/1999
892	NDA/MAL/HDP/2094	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT- 750	LEVOFLOXACI N 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

893	NDA/MAL/HDP/2095	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	PARACETAMO L	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
894	NDA/MAL/HDP/2098	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO QUININE	QUININE SULPHATE	300MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2006
895	NDA/MAL/HDP/2099	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROCORTIS ONE 1% CREAM	HYDROCORTIS ONE	1%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/1998

896	NDA/MAL/HDP/2101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITED- RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2010
897	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
898	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

899	NDA/MAL/HDP/2104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE/ NEVIRAPINE /ZIDOVUDINE DISPERSIBLE TABLETS	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2009
900	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	7/1/2011
901	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

902	NDA/MAL/HDP/2116	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	AMLOVAS-10	AMLODIPINE BESILATE	10MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET STRIP	7/1/2005
903	NDA/MAL/HDP/2122	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYMOL	PARACETAMO L	120MG/5ML	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/1997
904	NDA/MAL/HDP/2125	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	BECLATE 100	BECLOMETAS ONE	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

905	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,QUTHUBULAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	7/1/2010
906	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
907	NDA/MAL/HDP/2136	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT SUPOSITORY	HYDROCORTISONE+ CINCHOCAINE + ESCULOSIDE+ FRAMYCETIN	5MG + 5MG +10MG +10MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	7/1/2003

908	NDA/MAL/HDP/2141	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	INFLAZONE	MULTIINGRED IENT	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
909	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	PARENTERA L ORDINARY VIALS	1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE	7/1/2014
910	NDA/MAL/HDP/2149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPRO GESTERONE HEXANOATE	250MG	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERA L ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	7/1/1997

911	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
912	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
913	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

914	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
915	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	
916	NDA/MAL/HDP/2160	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ACEM-500	CLARITHROMY CIN	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

917	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
918	NDA/MAL/HDP/2165	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORI DE	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
919	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

920	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
921	NDA/MAL/HDP/2175	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLADON	PARACETAMOL	500MG	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0X4.0 TABLET STRIP,1.0X4.0 X4.0 TABLET STRIP	7/1/2005
922	NDA/MAL/HDP/2176	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2011

923	NDA/MAL/HDP/2181	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PHEN	PHENOXYMET HYL PENICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	100.0 TABLET CONTAINER,1 000.0 TABLET CONTAINER,5 00.0 TABLET CONTAINER,2 50.0 TABLET CONTAINER	7/1/1997
924	NDA/MAL/HDP/2185	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ROTARIX	LIVE ATTENUATED RIX4414 STRAIN OF HUMAN ROTAVIRUS OF THE G1P[8] TYPE	NOT LESS THAN 10 ⁶ CCID ₅₀ OF THE RIX4414 STRAIN	GLAXOSMITHKLINE AUSTRALIA.- GLAXOSMITHKLINE AUSTRALIA, 1061 MOUNTAIN HIGHWAY, BORONIA, VICTORIA, 3155 AUSTRALIA GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE 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
925	NDA/MAL/HDP/2186	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRA MINE PAEDIATRIC SYRUP	DIPHENHYDRA MINE 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

926	NDA/MAL/HDP/2189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL BETAMETHAS ONE	BETAMETHAS ONE	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
927	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
928	NDA/MAL/HDP/2195	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	EUDERM CREAM	UREA	10%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X45.0 G TUBE	7/1/1997

929	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
930	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
931	NDA/MAL/HDP/2201	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CLYCIN	CLINDAMYCIN PHOSPHATE	10MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LOTIONS	1.0X30.0 ML BOTTLE	

932	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
933	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
934	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

935	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),	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	7/1/1997
936	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,	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2005
937	NDA/MAL/HDP/2217	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMINOPHYLLINE	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

938	NDA/MAL/HDP/2219	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT N	NORETHISTER ONE	5MG	BAYER WEIMAR GMBH & CO. KG- DOBEREINERSTRASSE 20 D-99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X3.0.0 TABLET CONTAINER,1.0X2.0X15.0 TABLET BLISTER	7/1/1997
939	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,1.0X3.0 X10.0 TABLET BLISTER	7/1/2003
940	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

941	NDA/MAL/HDP/2232	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAS T	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
942	NDA/MAL/HDP/2233	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATAN LZ SE-151- 85,SWEDEN	SWEDEN	LUNG ADMINISTR ATION LIQUID FOR INHALATION	1.0X4.0X5.0X2 .0 ML VIAL	7/1/2011
943	NDA/MAL/HDP/2235	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-N	INSULIN HUMAN(RECO MBINANT DNA ORIGIN)	100IU/ML	WOCKHARDT- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA	INDIA	PARENTERA L ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	7/1/2006

944	NDA/MAL/HDP/2236	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL 200	CARBAMAZEPI NE	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
945	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
946	NDA/MAL/HDP/2239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL ORAL SUSPENSION	CARBAMAZEPI NE	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

947	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
948	NDA/MAL/HDP/2245	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOL E	100MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2008
949	NDA/MAL/HDP/2248	GALENTIC PHARMA (PVT)LTD	VITACARE LIMITED	TETRACYCLINE OPHTHALMIC	TETRACYCLINE	1%W/W	GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE, INDIA	INDIA	OPHTHALMI C OINTMENTS	1.0X3.5 G TUBE,1.0X5.0 G TUBE	7/1/2004

950	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	PARENTERA L ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	7/1/2006
951	NDA/MAL/HDP/2252	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOL E	500MG	JOHNSON & JOHNSON (PTY) LTD- 241 MAIN ROAD, RETREAT, 7945, CAPE TOWN	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	7/1/2000
952	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

953	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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X70.0 ML BOTTLE	7/1/2010
954	NDA/MAL/HDP/2258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/600MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD --PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X30.0 TABLET BOTTLE	7/1/2009
955	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

956	NDA/MAL/HDP/2265	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR/ LAMUVIDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG + 300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD- 22-110 IDA JEEDIMETLA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2010
957	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2007
958	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997

959	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	7/1/2010
960	NDA/MAL/HDP/2272	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA - 500	CLARITHROMYCIN	500MG	AJANTA PHARMA LTD.-B-4//5/6, MIDC INDUSTRIAL AREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER	7/1/2005
961	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

962	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
963	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
964	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

965	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,1.0X5 0.0 TABLET CARTON	7/1/1997
966	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,AURANGABA D- 431136 MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2008
967	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

968	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
969	NDA/MAL/HDP/2295	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 10	ROSUVASTATI N CALCIUM	10MG	DAR AI DAWA-NA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	7/1/2013
970	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

971	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
972	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,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	7/1/2013
973	NDA/MAL/HDP/2303	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 5/6.25	BISOPROLOL + HYDROCHLOR OTHIAZIDE	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

974	NDA/MAL/HDP/2304	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOR OTHIAZIDE	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
975	NDA/MAL/HDP/2305	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOR OTHIAZIDE	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
976	NDA/MAL/HDP/2306	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROLUT	LEVONORGEST REL	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

977	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
978	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
979	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

980	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 SUSPENSION S/SYRUPS/D ROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2006
981	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
982	NDA/MAL/HDP/2319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMOL	120MG/5ML	COSMOS LIMITED- RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	7/1/1998

983	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2006
984	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
985	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

986	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
987	NDA/MAL/HDP/2330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRIN E	20MG + 120MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRA SSE 4332 STEIN SWITZERLAND NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ İHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL -	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X3 0.0X24.0 TABLET BLISTER,1.0X3 0.0X6.0 TABLET BLISTER,1.0X3 6.0X6.0 TABLET BLISTER,1.0X3. 0X8.0 TABLET	7/1/2005
988	NDA/MAL/HDP/2333	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA & TETANUS VACCINE ADSORBED(PE DIATRIC)	DIPHTHERIA TOXOID+TETA NUS 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	PARENTERA L 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

989	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
990	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	7/1/2001
991	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	7/1/2003

992	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,1.0X2 0.0X5.0 TABLET BLISTER	7/1/2007
993	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 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X5.0 TABLET BLISTER	7/1/2007
994	NDA/MAL/HDP/2348	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDN A) ADULT	HEPATITIS B VACCINE(RDN A) 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),1.0X50.0 X1.0 ML VIAL (1 DOSE VIAL)	7/1/2005

995	NDA/MAL/HDP/2350	ASTRA ZENECA AB	MACNAUGHTON LIMITED	PULMICORT TURBUHALER	BUDESONIDE	200MCG	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X100.0 DOSE CANNISTER	
996	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
997	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

998	NDA/MAL/HDP/2354	STRIDES SHASUN LIMITED	DELMAW 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
999	NDA/MAL/HDP/2356	GITTOES PHARMACEUTICALS 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
1000	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

1001	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
1002	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
1003	NDA/MAL/HDP/2361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMY CIN	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

1004	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
1005	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,	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0 X10.0X10.0X2.0 ML AMPOULE	7/1/2005
1006	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

1007	NDA/MAL/HDP/2366	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	IFICIPRO INJECTION	CIPROFLOXACIN	200MG/100ML	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2005
1008	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2007
1009	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,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2007

1010	NDA/MAL/HDP/2371	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIZONE CREAM	FUSIDIC ACID + BETAMETHAS ONE 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
1011	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
1012	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	PARENTERA L ORDINARY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF SOLVENT	7/1/2014

1013	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,1.0X1 000.0 TABLET CONTAINER	7/1/1997
1014	NDA/MAL/HDP/2384	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CLARIX 500	CLARITHROMY CIN	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
1015	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,1.0X1 000.0 TABLET CONTAINER	7/1/2000

1016	NDA/MAL/HDP/2387	DAWA LIMITED	SUPER MEDIC LTD	VERMOUT	MEBENDAZOLE	100MG/5ML	DAWA LIMITED - BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2010
1017	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2011
1018	NDA/MAL/HDP/2390	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTE MISININ/ 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 SUSPENSION S/SYRUPS/D ROPS	1.0X80.0 ML BOTTLE,1.0X1 20.0 ML BOTTLE	7/1/2008

1019	NDA/MAL/HDP/2391	BIOMATRIX HEALTHCARE PVT LTD	MEDIWORLD PHARMA AFRICA LTD	HEAD AID TABLETS	ASPIRIN + CAFFEINE + PARACETAMO L	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
1020	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
1021	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

1022	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
1023	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
1024	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

1025	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
1026	NDA/MAL/HDP/2408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2001
1027	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

1028	NDA/MAL/HDP/2410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2007
1029	NDA/MAL/HDP/2411	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	POVIDONE IODINE + METRONIDAZOLE	5%W/W + 1%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X10.0 G TUBE,1.0X100.0 G TUBE,1.0X250.0 G TUBE	7/1/2010
1030	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1998

1031	NDA/MAL/HDP/2415	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SOLINA TABLETS	DIAZEPAM	5MG	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER,1.0X1 00.0X10.0 TABLET BLISTER	7/1/1997
1032	NDA/MAL/HDP/2423	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	ATORIN	ATORVASTAT IN	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
1033	NDA/MAL/HDP/2426	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PROBEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X225.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2000

1034	NDA/MAL/HDP/2427	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CLONEM	CLOTRIMAZOL E	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
1035	NDA/MAL/HDP/2428	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 1% CREAM	CLOTRIMAZOL E	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
1036	NDA/MAL/HDP/2429	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOL E	100MG	DENK PHARMA GMBH & CO.KG- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRABE 1,29439	GERMANY	VAGINAL TABLETS	1.0X6.0 PESSARY CARTON	7/1/1998

1037	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
1038	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
1039	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

1040	NDA/MAL/HDP/2451	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN 75 SR	DICLOFENAC SODIUM	75 MG	ACINO PHARMA AG- DORNACHERSTRASS E 114, CH-4147 AESCH	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2004
1041	NDA/MAL/HDP/2452	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELATED 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
1042	NDA/MAL/HDP/2458	XEPA SOUL PATTISON (M) SDN BHD	DELMAN ENTERPRISES LIMITED	PRISTINEX 2% CREAM	KETOCONAZO LE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	2.0X15.0 G TUBE	7/1/2006

1043	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
1044	NDA/MAL/HDP/2462	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	HISTALIN SYRUP	CHLORPHENIR AMINE MALEATE/PRO METHAZINE/DIPHENHYDRAMINE/EPHEDRINE/AMMONIUM CHLORIDE/SODIUM CITRATE	1.0MG+2.5MG+5.0MG+7.5MG+90.0MG+48.0MG/5ML.	REGAL PHARMACEUTICALS LTD..-PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	7/1/1997
1045	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

1046	NDA/MAL/HDP/2472	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TRAN-GEL	DICLOFENAC DIETHYLAMM ONIUM	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
1047	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
1048	NDA/MAL/HDP/2475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORI DE	50MG/ML	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0 X2.0 ML AMPOULE	7/1/2001

1049	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
1050	NDA/MAL/HDP/2478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMO L+DICLOFENA C	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
1051	NDA/MAL/HDP/2479	SANCE LABORATORIES PVT LTD	DELMAR 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

1052	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2004
1053	NDA/MAL/HDP/2500	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	CHLORAMPHE NICOL SODIUM SUCCINATE INJECTION BP	CHLORAMPHE NICOL SODIUM SUCCINATE	1G	MACLEODS PHARMACEUTICALS LTD -PLOT NO. 25- 27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2007
1054	NDA/MAL/HDP/2502	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	PROBETA N EYE DROP	BETAMETHAS ONE + NEOMYCIN	0.1%W/V+0.5 %W/V	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	OPHTHALMI C DROPS	1.0X7.5 ML VIAL	7/1/1997

1055	NDA/MAL/HDP/2504	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	RESTOCIN	PARACETAMO L + CHLORPHENIR AMINE MALEATE + CAFFEINE + PHENYLEPHRI NE 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	1.0X50.0X1.0X 4.0 TABLET STRIP	7/1/2008
1056	NDA/MAL/HDP/2506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	NADOXIN	NADIFLOXACI N	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
1057	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

1058	NDA/MAL/HDP/2508	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	HYOSCINE	HYOSCINE	20MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2011
1059	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,MOGA DISHU 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
1060	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	1.0X5.0X2.0X1 0.0 TABLET BLISTER	7/1/2013

1061	NDA/MAL/HDP/2511	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 5MG	REMIFENTANI L	5MG	GLAXOSMITHKLINE MANUFACTURING SPA ,,-STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	ITALY	PARENTERA L ORDINARY DRY VIALS	1.0X5.0 VIAL CARTON	7/1/1999
1062	NDA/MAL/HDP/2512	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	DICLOFENAC SODIUM INJECTABLE SOLUTION	DICLOFENAC SODIUM	25MG/ML	WUHAN FUXING BIOPHARMACEUTIC AL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X3.0 ML AMPOULE,1.0 X10.0X3.0 ML AMPOULE	7/1/2009
1063	NDA/MAL/HDP/2513	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMET HYLPENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997

1064	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,1.0X1 000.0 TABLET CONTAINER	
1065	NDA/MAL/HDP/2521	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	MOTINORM	DOMPERIDON E	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
1066	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

1067	NDA/MAL/HDP/2524	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PRIMODIL-5	AMLODIPINE BESYLATE	5MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005
1068	NDA/MAL/HDP/2525	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	10.0X10.0 TABLET BLISTER,1.0X1 0.0 TABLET BLISTER	7/1/1998
1069	NDA/MAL/HDP/2526	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOL E	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	VAGINAL COMBINATI ON PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE	7/1/2009

1070	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
1071	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
1072	NDA/MAL/HDP/2553	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ESQZ-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

1073	NDA/MAL/HDP/2554	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ESQZ	ESOMEPRAZO LE	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
1074	NDA/MAL/HDP/2555	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PHENOBARBIT ONE TABLETS BP 30MG	PHENOBARBIT ONE	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0 TABLET CONTAINER	7/1/1998
1075	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

1076	NDA/MAL/HDP/2558	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U/ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	7/1/2007
1077	NDA/MAL/HDP/2559	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ERYTHROREN	ERYTHROMYCIN STEARATE	250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/2007
1078	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

1079	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
1080	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.VALSA D,GUJARAT,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997
1081	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

1082	NDA/MAL/HDP/2569	SANOFI AVENTIS	SURGIPHARM (U) LIMITED	NO-SPA	DROTAVERINE HYDROCHLORIDE	40MG/2ML	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO. LTD CSANYIKVOLGY SITE-CSANYIKVOLGY, P.O.BOX 565.3510, MISKOLC, HUNGARY	HUNGARY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE,1.0 X25.0X2.0 ML AMPOULE	7/1/1998
1083	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,100.0 X10.0 CAPSULE BLISTER	7/1/1997
1084	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 SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	7/1/2010

1085	NDA/MAL/HDP/2576	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEQUINE TABLETS	CHLOROQUIN E PHOSPHATE	250MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER	7/1/2000
1086	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,K ENYA	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	7/1/1997
1087	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,K ENYA LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP	7/1/1998

1088	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
1089	NDA/MAL/HDP/2594	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FEF	FERROUS SULPHATE + FOLIC ACID	200MG + 0.4MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1090	NDA/MAL/HDP/2595	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	ZEPILEN	CEFAZOLIN	1000MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON	7/1/2009

1091	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,1.0X2.0 X5.0 SUPPOSITORY STRIP	7/1/2005
1092	NDA/MAL/HDP/2600	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE-OD	CLARITHROMYCIN(EXTENDED 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
1093	NDA/MAL/HDP/2601	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 750MG	CEFUROXIME	750MG	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON	7/1/2009

1094	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2010
1095	NDA/MAL/HDP/2603	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	VIRADAY	TENOFOVIR + EMTRICITABIN E + 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
1096	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

1097	NDA/MAL/HDP/2610	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ATROPINE	ATROPINE	1MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2009
1098	NDA/MAL/HDP/2612	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	7/1/2005
1099	NDA/MAL/HDP/2628	MICRO LABS LTD	LABOREX UGANDA LIMITED	AZILIDE-500	AZITHROMYCI N	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

1100	NDA/MAL/HDP/2641	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOUS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	7/1/2014
1101	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI	7/1/2009
1102	NDA/MAL/HDP/2645	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X20.0 ML VIAL	7/1/2010

1103	NDA/MAL/HDP/2647	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	IBUPROFEN DENK 400MG	IBUPROFEN	400MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2005
1104	NDA/MAL/HDP/2648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMO L	125MG	RUBIEPHARM ARZNEIMITTEL GMHH -GERMANY BENE-ARZNEIMITTEL GMBH- HERTERICHSTR. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITOR IES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0 X5.0 SUPPOSITORY STRIP	7/1/2005
1105	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2005

1106	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
1107	NDA/MAL/HDP/2653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	SONADERM-GM	CLOBETASOL + MICONAZOLE + GENTAMICIN	0.05%W/W + 2% W/W + 0.1%W/W	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE, VERNA GOA-403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	7/1/2007
1108	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

1109	NDA/MAL/HDP/2656	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	100MG	SCOTT-EDIL PHARMACIA LTD (UNIT I)-56, EPIP, PHASE-1, JHARMAJRI, BADDI, DISTT. SOLAN, (H.P), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2008
1110	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
1111	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

1112	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
1113	NDA/MAL/HDP/2679	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ALERID SYRUP	CETIRIZINE HYDROCHLORI DE	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
1114	NDA/MAL/HDP/2680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	7/1/2007

1115	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
1116	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
1117	NDA/MAL/HDP/2685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUSPENSION)	PARACETAMOL	120MG/5ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE	7/1/2007

1118	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
1119	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
1120	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

1121	NDA/MAL/HDP/2697	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTIS ONE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/1997
1122	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
1123	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

1124	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
1125	NDA/MAL/HDP/2704	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	PRIMACORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	MACLEODS PHARMACEUTICALS LTD-MAHIM ROAD, NEAR KULDEEP NAGAR REGAR(WO MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X100.0 MG VIAL	7/1/2005
1126	NDA/MAL/HDP/2705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATAN LZ SE-151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	7/1/2011

1127	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,2 50.0 CAPSULE CONTAINER,5 00.0 CAPSULE CONTAINER,1 000.0 CAPSULE CONTAINER,1 0.0 CAPSULE CONTAINER	7/1/1997
1128	NDA/MAL/HDP/2708	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HYPER TABLETS	PROPRANOLO L HYDROCHLORI DE	40MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X2.0X50.0 TABLET BLISTER	7/1/2000
1129	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

1130	NDA/MAL/HDP/2712	NEON LABARATORIES LTD.	NORVIK ENTERPRISES LIMITED	ANAWIN	BUPIVACAINE	0.025%W/V	NEON LABORATORIES LTD--PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO-OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	7/1/2014
1131	NDA/MAL/HDP/2715	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE	LAMIVUDINE	150MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X60.0 TABLET CONTAINER	7/1/2008
1132	NDA/MAL/HDP/2717	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	OCUMYCIN EYE OINTMENT	CHLORAMPHE NICOL	1%W/W	CENTAUR PHARMA PVT. LTD-PLOT 39-41, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	7/1/2000

1133	NDA/MAL/HDP/2718	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	GYNOMIN	Z	Z	SHAIGAN PHARMACEUTICALS (PVT) LIMITED-14 KM ADYALA RD, RAWALPINDI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	7/1/1997
1134	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
1135	NDA/MAL/HDP/2720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACIL LIN	125MG/5ML+ 125MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X80.0 ML BOTTLE	7/1/2007

1136	NDA/MAL/HDP/2721	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRIMAFEN TABLET	IBUPROFEN + PARACETAMO L	400MG + 325MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2007
1137	NDA/MAL/HDP/2722	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	NO SORES	CHOLINE SALICYLATE/LI DOCAINE	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
1138	NDA/MAL/HDP/2725	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	STREPTOMYCI N SULPHATE FOR INJECTION	STREPTOMYCI N SULPHATE	1GM	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X5.0X1.0X1 0.0 VIAL CARTON	7/1/2011

1139	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
1140	NDA/MAL/HDP/2737	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	SENEX FORTE	SECNIDAZOLE	1G	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	
1141	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	PARENTERA L ORDINARY I V VIALS	1.0X5.0X10.0 ML VIAL	7/1/2001

1142	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
1143	NDA/MAL/HDP/2743	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	DUO-COTECXIN	DIHYDROARTERISININ + 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, 1.0X3.0X9.0 TABLET BLISTER	7/1/2005
1144	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

1145	NDA/MAL/HDP/2746	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH & CO. KG- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER	7/1/2000
1146	NDA/MAL/HDP/2753	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRASIL	METOCLOPRA MIDE HYDROCHLORI DE	10MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1147	NDA/MAL/HDP/2754	FDC LTD	AIVEEN (U) LIMITED	ZATHRIN 500	AZITHROMYCI N 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	1.0X10.0X1.0X 3.0 TABLET BLISTER,1.0X5 0.0X1.0X1.0X3 .0 TABLET BLISTER	7/1/2016

1148	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
1149	NDA/MAL/HDP/2760	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	DELADED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+DEXTROMETHORPHAN+SODIUM CITRATE+MENTHOL	14MG+6.5MG +57MG+2MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997
1150	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, 1.0X10.0X10.0 TABLET BLISTER	7/1/2010

1151	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
1152	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
1153	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

1154	NDA/MAL/HDP/2776	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	TENSIMIN-100	ATENOLOL	100MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1 4.0X10.0 TABLET BLISTER	7/1/1997
1155	NDA/MAL/HDP/2777	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/12.5MG TABLETS	VALSARTAN + HYDROCHLOR OTHIAZIDE	160MG + 12.5MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRA SSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2. 0X14.0 TABLET BLISTER	7/1/2016
1156	NDA/MAL/HDP/2779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SURGICAL SCRUB	POVIDONE IODINE	7.5%W/V	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD- PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X4 50.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	

1157	NDA/MAL/HDP/2781	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 6.25	CARVEDILOL	6.25MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2011
1158	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
1159	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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	11/19/2017

1160	NDA/MAL/HDP/2788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIVITAMIN TABLETS	MULTIINGREDIENT	N/A	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2010
1161	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
1162	NDA/MAL/HDP/2797	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	LUMAREN	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER	7/1/2010

1163	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'ORLEANS, 28000 CHARTRES, FRANCE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO	DENMARK	PARENTERA L ORDINARY PRE-FILLED PENS	1.0X1.5 ML FLEXPEN,1.0X 3.0 ML FLEXPEN	7/1/1997
1164	NDA/MAL/HDP/2802	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	TASOL	CLOBETASOL	0.05%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2005
1165	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/1997

1166	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
1167	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
1168	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 SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2005

1169	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
1170	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
1171	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

1172	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
1173	NDA/MAL/HDP/2835	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	SOLUDINE-M	POVIDONE IODINE / METRONIDAZOLE	5%W/W / 1%W/W	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE,1.0X125.0 G TUBE	7/1/2011
1174	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

1175	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
1176	NDA/MAL/HDP/2850	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DISPERCAM	PIROXICAM	20MG	MEDICAL UNION PHARMACEUTICAL CO.-PLANT: ABU-SULTAN, ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE	7/1/2007
1177	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

1178	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
1179	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
1180	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

1181	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
1182	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
1183	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,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X6.0 TABLET BLISTER,1.0X24.0X28.0 TABLET BLISTER	7/1/2005

1184	NDA/MAL/HDP/2891	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	TORVAST 20	ATORVASTATI N	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
1185	NDA/MAL/HDP/2892	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	NICARDIA-20 TABLETS	NIFEDIPINE	20MG	UNIQUE PHARMACEUTICAL LABORATORIES- PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/1997
1186	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2009

1187	NDA/MAL/HDP/2894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSIUM HYDROXIDE + OXETHAZAINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO-10TH OF RAMADAN CITY- FIRST INDUSTRIAL AREA -EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSION S	1.0X125.0 ML BOTTLE	7/1/2005
1188	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
1189	NDA/MAL/HDP/2898	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	TORVAST 10	ATORVASTATI N	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

1190	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
1191	NDA/MAL/HDP/2902	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MEGALIS-20	TADALAFIL	20MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)-VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, HIMACHAL PRADESH - 174101, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X15.0X1.0X4.0 TABLET STRIP	7/1/2005
1192	NDA/MAL/HDP/2905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+EPHEDRINE HYDROCHLORIDE+DIPHENHYDRAMINE HYDROCHLORIDE+DEXTRORPHAN	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

1193	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
1194	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
1195	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

1196	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
1197	NDA/MAL/HDP/2914	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	CHLOROCIDE SUSPENSION	CHLORAMPHE NICOL 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
1198	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

1199	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
1200	NDA/MAL/HDP/2920	CENTAUR PHARMACEUTICALS 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
1201	NDA/MAL/HDP/2940	CENTAUR PHARMACEUTICALS PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	BENZOX 5 GEL	BENZOYL PEROXIDE	5%W/W	CENTAUR PHARMACEUTICALS LTD- PLOT NO. 39 TIVIN IN	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X20.0 G TUBE	7/1/2005

1202	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
1203	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
1204	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

1205	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 SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/1998
1206	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,1.0X5 00.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1. 0X250.0 BLISTER CARTON	7/1/1998
1207	NDA/MAL/HDP/2948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORI DE	850MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 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

1208	NDA/MAL/HDP/2950	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	XALATAN	LATANOPROST	0.005%W/V	PFIZER MANUFACTURING - NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	OPHTHALMI C DROPS	1.0X2.5 ML BOTTLE	7/1/1998
1209	NDA/MAL/HDP/2951	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART FORTE TABLETS	ARTEMETHER + LUMEFANTRIN E	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	1.0X10.0X2.0X 6.0 TABLET BLISTER	7/1/2007
1210	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

1211	NDA/MAL/HDP/2957	MEDIPHARM SALES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEDITROL	CALCITRIOL	0.25MCG	MEGA LIFE SCIENCES LIMITED-: PLANT I : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER	7/1/2009
1212	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
1213	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

1214	NDA/MAL/HDP/2963	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK 500	AZITHROMYCI N	500MG	WOCKHARDT LIMITED-PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL- NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER, 1.0X3.0 TABLET BLISTER	7/1/2014
1215	NDA/MAL/HDP/2969	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	TENSIMIN-50	ATENOLOL	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,14.0X 10.0 TABLET BLISTER	7/1/1997
1216	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

1217	NDA/MAL/HDP/2971	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2004
1218	NDA/MAL/HDP/2979	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N CREAM	BETAMETHAS ONE 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
1219	NDA/MAL/HDP/2980	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART TABLETS	ARTEMETHER + LUMEFANTRIN E	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	1.0X10.0X3.0X 8.0 TABLET BLISTER,1.0X6. 0 TABLET BLISTER,1.0X2. 0X6.0 TABLET BLISTER,1.0X3. 0X6.0 TABLET BLISTER,1.0X2 4.0 TABLET BLISTER,1.0X1 8.0 TABLET BLISTER,1.0X1	7/1/2007

1220	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
1221	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
1222	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

1223	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
1224	NDA/MAL/HDP/2995	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GALLOP	LOPERAMIDE HYDROCHLORIDE USP	2MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER	NULL
1225	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

1226	NDA/MAL/HDP/2998	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	FITIN-5	LEVOCETIRIZIN E DIHYDROCHLO RIDE	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
1227	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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0 TABLET BLISTER	7/1/2007
1228	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

1229	NDA/MAL/HDP/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOMAX 1.5G	CEFTRIAXONE +SULBACTAM	1000MG+500 MG	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
1230	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
1231	NDA/MAL/HDP/3013	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOZOLE	ALBENDAZOLE	400MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2007

1232	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,1.0X2 0.0X4.0 TABLET BLISTER	7/1/2001
1233	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
1234	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

1235	NDA/MAL/HDP/3021	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GLIBENCLAMI DE TABLETS	GLIBENCLAMI DE	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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2012
1236	NDA/MAL/HDP/3023	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRAX	LEVAMISOLE HYDROCHLORI DE	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
1237	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,AURANGABA D- 431136 MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2008

1238	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 SUSPENSION S	1.0X10.0 ML BOTTLE	7/1/2007
1239	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	PARENTERA L ORDINARY S C VIALS	1.0X10.0 ML VIAL	7/1/2008
1240	NDA/MAL/HDP/3031	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETHASO NE	DEXAMETHAS ONE	0.5MG	AGOG PHARMA LTD.- NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2007

1241	NDA/MAL/HDP/3032	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	XYLO-ACINO 0.05%	XYLOMETAZOL INE	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
1242	NDA/MAL/HDP/3035	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOFORTE TONIC	FERRIC AMMONIUM CITRATE + FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMID E + 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,1.0X6 0.0 ML BOTTLE,1.0X1. 0X100.0 ML BOTTLE	7/1/2007
1243	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

1244	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,1.0X1 000.0 CAPSULE CONTAINER,1. 0X100.0 CAPSULE CONTAINER,1. 0X10.0X10.0 CAPSULE BLISTER	7/1/2007
1245	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,2.0X1 0.0 CAPSULE BLISTER	7/1/1997
1246	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2009

1247	NDA/MAL/HDP/3048	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO-DS TABLETS	SULFAMETHO XAZOLE/TRIM ETHOPRIM	800MG/160M G	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,1.0X1 0.0X10.0 TABLET CONTAINER,1. 0X3.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2007
1248	NDA/MAL/HDP/3051	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE	DILOXANIDE FUROATE+ME TRONIDAZOLE BENZOATE+SI METHICONE	125MG+160M G+25MG	BETA HEALTHCARE INTERNATIONAL LTD --PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2005
1249	NDA/MAL/HDP/3057	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COLD-A-GO CAPSULES	PARACETAMO L + PHENYLEPHRI NE HYDROCHLORI DE + DIPHENHYDRA MINE + 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,1.0X1 0.0X10.0 CAPSULE BLISTER	7/1/2007

1250	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
1251	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
1252	NDA/MAL/HDP/3063	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODIC-50	DICLOFENAC SODIUM	50MG	AGOG PHARMA LTD.-NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER	7/1/2007

1253	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
1254	NDA/MAL/HDP/3067	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMAGO SYRUP	PROMETHAZI NE	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
1255	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,1.0X1 00.0 CAPSULE CONTAINER	7/1/2007

1256	NDA/MAL/HDP/3072	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL TABLETS(THA NE)	PARACETAMO L	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. 0X100.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/1998
1257	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
1258	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

1259	NDA/MAL/HDP/3077	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOL E + HYDROCORTIS ONE	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
1260	NDA/MAL/HDP/3078	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB ALLERGY CONGESTION	PARACETAMO L/ CHLORPHENIR AMINE/ EPHEDRINE	500MG/ 2MG/ 30MG	JOHNSON&JOHNSO N 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
1261	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

1262	NDA/MAL/HDP/3085	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD TABLETS	PARACETAMO L+PHENYLEPH RINE HCL+CAFFEINE +CHLORPHENI RAMINE HYDROCHLORI DE	500.MG+5.0M G+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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X4. 0 TABLET BLISTER,1.0X5 0.0X4.0 TABLET BLISTER	7/1/2007
1263	NDA/MAL/HDP/3090	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	100MG/5ML	PHARMA INTERNATIONAL CO.- AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X50.0 ML BOTTLE	7/1/2004
1264	NDA/MAL/HDP/3091	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ONDI	ONDANSETRO N	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	PARENTERA L ORDINARY AMPOULES	1.0X2.0X5.0X2 .0 ML AMPOULE	7/1/2013

1265	NDA/MAL/HDP/3092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG /12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOR OTHIAZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSETRA SSE 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
1266	NDA/MAL/HDP/3095	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	AMPHEN SUSPENSION	CHLORAMPHE NICOL PALMITATE	125MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2007
1267	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

1268	NDA/MAL/HDP/3099	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	ZONA 0.1% CREAM	HYDROCORTIS ONE 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
1269	NDA/MAL/HDP/3101	DAWA LIMITED	SUPER MEDIC LTD	DACOLD SYRUP	PARACETAMO L + PSEUDOEPHE DRINE HCL + CHLORPHENIR AMINE 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
1270	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 SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2007

1271	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
1272	NDA/MAL/HDP/3111	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CALPOL	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	
1273	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 SUSPENSION S/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/1997

1274	NDA/MAL/HDP/3117	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	HYDROCORTIS ONE SODIUM SUCCINATE	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X100. 0 MG VIAL,1.0X50.0 X100.0 MG VIAL	7/1/2010
1275	NDA/MAL/HDP/3118	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM	ARTEMETHER /LUMEFANTRI NE	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,1.0X3 0.0X18.0 TABLET BLISTER,1.0X3 0.0X24.0 TABLET BLISTER,1.0X3 0.0X12.0 TABLET BLISTER,1.0X3 0.0X6.0	7/1/2011
1276	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

1277	NDA/MAL/HDP/3123	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 250 SUPPOSITORY	PARACETAMOL BP	250 MG	BLISS GVS PHARMA LIMITED-PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	7/1/2007
1278	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
1279	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

1280	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
1281	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,JOR DAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2. 0X14.0 TABLET BLISTER	7/1/2009
1282	NDA/MAL/HDP/3140	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 1MG	REMIFENTANI L	1 MG	GLAXOSMITHKLINE MANUFACTURING SPA ,,-STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	ITALY	PARENTERA L ORDINARY VIALS	1.0X5.0 VIAL CARTON	7/1/1999

1283	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	1.0X10.0X1.0X 10.0 TABLET BLISTER	7/1/2007
1284	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
1285	NDA/MAL/HDP/3147	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 40/12.5	TELMISARTAN /HYDROCHLO ROTHIAZIDE	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

1286	NDA/MAL/HDP/3155	MEDREICH PLC	SURGIPHARM (U) LIMITED	BIOFERON	FERRIC AMMONIUM CITRATE + CYANOCOBAL AMIN + 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
1287	NDA/MAL/HDP/3156	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DAYTIME FLU	PSEUDOPHE DRINE 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
1288	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

1289	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
1290	NDA/MAL/HDP/3167	MJ BIOPHARM PVT LTD	KIMSY MEDS LTD	MONAN-0.5G	MEROPENEM	0.5G	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	7/1/2010
1291	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

1292	NDA/MAL/HDP/3176	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	DOXYRONE- 100	DOXYCYCLINE HYDROCHLORI DE	100	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1. 0X10.0X10.0 CAPSULE BLISTER	7/1/2005
1293	NDA/MAL/HDP/3177	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM CREAM	BETAMETHAS ONE 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
1294	NDA/MAL/HDP/3178	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENDURIC TABLETS	BENDROFLUM ETHIAZIDE	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,1.0X1 000.0 TABLET CONTAINER	7/1/2005

1295	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
1296	NDA/MAL/HDP/3180	MJ BIOPHARM PVT LTD	VITACARE LIMITED	LOFIN 500	METFORMIN HYDROCHLORI DE	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
1297	NDA/MAL/HDP/3184	M.J BOPHARM PUT LTD	KIMSY MEDS LTD	MONAN	MEROPENEM	1G	M.J BIOPHARM PUT LTD -L-7 MIDC INDUSTRIOL DIST GAIED TOLOJA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2008

1298	NDA/MAL/HDP/3191	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ERecto -100	SILDENAFIL CITRATE	100 MG	CIPLA LIMITED PUNE- MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	
1299	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
1300	NDA/MAL/HDP/3193	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ERecto- 50	SILDENAFIL CITRATE	50MG	CIPLA LIMITED PUNE- MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	

1301	NDA/MAL/HDP/3196	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	MOTINORM	DOMPERIDON E	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
1302	NDA/MAL/HDP/3198	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-125	PHENOXYMET HYL PENICILLIN POTASSIUM	125MG/ML	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X100.0 ML BOTTLE	7/1/2011
1303	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

1304	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
1305	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
1306	NDA/MAL/HDP/3204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	RELCER GEL	ALUMINIUM HYDROXIDE/MAGNESIUM HYDROXIDE/DIMETHICONE/LIQUORICE	6G+80MG+100MG+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

1307	NDA/MAL/HDP/3206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGEST REL	0.75MG	GEDEON RICHTER PLC-1103 BUDAPEST GYOMROI UT 19-21	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	7/1/2010
1308	NDA/MAL/HDP/3207	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 90	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORI DE	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
1309	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	PARENTERA L ORDINARY VIALS	1.0X10.0X1.0X 20.0 ML VIAL,1.0X10.0 X50.0 ML VIAL	7/1/2010

1310	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,1.0X1 0.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2005
1311	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
1312	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 ADMINISTR ATION CFC- FREE METERED- DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	7/1/2009

1313	NDA/MAL/HDP/3219	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL ORAL SUSPENSION	CHLORAMPHE NICOL	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/1998
1314	NDA/MAL/HDP/3220	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PYLO KIT	LANSOPRAZOL E+TINIDAZOLE +CLARITHROM YCIN	30MG+500MG +250 MG	CIPLA LIMITED PUNE- MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X1.0X6 .0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)	7/1/2005
1315	NDA/MAL/HDP/3221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHAS ONE/NEOMYC IN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD- 117 ALLAM	PAKISTAN	OPHTHALMI C DROPS	1.0X5.0 ML VIAL	7/1/1999

1316	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
1317	NDA/MAL/HDP/3225	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DIFLAME	DICLOFENAC DIETHYLAMIN E + 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
1318	NDA/MAL/HDP/3233	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	WHITFIELD'S OINTMENT BP	BENZOIC ACID + SALICYLIC ACID	0.06G+0.03G	NEM LABORATORIES PVT LTD-PLOT NO. 133 KRISHNA IND. ESTATE, VASAI E,DIST PALGHAR- 401210, MAHARASHTRA STATE	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	7/1/1997

1319	NDA/MAL/HDP/3237	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL CREAM	KETOCONAZO LE	2% W/W	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2008
1320	NDA/MAL/HDP/3241	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CLOTRILIN	CLOTRIMAZOL E	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
1321	NDA/MAL/HDP/3243	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RAPITUS	LEVODROPRO PIZINE	30MG/5ML	MACLEODS PHARMACEUTICALS LTD -BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	

1322	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
1323	NDA/MAL/HDP/3246	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2000
1324	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

1325	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
1326	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
1327	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

1328	NDA/MAL/HDP/3259	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	TIGBODERM	BETAMETHAS ONE + CHLOROCRES OL + 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
1329	NDA/MAL/HDP/3261	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABIN E + EFAVIRENZ	TENOFOVIR DF + EMTRICITABIN E + 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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2008
1330	NDA/MAL/HDP/3262	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	250MG + 250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2007

1331	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
1332	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, MOGA DISHU 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
1333	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

1334	NDA/MAL/HDP/3273	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL CREAM	BETAMETHAS ONE 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
1335	NDA/MAL/HDP/3275	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	MEFLIN-500	MEFENAMIC ACID	500MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2010
1336	NDA/MAL/HDP/3277	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 500MG	TRANEXAMIC ACID	500MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	7/1/2001

1337	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	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X2 50.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE	7/1/1997
1338	NDA/MAL/HDP/3282	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRI NE HCL + CHLORPHENIR AMINE MALEATE + DEXTROMETH ORPHAN	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
1339	NDA/MAL/HDP/3284	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	CHALEATE	CHLORPHENIR AMINE 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,1.0X1 000.0 TABLET CONTAINER	7/1/1997

1340	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997
1341	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
1342	NDA/MAL/HDP/3288	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED CHESTY COUGHS SYRUP	DIPHENHYDRA MINE HCL BP+AMMONIU M CHLORIDE BP+SODIUM CITRATE BP+MENTHOL BP	14MG+135MG +57MG+1.1M G/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/1997

1343	NDA/MAL/HDP/3289	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID DUSTING POWDER	CLOTRIMAZOL E	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X30.0 G BOTTLE,1.0X1 00.0 G BOTTLE	7/1/1999
1344	NDA/MAL/HDP/3291	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FINTOP	BUTENAFINE HCL	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2003
1345	NDA/MAL/HDP/3292	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELAED PAEDIATRIC SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE+SODIUM CITRATE+MEN THOL	7MG+28.5MG +0.55MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/1997

1346	NDA/MAL/HDP/3294	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORIDE	50 MG	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2004
1347	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
1348	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

1349	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2011
1350	NDA/MAL/HDP/3300	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MUCOSOL PEDIATRIC SYRUP	CARBOCISTEIN E	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
1351	NDA/MAL/HDP/3301	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 250	TRANEXAMIC ACID	250MG	HILTON PHARMA (PVT) LTD-PLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2000

1352	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2009
1353	NDA/MAL/HDP/3304	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN	CEFALEXIN MONOHYDRA TE	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
1354	NDA/MAL/HDP/3309	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	CLORIFORT VAGINAL TABLETS	CLOTRIMAZOL E	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

1355	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 ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2004
1356	NDA/MAL/HDP/3314	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	SILVEREX	SILVER SULFADIAZINE + CHLORHEXIDI NE 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
1357	NDA/MAL/HDP/3315	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ERO-250 TABLETS	ERYTHROMYCI N 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,1.0X1 000.0 TABLET CONTAINER	NULL

1358	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1998
1359	NDA/MAL/HDP/3318	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM TABLETS	CO-TRIMOXAZOLE	480MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2000
1360	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

1361	NDA/MAL/HDP/3321	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOLIN- GM	CLOBETASOL+ GENTAMICIN+ MICONAZOLE	0.05%W/W+0. 1%W/W+2%W /W	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2008
1362	NDA/MAL/HDP/3328	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZYLPENICI LLIN INJECTION	BENZYLPENICI LLIN	1 MU	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP - NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL,1.0X10.0 X1.0 MU VIAL	7/1/2001
1363	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	OPHTHALMI C DROPS	1.0X5.0 ML VIAL	7/1/1997

1364	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
1365	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
1366	NDA/MAL/HDP/3341	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-250	AZITHROMYCI N	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

1367	NDA/MAL/HDP/3343	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	MEDIVEN-CREAM	BETAMETHAS ONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/1997
1368	NDA/MAL/HDP/3346	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	ZEDEX	BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DEXTROMETH ORPHAN	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
1369	NDA/MAL/HDP/3347	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMET HYL PENICILLIN	250MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/1997

1370	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
1371	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
1372	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

1373	NDA/MAL/HDP/3357	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICALS LIMITED	ESOREST 20	ESOMEPRAZO LE	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
1374	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	PARENTERA L ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2011
1375	NDA/MAL/HDP/3364	CENTAUR PHAMACUITICALS	GITTOES PHARMACEUTICALS LIMITED	ESOREST 40	ESOMEPRAZO LE	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

1376	NDA/MAL/HDP/3367	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL SUSPENSION	PARACETAMO L	125 MG/5ML	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2000
1377	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
1378	NDA/MAL/HDP/3369	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-500	AZITHROMYCI N	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

1379	NDA/MAL/HDP/3370	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DERMOREN 500	GRISEOFULVIN	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1380	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
1381	NDA/MAL/HDP/3373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 625	AMOXILICIN/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

1382	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
1383	NDA/MAL/HDP/3377	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMILINE	AMITRIPTYLINE	25 MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	7/1/2011
1384	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

1385	NDA/MAL/HDP/3379	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFASI	HUMAN CHORIONIC GONADOTROP IN	5000I.U	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERA L ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON	7/1/2011
1386	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 SUSPENSION S	1.0X1.0X60.0 ML BOTTLE,1.0X1. 0X100.0 ML BOTTLE	7/1/2010
1387	NDA/MAL/HDP/3383	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ZEPIN-200	CARBAMAZEPI NE	200 MG	AGOG PHARMA LTD- PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10. 0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2010

1388	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
1389	NDA/MAL/HDP/3385	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL-P- SUSPENSION	MEFENAMIC ACID	100MG/5ML	BLUE CROSS LABORATORIES LTD- L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE	7/1/2007
1390	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

1391	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
1392	NDA/MAL/HDP/3390	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ALUGEL	ALUMINIUM HYDROXIDE / MAGNESIUM TRISILICATE	120MG/250MG	ELYS CHEMICAL INDUSTRIES LTD- ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X5.0 ML JERRYCAN	7/1/1997
1393	NDA/MAL/HDP/3391	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEZIN TABLET	CETIRIZINE	10MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,100.0X10.0 TABLET BLISTER	7/1/2017

1394	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
1395	NDA/MAL/HDP/3396	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	BUPICAN HEAVY	BUPIVACAINE HYDROCHLORI DE IN DEXTROSE	0.5%W/V	CLARIS INJECTABLES LIMITED--- CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X25.0X4.0 ML AMPOULE	
1396	NDA/MAL/HDP/3399	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 10	ROSUVASTATI N	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

1397	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
1398	NDA/MAL/HDP/3405	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL BABY AND INFANT 120MG/5ML	PARACETAMO L	120MG/5ML	FARMACLAIR -440 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2008
1399	NDA/MAL/HDP/3406	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	MICRONEMA	NYSTATIN ORAL SUSPENSION,S ODIUM 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,1.0X2 0.0 ML BOTTLE	7/1/2005

1400	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
1401	NDA/MAL/HDP/3411	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABNAL NASAL DROPS	SODIUM CHLORIDE	0.9%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	NASAL SYSTEMIC DROPS	1.0X10.0 ML VIAL	7/1/2011
1402	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 SCHAFFHAUSERTRASS E 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

1403	NDA/MAL/HDP/3415	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID V-1	CLOTRIMAZOL E	500MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X1.0 PESSARY STRIP	7/1/2004
1404	NDA/MAL/HDP/3426	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RUBEM CREAM	METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALIC YLATE	1%W/W+0.1% W/W+5%W/ W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	7/1/1997
1405	NDA/MAL/HDP/3429	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	EZEDE	LORATADINE	10MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2006

1406	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
1407	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
1408	NDA/MAL/HDP/3439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR CAPSULE	CHLORAMPHE NICOL	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 0.0X10.0 CAPSULE BLISTER	

1409	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
1410	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
1411	NDA/MAL/HDP/3449	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAXONE SODIUM	1000MG	VENUS REMEDIES LIMITED ,.-HILL TOP,INDUSTRIAL ESTATE,JHARMAJRI, EPIP,PHASE 1,(EXTN.) ,BHATOLI KALAN,BADDI - H.P.INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL,1.0X10.0 X1.0X10.0 ML VIAL	7/1/2008

1412	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
1413	NDA/MAL/HDP/3451	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL CAPSULES (THANE0	CHLORAMPHE NICOL	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,1.0X1 00.0 CAPSULE CONTAINER,1. 0X1000.0 CAPSULE CONTAINER,1. 0X500.0 CAPSULE CONTAINER	7/1/1998
1414	NDA/MAL/HDP/3453	MJ BIOPHARM PVT LTD	VITACARE LIMITED	AMINOPHYLLI NE	AMINOPHYLLI NE	25MG/ML	M.J BIOPHARM PVT LTD-TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X10.0 ML AMPOULE	7/1/2014

1415	NDA/MAL/HDP/3456	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	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
1416	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
1417	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

1418	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
1419	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
1420	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&JOHNSO N PTY LTD...-241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X500.0 ML BOTTLE,1.0X2 50.0 ML BOTTLE	7/1/2007

1421	NDA/MAL/HDP/3465	MONDI-MUNDI PHARMA PVT LIMITED	SURGIPHARM (U) LIMITED	FECONTIN-Z	FERROUS GLYCINE SULPHATE+ZINC SULPHATE+FOLIC ACID	100MG+61.8 MG+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
1422	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
1423	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

1424	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,IN DIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0 X1.0 G VIAL	
1425	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2008
1426	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

1427	NDA/MAL/HDP/3478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1428	NDA/MAL/HDP/3482	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLOX-250	CLOXACILLIN	250MG	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2011
1429	NDA/MAL/HDP/3483	JOHNSON&JOHNSON PTY LTD. 241	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB 3-WAY	IBUPROFEN + PSEUDOEPHEDRINE HCL	200MG + 30MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2007

1430	NDA/MAL/HDP/3485	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ERGOMETRIN E	ERGOMETRIN E 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
1431	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
1432	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

1433	NDA/MAL/HDP/3494	FERRER INTERNATIONAL, S.A.	LABOREX UGANDA LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC ACID + VITAMIN B6	2G + 2G + 1G +1G	FERRER INTERNATIONAL, S.A.-C/JOAN BUSCALLA, 1-9.08173 SANT CUGAT DEL VALLES, BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X80.0 ML BOTTLE	7/1/2015
1434	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
1435	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

1436	NDA/MAL/HDP/3502	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HYDROCORTIS ONE SODIUM SUCCINATE	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERA L ORDINARY DRY VIALS	1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI	7/1/2010
1437	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
1438	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,1.0X1 000.0 CAPSULE CONTAINER	7/1/2015

1439	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
1440	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	7/1/2007
1441	NDA/MAL/HDP/3516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHXYPHENIDYL 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

1442	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
1443	NDA/MAL/HDP/3519	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2010
1444	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

1445	NDA/MAL/HDP/3522	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP - NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERA L ORDINARY VIALS	1.0X10.0X500. 0 MG VIAL	NULL
1446	NDA/MAL/HDP/3525	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLLIN	AMPICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER,1. 0X100.0X10.0 CAPSULE BLISTER	7/1/1998
1447	NDA/MAL/HDP/3527	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-500	LEVOFLOXACI N	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

1448	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
1449	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,MOGA DISHU 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
1450	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,PATANCHE RU MANDAL, MEDAK DISTRICT PIN CODE 502307, ANDHRA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2008

1451	NDA/MAL/HDP/3545	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID MOUTH PAINT	CLOTRIMAZOL E	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL TOPICAL LIQUIDS	1.0X15.0 ML BOTTLE	7/1/2000
1452	NDA/MAL/HDP/3546	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM D.S	SULPHAMETH OXAZOLE + TRIMETHOPRI M	800MG + 160MG	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5 00.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER	7/1/2013
1453	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

1454	NDA/MAL/HDP/3548	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	BECORT 200	BECLOMETAS ONE	200MCG/DOS E	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTR ATION METERED- DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	7/1/2009
1455	NDA/MAL/HDP/3549	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIR AMINE MALEATE+PSE UDO EPHEDRINE HCL+GUAIPHE NISIN+MENTH OL	1.0MG+15.0M G+50.0MG+0. 5MG / 5ML	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	7/1/2007
1456	NDA/MAL/HDP/3551	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA-500MG	AZITHROMYCI N	500MG	AJANTA PHARMA LIMITED PAITHAN- MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA AJANTA PHARMA LIMITED-PLOT NO.Z/103/A,DAHEJ SEZ PART 11,DISTRICT:	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X1 0.0X1.0X3.0 TABLET BLISTER	7/1/2009

1457	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
1458	NDA/MAL/HDP/3558	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	SEROFLO-250	SALMETEROL+ FLUTICASON PROPRIONATE	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
1459	NDA/MAL/HDP/3561	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCILLIN ORAL SUSPENSION	AMPICILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1998

1460	NDA/MAL/HDP/3563	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	LEVOLIFE	LEVOFLOXACIN	500MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2010
1461	NDA/MAL/HDP/3566	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	60 MG	GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5% NAHCO3 + 5 ML NACL INJECTION	7/1/2008
1462	NDA/MAL/HDP/3569	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CARBADAC-200	CARBAMAZEPI NE	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

1463	NDA/MAL/HDP/3573	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PARIN-E	ENOXAPARIN SODIUM	40MG/0.4ML	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X2.0X0.4 ML PRE- FILLED SYRINGE	7/1/2008
1464	NDA/MAL/HDP/3574	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METUZ 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT I-PLOT3,TIVIM INDUSTRIAL ESTATE,KARASWAD A,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2007
1465	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

1466	NDA/MAL/HDP/3577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	5MG/ML	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE, 1.0X10.0X10.0X2.0 ML AMPOULE	7/1/2009
1467	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
1468	NDA/MAL/HDP/3580	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	7/1/2008

1469	NDA/MAL/HDP/3581	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOZ 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT I- PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWAD A,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2007
1470	NDA/MAL/HDP/3582	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	SULPHADIMID INE	SULPHADIMID INE	500MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2009
1471	NDA/MAL/HDP/3588	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-180	FEXOFENADIN E	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

1472	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
1473	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	PARENTERA L ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE	7/1/1998
1474	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	PARENTERA L ORDINARY I M AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2001

1475	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
1476	NDA/MAL/HDP/3600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTHE MISININ + 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
1477	NDA/MAL/HDP/3606	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	CELLTRIAXON	CEFTRIAZONE	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	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2010

1478	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
1479	NDA/MAL/HDP/3610	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROMETHAZI NE TABLETS BP 25MG	PROMETHAZI NE HYDROCHLORI DE	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0 TABLET CONTAINER	7/1/1998
1480	NDA/MAL/HDP/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRI L SYRUP	PARACETAMO L + CHLORPHENIR AMINE + PSEUDOEPHE DRINE	120MG+1MG+ 10MG	BETA HEALTHCARE INTERNATIONAL LIMITED-PLOT NUMBER LR 209/6554,MOGADIS HU 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

1481	NDA/MAL/HDP/3612	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-H 12.5	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2011
1482	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
1483	NDA/MAL/HDP/3614	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ERYTHROREN SUSPENSION	ERYTHROMYCI N STEARATE	125MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2008

1484	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
1485	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
1486	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

1487	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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X50.0 ML BOTTLE	7/1/2007
1488	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/1997
1489	NDA/MAL/HDP/3628	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 5S	AMINO ACIDS/SORBIT OL	5%W/V+5%W /V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD- VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERA L ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	7/1/2001

1490	NDA/MAL/HDP/3630	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 600	THEOPHYLLIN E	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
1491	NDA/MAL/HDP/3631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008
1492	NDA/MAL/HDP/3634	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPLUS	PARACETAMO L+DEXTROMET HORPHAN HCL+ CHLORPHENIR AMINE+PHEN YLEPHRINE 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

1493	NDA/MAL/HDP/3635	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIROGAN	PROMETHAZI NE HYDROCHLORI DE	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2011
1494	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
1495	NDA/MAL/HDP/3639	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL ADVANCE	PARACETAMO L	500MG	GLAXOSMITHKLINE LIMITED - -78392- 00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X11.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER,1.0X2. 0X10.0 TABLET BLISTER	7/1/2010

1496	NDA/MAL/HDP/3641	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	TRD-CONTIN 100	TRAMADOL HYDROCHLORI DE	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
1497	NDA/MAL/HDP/3642	IND-SWIFT	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE 250	CLARITHROMY CIN	250MG	IND-SWIFT-LTD,- GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X 7.0 TABLET BLISTER	7/1/2007
1498	NDA/MAL/HDP/3647	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	NYSTAGO ORAL SUSPENSION	NYSTATIN	100000 IU	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL TOPICAL SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2008

1499	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
1500	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
1501	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	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997

1502	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:	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	7/1/2008
1503	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
1504	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	10.0X10.0 TABLET STRIP,1.0X3.0 X10.0 TABLET BLISTER	7/1/2003

1505	NDA/MAL/HDP/3664	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	AZZY	AZITHROMYCI N	500MG	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	7/1/2011
1506	NDA/MAL/HDP/3666	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM 50	TRAMADOL HYDROCHLORI DE	50MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2008
1507	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE,1.0X1 40.0 ML BOTTLE	7/1/1998

1508	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 SUSPENSION S	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE	7/1/2014
1509	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
1510	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

1511	NDA/MAL/HDP/3672	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 6.4	NITROGLYCERI N	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
1512	NDA/MAL/HDP/3673	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	PROMETHAZI NE INJECTABLE SOLUTION	PROMETHAZI NE HCL	25MG/ML	WUHAN FUXING BIOPHARMACEUTIC AL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE,1.0 X10.0X2.0 ML AMPOULE	7/1/2010
1513	NDA/MAL/HDP/3674	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZI NE HYDROCHLORI DE	5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5. 0 L JERRYCAN	7/1/1997

1514	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
1515	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
1516	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

1517	NDA/MAL/HDP/3686	ACINO PHARMA AG -	GOODMAN INTERNATIONAL LTD	NEURORUBIN E™-FORTE 20 FILM-COATED TABLETS	MULTIVITAMI N	MULTINGREDI ENT	ACINO PHARMA AG- BIRSWEG 2, 4253, LIESBERG - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X1 00.0X10.0 TABLET BLISTER	7/1/1997
1518	NDA/MAL/HDP/3687	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZI NE HCL	5MG/5ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE	7/1/2010
1519	NDA/MAL/HDP/3688	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX MINT FLAVOUR	ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG +250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C- 4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X200.0 ML BOTTLE,1.0X3 0.0 ML BOTTLE	7/1/2013

1520	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,1.0X1 000.0 TABLET CONTAINER	7/1/2011
1521	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
1522	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997

1523	NDA/MAL/HDP/3699	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2005
1524	NDA/MAL/HDP/3702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATI N	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
1525	NDA/MAL/HDP/3703	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPYRIDINI UM CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	7/1/2014

1526	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,1.0X2.0.0X4.0 TABLET BLISTER	7/1/2002
1527	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
1528	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

1529	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
1530	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
1531	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

1532	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
1533	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
1534	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

1535	NDA/MAL/HDP/3717	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEFTRIAXONE SODIUM	CEFTRIAXONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICALS LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY CHINA	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0 X1.0 G VIAL	7/1/2011
1536	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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X100.0 ML BOTTLE	7/7/1997
1537	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

1538	NDA/MAL/HDP/3725	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	NEW TUXIRIL	DEXTROMETH ORPHAN HBR + PHENYLEPHRI NE 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
1539	NDA/MAL/HDP/3728	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 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
1540	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,1.0X3.0 X10.0 TABLET STRIP	7/1/2008

1541	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
1542	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
1543	NDA/MAL/HDP/3734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTISONE	2%W/W + 1%W/W	XEPA SAUL PATTINSON MALAYSIA-1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/1998

1544	NDA/MAL/HDP/3736	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 125 SUPPOSITORY	PARACETAMOL	125MG	BLISS GVS PHARMA LIMITED-PLOT NO. 10/11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE	INDIA	RECTAL SYSTEMIC SUPPOSITORY	1.0X1.0X5.0 SUPPOSITORY BLISTER	7/1/2007
1545	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
1546	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,1.0X50.0 X500.0 MG VIAL	7/1/2010

1547	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
1548	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
1549	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

1550	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
1551	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
1552	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

1553	NDA/MAL/HDP/3747	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	30.0X2.0 TABLET BLISTER	7/1/2002
1554	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
1555	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

1556	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
1557	NDA/MAL/HDP/3754	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	SINAREST PD NASAL DROPS	OXYMETAZOLINE HYDROCHLORIDE	0.025%W/V	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	7/1/2006
1558	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

1559	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,1.0X1 000.0 TABLET CONTAINER	7/1/1997
1560	NDA/MAL/HDP/3761	COSMOS LTD	ASTRA PHARMA (U) LIMITED	RIFACOS-300	RIFAMPICIN	300 MG	COSMOS LIMITED- RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER	7/1/1998
1561	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

1562	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
1563	NDA/MAL/HDP/3770	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	7/1/2005
1564	NDA/MAL/HDP/3771	PLEX LIFE PROVIDER	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BRONQUIDIAZINA C.R	TRIMETHOPRIM/SULFAMETHOXAZOLE/BROMHEXINE/SODIUM BENZOATE/TOLU BALSAM	80MG/400MG /4MG/250MG /325MG	FAES FARMA, S.A - MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X150.0 ML BOTTLE	7/1/2014

1565	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
1566	NDA/MAL/HDP/3773	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBUTOL-4	SALBUTAMOL SULPHATE	4 MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	7/1/2005
1567	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

1568	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 SUSPENSION S	1.0X20.0 ML BOTTLE	7/1/2014
1569	NDA/MAL/HDP/3782	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAE-PEN V	PHENOXYMET HYLPENICILLIN	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
1570	NDA/MAL/HDP/3784	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	CIPIUM	CHLORPHENIR AMINE	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,1.0X6 0.0 ML BOTTLE	7/1/2011

1571	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
1572	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
1573	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

1574	NDA/MAL/HDP/3792	MEDREICH PLC	SURGIPHARM (U) LIMITED	FLEMING 228.5	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	200MG+28.5 MG	MEDREICH LIMITED UNIT 1-12TH MILE, OLD MADRAS ROAD, VIRGONAGAR, BANGOLORE-560049	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2007
1575	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
1576	NDA/MAL/HDP/3797	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	PROVIVE 1%	PROPOFOL	10MG/ML	BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITED- CHACHARWADI - VASANA, AHMEDABAD, IN 382213	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	

1577	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
1578	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 SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2002
1579	NDA/MAL/HDP/3802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDRO CHLORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG - 51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	7/1/2005

1580	NDA/MAL/HDP/3803	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	DICLODYNE SUPPOSITORY	DICLOFENAC SODIUM	100MG	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	7/1/2007
1581	NDA/MAL/HDP/3804	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBIN E 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
1582	NDA/MAL/HDP/3807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	NINGBO DAHONGYING PHARMACEUTICALS-NO.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2008

1583	NDA/MAL/HDP/3808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIE S 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 SUPPOSITOR IES	1.0X2.0X5.0 SUPPOSITORY STRIP	7/1/2006
1584	NDA/MAL/HDP/3809	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID DAY & NIGHT	PARACETAMO L+CHLORPHEN IRAMINE MALEATE+PHE NYLEPRINE HYDROCHLORI DE + 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
1585	NDA/MAL/HDP/3812	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	B-TONE	PHENOBARBIT ONE	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

1586	NDA/MAL/HDP/3813	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ACTIPAR	PIPERAZINE CITRATE	500MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	7/1/1997
1587	NDA/MAL/HDP/3814	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	50MG/1ML	MARTINDALE PHARMACEUTICAL LIMITED -BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/1997
1588	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

1589	NDA/MAL/HDP/3827	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-10	ATORVASTATI N	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
1590	NDA/MAL/HDP/3829	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	DRIED ALUMINUM HYDROXIDE/M AGNESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIME THICANE	300MG / 25MG / 50MG / 25MG	BETA HEALTHCARE INTERNATIONAL LTD -- PLOT NO.209/6554,MOGA DISHU 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
1591	NDA/MAL/HDP/3831	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA	LOPINAVIR+RI TONAVIR	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

1592	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
1593	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,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	7/1/1997
1594	NDA/MAL/HDP/3837	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NITROFURANT OIN	NITROFURANT OIN	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

1595	NDA/MAL/HDP/3839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOP HEN + 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
1596	NDA/MAL/HDP/3840	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TORACTIN TABLETS	CYPROHEPTA DINE	4MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2000
1597	NDA/MAL/HDP/3843	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK	AZITHROMYCI N	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

1598	NDA/MAL/HDP/3844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSE TRASSE 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
1599	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
1600	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

1601	NDA/MAL/HDP/3848	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK	AZITHROMYCI N	200MG/5ML	WOCKHARDT LIMITED --PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL- NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X15.0 ML BOTTLE	7/1/1998
1602	NDA/MAL/HDP/3850	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	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
1603	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

1604	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,1.0X6 0.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE	7/1/2009
1605	NDA/MAL/HDP/3862	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LAMITOR 100	LAMOTRIGINE	100MG	TORRENT PHARMACEUTICALS LTD-TORRENT PHAMACEUTICALS LTD INDRAD 382721 DIST MEHSANA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008
1606	NDA/MAL/HDP/3866	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	RL	COMPOUND SODIUM LACTATE INFUSION BP	0.6/ 0.25 /0.04 / 0.027 % W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X250.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	7/1/2010

1607	NDA/MAL/HDP/3867	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM OINTMENT	BETAMETHAS ONE 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
1608	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
1609	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

1610	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
1611	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2009
1612	NDA/MAL/HDP/3882	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	PEDIVIT FORTE CAPSULES	MULTIINGRED IENT	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

1613	NDA/MAL/HDP/3883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLATE SODIUM	360MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSE TRASSE 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
1614	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
1615	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

1616	NDA/MAL/HDP/3888	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PYRIREN	PYRIDOXINE HYDROCHLORIDE	25MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/2014
1617	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
1618	NDA/MAL/HDP/3892	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TETRAX	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	7/1/1997

1619	NDA/MAL/HDP/3893	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	EPINEPHRINE INJECTION USP	EPINEPHRINE HCL	1MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR,	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2008
1620	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
1621	NDA/MAL/HDP/3897	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/ CLAVULANIC ACID	875MG/125M G	DAR AL DAWA- NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	7/1/2010

1622	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
1623	NDA/MAL/HDP/3906	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	LEROLE	PANTOPRAZOLE	40MG	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL 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
1624	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

1625	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
1626	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,	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE, 1.0 X10.0X10.0X2.0 ML AMPOULE	
1627	NDA/MAL/HDP/3922	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	DIAZI	DIAZEPAM	5MG/ML	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2011

1628	NDA/MAL/HDP/3924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMO L+PSEUDOPH EDRINE HYDROCHLORI DE+TRIPOLIDI NE HYDROCHLORI DE	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	7/1/1997
1629	NDA/MAL/HDP/3925	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CALCIUM GLUCONATE INJECTION	CALCIUM GLUCONATE	10 %W/V	NINGBO DAHONGYING PHARMACEUTICALS- NO.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	7/1/2009
1630	NDA/MAL/HDP/3926	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	MIFUPEN TABLETS	ACETYLSALICY LIC 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

1631	NDA/MAL/HDP/3928	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MALAREN	SULPHADOXIN E + PYRIMETHAMINE	500MG/25MG	RENE INDUSTRIES LTD .-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X50.0X3.0 TABLET BLISTER	7/1/2004
1632	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
1633	NDA/MAL/HDP/3932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEP OXIDE	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

1634	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 ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	7/1/2001
1635	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2011
1636	NDA/MAL/HDP/3947	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RABTAS-20	RABEPRAZOLE SODIUM	20 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ- BAVLA HIGHWAY	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2008

1637	NDA/MAL/HDP/3948	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	50MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2009
1638	NDA/MAL/HDP/3949	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION			REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/1997
1639	NDA/MAL/HDP/3950	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM	TRAMADOL HYDROCHLORI DE	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2014

1640	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
1641	NDA/MAL/HDP/3954	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	POWERCEF 1GM INJECTION	CEFTRIAXONE SODIUM	1GM	ZEISS PHARMACEUTICALS PVT. LIMITED-PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA WOCKHARDT LIMITED-B-15/2 MIDC, WALUJ, AURANGABAD 431136, MAHARASHTRA STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2001
1642	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

1643	NDA/MAL/HDP/3963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	NOVARTIS URUNLERI TURKEY-YENISEHIR MAHALLESİ, IHLARA VADISI SOKAK, NO. 2, TR 34912, PENDİK, İSTANBUL, TURKEY.	UNITED STATES	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X3.0X6.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,2.0X1.0X24.0 TABLET BLISTER,2.0X1.0X18.0 TABLET BLISTER,1.0X3.6X6.0	7/1/2009
1644	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
1645	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/2011

1646	NDA/MAL/HDP/3969	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/ GRANULES	1.0X6.5 G SACHET	7/1/2002
1647	NDA/MAL/HDP/3970	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	CO- TRIMOXAZOLE	480MG	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/1997
1648	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

1649	NDA/MAL/HDP/3977	CHINOIN PHARMACEUTICALS AND CHEMICAL WORKS, CO. LTD	SURGIPHARM (U) LIMITED	NO-SPA 40MG	DROTAVERINE HYDROCHLORI DE	40MG	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO.LTD-H-2112, VERESEGYHAZ, LEVAI U.5.HUNGARY	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2. 0X10.0 TABLET BLISTER	7/1/1998
1650	NDA/MAL/HDP/3983	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMO L/CAFFEINE TABLETS	500MG/65MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILSHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5 0.0X2.0 TABLET BLISTER	7/1/2008
1651	NDA/MAL/HDP/3985	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMYCIN SUSPENSION	ERYTHROMYCI N ESTOLATE	125MG/5ML	AGOG PHARMA- PLOT 33 SECTOR THE VASAI-TULUKA CO- OP ESTATE LTD INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X100.0 ML BOTTLE	7/1/2008

1652	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
1653	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
1654	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

1655	NDA/MAL/HDP/3996	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTOIN TABLETS	NITROFURANT OIN 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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2007
1656	NDA/MAL/HDP/3998	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN +BROMHEXIN E HYDROCHLORI DE +LEVOMENTH OL	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
1657	NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENA RIMINE MALEATE/DEX AMETHASONE	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

1658	NDA/MAL/HDP/4001	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD PLUS SYRUP	PARACETAMO L+PHENYLEPH RINE+CHLORP HENIRAMINE+ 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
1659	NDA/MAL/HDP/4002	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCID	ALUMINIUM HYDROXIDE+ MAGNESIUM HYDROXIDE	250MG/5ML+ 250MG/5ML	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X1 70.0 ML BOTTLE	7/1/2007
1660	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

1661	NDA/MAL/HDP/4007	SANOI 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 FORMALDEHY	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 IM VIALS	1.0X10.0X1.5 ML VIAL (1 DOSE)	7/1/2016
1662	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	7/1/1997
1663	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

1664	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 SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE	7/1/2005
1665	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
1666	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

1667	NDA/MAL/HDP/4023	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST LINCTUS	CHLORPHENIR AMINE+DEXTR OMETHORPHA N+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
1668	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
1669	NDA/MAL/HDP/4033	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN PAEDIATRIC SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE	7MG/5ML	JOHNSON&JOHNSO N 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

1670	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
1671	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
1672	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

1673	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,1.0X6.0X2.0X5.0 TABLET BLISTER	7/1/2004
1674	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
1675	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

1676	NDA/MAL/HDP/4060	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	TOBRADEX	TOBRAMYCIN/ DEXAMETHAS ONE	0.3%W/V+ 0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/1997
1677	NDA/MAL/HDP/4062	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	KIVEXA	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)- PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1. 0X3.0X10.0 TABLET BLISTER	7/1/2006
1678	NDA/MAL/HDP/4064	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TERAFINE	TERBINAFINE	250MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	7/1/2010

1679	NDA/MAL/HDP/4066	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	UNIBROL	AMINOSIDINE	125MG/ML	UNIVERSAL CORPORATION LTD- KIKUYU NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	7/1/2011
1680	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
1681	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

1682	NDA/MAL/HDP/4075	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	CHERICOF COUGH FORMULAR	CHLORPHENIR AMINE/DEXTR OMETHORPHA N HBR/PHENYLE PHRINE 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
1683	NDA/MAL/HDP/4079	PHARMA INTL CO..	OMAB UGANDA LIMITED	NERVAMINE	MECOBALAMI N	500MCG	PHARMA INTERNATIONAL CO.- AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2009
1684	NDA/MAL/HDP/4085	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINACEF	CEFUROXIME SODIUM	750MG	GLAXO WELLCOME - VERONA ITALY	ITALY	PARENTERA L ORDINARY DRY VIALS	1.0X750.0 MG VIAL	7/1/1997

1685	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
1686	NDA/MAL/HDP/4093	LEBEN LABORATORIES LTD	MALIX PHARMA (U) LIMITED	BECLOMIN OINTMENT	BECLOMETHASONE+MICONAZOLE+NEOMYCIN	0.025%W/W + 2%W/W + 0.5%W/W	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/2007
1687	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

1688	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
1689	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
1690	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

1691	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
1692	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
1693	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,1.0X1 000.0 TABLET CONTAINER	

1694	NDA/MAL/HDP/4113	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTIN 10	EBASTINE	10 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	7/1/2005
1695	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
1696	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,1.0X10.0X10.0 TABLET BLISTER	7/1/2007

1697	NDA/MAL/HDP/4118	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	OCUREST-AH	PHENYLEPHRI NE HYDROCHLORI DE+NAPHAZO LINE HYDROCHLORI DE+CHLORPHR ENIRAMINE MALEATE+ME NTHOL+CAMP HOR	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	OPHTHALMI C DROPS	1.0X10.0 ML VIAL	7/1/2005
1698	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,1.0X3 00.0 ML BOTTLE	7/1/1998
1699	NDA/MAL/HDP/4128	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAREN SYRUP	VITAMIN A + VITAMIN B2 + VITAMIN B1 + VITAMIN B6 + VITAMIN C + VITAMIN E + VITAMIN B3	1500IU/5ML + 1MG/5ML + 1MG/5ML + 0.5MG/5ML + 20MG/5ML + 100 IU/5ML + 10MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1. 0X100.0 ML BOTTLE	7/1/2008

1700	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
1701	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
1702	NDA/MAL/HDP/4143	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	TAM CONTIN 0.4	TAMSULOSIN HYDROCHLORI DE	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

1703	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,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2011
1704	NDA/MAL/HDP/4147	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	NIFEDI-DENK 20 RETARD	NIFEDIPINE	20MG	DENK PHARMA GMBH & CO.KG- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2000
1705	NDA/MAL/HDP/4148	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	AMITRIPTYLIN E TABLETS	AMITRIPTYLIN E	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,1.0X1 00.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER	7/1/1998

1706	NDA/MAL/HDP/4150	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	7/1/1997
1707	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	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2001
1708	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

1709	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
1710	NDA/MAL/HDP/4171	SHIJIAZHUANG AOSUO INTERNATIONAL TRADE CO. 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
1711	NDA/MAL/HDP/4172	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	KOF OFF EXPECTORANT	MULTI-INGREDIENT	MULTI-INGREDIENT	RENE INDUSTRIES-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X110.0 ML BOTTLE	7/1/2005

1712	NDA/MAL/HDP/4173	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	NASONEX	MOMETASON E FUROATE MONOHYDRA TE	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
1713	NDA/MAL/HDP/4182	CENTAUR PHARMACEUTICALS 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,1.0X5 0.0X4.0 TABLET STRIP	7/1/2007
1714	NDA/MAL/HDP/4183	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORPROMA ZINE	CHLORPROMA ZINE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2011

1715	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
1716	NDA/MAL/HDP/4188	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRAZ	PRAZIQUANTEL	600MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X4.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER	7/1/2013
1717	NDA/MAL/HDP/4209	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	POZINEG 1000	CEFEPIME	1000MG	AUROBINDO PHARMA LIMITED, UNIT III-SURVEY NO. 313 & 314, BACHUPALLY (MANDAL), MEDCHAL - MALKAJGIRI (DISTRICT) - 500090 TELEGANA (STATE)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 1*1AMP WATER FOR INJECTION	7/1/2008

1718	NDA/MAL/HDP/4241	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMPICILLIN SODIUM FOR INJECTION BP	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP - NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X500. 0 MG VIAL	7/1/2011
1719	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	SWITZERLAND	PARENTERA L ORDINARY VIALS	1.0X4.0 ML VIAL	7/1/2016
1720	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	PARENTERA L ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 5 ML NACL + 1 ML SODIUM BICARBONATE	7/1/2013

1721	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,1.0X2 50.0 ML BOTTLE	7/1/2014
1722	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
1723	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2013

1724	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	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL	7/1/2016
1725	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, 1.0X50.0 X10.0 ML VIAL	7/1/2010
1726	NDA/MAL/HDP/4291	GITTOES PHARMACEUTICALS 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

1727	NDA/MAL/HDP/4303	PFIZER LABORATORIES (PTY)	LABOREX UGANDA LIMITED	SAYANA PRESS	MEDROXYPROGESTERONE ACETATE	104MG/0.65ML	PFIZER MANUFACTURING - NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY IM PRE-FILLED SYRINGES	1.0X200.0X0.65 ML PRE-FILLED SYRINGE	
1728	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
1729	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	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2010

1730	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,15.7002 6 MODUGNO (BA).ITALY MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI	7/1/2016
1731	NDA/MAL/HDP/4315	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	DESLORA- DENK 5	DESLORATIDIN E	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
1732	NDA/MAL/HDP/4317	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	COLOSAR- DENK 50/12.5	LOSARTAN + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTESTR.7 9.81675 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

1733	NDA/MAL/HDP/4318	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	AKUGABALIN	PREGABALIN	75 MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	1/7/2016
1734	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
1735	NDA/MAL/HDP/4329	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIR AMINE 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

1736	NDA/MAL/HDP/4330	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILL IN CAPSULES	FLUCLOXACILL IN	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
1737	NDA/MAL/HDP/4331	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC	ACECLOFENAC	100MG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C- 4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2010
1738	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

1739	NDA/MAL/HDP/4335	DAWA LIMITED	SUPER MEDIC LTD	CURAMOL SUSPENSION	PARACETAMOL	120MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2009
1740	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 ADMINISTR ATION CFC- FREE METERED- DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	7/1/2007
1741	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,K ENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1997

1742	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	7/1/1997
1743	NDA/MAL/HDP/4352	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN SYRUP	QUININE HYDROCHLORI DE	100MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2001
1744	NDA/MAL/HDP/4358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGICTICS AND SERVICES-VIA 3 SETTE SANTI FLORENCE 50131 ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	7/1/2016

1745	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
1746	NDA/MAL/HDP/4362	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LEVOMAC 750	LEVOFLOXACIN HEMIHYDRATE	750MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2016
1747	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

1748	NDA/MAL/HDP/4366	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA	CLOXACILLIN	250MG	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER	7/1/2004
1749	NDA/MAL/HDP/4367	ASTRAZENECA AG	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
1750	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,BORGOSAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	

1751	NDA/MAL/HDP/4379	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	SINURHON	MULTI- INGREDIENT	5MG/ 2MG/ 500MG / 30MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X12.0X40.0 TABLET BLISTER,1.0X1. 0X6.0X20.0 TABLET BLISTER,1.0X5 00.0 TABLET CONTAINER	7/1/2010
1752	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE,1.0X5 0.0 ML BOTTLE	7/1/1998
1753	NDA/MAL/HDP/4383	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORI DE BP	150MG	THE MADRAS PHARMACEUTICALS- 137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM ,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2016

1754	NDA/MAL/HDP/4388	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	TAZOBAC	PIPERACILLIN SODIUM + TAZOBACTAM SODIUM	4.0G + 0.5G	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X4.5 G VIAL	7/1/2016
1755	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
1756	NDA/MAL/HDP/4390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHE NICOL	0.5%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMI C DROPS	1.0X10.0 ML BOTTLE	7/1/2016

1757	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
1758	NDA/MAL/HDP/4394	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NS	SODIUM CHLORIDE	0.9% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X500.0 ML BOTTLE,1.0X2 50.0 ML BOTTLE	7/1/2010
1759	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,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	7/1/2007

1760	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
1761	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
1762	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

1763	NDA/MAL/HDP/4402	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	CLOTRILIN	CLOTRIMAZOLE	100MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	7/1/2014
1764	NDA/MAL/HDP/4404	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF	RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE	75I.U/ VIAL	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K 27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2016
1765	NDA/MAL/HDP/4406	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	SATISFIL -100	SILDENAFIL	100MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	7/1/2011

1766	NDA/MAL/HDP/4407	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	SUXAMETHON IUM CHLORIDE- FRESENIUS	SUXAMETHON IUM CHLORIDE	100MG/2ML	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD v-6 GIBAUD...ROAD KORSTEN, PORT ELIZABETH, SOUTH AFRICA.	SOUTH AFRICA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2016
1767	NDA/MAL/HDP/4408	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOL E	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	7/1/1997
1768	NDA/MAL/HDP/4411	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND PLUS	CANDESARTA N + HYDROCHLOR OTHIAZIDE	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

1769	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL (+ 1 GLASS AMPOULE OF 10ML WFI)	7/1/2011
1770	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	10.0X10.0 TABLET BLISTER,1.0X2. 0X10.0 TABLET BLISTER	7/1/1997
1771	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	PARENTERA L ORDINARY DRY VIALS	1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES	7/1/2014

1772	NDA/MAL/HDP/4419	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROP HIN	75IU/5ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERA L ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NACL	7/1/2010
1773	NDA/MAL/HDP/4425	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN FC	QUININE	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	7/1/2011
1774	NDA/MAL/HDP/4468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZO LE SODIUM SESQUIHYDRA TE	40MG	AUROBINDOPHARM A 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	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016

1775	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
1776	NDA/MAL/HDP/4519	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 5	AMLODIPINE BESILATE	5MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X3.0X10.0 TABLET BLISTER	7/1/2007
1777	NDA/MAL/HDP/4522	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 2.5	AMLODIPINE BESILATE	2.5 MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X1.0X3.0X10.0 TABLET BLISTER	7/1/2007

1778	NDA/MAL/HDP/4523	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	BIGOMET SR 500	METFORMIN HYDROCHLORI DE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2008
1779	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
1780	NDA/MAL/HDP/4526	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-500	AZITHROMYCI N	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

1781	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
1782	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
1783	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

1784	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
1785	NDA/MAL/HDP/4534	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	LORYTEC 10	LORATADINE	10MG	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	7/1/2007
1786	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

1787	NDA/MAL/HDP/4540	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIPROLOX 500	CIPROFLOXACIN	500MG	DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	7/1/2008
1788	NDA/MAL/HDP/4542	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CLERON 500	CLARITHROMY CIN	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
1789	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,1.0X1 00.0 TABLET CONTAINER	7/1/2000

1790	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
1791	NDA/MAL/HDP/4550	SANOVI AVENTS 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
1792	NDA/MAL/HDP/4553	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	ARTESUN	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE	7/1/2011

1793	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
1794	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
1795	NDA/MAL/HDP/4559	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	PREGASAFE 75	PREGABALIN	75MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2014

1796	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
1797	NDA/MAL/HDP/4575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASONE+GENTAMICIN	0.1%+0.3%W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/2010
1798	NDA/MAL/HDP/4579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 500 IV VIALS	CEFTRIAZONE	500MG	LABESFAL LABORATORIOS ALMIRO, S.A ,.-ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*5 ML WFI AMPOULE	7/1/2005

1799	NDA/MAL/HDP/4581	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	ALKEM LABORATORIES LTD--167/1, VILLAGE DABHEL, AMALIYA DAMAN-396210, INDIA INDICHEMIE HEALTH SPECIALTIES PVT. LTD-(UNIT 3 BETA LACTAM BLOCK) VILLAGE: THANA, TEHSIL: BADDI, DISTRICT: SOLAN HIMACHAL	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	7/1/2005
1800	NDA/MAL/HDP/4588	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	FLUCAN 200	FLUCONAZOLE	200MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0 TABLET BLISTER	7/1/2011
1801	NDA/MAL/HDP/4589	FEROZSONS LABORATORIES LTD	HARLEYS UGANDA LIMITED	LEFOX CIN-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

1802	NDA/MAL/HDP/4591	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SILVER KANT	SILVER SULPHADIAZIN E 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
1803	NDA/MAL/HDP/4592	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	PENTALINK 40	PANTOPRAZO LE	40MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X3.0 X10.0 TABLET BLISTER	7/1/2008
1804	NDA/MAL/HDP/4593	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKAN T-250	ERYTHROMYCI N 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

1805	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
1806	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
1807	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

1808	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
1809	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
1810	NDA/MAL/HDP/4605	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTRO METHORPHAN HBR+AMMONIUM CHLORIDE+METHOL	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

1811	NDA/MAL/HDP/4606	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATI N	10MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
1812	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2011
1813	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

1814	NDA/MAL/HDP/4615	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 150	NILOTONIB HYDROCHLORIDE MONOHYDRATE	150MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	7/1/2014
1815	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
1816	NDA/MAL/HDP/4619	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CHLORAMPHE NICOL SODIUM SUCCINATE	CHLORAMPHE NICOL 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

1817	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
1818	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
1819	NDA/MAL/HDP/4622	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	CLOXAREN	CLOXACILLIN	250MG	RENE INDUSTRIES- PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	7/1/2007

1820	NDA/MAL/HDP/4623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORIDE	2MG	RENE INDUSTRIAL LTD-RENE INDUSTRIES LTD, PLOT 680, KAMULI-KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2007
1821	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
1822	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

1823	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
1824	NDA/MAL/HDP/4636	DELOBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLARAM 0.5	ALPRAZOLAM	0.5MG	DELOBIS 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
1825	NDA/MAL/HDP/4641	YURIA PHARM LTD- UKRAINE	PHARMA VILLE LIMITED	RHEOSORBILA CT	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X200.0 ML BOTTLE,1.0X4 00.0 ML BOTTLE	7/1/2013

1826	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
1827	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
1828	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

1829	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),1.0 X10.0 ML VIAL (20 DOSE VIAL)	7/1/1997
1830	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
1831	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

1832	NDA/MAL/HDP/4677	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF	CEFUROXIME	125MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205 EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X30.0 ML BOTTLE,1.0X7 0.0 ML BOTTLE	7/1/2011
1833	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
1834	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2011

1835	NDA/MAL/HDP/4694	MERCK SHARP & DOHME INTAPHARMA	SURGIPHARM (U) LIMITED	ROTATEQ	ROTAVIRUS LIVE REASSORTANT VIRUS G1+G2+G3+G4 &P1	2.2M IU+2.8M IU+2.2M IU+2.0M IU	MERK & CO. INC- SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	ORAL LIQUID ORDINARY EMULSIONS	1.0X10.0 ML BOTTLE	7/1/2011
1836	NDA/MAL/HDP/4697	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	SANBE CLANEKSI	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	PT SANBE FARMA-JI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERA L ORDINARY VIALS	1.0X6.0 VIAL CARTON	7/1/2011
1837	NDA/MAL/HDP/4701	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	MEBRONE 100 TABLETS	MEBENDAZOL E	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,1.0X1 000.0 TABLET CONTAINER	7/1/1997

1838	NDA/MAL/HDP/4702	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABTOL 20%W/V	MANNITOL	200MG/ML	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, ☒ MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2011
1839	NDA/MAL/HDP/4703	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZOLE	500MG	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, ☒ MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	7/1/2011
1840	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

1841	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
1842	NDA/MAL/HDP/4712	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFINAL-500	MEFENAMIC ACID	500MG	KESAR PHARMA PVT LTD-PLOT SURVEY NO. 50/2. VILLAGE BILESHWARPURA CHHATRAL- -382729 TA. KALOL, DIST. GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2009
1843	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	7/1/1998

1844	NDA/MAL/HDP/4715	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL FORTE	MEFENAMIC ACID + PARACETAMO L	500MG + 450MG	BLUE CROSS LABORATORIES LTD- L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X1 0.0 TABLET BLISTER	7/1/2008
1845	NDA/MAL/HDP/4717	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL-SPAS	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORI DE	250MG + 10MG	BLUE CROSS LABORATORIES LTD- L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA- 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2. 0X3.0X10.0 TABLET BLISTER,1.0X1 0.0X3.0X10.0 TABLET BLISTER	7/1/2008
1846	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

1847	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
1848	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
1849	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

1850	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
1851	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
1852	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	

1853	NDA/MAL/HDP/4728	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	ADRENALINE	ADRENALINE	IMG/ML	M.J BIOPHARM PVT LTD-TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 X1.0 ML AMPOULE	7/1/2014
1854	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
1855	NDA/MAL/HDP/4739	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2011

1856	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	PARENTERA L ORDINARY VIALS	1.0X1000.0 MG VIAL	7/1/2013
1857	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	PARENTERA L ORDINARY DRY VIALS	1.0X500.0 MG VIAL	7/1/2013
1858	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL + STERILIZED WATER FOR INJECTION	7/1/2014

1859	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 SUSPENSION S/SYRUPS/DROPS	1.0X22.5 ML BOTTLE	7/1/2011
1860	NDA/MAL/HDP/4748	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE +SIMETHICONE	720MG+25MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER	7/1/2006
1861	NDA/MAL/HDP/4751	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FEROL	FERROUS SULPHATE	200MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER	7/1/2009

1862	NDA/MAL/HDP/4757	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	METFORMIN-DENK 500	METFORMIN	500MG	DENK PHARMA GMBH & CO. KG--PRINZREGENTESTR.7 9.81675 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
1863	NDA/MAL/HDP/4758	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	METFORMIN-DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH & CO. KG--PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	7/1/2011
1864	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

1865	NDA/MAL/HDP/4768	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	METHACHLOR EYE DROPS	DEXAMETHAS ONE/CHLORA MPHENICOL	1MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD- 117 ALLAM	PAKISTAN	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/1999
1866	NDA/MAL/HDP/4769	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEX	MEBENDAZOL E	100MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER,1.0X1 00.0X10.0 TABLET BLISTER	7/1/2009
1867	NDA/MAL/HDP/4774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT- Z	FERROUS SULPHATE+FO LIC ACID+ASCORBI C ACID+THIAMI NE MONONITRAT E+RIBOTLAVIN E+PYRIDOXINE HCL+NICOTIN AMIDE+ZINC	150MG+0.5M G+50MG+2M G+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

1868	NDA/MAL/HDP/4778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CURISAFE	CEFADROXIL MONOHYDRA TE	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 SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	7/1/2000
1869	NDA/MAL/HDP/4784	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D50	GLUCOSE INTRAVENOUS INFUSION	50%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2011
1870	NDA/MAL/HDP/4789	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORI DE	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

1871	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
1872	NDA/MAL/HDP/4792	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PHOSPHATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV- RIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL,1.0X2.0 ML VIAL	7/1/1997
1873	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

1874	NDA/MAL/HDP/4796	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DARROWS SOLUTION (HALF STRENGTH)	POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE	0.13%+0.20%+0.30%	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	7/1/2011
1875	NDA/MAL/HDP/4799	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITROLIN SOLUTION	CETRIMIDE+LIDOCAINE	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
1876	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

1877	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	10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2000
1878	NDA/MAL/HDP/4806	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOFER	FERROUS SULPHATE+FO LIC ACID	200MG + 0.25MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2009
1879	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,1.0X1 000.0 TABLET CONTAINER	7/1/2011

1880	NDA/MAL/HDP/4809	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCORT SKIN CREAM	HYDROCORTIS ONE	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
1881	NDA/MAL/HDP/4811	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOGYL	METRONIDAZ OLE	200MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER,1.0X1 00.0X10.0 TABLET BLISTER	7/1/2009
1882	NDA/MAL/HDP/4812	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL SUSPENSION	METRONIDAZ OLE 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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2001

1883	NDA/MAL/HDP/4813	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL TABLETS (THANE)	METRONIDAZ OLE	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,1 0.0X10.0 TABLET BLISTER	7/1/1998
1884	NDA/MAL/HDP/4814	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	METLIFE	METRONIDAZ OLE	500MG/100M L	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2010
1885	NDA/MAL/HDP/4815	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROLIC-LF	FERROUS SULPHATE +FOLIC ACID	200MG+0.4M G	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

1886	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
1887	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
1888	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

1889	NDA/MAL/HDP/4823	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	METRIS INFUSION	METRONIDAZ OLE	5MG/ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD- VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/1997
1890	NDA/MAL/HDP/4826	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL DENTA GEL	METRONIDAZ OLE + CHLORHEXIDI NE	1%W/W + 0.25%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	7/1/2004
1891	NDA/MAL/HDP/4828	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL GEL	METRONIDAZ OLE	1%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X30.0 G TUBE (ALUMINIUM TUBE),1.0X30. 0 G TUBE (LAMINATED TUBE)	7/1/2001

1892	NDA/MAL/HDP/4830	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL INJECTION	METRONIDAZ OLE	5MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116 UNIQUE PHARMACEUTICAL LABORATORIES (A	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	
1893	NDA/MAL/HDP/4832	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL SUSPENSION	METRONIDAZ OLE	200MG/5ML	UNIQUE PHARMACEUTICAL LABORATORIES- PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA. J.B. CHEMICALS AND PHARMACEUTICALS LTD .-128/1, GIDC, ANKLESHWAR 393	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/1997
1894	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

1895	NDA/MAL/HDP/4836	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METRON	METRONIDAZ OLE	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,1.0X1 00.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2009
1896	NDA/MAL/HDP/4839	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOC AINE+HYDROC ORTISONE+AL LANTOIN	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 SUPPOSITOR IES	1.0X1.0X5.0 SUPPOSITORY BLISTER,1.0X2. 0X5.0 SUPPOSITORY BLISTER	7/1/2007
1897	NDA/MAL/HDP/4845	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ANTIDEP	IMIPRAMINE	25MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDI A.AT:VILL.MANAKPU R,TEH.NALAGARH,DI ST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/1997

1898	NDA/MAL/HDP/4851	SHAIGAN PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CLOZOX V	CLOTRIMAZOL E	100MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	VAGINAL TABLETS	1.0X1.0X6.0 TABLET BLISTER	
1899	NDA/MAL/HDP/4854	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN FC	METRONIDAZ OLE	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
1900	NDA/MAL/HDP/4855	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL EXPECTORANT	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORI DE + 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,1.0X1 00.0 ML BOTTLE	7/1/2000

1901	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,1.0X100.0 TABLET CONTAINER	7/1/2001
1902	NDA/MAL/HDP/4858	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	METROREN SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2001
1903	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

1904	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
1905	NDA/MAL/HDP/4867	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	MICONA ORAL GEL	MICONAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X40.0 G TUBE,1.0X20.0 G TUBE	7/1/2003
1906	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2011

1907	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
1908	NDA/MAL/HDP/4874	SANOFI-AVENTIS	LABOREX UGANDA 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	1.0X2.0X0.6 ML PRE-FILLED SYRINGE	7/1/2009
1909	NDA/MAL/HDP/4876	SANOFI-AVENTIS	LABOREX UGANDA 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

1910	NDA/MAL/HDP/4877	SANOFI-AVENTIS	LABOREX UGANDA 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
1911	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
1912	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

1913	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,1.0X1 5.0X4.0 TABLET BLISTER	7/1/2014
1914	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
1915	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

1916	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
1917	NDA/MAL/HDP/4891	REGAL PHARMA U LIMITED	REGAL PHARMA (U) LTD	ASPEC TABLET	ASPIRIN+PARA CETAMOL+CA FFEINE ANHYDROUS	150MG+250M G+300MG	REGAL PHARMACEUTICALS LTD-OFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X5 00.0 TABLET CONTAINER,1. 0X100.0 TABLET CONTAINER	7/1/1997
1918	NDA/MAL/HDP/4903	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+D RIED ALUMINIUM HYDROXIDE+P EPPERMINT OIL	250MG+120M G+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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2008

1919	NDA/MAL/HDP/4904	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30	INSULIN HUMAN	100 I.U/ML	NOVO NORDISK PHARMA-NOVO ALLE	DENMARK	PARENTERA L ORDINARY S C VIALS	1.0X10.0 ML VIAL	7/1/1997
1920	NDA/MAL/HDP/4905	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX CREAM	ACYCLOVIR	5%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	7/1/1997
1921	NDA/MAL/HDP/4906	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	200MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	7/1/1997

1922	NDA/MAL/HDP/4907	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	400MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	7/1/1997
1923	NDA/MAL/HDP/4908	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK	PARENTERA L ORDINARY CARTRIDGES	1.0X1.5 ML FLEXPEN,1.0X 5.0X3.0 ML FLEXPEN	7/1/1997
1924	NDA/MAL/HDP/4909	AXA PARENTERALS LTD	VITACARE LIMITED	AXAGYL	METRONIDAZ OLE	0.5%W/V	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKE E 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2015

1925	NDA/MAL/HDP/4911	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	MOFILET-500	MYCOPHENOL ATE MOFETIL	500MG	EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2008
1926	NDA/MAL/HDP/4917	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SI METHICONE	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 SUSPENSION S	1.0X120.0 ML BOTTLE	7/1/2010
1927	NDA/MAL/HDP/4919	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FUSIDIC ACID- B CREAM	FUSIDIC ACID+BETAME THASONE 17 VALERATE	2%,W/W,+0.1 % W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/2008

1928	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
1929	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
1930	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

1931	NDA/MAL/HDP/4926	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	FOLIC ACID	FOLIC ACID	5MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER	7/1/1997
1932	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
1933	NDA/MAL/HDP/4928	AFRICURE PHARMACEUTICALS (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	FOLIC ACID TABLETS	FOLIC ACID	5MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP	7/1/1997

1934	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
1935	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
1936	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	7/1/1997

1937	NDA/MAL/HDP/4936	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COMBIFEN	IBUPROFEN + PARACETAMOL	400MG + 500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2011
1938	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
1939	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

1940	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
1941	NDA/MAL/HDP/4944	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	BENA EXPECTORANT	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE	14MG + 135MG + 57.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	7/1/1997
1942	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

1943	NDA/MAL/HDP/4949	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETH ORPHAN HYDROBROMI DE	15MG/ML	JOHNSON&JOHNSO N 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
1944	NDA/MAL/HDP/4951	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN ORIGINAL	DIPHENHYDRA MINE HYDROCHLORI DE + AMMONIUM CHLORIDE	12.5 MG/5ML + 125 MG/5ML	JOHNSON&JOHNSO N PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE,1.0X2. 5 L BOTTLE	7/1/1997
1945	NDA/MAL/HDP/4952	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN WITH CODEINE	DIPHENHYDRA MINE HCL + AMMONIUM CHLORIDE + CODEINE PHOSPHATE	12.5MG/5ML +125MG/5ML +10MG/5ML	JOHNSON&JOHNSO N PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2 00.0 ML BOTTLE	7/1/1997

1946	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
1947	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
1948	NDA/MAL/HDP/4956	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	CONTRAPAQUE 350	IOHEXOL	350MG	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	7/1/2010

1949	NDA/MAL/HDP/4957	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	MUMFER	IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID	100MG + 500MCG	GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2004
1950	NDA/MAL/HDP/4958	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BENZOSED	MIDAZOLAM	1MG/ML	TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERA L ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	7/1/2011
1951	NDA/MAL/HDP/4959	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC LINCTUS	CHLORPHENIR AMINE / PHENYLEPHRI NE / DEXTROMETH ORPHAN	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

1952	NDA/MAL/HDP/4962	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	BETAD	BETAMETHAS ONE DIPROPIONA TE	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,1.0X1.0X 15.0 G TUBE	7/1/2010
1953	NDA/MAL/HDP/4964	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENA MINE+PHENYL EPHRINE+PAR ACETAMOL	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 SUSPENSION S	1.0X50.0 ML BOTTLE	7/1/2011
1954	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,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2001

1955	NDA/MAL/HDP/4966	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS-650	CHLORPHENIR AMINE + PHENYLEPHRI NE + PARACETAMO L	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,1.0X5 0.0X1.0X6.0 TABLET BLISTER	7/1/2010
1956	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,	CHINA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2008
1957	NDA/MAL/HDP/4969	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP - NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X2.4 MU VIAL	7/1/2001

1958	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,1.0X100 0.0 TABLET CONTAINER	7/1/1997
1959	NDA/MAL/HDP/4972	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	COOLMINT LISTERINE	MENTHOL + ALCOHOL 95%	0.02% + 4.58ML	JOHNSON&JOHNSO N 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
1960	NDA/MAL/HDP/4973	MERCK	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS	FOLLITROPIN ALFA/LUTROPI N ALFA	150 I.U/75 I.U	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI	7/1/2014

1961	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
1962	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
1963	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,DIS T.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2010

1964	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
1965	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
1966	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

1967	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	1.0X10.0X10.0 X2.0 ML AMPOULE,1.0 X10.0X2.0 ML AMPOULE	7/1/2007
1968	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
1969	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,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-	KENYA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X150.0 TABLET CARTON	7/1/1997

1970	NDA/MAL/HDP/5005	SHIJIAZHUANG AOSUO INTERNATIONAL TRADE CO. LTD	SHURIK LTD	COLD GO	PARACETAMO L+PHENYLEPH RINE HYDROCHLORI DE+CHLORPHE NIRAMINE MALEATE+CAF FEINE	325MG+10MG +2MG+30MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X 4.0 TABLET BLISTER	7/1/2010
1971	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,1.0X2 5.0 TABLET CONTAINER	7/1/1997
1972	NDA/MAL/HDP/5010	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	ZARIN CREAM	CLOTRIMAZOL E	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/1997

1973	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	7/1/1997
1974	NDA/MAL/HDP/5016	MACLEODS PHARMACEUTICALS LTD	KIMSY MEDS LTD	GENTAMYCIN INJECTION	GENTAMYCIN SULPHATE	40MG/ML	GLAND PHARMA LTD -D.P PALLY DUNDIGAL POST QUTBULLAPUR MANDAL RANGA REDDY DISTRICT HYDERABAD 500043 GLAND PHARMA LTD PLOT NO. 42 TO 52, SY NO. 166, 171, 172 & 177, TSIC, PHASE III, PASHAMYLARAM (V) PATANCHERU	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2000
1975	NDA/MAL/HDP/5017	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP SYRUP	PARACETAMOL+PROMETHAZINE HYDROCHLORIDE+CODEINE PHOSPHATE+PSEUDOEPHEDRINE 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

1976	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
1977	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
1978	NDA/MAL/HDP/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTREL+FERROUS 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	GERMANY FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X100.0X28.0 TABLET BLISTER	7/1/2011

1979	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
1980	NDA/MAL/HDP/5030	PFIZER LAB LTD	LABOREX UGANDA LIMITED	SOLU-MEDROL	METHYLPREDNISOLONE HEMISUCCINATE	125MG/2ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL,1.0X8.0 ML VIAL	7/1/1997
1981	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

1982	NDA/MAL/HDP/5032	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELATED DRY COUGH SYRUP (NON DROWSY)	DEXTROMETH ORPHAN	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
1983	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
1984	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

1985	NDA/MAL/HDP/5040	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-MEDROL	METHYLPRED NISOLONE ACETATE	40MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL,1.0X2.0 ML VIAL,1.0X5.0 ML VIAL	7/1/1997
1986	NDA/MAL/HDP/5041	NORVATIS PHARMAG- 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
1987	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

1988	NDA/MAL/HDP/5043	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXITROL	DEXAMETHAS ONE/NEOMYC IN/POLYMYXI N B	0.1%W/W+35 00I.U/ML+600 0I.U/ML	ALCON COUVREUR NV-RIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/1997
1989	NDA/MAL/HDP/5044	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO- PROVERA	MEDROXYPRO GESTERONE ACETATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV- RIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERA L ORDINARY I M VIALS	1.0X3.5 ML VIAL,1.0X1.0 ML VIAL	7/1/1997
1990	NDA/MAL/HDP/5050	NORVATIS PHARMA AG- SWITZERLAND	LABOREX UGANDA LIMITED	MAXIDEX	DEXAMETHAS ONE	0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B- 2870 PUURS BELGIUM	BELGIUM	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/1997

1991	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
1992	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
1993	NDA/MAL/HDP/5059	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	SURGIPHARM (U) LIMITED	MAALOX PLUS SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SILICONE	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

1994	NDA/MAL/HDP/5062	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANNILIFE	MANNITOL	20MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2010
1995	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2011
1996	NDA/MAL/HDP/5065	N.V. ORGANON	SURGIPHARM (U) LIMITED	MARVELON	DESOGESTREL /ETHINYLESTR ADIOL	150MG/30MG	N.V. ORGANON- KLOOSTERSTRAAT 6, 5349 AB OSS, THE NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X100.0X1.0 X28.0 TABLET BLISTER	7/1/2015

1997	NDA/MAL/HDP/5066	M.J.BIOPHARM PVT LTD	VITACARE LIMITED	DEXAMETHAS ONE SODIUM PHOSPHATE	DEXAMETHAS ONE 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
1998	NDA/MAL/HDP/5068	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DEXAMETHAS ONE SODIUM PHOSPHATE	DEXAMETHAS ONE 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
1999	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

2000	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	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	7/1/2009
2001	NDA/MAL/HDP/5073	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA EYE/EAR DROP	DEXAMATHAS ONE SODIUM PHOSPHATE+ NEOMYCIN SULPHATE	0.35%W/V+0. 1%W/V	AHLCON PARENTERALS (INDIA) LTD-SP-917- 918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE,1.0X2. 5 ML BOTTLE	7/1/1997
2002	NDA/MAL/HDP/5075	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA TABLETS	DEXAMETHAS ONE	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

2003	NDA/MAL/HDP/5076	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	DEXTRACIN EYE DROPS	DEXAMETHASONE + NEOMYCIN	0.1MG + 0.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/1997
2004	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
2005	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

2006	NDA/MAL/HDP/5087	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIABEN TABLETS	GLIBENCLAMI DE	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
2007	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
2008	NDA/MAL/HDP/5093	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LIPODAR 10	ATORVASTATI N	10MG	DAR AI DAWA-NA UR PLANT,AMMAN,JOR DAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2011

2009	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
2010	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
2011	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

2012	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 SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2011
2013	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
2014	NDA/MAL/HDP/5100	LINCOLN PHARMACEUTICALS 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

2015	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,1.0X3 0.0 TABLET BLISTER	1/7/2010
2016	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
2017	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	PARENTERA L ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	7/1/2014

2018	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
2019	NDA/MAL/HDP/5107	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	INDOREN CAPSULES	INDOMETHACI N	25MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER	7/1/2000
2020	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

2021	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
2022	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
2023	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

2024	NDA/MAL/HDP/5117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMMEDIES- UNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	7/1/2011
2025	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
2026	NDA/MAL/HDP/5121	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN GEL	DICLOFENAC DIETHYLAMMONIUM	1%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	7/1/1997

2027	NDA/MAL/HDP/5122	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	KOFAREST SYRUP	SALBUTAMOL SULPHATE/AM BROXOL SULPHATE/GU AFENESIN/ME NTHOL	2MG+30MG+1 00MG+5MG/1 0ML	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/2007
2028	NDA/MAL/HDP/5124	GLAXOSMITHKLINE LTD BELGIUM	UNITED HEALTHCARE DISTRIBUTORS LTD	INFANRIX- HEXA	DIPHThERIA TOXOID+TETA NUS TOXOID+PERT USSIS TOXOID(PT)+FI LAMENTOUS HAEMAGGLUT ININ(FHA)+PE RTACTIN(69KD A OMP)+HBSAG PURIFIED,INAC	MIN 30 I.U+MIN 40 I.U+25MG+25 MG+8MG+10 MG,40DU+8D U+32DU+10M G	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE l'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERA L ORDINARY COMBINATI ON PACK VIALS	1.0X1.0 PACK CARTON (DTPA-HBV- IPV IN PREFILLED SYRINGE + 2 NEEDLES+FRE EZE DRIED HIB IN A VIAL)	7/1/2013
2029	NDA/MAL/HDP/5125	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	GLYGESIC FORTE RHUMETIC CREAM	MULTI INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	7/1/1998

2030	NDA/MAL/HDP/5126	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	KNAC-75	DICLOFENAC	75MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2011
2031	NDA/MAL/HDP/5127	UNIQUE PHARMACEUTICALS 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,1.0 X5.0X3.0 ML AMPOULE	7/1/1997
2032	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

2033	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
2034	NDA/MAL/HDP/5130	UNIQUE PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN MS GEL	DICLOFENAC+ METHYL SALICYLATE+ MENTHOL	1%W/W+10% W/W+5%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	7/1/2005
2035	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

2036	NDA/MAL/HDP/5132	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	KETROZOL 200 TABLETS	KETOCONAZO LE	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
2037	NDA/MAL/HDP/5133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66MCG/1.5ML)	FOLLITROPIN ALFA	66MCG/1.5ML	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND MERCK SERONO SPA (BARI)-VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO,	SWITZERLAND	PARENTERA L ORDINARY PRE-FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 20 NEEDLES FOR INJECTION,1.0 X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION.	7/1/2015
2038	NDA/MAL/HDP/5134	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	GOODMORNI NG COUGH TABLETS	MULTIINGRED IENT	N/A	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU 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

2039	NDA/MAL/HDP/5135	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	KETOZ	KETOCONAZO LE	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
2040	NDA/MAL/HDP/5136	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	GOODMORNI NG LUNG TONIC	MULTIINGRED IENT	N/A	BETA HEALTHCARE INTERNATIONAL LTD --PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5 0.0 ML BOTTLE	7/1/1997
2041	NDA/MAL/HDP/5137	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	KETOREN	KETOCONAZO LE	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2010

2042	NDA/MAL/HDP/5139	NOVO NORDISK	STAR PHARMACEUTICALS LTD	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PHARMA-NOVO ALLE NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA-AV. "C", 1413, DISTRITO INDUSTRIAL - 390404 004 MONTES CLAROS, MINAS GERAIS - BRAZIL	DENMARK	PARENTERA L ORDINARY CARTRIDGES	1.0X1.5 ML FLEXPEN,1.0X 3.0 ML FLEXPEN	7/1/1997
2043	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
2044	NDA/MAL/HDP/5141	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KETOMAC SHAMPOO	KETOCONAZO LE	2%W/V	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WAS HES	75.0 ML BOTTLE	7/1/2003

2045	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,K ENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400. 0 G TUBE	7/1/1997
2046	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
2047	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

2048	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
2049	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,1.0X5.0X3.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X2.0X50.0 TABLET BLISTER	7/1/1997
2050	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

2051	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,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569- 001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X50.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	7/1/1997
2052	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
2053	NDA/MAL/HDP/5157	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	BETAVEL N	BETAMETHAS ONE+NEOMYC IN 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

2054	NDA/MAL/HDP/5164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BR OMHEXINE HYDROCHLORIDE+GUAIFENE SIN+MENTHOL	1MG+2MG+50MG+0.5MG	COSMOS LTD.- RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2010
2055	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
2056	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

2057	NDA/MAL/HDP/5167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMO L	400MG + 300MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED -INDUSTRIAL AREA 3, A.B. ROAD, DEWAS 455001, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,2.0X1 0.0 TABLET BLISTER	7/1/1998
2058	NDA/MAL/HDP/5170	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDITRAL CAPSULE	ITRACONAZOL E	100MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE STRIP	7/1/2000
2059	NDA/MAL/HDP/5171	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KETAMAX-50	KETAMINE	50MG/ML	TROIKAA PHARMACEUTICALS LIMITED-C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERA L ORDINARY VIALS	1.0X10.0 ML VIAL	7/1/2011

2060	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
2061	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
2062	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

2063	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
2064	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
2065	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

2066	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
2067	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 INHALATION S	1.0X250.0 ML BOTTLE	7/1/2014
2068	NDA/MAL/HDP/5187	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	HEALIT SKIN OINTMENT	BACITRACIN+P OLYMYXIN B SO4+NEOMYCIN+LIDOCAINE	500UNITS+500 0UNITS+3.5M G+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

2069	NDA/MAL/HDP/5188	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ITRAZ CAPSULES	ITRACONAZOL E	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
2070	NDA/MAL/HDP/5200	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYDRALAZINE TABLETS B.P 25MG.	HYDRALAZINE HYDROCHLORI DE	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
2071	NDA/MAL/HDP/5201	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM BENDAZOLE	MEBENDAZOL E	100MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.- PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10. 0 TABLET BLISTER,1.0X2 50.0 TABLET CONTAINER,1. 0X500.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET	7/1/1997

2072	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,1.0X1 00.0 TABLET CARTON,1.0X2 50.0 TABLET JAR,1.0X500.0 TABLET JAR,1.0X1000. 0 TABLET CONTAINER	7/1/1997
2073	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,1.0X1 000.0 TABLET CONTAINER	7/1/2013
2074	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

2075	NDA/MAL/HDP/5214	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	NIRMET	METRONIDAZOLE	500MG/100ML	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
2076	NDA/MAL/HDP/5215	J.B CHEMICALS & PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	METROGYL TABLETS	METRONIDAZOLE	200MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .-128/1, GIDC, ANKLESHWAR 393 002, GUJARAT GLOBELA PHARMA PVT.LTD.-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,1.0X2 0.0X5.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1. 0X5.0X2.0X10. 0 TABLET BLISTER	7/1/2001
2077	NDA/MAL/HDP/5221	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY,	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 X3.0 ML AMPOULE,1.0 X10.0X3.0 ML AMPOULE	7/1/2006

2078	NDA/MAL/HDP/5222	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EMTRICITABIN E+TENOFVIR DF	EMTRICITABIN E/TENOFVIR	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.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	7/7/2008
2079	NDA/MAL/HDP/5224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EMTRICITABIN E+TENOFVIR DISOPROXIL FUMERATE	EMTRICITABIN E/TENOFVIR 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
2080	NDA/MAL/HDP/5226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABIN E+TENOFVIR DISOPROXIL FUMERATE	EMTRICITABIN E+TENOFVIR DISOPROXIL FUMERATE	200MG/300M G	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) MAHABOONNAGAR DISTRICT, ANDHRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2013

2081	NDA/MAL/HDP/5228	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	DICLOGENTA	DICLOFENAC SODIUM+GEN TAMICIN SULPHATE	1MG/ML+3M G/ML	CENTAUR PHARMACEUTICALS PVT LTD --PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/2009
2082	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(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI-	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005
2083	NDA/MAL/HDP/5232	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2006

2084	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
2085	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
2086	NDA/MAL/HDP/5235	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN DELAYED- RELEASE TABLETS	DICLOFENAC SODIUM	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH GLOBELA PHARMA PVT.LTD.-PLOT NO.357,G.I.D.C	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,5. 0X2.0X10.0 TABLET BLISTER	7/1/1997

2087	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
2088	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
2089	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

2090	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	7/1/1997
2091	NDA/MAL/HDP/5249	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ENCIFER	IRON SUCROSE	100MG/5ML	EMCURE PHARMACEUTICALS LTD -PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERA L ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	7/1/2013
2092	NDA/MAL/HDP/5250	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	7/1/1998

2093	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
2094	NDA/MAL/HDP/5253	PHARCO PHARMACEUTICALS	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
2095	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/G RANULES	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

2096	NDA/MAL/HDP/5256	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROFOS INJECTION	BETAMETHAS ONE DISODIUM PHOSPHATE + BETAMETHAS ONE 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
2097	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
2098	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

2099	NDA/MAL/HDP/5263	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	DIPROSALIC OINTMENT	BETAMETHASONE + SALICYLIC ACID	0.5 %W/W + 0.3 %W/W	SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 MG TUBE	7/1/2001
2100	NDA/MAL/HDP/5269	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2010
2101	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 SUSPENSION S/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	7/1/1997

2102	NDA/MAL/HDP/5272	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DIX	DIGOXIN	0.25MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2011
2103	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
2104	NDA/MAL/HDP/5277	MACLEODS PHARMACEUTICALS 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

2105	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
2106	NDA/MAL/HDP/5281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ+E MTRICITABINE +TENOFVIR DISOPROXIL	EFAVIRENZ + EMTRICITABIN E + 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
2107	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

2108	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
2109	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,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	7/1/2015
2110	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

2111	NDA/MAL/HDP/5290	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ELOCOM CREAM	MOMETASON E 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
2112	NDA/MAL/HDP/5291	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	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
2113	NDA/MAL/HDP/5292	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DOMI 10	DOMPERIDONE	10MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2011

2114	NDA/MAL/HDP/5294	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	ELOCOM OINTMENT	MOMETASON E 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
2115	NDA/MAL/HDP/5295	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	DOXY	DOXYCYCLINE	100MG	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X280.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER	7/1/2000
2116	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

2117	NDA/MAL/HDP/5299	PHARMA INTERNATIONAL.CO	OMAB UGANDA LIMITED	KENAZOLE	KETOCONAZO LE	20MG/ML	PHARMA INTERNATIONAL COMPANY ,,-AL- QASTAL INDUSTRIAL AREA/AMMAN	JORDAN	TOPICAL EXTERNAL LIQUID SOAPS/WAS HES	1.0X100.0 ML BOTTLE	7/1/2014
2118	NDA/MAL/HDP/5300	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DOLAC	KETOROLAC TROMETHAMI NE	30MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2015
2119	NDA/MAL/HDP/5302	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	IBUGO-COMBI	IBUPROFEN + PARACETAMO L + 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,1.0X1 0.0X10.0 CAPSULE BLISTER,1.0X1 00.0X10.0 CAPSULE BLISTER	7/1/2014

2120	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,1.0X1 000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2008
2121	NDA/MAL/HDP/5307	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DUOTROL	GLYBURIDE + METFORMIN HYDROCHLORI DE	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
2122	NDA/MAL/HDP/5311	ABBOTT HEALTHCARE PRODUCTS B.V.	HARLEYS UGANDA LIMITED	DUPHASTON TABLETS	DYDROGESTER ONE	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

2123	NDA/MAL/HDP/5316	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR	DICLOFENAC SODIUM + PARACETAMO L	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
2124	NDA/MAL/HDP/5317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FORMULA	TERBUTALINE SULPHATE+BR OMHEXINE HYDROCHLORI DE+GUAIFENE SIN+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
2125	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	7/1/2009

2126	NDA/MAL/HDP/5320	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	INDOL	INDOMETHACI N	25MG	LEBEN LAB PVT LTD- L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1. 0X10.0X10.0 CAPSULE BLISTER,1.0X1 00.0X10.0 CAPSULE BLISTER	7/1/2010
2127	NDA/MAL/HDP/5323	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	IODINATED POVIDONE + METRONIDAZ OLE	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
2128	NDA/MAL/HDP/5326	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	ECODAX G CREAM	ECONAZOLE NITRATE + GENTAMYCIN + BECLAMETAS ONE	1%+0.1%+0.02 5%	UNIQUE PHARMACEUTICAL LABORATORIES- PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X100. 0 G TUBE	7/1/1997

2129	NDA/MAL/HDP/5330	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ-V	MICONAZOLE + METRONIDAZ OLE	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
2130	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,1 000.0 TABLET CONTAINER,2 50.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/1997
2131	NDA/MAL/HDP/5338	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	HYDROSIL TABLETS	ALUMINIUM HYDROXIDE+ MAGNESIUM HYDROXIDE+SI METHICONE	200MG+200M G+20MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X20.0 TABLET BLISTER	7/1/1997

2132	NDA/MAL/HDP/5341	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	HYDOPA	METHYLDOPA	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	7/1/1997
2133	NDA/MAL/HDP/5343	PHARCO PHARMACEUTICALS 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
2134	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

2135	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
2136	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X250.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	7/1/2005
2137	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

2138	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
2139	NDA/MAL/HDP/5358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	GUAIFENESIN+ AMMONIUM CHLORIDE+CH LORPHENIRA MINE+SODIU M 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,1.0X6 0.0 ML BOTTLE	7/1/1997
2140	NDA/MAL/HDP/5361	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	CALFIC	MULTI- INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997

2141	NDA/MAL/HDP/5362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELD-CHESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP	7/1/2001
2142	NDA/MAL/HDP/5363	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 50MG	BICALUTAMIDE	50MG	ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, BULK CORDEN PHARMA GMBH-OTT HAHN STRASSE ,68723 GERMANY	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/1997
2143	NDA/MAL/HDP/5368	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFIX 100MG/5ML DRY SUSPENSION	CEFIXIME	100MG/5ML	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	7/1/2007

2144	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
2145	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
2146	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

2147	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
2148	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
2149	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

2150	NDA/MAL/HDP/5389	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM	ARTEMETHER + LUMEFANTRIN E	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,1.0X3 0.0X6.0 TABLET BLISTER,1.0X1. 0X12.0 TABLET BLISTER,1.0X1. 0X18.0 TABLET BLISTER,1.0X3 0.0X12.0	7/1/2011
2151	NDA/MAL/HDP/5391	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	NITROFURANT OIN	NITROFURANT OIN	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
2152	NDA/MAL/HDP/5392	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRA TE	10MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2008

2153	NDA/MAL/HDP/5393	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH & CO. KG- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2008
2154	NDA/MAL/HDP/5395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2005
2155	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

2156	NDA/MAL/HDP/5401	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	HALOTHANE	HALOTHANE	250ML	PIRAMAL ENTERPRISES LTD -- DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT, ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	7/1/2005
2157	NDA/MAL/HDP/5404	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	INTAS PHARMACEUTICALS LIMITED - CAMP ROAD, SELAQUI-248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2013
2158	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

2159	NDA/MAL/HDP/5406	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARM A DIVISION)-CAMP ROAD SELAQUI- 248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	7/1/2007
2160	NDA/MAL/HDP/5409	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	MINTO GEL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	150 MG + 150 MG + 25 MG	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X180.0 ML BOTTLE	7/1/2012
2161	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2009

2162	NDA/MAL/HDP/5414	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	XYLO-ACINO 0.1%	XYLOMETAZOL INE	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
2163	NDA/MAL/HDP/5415	CENTAUR PHARMACEUTICALS PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST	OXYMETAZOLI NE	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
2164	NDA/MAL/HDP/5416	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CIPROX	CIPROFLOXACI N	0.2%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD- VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2005

2165	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
2166	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 SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2005
2167	NDA/MAL/HDP/5419	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIR AMINE	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,1.0X1 000.0 TABLET CONTAINER,1. 0X100.0X10.0 TABLET BLISTER	7/1/2005

2168	NDA/MAL/HDP/5423	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+LAMIVUDINE+TENOFVIR	EFAVIRENZ+LAMIVUDINE+TENOFVIR	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER,1.0X90.0 TABLET JAR,1.0X100.0 TABLET JAR	7/1/2013
2169	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
2170	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

2171	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
2172	NDA/MAL/HDP/5438	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	TAMIN	PARACETAMOL	10MG/ML	CLARIS INJECTABLES LIMITED--- CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML VIAL	
2173	NDA/MAL/HDP/5439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENIRON SYRUP	VITAMIN B6 + FERROUS GLUCONATE + VITAMIN B1 + VITAMIN C + VITAMIN B2	2MG/5ML + 200MG/5ML + 2MG/5ML + 20MG/5ML + 2MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2001

2174	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
2175	NDA/MAL/HDP/5442	SHOSAAN ASIC PACIFIC	RENE PHARMACY LTD	CHLORAMPHE NICOL OPHTHALMIC OINTMENT USP 1%	CHLORAMPHE NICOL	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
2176	NDA/MAL/HDP/5444	MSD (PTY) LIMITED SA	SURGIPHARM (U) LIMITED	AERIUS TABLETS	DESLOTRATIDINE	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

2177	NDA/MAL/HDP/5447	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	TRIVENI FORMULATION LTD- PLOT NO.52,53,54,63,62,6 4, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2012
2178	NDA/MAL/HDP/5453	PHARCO PHARMACEUTICALS 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 SUSPENSION S/SYRUPS/D ROPS	1.0X10.0 ML BOTTLE	7/1/1998
2179	NDA/MAL/HDP/5454	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	MOXILEB	AMOXICILLIN	125MG/5ML	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	

2180	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/1998
2181	NDA/MAL/HDP/5460	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE+ AMODIAQUIN E	50MG+135MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X2 0.0 TABLET BLISTER,1.0X2 5.0X3.0 TABLET BLISTER,1.0X2 5.0X6.0 TABLET BLISTER	7/1/2011
2182	NDA/MAL/HDP/5464	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRIN E	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.	7/1/2007

2183	NDA/MAL/HDP/5467	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSIDAR	SULFADOXINE /PYRIMETHA MINE	525MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.- PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X1 00.0 TABLET CARTON,1.0X2 50.0 TABLET CONTAINER,1. 0X500.0 TABLET CONTAINER,1. 0X1000.0 TABLET CONTAINER	7/1/1997
2184	NDA/MAL/HDP/5469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	BAYER PHARMA AG - 51368 LEVERKUSEN GERMANY	GERMANY	PARENTERA L ORDINARY I V VIALS	1.0X50.0 ML VIAL	7/1/2009
2185	NDA/MAL/HDP/5471	MICRO LABS LTD	LABOREX UGANDA LIMITED	AVAS 40	ATORVASTATI N	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

2186	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
2187	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
2188	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

2189	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
2190	NDA/MAL/HDP/5478	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	BECORT 50	BECLOMETHA SONE DIPROPIONAT E	50MCG/ACTU ATION	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTR ATION METERED- DOSE INHALER	1.0X1.0X200.0 METERED DOSE CANNISTER	7/1/2010
2191	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

2192	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,1.0X6 0.0 ML BOTTLE	7/1/2010
2193	NDA/MAL/HDP/5483	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	ASAQ GPSC	ARTESUNATE + AMODIAQUIN E	25 MG + 67.5 MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X2 0.0 TABLET BLISTER,1.0X2 5.0X3.0 TABLET BLISTER,1.0X2 5.0X6.0 TABLET BLISTER	7/1/2011
2194	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

2195	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
2196	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
2197	NDA/MAL/HDP/5496	ASTRAZENECA AG	MACNAUGHTON LIMITED	ATACAND 16MG	CANDESARTA N 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

2198	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, 1.0X10.0 X1.0 MU VIAL, 1.0X100.0X1.0 MU VIAL	7/1/2011
2199	NDA/MAL/HDP/5591	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	SWISSCILLIN	AMPICILLIN	500MG	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	7/1/2011
2200	NDA/MAL/HDP/5619	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	RABELOC 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDABAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	7/1/2006

2201	NDA/MAL/HDP/5644	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNITS	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP - NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERA L ORDINARY VIALS	1.0X4.0 MU VIAL	7/1/2001
2202	NDA/MAL/HDP/5648	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X500. 0 MG VIAL	7/1/2010
2203	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

2204	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 DISINTEGRA TING TABLETS	1.0X10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER,1.0X2. 0X10.0 TABLET BLISTER	7/1/2016
2205	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
2206	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,1.0X1 0.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE JAR	7/1/2017

2207	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
2208	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
2209	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

2210	NDA/MAL/HDP/6048	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	MOMATE AZ	MOMETASON E FUROATE / AZELASTINE HYDROCHLORI DE	50MCG/140M CG	GLENMARK PHARMACEUTICALS LTD-VILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X150.0 METERED DOSE BOTTLE	7/1/2017
2211	NDA/MAL/HDP/6050	MICRO LABS LTD	LABOREX UGANDA LIMITED	ITACARE	ITRACONAZOL E	100MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X1 0.0 CAPSULE BLISTER	7/1/2017
2212	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2009

2213	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2017
2214	NDA/MAL/HDP/6059	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI CARE LIMITED	NEUROZONE	MECOBALAMI N + 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
2215	NDA/MAL/HDP/6060	NOVARTIS ACCESS	SURGIPHARM (U) LIMITED	SALBUTAMOL	SALBUTAMOL	100MCG	AEROPHARM GMBH...- RUDOLSTADT ALLEMAGNE	GERMANY	LUNG ADMINISTR ATION LIQUID FOR INHALATION	1.0X200.0 METERED DOSE CONTAINER	7/1/2017

2216	NDA/MAL/HDP/6061	CIPLA LTD..	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	NASEHALER	MOMETASON E 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
2217	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
2218	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

2219	NDA/MAL/HDP/6073	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MILGA	BENFOTIAMIN E + PYRIDOXINE + CYANOCOBAL AMIN	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
2220	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
2221	NDA/MAL/HDP/6076	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	FALCI CARE	ARTESUNATE	30MG	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL 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

2222	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	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	7/1/2017
2223	NDA/MAL/HDP/6079	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ALLERGEX	CHLORPHENIR AMINE 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
2224	NDA/MAL/HDP/6080	EXPHAR SA	SURGIPHARM (U) LIMITED	FEBRILEX JUNIOR	PARACETAMO L+CHLORPHEN IRAMINE 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

2225	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
2226	NDA/MAL/HDP/6082	EXPHAR SA	SURGIPHARM (U) LIMITED	CROMSOL	SODIUM CROMOGLYCATATE	2%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/2017
2227	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017

2228	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	7/1/2017
2229	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
2230	NDA/MAL/HDP/6099	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HARIPIL-60	ARTESUNATE	60MG	PSYCHOTROPICS INDIA LTD -PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML OF 0.9% W/V NACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE	7/1/2017

2231	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
2232	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
2233	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

2234	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 IV AMPOULES	1.0X10.0X10.0 X2.0 ML AMPOULE	7/1/2017
2235	NDA/MAL/HDP/6105	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPI 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
2236	NDA/MAL/HDP/6110	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMBROX	AMBROXOL HYDROCHLORIDE	15MG/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)-SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2017

2237	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
2238	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, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET STRIP	
2239	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

2240	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
2241	NDA/MAL/HDP/6121	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	DEXIREN	DEKETOPIROFEN TROMETAMOL	25MG	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	7/1/2017
2242	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: ABUSULTAN, ISMAILIA, EGYPT	EGYPT	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	7/1/2016

2243	NDA/MAL/HDP/6127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	7/1/2016
2244	NDA/MAL/HDP/6129	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TRIUMEQ	DOLUTEGRAVI R + 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
2245	NDA/MAL/HDP/6134	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ZAMADOL P	TRAMADOL HYDROCHLORI DE+ACETAMIN OPHEN	37.5MG+325 MG	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

2246	NDA/MAL/HDP/6135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAXONE SODIUM+SULBACTAM	1000MG+500 MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	7/1/2016
2247	NDA/MAL/HDP/6136	CADILA HEALTH CARE 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
2248	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	

2249	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
2250	NDA/MAL/HDP/6142	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCARB	ACTIVATED CHARCOAL	0.25GM	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0X10.0 TABLET BLISTER	7/1/2016
2251	NDA/MAL/HDP/6143	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICALS LIMITED	CONTRACTUB EX	EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLANTOIN	10G+5000 I.U.+1G/100G	MARCYRL PHARMACEUTICAL INDUSTRIES.-EL BOOUR CITY CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	7/1/2016

2252	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
2253	NDA/MAL/HDP/6151	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	NITCAINE	LIDOCAINE	2%W/V	NITIN LIFESCIENCES LTD..-RAMPUR GHAT ROAD, PAOMTA SAHIB DIST. SIRMOUR H.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X30.0 ML VIAL	7/1/2016
2254	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

2255	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
2256	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	PARENTERA L ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	1/7/2016
2257	NDA/MAL/HDP/6169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	7/1/2016

2258	NDA/MAL/HDP/6171	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	SUXAMETHON IUM CHLORIDE	SUXAMETHON IUM CHLORIDE	50MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERA L ORDINARY DRY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/2016
2259	NDA/MAL/HDP/6173	CIPLA LTD..	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	MONTAIR 5	MONTELUKAS T 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
2260	NDA/MAL/HDP/6174	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	FLUPHENAZIN E DECANOATE INJECTION USP 25MG/ML	FLUPHENAZIN E DECANOATE	25MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2016

2261	NDA/MAL/HDP/6179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON-DENK 4MG ODT	ONDANSENTRON	4MG	DENK PHARMA GMBH & CO. KG - GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	7/1/2016
2262	NDA/MAL/HDP/6181	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZINOWEL-500	AZITHROMYCIN	500MG	AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER	7/1/2016
2263	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

2264	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
2265	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
2266	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

2267	NDA/MAL/HDP/6189	UNEEED 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
2268	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	2.7MG+0.52MG+0.58MG+0.30MG PER 200ML SACHET,6.75 MG+1.30MG+1.45MG+0.75 MG PER 500ML SACHET,13.5 MG+2.60MG+2.90MG+1.50 MG PER	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
2269	NDA/MAL/HDP/6191	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON AMPOULE	TRANEXAMIC ACID	500MG/5ML	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUNIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	7/1/2016

2270	NDA/MAL/HDP/6193	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	CEFTRIAXONE SANDOZ	CEFTRIAXONE SODIUM	1G	SANDOZ GMBH-BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2016
2271	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
2272	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

2273	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	7/1/2016
2274	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
2275	NDA/MAL/HDP/6201	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPAMOXIFLOX	AMOXICILLIN TRIHYDRATE + FLUCLOXACILLIN IN SODIUM	250MG + 250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHA BAVAD,JAMNAGAR- 361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	7/1/2016

2276	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
2277	NDA/MAL/HDP/6207	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	GO!GEL	DICLOFENAC DIETHYLAMIN E+METHYL SALICYLATE	1.16%W/W + 10%W/W	S KANT HEALTHCARE LTD- PLOT NO. 1802- 1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	7/1/2016
2278	NDA/MAL/HDP/6211	EXPHAR SA	SURGIPHARM (U) LIMITED	CLOFAINS	PARACETAMO L/DICLOFENAC SODIUM	500MG/50MG	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTR A-410209,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016

2279	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	PARENTERA L ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE VIAL)	7/1/2016
2280	NDA/MAL/HDP/6218	ASTRA ZENECA	MACNAUGHTON LIMITED	FORXIGA	DAPAGLIFLOZI N	10MG	BRISTOL-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2016
2281	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

2282	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	OPHTHALMI C DROPS	1.0X2.5 ML BOTTLE	7/1/2016
2283	NDA/MAL/HDP/6224	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	NICLOFEN	DICLOFENAC SODIUM	75MG/3ML	NITIN LIFESCIENCES LTD--RAMPUR ROAD PAONTA SAHIB DIST. SIRMOUR (H.P) 173 025	INDIA	PARENTERA L ORDINARY I M AMPOULES	1.0X10.0X5.0X 2.0 ML AMPOULE	7/1/2016
2284	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

2285	NDA/MAL/HDP/6228	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	ACINET	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	ALKEM LABORATORIES LTD-- PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X2.0X7.0 TABLET BLISTER	7/1/2016
2286	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	7/1/2016
2287	NDA/MAL/HDP/6230	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	EMITINO	ONDANSETRON	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

2288	NDA/MAL/HDP/6231	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTE MISININ/PIPE RAQUINE	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
2289	NDA/MAL/HDP/6232	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	H-CURE	LANSOPRAZOL E + CLARITHROMY CIN + 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 LANSOPRAZOL E + 2 TABLETS OF CLARITHROMY CIN + 2 TABLETS OF TINIDAZOLE)	7/1/2016
2290	NDA/MAL/HDP/6234	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP DISPERSIBLE	DIHYDROARTE MESININE/ 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

2291	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
2292	NDA/MAL/HDP/6236	MOONLINK PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL ADVANCE	PARACETAMO L + IBUPROFEN + CAFFEINE	325 MG + 400 MG + 40 MG	FREDUN PHARMACEUTICALS LTD-VEOOR PALGHAR (E) 401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X40.0X2.0X 10.0 CAPSULE BLISTER	7/1/2016
2293	NDA/MAL/HDP/6237	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR/RI TONAVIR	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,1.0X6 0.0 TABLET CONTAINER	7/1/2016

2294	NDA/MAL/HDP/6238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG - AM	NEBIVOLOL HYDROCHLORI DE + 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
2295	NDA/MAL/HDP/6239	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE	ARTESUNATE	60MG	BLISS GVS PHARMA LTD- PLOT 73 -76 SILVER INDUSTRIAL ESTATE BHIMPORE DAMAN 396 210 (UT) EAST AFRICAN (INDIA) OVERSEAS- PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML AMPOULE OF 0.9%W/V NACL + 1*1 ML OF 5%W/V SODIUM BICARBONATE	7/1/2016
2296	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

2297	NDA/MAL/HDP/6242	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP	DIHYDROARTE MESININ/PIPE RAQUINE 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
2298	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 INSTILLATIO N VIALS	1.0X4.0 ML VIAL,1.0X8.0 ML VIAL	7/1/2016
2299	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

2300	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 IM AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2016
2301	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
2302	NDA/MAL/HDP/6248	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	ARTEMETHER	ARTEMETHER	80MG/ML	NITIN LIFESCIENCES LTD..-RAMPUR GHAT ROAD, PAOMTA SAHIB DIST. SIRMOUR H.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X6.0X1.0 ML AMPOULE	7/1/2016

2303	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
2304	NDA/MAL/HDP/6251	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TORGABALIN 75	PREGABALIN	75MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA ,INDRAD-382721	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2016
2305	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

2306	NDA/MAL/HDP/6264	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	PARACONICA 1000 MG IV	PARACETAMO L	10MG/ML	S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO- POTENZA (PZ) ITALY	ITALY	PARENTERA L ORDINARY I V VIALS	1.0X100.0 ML VIAL	7/1/2016
2307	NDA/MAL/HDP/6267	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TRAMADOL DENK 50	TRAMADOL HYDROCHLORI DE	50MG	LOSAN PHARMA GMBH- OTTO-HAHN- STR 13 79395 NEUENBURG	GERMANY	ORAL SOLID ORDINARY EFFERVESCE NT TABLETS	1.0X10.0 TABLET BOTTLE	7/1/2016
2308	NDA/MAL/HDP/6270	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	FEBUMAC 80	FEBUXOSTAT	80MG	MACLEODS PHARMACEUTICALS LTD - - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3. 0X10.0 TABLET BLISTER	7/1/2017

2309	NDA/MAL/HDP/6275	SEV PHARMACEUTICALS 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	
2310	NDA/MAL/HDP/6281	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	HOMAGON	CHLORPHENA MINE MALEATE + CAFFEINE ANHYDROUS + PSEUDOEPHE DRINE HYDROCHLORI DE + PARACETAMO L	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,1.0X1 0.0X10.0 CAPSULE BLISTER	1/25/2019
2311	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

2312	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
2313	NDA/MAL/HDP/6284	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	PAEDIATRIC PARACETAMO L ORAL SOLUTION	PARACETAMO L	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
2314	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	SWEDEN AUSTRIA	PARENTERA L ORDINARY INFUSION BAGS	1.0X493.0 ML BAG (1*[250ML AMINO ACID SOLUTION WITH ELECTROLYTES + 149ML GLUCOSE 42% SOLUTION + 94ML LIPID EMULSION], MULTI-	11/7/2018

2315	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	PARENTERA L ORDINARY INFUSION BAGS	1.0X1206.0 ML BAG (1*[656ML GLUCOSE 13% SOLUTION + 380ML AMINO ACID SOLUTION WITH ELECTROLYTES + 170ML LIPID EMULSION], MULTI-	1/25/2019
2316	NDA/MAL/HDP/6288	THEON PHARMACEUTICALS 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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X60.0 ML BOTTLE	12/17/2018
2317	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

2318	NDA/MAL/HDP/6293	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	NEUROGAB 150	PREGABALIN	150MG	"MACLEODS PHARMACEUTICALS LTD,--BLOCK N2, VILLAGE THEDA, POST OFFICE LODHIMAJRA, TEHSIL BADDI, DISTRICT SOLAN, HIMACHAL PRADESH – 174101 INDIA."	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	12/17/2018
2319	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
2320	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

2321	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
2322	NDA/MAL/HDP/6302	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	PLENOX	OFLOXACIN	200MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/28/2019
2323	NDA/MAL/HDP/6304	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	UNOSURE 72	LEVONORGEST REL	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

2324	NDA/MAL/HDP/6314	YELURI FORMULATIONS PVT LTD	ESCORTS PHARMACEUTICALS LIMITED	ELMOX-CV 625	AMOXICILLIN TRIHYDRATE+ CLAVULANATE POTASSIUM	500MG+125M G	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
2325	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
2326	NDA/MAL/HDP/6322	CACHET PHARMACEUTICALS 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

2327	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
2328	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
2329	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

2330	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 SC VIALS	1.0X1.0X10.0 ML VIAL, 1.0X5.0X3.0 ML CARTRIDGE	3/28/2019
2331	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
2332	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

2333	NDA/MAL/HDP/6341	MACLEODS PHARMACEUTICALS LTDS LTD	VITACARE LIMITED	ROSUMAC 20	ROSUVASTATI N 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
2334	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	OPHTHALMI C DROPS	1.0X1.0X5.0 ML BOTTLE	5/30/2018
2335	NDA/MAL/HDP/6343	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN N	ISOPHANE HUMAN HUMAN OF RECOMBINAN T DNA ORIGIN	100 IU/ML	BIOTON S.A- MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERA L ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X 3.0 ML CARTRIDGE	3/28/2019

2336	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
2337	NDA/MAL/HDP/6345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 600MG VIAL	AMOXYCILLIN SODIUM/ CLAVULANATE POTASSIUM	500MG/100M G	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/25/2018
2338	NDA/MAL/HDP/6346	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN R	SOLUBLE HUMAN INSULIN OF RECOMBINAN T DNA ORIGIN	100 IU/ML	BIOTON S.A- MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERA L ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X 3.0 ML CARTRIDGE	3/28/2019

2339	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	9/26/2018
2340	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,PAL GHAR,MAHARASHTRA 401404,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	3/28/2019
2341	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

2342	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
2343	NDA/MAL/HDP/6353	LAURUS LABS LIMITED	BEYOND LOGISTICS LTD	DOLUTEGRAVIR/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE TABLETS 50MG/300MG /300MG	DOLUTEGRAVIR+LAMIVUDINE+TENOFOVIR DISOPROXIL FUMARATE TABLETS	50MG+300MG +300MG	LAURUS LABS LIMITED, (UNIT-2) - - PLOT NO:19, 20 & 21,WESTERN SECTOR, APSEZ, ATCHUTAPURAM MANDAL, VISAKHAPATNAM-DISTRICT-531011, ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X1.0X90.0 TABLET BOTTLE	12/11/2019
2344	NDA/MAL/HDP/6354	EXPHAR SA.	SURGIPHARM (U) LIMITED	TIMOSOL ®	TIMOLOL MALEATE	0.5%W/V	AHLCONPARENTERALS (INDIA) LIMITED- SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	7/1/2017

2345	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
2346	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
2347	NDA/MAL/HDP/6359	CCL PHARMACEUTICALS (PVT.)LTD.	HARLEYS UGANDA LIMITED	NEO-KLAR 250MG	CLARITHROMY CIN	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

2348	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 SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2017
2349	NDA/MAL/HDP/6365	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	EASY PILL	LEVONORGEST REL	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
2350	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 SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	1/31/2018

2351	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
2352	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
2353	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

2354	NDA/MAL/HDP/6381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTAONAZ OLE 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
2355	NDA/MAL/HDP/6383	EXPHAR SA.	SURGIPHARM (U) LIMITED	EXXIB	CELECOXIB	200MG	GRACURE PHARMACEUTICALS LIMITED -E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017
2356	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

2357	NDA/MAL/HDP/6386	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 60K GRANULES	COLECALCIFER OL	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
2358	NDA/MAL/HDP/6390	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ROSUMAC 10	ROSUVASTATI N 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
2359	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

2360	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
2361	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
2362	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

2363	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
2364	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
2365	NDA/MAL/HDP/6401	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 250 SUPPOSITORIES	ACETAMINOPHEN	250MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	7/1/2017

2366	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
2367	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
2368	NDA/MAL/HDP/6406	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	LIDOCAINE INJECTION BP 2%	LIDOCAINE HYDROCHLORI DE	2% W/V	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERA L ORDINARY VIALS	1.0X25.0X30.0 ML VIAL	2/6/2019

2369	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
2370	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
2371	NDA/MAL/HDP/6412	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BUCCAZOLE ORAL GEL	MICONAZOLE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	7/1/2017

2372	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,1.0X1.0X 2.5 ML VIAL,1.0X1.0X 5.0 ML VIAL	5/29/2019
2373	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
2374	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

2375	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
2376	NDA/MAL/HDP/6424	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL LS	LEVOSALBUTAMOL SULPHATE + AMBROXOL HYDROCHLORIDE + GUAIFENESIN	1 MG + 30 MG + 100 MG	GLENMARK PHARMACEUTICALS LTD .-VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	3/27/2019
2377	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

2378	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2379	NDA/MAL/HDP/6432	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	UMBI-GEL	CHLORHEXIDI NE GLUCONATE	4 % W/W	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTD- STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X50.0X1.0X 5.0 G TUBE	3/27/2019
2380	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

2381	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,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2017
2382	NDA/MAL/HDP/6436	GUILIN PHARMACEUTICALS CO.LTD	TRIDEM PHARMA UGANDA LIMITED	MOXAF	MOXIFLOXACI N HYDROCHLORI DE	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
2383	NDA/MAL/HDP/6437	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	PILORECT	HYDROCORTIS ONE 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 SUPPOSITOR IES	1.0X1.0X6.0 SUPPOSITORY STRIP	11/29/2017

2384	NDA/MAL/HDP/6438	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL PLUS	PARACETAMO L + 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
2385	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
2386	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

2387	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 SUSPENSION S/SYRUPS/DROPS	1.0X30.0 ML BOTTLE, 1.0X15.0 ML BOTTLE	7/1/2018
2388	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 SUSPENSION S	1.0X1.0X100.0 ML BOTTLE	3/27/2019
2389	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

2390	NDA/MAL/HDP/6448	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE- DEPOT 40 MG/ 1 ML VIAL	METHYLPRED NISOLONE ACETATE	40 MG/ ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERA L ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	7/25/2018
2391	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
2392	NDA/MAL/HDP/6453	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ALLMYCIN	ERYTHROMYCI N 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 SUSPENSION S	1.0X100.0 ML BOTTLE WITH 10ML PLASTIC DOSING CAP	3/27/2019

2393	NDA/MAL/HDP/6454	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MAGRILAN 20MG	FLUOXETINE HYDROCHLORI DE	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
2394	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
2395	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

2396	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
2397	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
2398	NDA/MAL/HDP/6465	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	NEUROGAB 75	PREGABALIN	75MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	7/1/2017

2399	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
2400	NDA/MAL/HDP/6472	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MOXICLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULINIC ACID	250MG + 125MG	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X10.0 CAPSULE STRIP	2/4/2019
2401	NDA/MAL/HDP/6477	MEDOCHEMIE LTD	LABOREX UGANDA LIMITED	MEDOFULVIN	GRISEOFULVIN	500 MG	MEDOCHEMIE (FACTORY AZ).-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER	3/27/2019

2402	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
2403	NDA/MAL/HDP/6481	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	MOXAL PLUS CHEWABLE TABLETS	DRIED ALUMINIUM HYDROXIDE GEL+MAGNESIUM HYDROXIDE+SILICONE	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
2404	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

2405	NDA/MAL/HDP/6485	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	CEFUZIME 750	CEFUROXIME SODIUM	750MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	1/31/2018
2406	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	1.0X10.0X10.0 X2.0 ML AMPOULE	5/30/2018
2407	NDA/MAL/HDP/6489	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL-SF	SALBUTAMOL +BROMHEXINE HYDROCHLORIDE+GUAIFENESIN	2MG+4MG+100MG/10ML	GLENMARK PHARMACEUTICALS LTD .-VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2017

2408	NDA/MAL/HDP/6491	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAM IN	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
2409	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
2410	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

2411	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
2412	NDA/MAL/HDP/6501	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARTROGYL 200 TABLET	METRONIDAZ OLE	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
2413	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

2414	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
2415	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	PARENTERA L ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	5/29/2019
2416	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

2417	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
2418	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
2419	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

2420	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
2421	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
2422	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

2423	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
2424	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
2425	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

2426	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
2427	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,1.0X5 0.0X10.0 TABLET BLISTER	3/28/2018
2428	NDA/MAL/HDP/6532	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	BUNASE 200	BUDESONIDE	200MCG / ACTUATION	OXALIS LABS-- VILLAGE THEDA,P.O.LODHIM AJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	3/28/2018

2429	NDA/MAL/HDP/6537	EXPHAR SA	SURGIPHARM (U) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	1/31/2018
2430	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
2431	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

2432	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
2433	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
2434	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

2435	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
2436	NDA/MAL/HDP/6549	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PIRAV-75	PREGABALIN	75MG	RAVIAN LIFE SCIENCE PVT LTD- PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	3/28/2019
2437	NDA/MAL/HDP/6550	REDDYS PHARMA LIMITED	REDDYS PHARMA LIMITED	REDCEPHIN	CEFTRIAXONE	1 G	INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	3/27/2019

2438	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
2439	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
2440	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

2441	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
2442	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
2443	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,1.0X3.0X6.0 TABLET BLISTER,1.0X3.0X12.0 TABLET BLISTER	3/29/2019

2444	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
2445	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
2446	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

2447	NDA/MAL/HDP/6563	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANATAX ® 16MG	BETAHISTINE DIHYDROCHLO RIDE	16MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY-JORDAN - NUZHAT SAHAB	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	3/28/2019
2448	NDA/MAL/HDP/6564	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANATAX ® 24MG	BETAHISTINE DIHYDROCHLO RIDE	24MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY-JORDAN - NUZHAT SAHAB	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	3/28/2019
2449	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

2450	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
2451	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
2452	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

2453	NDA/MAL/HDP/6577	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	CEFIWEL-200	CEFIXIME	200MG	MALIK LIFESCIENCES PRIVATE LIMITED- PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	1/13/2020
2454	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	8/28/2019
2455	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

2456	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
2457	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
2458	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

2459	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
2460	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
2461	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

2462	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
2463	NDA/MAL/HDP/6598	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHZY-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
2464	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

2465	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
2466	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
2467	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/GRANULES	1.0X6.0X5.4 G SACHET	5/29/2019

2468	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
2469	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,1.0 X4.0X4.0 ML AMPOULE	7/1/2017
2470	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

2471	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
2472	NDA/MAL/HDP/6616	SHIN POONG PHARMACEUTICALS CO.LTD	ESCORTS PHARMACEUTICALS LIMITED	PYRAMAX	PYRONARIDIN E TETRAPHOSPH ATE + ARTESUNATE	180MG + 60MG	SHIN POONG PHARM. CO., LTD- 70, SANDAN-RO, 19 BEON-GIL, DANWON- GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER	7/1/2016
2473	NDA/MAL/HDP/6617	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APFLU	CHLOROPHEN ERAMINE + PARACETAMO L + 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

2474	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
2475	NDA/MAL/HDP/6620	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET 5MG	NEBIVOLOL HYDROCHLORI DE	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
2476	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

2477	NDA/MAL/HDP/6622	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL-100 DT	CEFIXIME TRIHYDRATE	100MG	MALIK LIFESCENCES PRIVATE LIMITED- PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0 TABLET BLISTER	7/1/2016
2478	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,-	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
2479	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

2480	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,2.0X1 2.0 LOZENGE BLISTER	7/1/1997
2481	NDA/MAL/HDP/6629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+H YDROCHLORO THIAZIDE	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
2482	NDA/MAL/HDP/6630	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZO LE	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,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016

2483	NDA/MAL/HDP/6631	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBURN	SILVER SULFADIAZINE	1%W/W	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X500. 0 G JAR	7/1/2016
2484	NDA/MAL/HDP/6632	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	CIPROFLOXACI N	CIPROFLOXACI N	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
2485	NDA/MAL/HDP/6633	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	PARACETAMO L + CHLORPHENIR AMINE MALEATE + PSEUDOEPHE DRINE HCL	500MG + 30MG + 2MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGA DISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O. BOX 42569- 001000 NAIROBI,KENYA	TANZANIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 2.0X1.0X2.0X1 0.0 CAPSULE BLISTER	7/1/2010

2486	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
2487	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
2488	NDA/MAL/HDP/6641	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFTRISONE- S 1.5G	CEFTRIAZONE 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

2489	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
2490	NDA/MAL/HDP/6647	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	JOYCLAV -625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG + 125MG	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	1.0X3.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER	7/1/2016
2491	NDA/MAL/HDP/6648	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	DEXAMETHAS ONE INJECTION	DEXAMETHAS ONE 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

2492	NDA/MAL/HDP/6650	INDUS LIFE SCIENCES PVT LIMITED	NORVIK ENTERPRISES LIMITED	INTRIAX-S-1	CEFTRIAXONE SODIUM+SULB ACTAM SODIUM	1G+0.5G	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2016
2493	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
2494	NDA/MAL/HDP/6652	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE +TENOFVIR DISOPROXIL FUMARATE	LAMIVUDINE+ TENOFVIR DISOPROXIL FUMARATE	300MG+300M G	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

2495	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
2496	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
2497	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

2498	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2016
2499	NDA/MAL/HDP/6665	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,K ENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/1997
2500	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

2501	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,LAKHA BAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	7/1/2016
2502	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
2503	NDA/MAL/HDP/6670	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	METROSIM-200	METRONIDAZOLE	200MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER	

2504	NDA/MAL/HDP/6673	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-TZ	CEFTRIAXONE SODIUM + TAZOBACTAM	1000MG + 125MG	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	7/1/2016
2505	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
2506	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

2507	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	
2508	NDA/MAL/HDP/6681	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	WELQUINE	LEVOFLOXACIN	0.5%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD. -PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2016
2509	NDA/MAL/HDP/6682	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	PROCILIN	FORTIFIED PROCAINE BENZYL PENICILLIN	4MU	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD-PRIVATE ECONOMY GARDEN,XINYAN JINING CITY,SHANDONG,CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X5 0.0 VIAL CARTON	

2510	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
2511	NDA/MAL/HDP/6688	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	CAREOCEF	CEFTRIAXONE SODIUM	1G	NITIN LIFESCIENCES LTD..-RAMPUR GHAT ROAD, PAOMTA SAHIB DIST. SIRMOUR H.	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 G VIAL	7/1/2016
2512	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

2513	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
2514	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
2515	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

2516	NDA/MAL/HDP/6695	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ORAV-OZ	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	RAVIAN LIFE SCIENCE PVT LTD- PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	5/29/2019
2517	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
2518	NDA/MAL/HDP/6699	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ATVIN-20	ATORVASTATIN	20MG	RAVIAN LIFE SCIENCE PVT LTD- PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	5/29/2019

2519	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
2520	NDA/MAL/HDP/6705	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHEWORM	MEBENDAZOL E	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,1.0X1 000.0 TABLET CONTAINER	7/1/2010
2521	NDA/MAL/HDP/6706	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-E- WORM	MEBENDAZOL E	100MG/5ML	CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X30.0 ML BOTTLE	7/1/2009

2522	NDA/MAL/HDP/6709	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHPAR	PARACETAMO L	500MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2012
2523	NDA/MAL/HDP/6711	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHPAR	PARACETAMO L	125MG/5ML	CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X60.0 ML BOTTLE,1.0X1 00.0 ML BOTTLE	7/1/2009
2524	NDA/MAL/HDP/6712	CACHET PHARMACEUTICALS 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

2525	NDA/MAL/HDP/6713	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAMET	METOCLOPRA MIDE HYDROCHLORI DE	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
2526	NDA/MAL/HDP/6714	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLLIN SYRUP	AMINOPHYLLI NE+ AMMONIUM HCL+ DIPHENHYDRA MINE HCL	32MG +300MG+8MG	THE SEARLE COMPANY-32-KM MULTAN ROAD, LAHORE	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	7/1/1997
2527	NDA/MAL/HDP/6715	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAZITHRO	AZITHROMYCI N	200MG/5ML	CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X15.0 ML BOTTLE	7/1/2009

2528	NDA/MAL/HDP/6717	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAZITHRO	AZITHROMYCI N	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
2529	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
2530	NDA/MAL/HDP/6728	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CIPROCOS-500 TABLETS	CIPROFLOXACI N	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,10.0X 10.0 TABLET BLISTER	7/1/2000

2531	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
2532	NDA/MAL/HDP/6731	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	PIPTAZO 4.5G	PIPERACILLIN SODIUM+TAZ OBACTAM 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
2533	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

2534	NDA/MAL/HDP/6734	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	EASCOF	BROMHEXIDIN E HCL + SALBUTAMOL SULPHATE + GUAIPHENESI N	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
2535	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	7/1/2016
2536	NDA/MAL/HDP/6738	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SEEBRI BREEZHALER	GLYCOPYRRO NIUM BROMIDE	50MCG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTR ATION INHALER CAPSULES	1.0X1.0 CANNISTER CARTON + 30 CAPSULE BLISTER	7/1/2016

2537	NDA/MAL/HDP/6741	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ULTIBRO BREEZHALER	INDACATEROL MALEATE+GLY COPYRRONIUM BROMIDE	110MCG+50MCG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X30.0 CAPSULE BLISTER	7/1/2016
2538	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
2539	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

2540	NDA/MAL/HDP/6752	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	VITACEE	ASCORBIC ACID	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	7/1/2000
2541	NDA/MAL/HDP/6754	INDIAN IMMUNOLOGICALS LIMITED	TATA UGANDA LIMITED	ABHAYRAB	RABIES ANTIGEN DERIVED FROM RABIES VIRUS(L.PASTE UR 2061/VERO STRAIN)	>2.5 I.U PER VIAL	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD) .-KOZHIPANNAI PUDUMUND P.O DR. BASAVAI AH NAGAR UDHAGAMANDALA M PIN: 643007 TAMIL NADU	INDIA	PARENTERA L 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
2542	NDA/MAL/HDP/6758	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	ADCO- NAPAMOL	PARACETAMO L	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

2543	NDA/MAL/HDP/6764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	IZRA 40	ESOMEPRAZO LE 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
2544	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,1.0X1 000.0 TABLET CONTAINER	7/1/2010
2545	NDA/MAL/HDP/6767	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MEDI-KEEL A	BENZOCAINE+ CETYLPYRIDINI UM 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

2546	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
2547	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
2548	NDA/MAL/HDP/6774	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FLEMIN EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE +AMMONIUM CHLORIDE	12.5MG+130 MG/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,1.0X100.0 ML BOTTLE	7/1/2008

2549	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
2550	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 MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	7/1/2016
2551	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

2552	NDA/MAL/HDP/6781	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NETAZOX-500	NITAZOXANID E	500MG	IND-SWIFT LIMITED- INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X 6.0 TABLET BLISTER	7/1/2007
2553	NDA/MAL/HDP/6785	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NETAZOX DT	NITAZOXANID E	200MG	IND-SWIFT LIMITED- INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRA TING TABLETS	1.0X10.0X1.0X 6.0 TABLET BLISTER	7/1/2008
2554	NDA/MAL/HDP/6787	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NETAZOX	NITAZOXANID E	100MG/5ML	IND-SWIFT LIMITED- INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X30.0 ML BOTTLE	7/1/2008

2555	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
2556	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
2557	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

2558	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
2559	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 MOLEPALL Y VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X 10.0 TABLET BLISTER,1.0X1 0.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2017
2560	NDA/MAL/HDP/6795	PHARAONIA PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CRONOMESO NE OINTMENT	BETAMETHAS ONE VALERATE	1%W/W	PHARAONIA PHARMACEUTICALS- NEW BORG EL ARAB CITY-ALEXANDRIA	EGYPT	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	7/1/2016

2561	NDA/MAL/HDP/6797	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	100MG/2ML	MARTINDALE PHARMACEUTICAL LIMITED -BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	7/1/1997
2562	NDA/MAL/HDP/6798	UMEDICA LABORATORIES PVT LTD	VITACARE LIMITED	PRAZIQUANTE L TABLETS USP 600MG	PRAZIQUANTE L	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
2563	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	PARENTERA L 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

2564	NDA/MAL/HDP/6812	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NOFLOX	NORFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LIMITED-PLOT 114, BLOCK 191	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE	7/1/2016
2565	NDA/MAL/HDP/6815	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCROM EYE DROPS	SODIUM CROMOGLYCAT	2%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE	7/1/2016
2566	NDA/MAL/HDP/6817	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH-SCHLEEBRÜGGENKA MP 15 48159 MÜNSTER GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2016

2567	NDA/MAL/HDP/6818	SANOFI 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	SANOFI PASTEUR-MÉRIEUX 69280 MARCY L'ETOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	7/1/2016
2568	NDA/MAL/HDP/6820	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABBORI EAR DROPS	BORIC ACID	1.83%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML BOTTLE	7/1/2017
2569	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

2570	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
2571	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
2572	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

2573	NDA/MAL/HDP/6843	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	FYTOBACT	CEFOPERAZON E + SULBACTAM	0.5 G + 0.5 G	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	7/1/2009
2574	NDA/MAL/HDP/6845	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	FYTOBACT 2G	SULBACTAM SODIUM + CEFOPERAZON E SODIUM	1G + 1G	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X2.0 G VIAL	7/1/2017
2575	NDA/MAL/HDP/6857	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRUCIPRO TABLETS	CIPROFLOXACI N	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

2576	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
2577	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
2578	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

2579	NDA/MAL/HDP/6870	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	HYDROSONE 100MG	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON (1*100MG GLASS VIAL + 1*2ML AMP WFI),1.0X50.0 VIAL CARTON	11/29/2017
2580	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
2581	NDA/MAL/HDP/6872	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	NETRACORTIL EYE/EAR SUSPENSION	OXYTETRACYC LINE HYDROCHLORI DE +HYDROCORTI SONE ACETATE+POL YMYXIN B SULPHATE	10MG+5MG+1 0000I.U	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	OPHTHALMI C SUSPENSION S	1.0X5.0 ML BOTTLE	7/1/2017

2582	NDA/MAL/HDP/6873	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	ROXITHIN TABLETS	ROXITHROMY CIN	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
2583	NDA/MAL/HDP/6874	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	CITRAX TABLETS	CETIRIZINE HYDROCHLORI DE	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
2584	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

2585	NDA/MAL/HDP/6882	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VORM-400	ALBENDAZOLE	400MG	RAVIAN LIFE SCIENCE PVT LTD- PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X1.0 TABLET BLISTER	5/29/2019
2586	NDA/MAL/HDP/6887	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN-L	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	RAVIAN LIFE SCIENCE PVT LTD- PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	5/29/2019
2587	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

2588	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
2589	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
2590	NDA/MAL/HDP/6909	F.HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	HERCEPTIN	TRASFUZUMA B	600 MG	F.HOFFMANN LA ROACHE AG, KAISRAUGST - BETRIEBSSTANDORT KAISERAUGST, 4303 KAIERAUGST	SWITZERLAND	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	8/28/2019

2591	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	
2592	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
2593	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

2594	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
2595	NDA/MAL/HDP/6919	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MACSUNATE AQ JUNIOR	ARTESUNATE + AMODIAQUIN E	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,1.0X2 5.0X3.0 TABLET BLISTER	3/27/2019
2596	NDA/MAL/HDP/6920	I CARE PHARMA LIMITED	AIVEEN (U) LTD - WILSON ROAD	OFZOLE	OFLOXACIN+O RNIDAZOLE	200MG+500M G	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

2597	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
2598	NDA/MAL/HDP/6922	EXPHAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	SURGIPHARM (U) LIMITED	FLUCAZOL	FLUCONAZOLE	50 MG / 5 ML	GRACURE PHARMACEUTICALS LIMITED -E- 1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN- 301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	1/25/2019
2599	NDA/MAL/HDP/6923	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MACSUNATE AQ KID	ARTESUNATE + AMODIAQUIN E	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,1.0X2 5.0X3.0 TABLET BLISTER	3/27/2019

2600	NDA/MAL/HDP/6924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PARACETAMOL+CHLORZOXAZONE	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
2601	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
2602	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

2603	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
2604	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
2605	NDA/MAL/HDP/6932	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE-200	SODIUM VALPROATE	200 MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0x10.0x10.0 TABLET BLISTER	7/25/2018

2606	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
2607	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
2608	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

2609	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
2610	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
2611	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

2612	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 SUPPOSITOR IES	1.0X1.0X5.0 SUPPOSITORY STRIP	5/29/2019
2613	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
2614	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

2615	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
2616	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
2617	NDA/MAL/HDP/6953	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MISO FREE	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

2618	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 INHALATION S	1.0X250.0 ML BOTTLE	5/29/2019
2619	NDA/MAL/HDP/6956	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	NUROTROY SR	MECOBALAMI N + FOLIC ACID + PYRIDOXINE HYDROCHLORI DE	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
2620	NDA/MAL/HDP/6957	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	ZEECIN	AZITHROMYCI N 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

2621	NDA/MAL/HDP/6958	WILSHIRE LABORATORIES (PVT) LTD	HEALTHCARE LTD.	ZEECIN	AZITHROMYCI N 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
2622	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
2623	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,	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X20.0 ML VIAL	5/29/2019

2624	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
2625	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
2626	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

2627	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
2628	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
2629	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

2630	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
2631	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
2632	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

2633	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
2634	NDA/MAL/HDP/6985	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID SYRUP	CETIRIZINE DIHYDROCHLORIDE + PHENYLEPHRINE HCL + PARACETAMOL	2.5MG + 5MG + 125MG	MEDLEY PHARMACEUTICALS, LTD-PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	7/1/2017
2635	NDA/MAL/HDP/6986	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	REPRAZ 20 TABLETS	RABEPRAZOLE SODIUM	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017

2636	NDA/MAL/HDP/6987	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PORAZ CAPSULES	OMEPRAZOLE	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	7/1/2017
2637	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
2638	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

2639	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
2640	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
2641	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

2642	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 SUSPENSION S/SYRUPS/D ROPS	1.0X30.0 ML BOTTLE	1/31/2018
2643	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
2644	NDA/MAL/HDP/7002	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LOPINAVIR AND RITONAVIR	LOPINAVIR + RITONAVIR	40MG + 10MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S-112, L-147/1 TO L-147/3, L-138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X120.0 CAPSULE BOTTLE	9/6/2019

2645	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
2646	NDA/MAL/HDP/7004	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	DUOCETZ	PARACETAMOL + TRAMADOL HYDROCHLORIDE	325MG+37.5 MG	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
2647	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

2648	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
2649	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
2650	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

2651	NDA/MAL/HDP/7011	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	URSOLIV 250	URSODEOXYC HOLIC 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
2652	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
2653	NDA/MAL/HDP/7013	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AZITHRAA 500	AZITHROMYCI N	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

2654	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
2655	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
2656	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	8/28/2019

2657	NDA/MAL/HDP/7019	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	SULFAMETHO XAZOLE + TRIMETHOPRI M	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
2658	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,1.0X1 0.0 TABLET BLISTER,1.0X2. 0X10.0 TABLET BLISTER	8/28/2019
2659	NDA/MAL/HDP/7021	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNOFEC PLUS	ACECLOFENAC +PARACETAM OL	100MG+500M G	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

2660	NDA/MAL/HDP/7022	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNAFLAM PLUS	DICLOFENAC SODIUM+PAR ACETAMOL	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
2661	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 SUSPENSION S	1.0X1.0X10.0 ML BOTTLE,1.0X2 0.0X10.0 ML BOTTLE	3/28/2018
2662	NDA/MAL/HDP/7024	EXPHAR SA.	SURGIPHARM (U) LIMITED	MICOZAL	KETOCONAZO LE	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

2663	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
2664	NDA/MAL/HDP/7044	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	R.B. TONE HAEMATINIC CAPSULES	FERROUS GLUCONATE + FOLIC ACID + CALCIUM LACTATE + ZINC SULFATE + VITAMIN B12	259MG + 0.5MG + 100MG + 33MG + 2.5MG	MEDLEY PHARMACEUTICALS LTD..-PLOT NO. 18 & 19, SURVEY NO. 378 / 7 & 8 & 379 / 2 & 3, ZARI CAUSEWAY ROAD, KACHIGAM, DAMAN (U.T) 396210 - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X2.0X15.0 CAPSULE BLISTER	8/28/2019
2665	NDA/MAL/HDP/7046	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	XEMADERM 0.1% CREAM	MOMETASON E 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

2666	NDA/MAL/HDP/7047	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	XEMADERMO. 1% OINTMENT	MOMETASON E 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
2667	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
2668	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

2669	NDA/MAL/HDP/7066	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MABRON SR	TRAMADOL HYDROCHLORI DE	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
2670	NDA/MAL/HDP/7067	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 125	PARACETAMO L	125MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITOR IES	1.0X2.0X5.0 SUPPOSITORY STRIP	8/28/2019
2671	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 SUPPOSITOR IES	1.0X1.0X5.0 SUPPOSITORY STRIP	8/28/2019

2672	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 ADMINISTR ATION METERED- DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	7/25/2018
2673	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 ADMINISTR ATION METERED- DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	7/25/2018
2674	NDA/MAL/HDP/7077	CIPLA LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	FORACORT- 400	FORMOTEROL FUMARATE DIHYDRATE + BUDESONIDE	6MCG + 400MCG	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	LUNG ADMINISTR ATION METERED- DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	7/25/2018

2675	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
2676	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 SUSPENSION S/SYRUPS/D ROPS	1.0X30.0 ML BOTTLE	8/28/2019
2677	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

2678	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
2679	NDA/MAL/HDP/7089	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ES-LOPROT	ESOMEPRAZO LE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	PARENTERA L ORDINARY VIALS	1.0X10.0 ML VIAL	8/28/2019
2680	NDA/MAL/HDP/7091	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARLEFLOX 500 TABLETS	LEVOFLOXACI N 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

2681	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
2682	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
2683	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

2684	NDA/MAL/HDP/7096	GAMA PHARMACEUTICALS (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DEXAPHEN SYRUP	DEXAMETHAS ONE + CHLORPHENIR AMINE 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
2685	NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC +PARACETAM OL+SERRATIO PEPTIDASE	100MG+325M G+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
2686	NDA/MAL/HDP/7099	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYGESTY	MEDROXYPRO GESTERONE ACETATE	150MG/ML	MYLAN LABORATORIES LIMITED-PLOT NO. 20 & 21, PHARMEZ, SARKHEJ - BAVLA, NATIONAL HIGHWAY NO. 8 - A, NEAR VILLAGE - MATODA, TAL - SANAND, DIST., AHMEDABAD - 382213	INDIA	PARENTERA L ORDINARY VIALS	1.0X12.0X1.0 ML VIAL,1.0X25.0 X1.0 ML VIAL	11/27/2019

2687	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
2688	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
2689	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

2690	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	11/27/2019
2691	NDA/MAL/HDP/7104	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISOPT	DOROZOLAMI DE + TIMOLOL	20MG/1ML + 5MG/1ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMI C DROPS	1.0X5.0 ML BOTTLE	5/30/2018
2692	NDA/MAL/HDP/7105	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	TRAMACETAL TABLETS	ACETAMINOP HEN +TRAMADOL HYDROCHLORI DE	325MG+37.5 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	1.0X10.0 TABLET BLISTER	7/1/2017

2693	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
2694	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	3/27/2019
2695	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

2696	NDA/MAL/HDP/7110	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA SYRUP 120ML	TRIPROLIDINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE + DEXTROMETHORPHAN + GUAIFENESIN	1.25MG + 10MG + 7.5MG + 50MG/5ML	UNITED PHARMACEUTICALS MANUFACTURING LTD CO-AL-RAGEEM, SAHAB, P.O BOX 69, AMMAN 11591, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	11/27/2019
2697	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
2698	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

2699	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
2700	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
2701	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

2702	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
2703	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
2704	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

2705	NDA/MAL/HDP/7120	BESINS HEALTHCARE BENELUX SA	SURGIPHARM (U) LIMITED	ANDROGEL	TESTOSTERON E	16.2MG/G	BESINS MANUFACTURING BELGIUM (BMB)- GROOT BIJGAARDENSTRAAT , 128. 1620	BELGIUM	TOPICAL EXTERNAL EMULSION GELS	1.0X88.0 G CANNISTER	11/27/2019
2706	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
2707	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

2708	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
2709	NDA/MAL/HDP/7125	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	I-FREE 72	LEVONORGEST REL	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
2710	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	11/7/2018

2711	NDA/MAL/HDP/7128	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	COTRIKANT- 960	TRIMETHOPRI M+SULFAMET HOXAZOLE	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
2712	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2713	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	11/7/2018

2714	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	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
2715	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
2716	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

2717	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,1.0X1 0.0X10.0 TABLET STRIP	7/25/2018
2718	NDA/MAL/HDP/7149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLOPAT OD	OLOPATADINE HYDROCHLORI DE	0.2% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMI C DROPS	1.0X1.0X3.0 ML VIAL	5/30/2018
2719	NDA/MAL/HDP/7151	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS DX	MOXIFLOXACI N HYDROCHLORI DE + DEXAMETHAS ONE SODIUM PHOSPHATE	5MG+1MG/M L	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N- 119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMI C DROPS	1.0X1.0X5.0 ML VIAL	5/30/2018

2720	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
2721	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
2722	NDA/MAL/HDP/7159	SQUARE PHARMACEUTICALS 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

2723	NDA/MAL/HDP/7161	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.025%	OXYMETAZOLI NE HYDROCHLORI DE	0.025W/V%	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	8/29/2019
2724	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
2725	NDA/MAL/HDP/7163	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	STODIL	LOPERAMIDE HYDROCHLORI DE	2MG	TRIVENI FORMULATIONS LTD- PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIUAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	8/29/2019

2726	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
2727	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 SUSPENSION S	1.0X100.0 ML BOTTLE	8/29/2019
2728	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

2729	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON +1X20ML WFI AMPOULE	8/29/2019
2730	NDA/MAL/HDP/7173	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	TRICLOFEM®	MEDROXYPRO GESTERONE ACETATE	150MG/ML	P.T. TUNGAL IDAMAN ABDI- JALAN ACHMAD YANI NO. 7 JAKARTA TIMUR 13230	INDONESIA	PARENTERA L ORDINARY VIALS	1.0X4.0X5.0 ML VIAL	8/29/2019
2731	NDA/MAL/HDP/7175	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-AM 40/5	TELMISARTAN + AMLODIPINE BESYLATE	40MG + 5MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0x3.0x10.0 TABLET BLISTER	7/25/2018

2732	NDA/MAL/HDP/7179	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AVONZA	TENOFOVIR DISOPROXIL FUMARATE+L AMIVUDINE+E FAVIRENZ	300MG+300M G+400MG	MYLAN LABORATORIES LIMITEDD ,-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1. 0X90.0 TABLET CONTAINER	11/7/2018
2733	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X5.0X3 .0 ML AMPOULE	8/29/2019
2734	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

2735	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,1.0X1 0.0 TABLET BLISTER	8/29/2019
2736	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
2737	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

2738	NDA/MAL/HDP/7191	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROSOL	HYPROMELLO SE	0.7%W/V	AUROLAB -NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMI C LIQUIDS	1.0X1.0X10.0 ML VIAL	2/6/2019
2739	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
2740	NDA/MAL/HDP/7193	EXPHAR SA.	SURGIPHARM (U) LIMITED	FLUOXINE	CIPROFLOXACI N	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

2741	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 + 1ML DILUENT AMPOULE	8/29/2019
2742	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
2743	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, 1.0X 50.0X1.0 DOSE VIAL + 1ML DILUENT	8/29/2019

2744	NDA/MAL/HDP/7202	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VILDAGLIPTIN	VILDAGLIPTIN	50MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSE TRASSE 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
2745	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
2746	NDA/MAL/HDP/7216	SHIN POONG PHARMACEUTICALS CO.LTD	ESCORTS PHARMACEUTICALS LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHATE + ARTESUNATE	60MG + 20MG	SHIN POONG PHARM. CO., LTD- 70, SANDAN-RO, 19 BEON-GIL, DANWONGU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL LIQUID ORDINARY OTHER POWDERS/G RANULES	1.0X90.0 SACHET CARTON	8/29/2019

2747	NDA/MAL/HDP/7217	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARPANTO 40	PANTOPRAZO LE	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
2748	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
2749	NDA/MAL/HDP/7219	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAXONE	1G	THEON PHARMACEUTICALS LTD.-VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	11/29/2017

2750	NDA/MAL/HDP/7222	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	SAMSUNATE	ARTESUNATE	60MG	SAMRUDH PHARMACEUTICALS PVT LTD-J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL OF ARTESUNATE +(1*1ML AMPOULE OF SODIUM BICARBONATE BP 5%W/V)+(1*5 ML SODIUM CHLORIDE BP 0.9%W/V)	11/27/2019
2751	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
2752	NDA/MAL/HDP/7225	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER 80/480	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	11/27/2019

2753	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,1.0X1 00.0X10.0 TABLET BLISTER	7/1/2017
2754	NDA/MAL/HDP/7229	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARCIFLOX 500	CIPROFLOXACI N	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
2755	NDA/MAL/HDP/7237	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC	CHLORPHENA MINE MALEATE + PHENYLEPHRI NE HYDROCHLORI DE	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

2756	NDA/MAL/HDP/7238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-10	NEBIVOLOL HYDROCHLORI DE	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
2757	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 SUSPENSION S	1.0X12.0X10.0 ML SACHET,1.0X2 00.0 ML BOTTLE	5/29/2019
2758	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

2759	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
2760	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
2761	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,HIMACHAL PRADESH-173025, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	2/4/2019

2762	NDA/MAL/HDP/7247	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	VITAFIL-Z	MULTIVITAMI NS, 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,1.0X3 0.0 ML BOTTLE	11/27/2019
2763	NDA/MAL/HDP/7248	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 20	ESOMEPRAZO LE	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
2764	NDA/MAL/HDP/7249	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 40	ESOMEPRAZO LE 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

2765	NDA/MAL/HDP/7250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVI R SODIUM, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVI R SODIUM +LAMIVUDINE +TENOFVIR 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,1.0X9 0.0 TABLET BOTTLE	11/29/2019
2766	NDA/MAL/HDP/7251	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROXYURE A	HYDROXYCAR BAMIDE	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
2767	NDA/MAL/HDP/7253	MANKIND PHARM LTD	TATA UGANDA LIMITED	MONTICOPE	MONTELUKAS T SODIUM + LEVOCETIRIZIN E DIHYDROCHLO RIDE	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

2768	NDA/MAL/HDP/7256	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG KIT	AMOXICILLIN + CLARITHROMY CIN + 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
2769	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
2770	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 STRAÙE 51-61,59320 ENNIGERLOH,GERM ANY	CANADA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	1/31/2018

2771	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
2772	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
2773	NDA/MAL/HDP/7264	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE +SIMETHICONE	540MG + 40MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2017

2774	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
2775	NDA/MAL/HDP/7269	EXPHAR SA.	SURGIPHARM (U) LIMITED	FEBRILEX SYRUP	PARACETAMOL+DEXTROMETORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE	125MG+5MG+1MG/5 ML	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	7/1/2017
2776	NDA/MAL/HDP/7270	ADCOCK INGRAM LIMITED	SURGIPHARM (U) LIMITED	MYPAIN	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	

2777	NDA/MAL/HDP/7271	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TURBOVAS CP	ROSUVASTATI N 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
2778	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
2779	NDA/MAL/HDP/7275	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TILYPTIN 20	TENELIGLIPTIN HYDROBROMI DE HYDRATE	20MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	INDIA	TOPICAL EXTERNAL TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/27/2019

2780	NDA/MAL/HDP/7277	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ALERINIT	LEVOCETIRIZIN E HYDROCHLORI DE	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	1.0X2.0X20.0 TABLET BLISTER	8/28/2019
2781	NDA/MAL/HDP/7284	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATI N 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
2782	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	OPHTHALMI C OINTMENTS	1.0X5.0 G TUBE	7/1/2017

2783	NDA/MAL/HDP/7287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPH ATE	0.05%W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERA L ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	7/1/2017
2784	NDA/MAL/HDP/7288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE FILM COATED TABLETS	DEXKETOPROF EN 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
2785	NDA/MAL/HDP/7292	LEBEN LABORATORIES PVT LTD	MALIX PHARMA (U) LIMITED	IBUPLUS SUSPENSION	IBUPROFEN+.P ARACETAMOL	100MG + 125MG / 5ML	LEBEN LABORATORIES PVT LTD .-L-14 PHASE III MIDC AKOLA 444 104	NULL	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X100.0 ML BOTTLE,1.0X6 0.0 ML BOTTLE	11/27/2019

2786	NDA/MAL/HDP/7293	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	ALRINAST	DES Loratadine	5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANIZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	11/29/2017
2787	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
2788	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

2789	NDA/MAL/HDP/7302	JAMJOOM PHARMACEUTICALS 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
2790	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	2/6/2019
2791	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

2792	NDA/MAL/HDP/7310	JAMJOOM PHARMACEUTICALS 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
2793	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
2794	NDA/MAL/HDP/7317	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	EMITINO TABLETS 8MG	ONDANSETRO N	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

2795	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
2796	NDA/MAL/HDP/7319	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.- 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
2797	NDA/MAL/HDP/7325	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DALMAN AQ NASAL SPRAY	FLUTICASONE PROPIONATE	0.05%W/V	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş. -- ESENBOĞA MERKEZ MAH. ÇUBUK CADDESİ NO: 31 06760 ANKARA - TURKEY	TURKEY	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE	7/25/2018

2798	NDA/MAL/HDP/7329	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+CHLORZOXAZONE	500 MG+100 MG +375 MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/28/2018
2799	NDA/MAL/HDP/7332	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DIVATOR 20MG FILM TABLET	ATORVASTATIN	20MG	DROGSAN ILACLARI SAN VE TIC. A.S.- ESENBOGA MERKEZ MAH. CUBUK CAD. NO. 31 CUBUK/ANKAEA-TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/29/2019
2800	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

2801	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	1.0X15.0X2.0X 20.0 TABLET BLISTER	12/5/2019
2802	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
2803	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

2804	NDA/MAL/HDP/7341	M/S.MAXHEAL PHARMACEUTICALS(IN DIA)	ABACUS PHARMA (AFRICA) LIMITED	ZITHROHEAL 500	AZITHROMYCI N	500MG	PINNACLE LIFE SCIENCE PVT LTD- KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	11/28/2019
2805	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
2806	NDA/MAL/HDP/7343	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	GLEVIX	LEVOFLOXACI N + SODIUM CHLORIDE	0.5G + 0.9G	WUHAN FUXING BIOPHARMACEUTIC AL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	11/28/2019

2807	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
2808	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
2809	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

2810	NDA/MAL/HDP/7350	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	SULCEF	CEFOPERAZON E+ SULBACTUM	1G+1G	MEDOCHEMIE (FACTORY C)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X1.0 ML VIAL	3/27/2019
2811	NDA/MAL/HDP/7351	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLA VULANIC ACID	50MG+31.25 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2812	NDA/MAL/HDP/7352	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	DOLOMOL PAEDIATRIC DROPS	PARACETAMO L	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 SUSPENSION S	1.0X15.0 ML BOTTLE	1/7/2019

2813	NDA/MAL/HDP/7353	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 500MG	METFORMIN HYDROCHLORI DE	500MG	MERCK KGAA- PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D- 64293, DARMSTADT MERCK SANTÉ S.A.S.- 2 RUE DU PRESOI VERT 45400 SEMOY FRANCE	GERMANY	ORAL SOLID RETARD TABLETS	1.0X6.0X15.0 TABLET BLISTER	3/28/2018
2814	NDA/MAL/HDP/7354	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	OSMOTICARE	SODIUM CHLORIDE	0.9%W/V	WUHAN FUXING BIOPHARMACEUTIC AL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE,1.0X2 50.0 ML BOTTLE,1.0X5 00.0 ML BOTTLE	11/28/2019
2815	NDA/MAL/HDP/7355	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN SUSPENSION	ARTEMETHER +LUMEFANTRI NE	180MG+1080 MG	AJANTA PHARMA LIMITED.-B-41516, MIDC INDUSTRIAL AREA, PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA,INDI A	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	1/31/2018

2816	NDA/MAL/HDP/7357	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	PAMAGIN-C SYRUP	CETIRIZINE HYDROCHLORI DE+DEXTROM ETHORPHAN HYDROBROMI DE+ACETAMIN OPHEN+PHEN YLEPHRINE HYDROCHLORI DE+ZINC GLUCONATE+ MENTHOL	2.5MG+7.5MG +125MG+5MG +7.5MG+2.5M G/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
2817	NDA/MAL/HDP/7359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	AARON PHARMACEUTICALS LIMITED	INDCLAV 625	AMOXICILLIN+ CLAVULANATE POTASSIUM	500MG+125M G	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
2818	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, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSION S	1.0X150.0 ML BOTTLE,1.0X3 00.0 ML BOTTLE,1.0X1 2.0X10.0 ML SACHET	11/28/2019

2819	NDA/MAL/HDP/7361	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	DOLUTEGRAVI R	DOLUTEGRAVI R 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,1.0X3 0.0 TABLET BOTTLE	11/28/2019
2820	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2821	NDA/MAL/HDP/7364	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACI N HYDROCHLORI DE	400MG	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	1.0X7.0 TABLET BLISTER	7/1/2017

2822	NDA/MAL/HDP/7365	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	DOLOACT MR	PARACETAMO L+ DICLOFENAC POTASSIUM+C HLORZOXAZO NE	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
2823	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
2824	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017

2825	NDA/MAL/HDP/7369	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	200MG+28.5 MG/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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2826	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
2827	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

2828	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
2829	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
2830	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017

2831	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
2832	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
2833	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

2834	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
2835	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
2836	NDA/MAL/HDP/7396	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	HARVONI	SOFOSBUVIR+ LEDIPASVIR	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

2837	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
2838	NDA/MAL/HDP/7407	HETERO LABS LTD	AIVEEN (U) LIMITED	MONAST 5	MONTELUKAS T SODIUM	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	11/28/2019
2839	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

2840	NDA/MAL/HDP/7413	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARIACT	ARTEMETHER + LUMEFANTRIN E	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
2841	NDA/MAL/HDP/7414	KHANDELWAL LABORATORIES PVT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	RIBOREA	HYDROXYURE A	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
2842	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

2843	NDA/MAL/HDP/7417	INTAS PHARMACEUTICALS 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
2844	NDA/MAL/HDP/7418	INTAS PHARMACEUTICALS 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	PARENTERA L ORDINARY VIALS	1.0X1.92 ML VIAL	11/28/2019
2845	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

2846	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
2847	NDA/MAL/HDP/7424	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	ZINC SULFATE TABLETS USP 20MG	ZINC SULFATE MONOHYDRA TE	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
2848	NDA/MAL/HDP/7425	AUROCHEM LABORATORIES(I) PVT LTD	AIVEEN (U) LIMITED	DOLOACT PLUS	ACECLOFENAC + PARACETAMO L	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

2849	NDA/MAL/HDP/7426	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDOFED	GUAIFENESIN + DEXTROMETH ORPHAN HYDROBROMIDE + PSEUDOEPHEDRINE HYDROCHLORIDE AND + TRIPROLIDINE HYDROCHLORIDE	100MG + 15MG + 20MG + 1.25MG/5ML	MEDOCHEMIE ACTORY).....-1-10 CONSTANTINOUPOL EOS STREET, 3011, LIMASSOL	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	11/28/2019
2850	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
2851	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	1.0X10.0X13.8 1 G SACHET	9/26/2018

2852	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
2853	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
2854	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

2855	NDA/MAL/HDP/7441	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH XL	SODIUM HYALURONAT E	8MG/ML	VIRCHOW BIOTECH PVT LTD-SURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MA NDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA	INDIA	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X6.0 ML PRE- FILLED SYRINGE	11/29/2017
2856	NDA/MAL/HDP/7442	DAWA LIMITED-	SUPER MEDIC LTD	NERVILIN NT	PREGABALIN + NORTRIPTYLIN E HYDROCHLORI DE	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
2857	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

2858	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
2859	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
2860	NDA/MAL/HDP/7448	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	SORID OINTMENT	CALCIPOTRIOL MONOHYDRA TE + BETAMETHAS ONE DIPROPIONAT E	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

2861	NDA/MAL/HDP/7449	SURGIPHARM (U) LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/TENOFOVIR DF 300/300MG	LAMIVUDINE+ TENOFOVIR DISOPROXIL FUMARATE	300MG+300MG	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED- -PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE	1/31/2018
2862	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
2863	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

2864	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
2865	NDA/MAL/HDP/7453	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANTIDIAZOX	NITAZOXANIDE	100MG/5ML	GLOBAL NAPI PHARMACEUTICALS - 2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	7/1/2017
2866	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

2867	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
2868	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
2869	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

2870	NDA/MAL/HDP/7460	MERIL LIFE SCIENCES PRIVATE LIMITED	EUROPA HEALTHCARE (U) LTD	SEGABIN SR 75	PREGABALIN	75MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/28/2019
2871	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
2872	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

2873	NDA/MAL/HDP/7464	MERIL LIFE SCIENCES PRIVATE LIMITED	EUROPA HEALTHCARE (U) LTD	SEGABIN M 75	PREGABALIN + METHYCOBAL AMIN	75MG + 1500MCG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/28/2019
2874	NDA/MAL/HDP/7465	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TS	DIHYDROARTE MISININ + 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
2875	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

2876	NDA/MAL/HDP/7468	AKRITI PHARMACEUTICALS PVT LTD	PHARMA VILLE LIMITED	GYNO PLUS	METRONIDAZ OLE + 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
2877	NDA/MAL/HDP/7469	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.03% OINTMENT	TACROLIMUS MONOHYDRA TE	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
2878	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	11/28/2019

2879	NDA/MAL/HDP/7471	AMRING FARMA S.R.L	ERIS LTD	BEVACIZUMAB AMRING	BEVACIZUMAB	100 MG/4 ML	SINERGium BIOTECH SA-RUTA PANAMERICANA KM 38.7 GARIN BUENOS AIRES, MABXIENCE S.A.U- CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	ARGENTINA	PARENTERA L ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	11/27/2019
2880	NDA/MAL/HDP/7472	AMRING FARMA S.R.L	ERIS LTD	BEVACIZUMAB AMRING	BEVACIZUMAB	400 MG/16 ML	SINERGium BIOTECH SA-RUTA PANAMERICANA KM 38.7 GARIN BUENOS AIRES, MABXIENCE S.A.U- CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	ARGENTINA	PARENTERA L ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	11/27/2019
2881	NDA/MAL/HDP/7473	MERIL LIFE SCIENCES PRIVATE LIMITED	EUROPA HEALTHCARE (U) LTD	AFLODOR 16	ACECLOFENAC + THIOLCHIC OSIDE	200MG + 16MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	11/27/2019

2882	NDA/MAL/HDP/7474	MERIL LIFE SCIENCES PRIVATE LIMITED	EUROPA HEALTHCARE (U) LTD	AFLODOR 8	ACECLOFENAC + THIOLCHIC OSIDE	200 MG + 8 MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X5.0 CAPSULE BLISTER	11/27/2019
2883	NDA/MAL/HDP/7475	UNI MEDICO LAB	ROYAL PHARMA 2011 LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+ CLOXACILLIN SODIUM	250MG+250M G	UNI MEDICOLABS.- 21-22 PHARMACY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	7/1/2015
2884	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

2885	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
2886	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
2887	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

2888	NDA/MAL/HDP/7483	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APISOPT PLUS	DORZOLAMID E HYDROCHLORI DE + TIMOLOL MALEATE	2%W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMI C LIQUIDS	1.0X5.0 ML VIAL	11/27/2019
2889	NDA/MAL/HDP/7484	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 10/20	AMLODIPINE BESYLATE + ATORVASTATI N 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
2890	NDA/MAL/HDP/7485	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 5/10	AMLODIPINE BESYLATE + ATORVASTATI N 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

2891	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
2892	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
2893	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

2894	NDA/MAL/HDP/7489	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	DOLUTEGRAVI R, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVI R + LAMIVUDINE + TENOFVIR 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,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X9 0.0 TABLET BOTTLE,1.0X1 00.0 TABLET BOTTLE,1.0X1 80.0 TABLET BOTTLE	11/27/2019
2895	NDA/MAL/HDP/7490	INTAS PHARMACEUTICALS 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
2896	NDA/MAL/HDP/7491	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	CIPRO-DENK 750	CIPROFLOXACI N HYDROCHLORI DE	750MG	ALLPHAMED PHARBIL ARZNEIMITTEL GMBH. - HILDEBRANDSTRABE 12 37081 GOTTINGEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017

2897	NDA/MAL/HDP/7492	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE	CYPROHEPTA DINE HYDROCHLORI DE	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
2898	NDA/MAL/HDP/7494	LINCON PHARMCUETICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE TABLET	CYPROHEPTA DINE HYDROCHLORI DE	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
2899	NDA/MAL/HDP/7500	RESONANT PHARMACEUTICALS	SHREEJI CARE LIMITED	DICLOZONE MR TABLETS	DICLOFENAC POTASSIUM + PARACETAMO L + CHLORZOXAZ ONE	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

2900	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
2901	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
2902	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,1.0X1 0.0X10.0 TABLET STRIP,1.0X3.0 X10.0 TABLET BLISTER	11/27/2019

2903	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	OPHTHALMI C OINTMENTS	1.0X5.0 G TUBE	5/29/2019
2904	NDA/MAL/HDP/7514	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 500	LEVOFLOXACI N HEMIHYDRATE	500 MG	ILKO ILAC SANAYI VE TICARET A.S- 3.ORGANIZE SANAYI BOLGESI, BUYUK KAYACIK MAH. KUDDISI CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	11/27/2019
2905	NDA/MAL/HDP/7515	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HEPBEST	PREGABALIN + NORTRIPTYLIN E (AS HYDROCHLORI DE)	75MG + 10MG	MYLAN LABORATORIES LTD- PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR - 454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	11/27/2019

2906	NDA/MAL/HDP/7516	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	ILKO İLAC SANAYİ VE TİCARET A.Ş- 3.ORGANİZE SANAYİ BOLGESİ, BÜYÜK KAYACIK MAH. KUDDİSİ CAD.23 SOKAKNO. 1 42050 SELCUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	11/27/2019
2907	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
2908	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

2909	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
2910	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
2911	NDA/MAL/HDP/7523	DENK PHARMA GMBH &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

2912	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	OPHTHALMI C LIQUIDS	1.0X2.5 ML VIAL	11/27/2019
2913	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
2914	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

2915	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
2916	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
2917	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

2918	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), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO LABS LTD UNIT III-22-110 IDA JEEDIMETIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	11/7/2018
2919	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
2920	NDA/MAL/HDP/7536	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	SPINESIA-D	BUPIVACAINE HYDROCHLORIDE + DEXTROSE	5MG + 80MG /ML	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO.4, PHASE IV, GIDC, INDUSTRIAL AREA, PANOLI- 394 116,	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

2921	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
2922	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
2923	NDA/MAL/HDP/7588	OCHOA LABORATORIES LIMITED -	SUPER MEDIC LTD	EXEVATE-MF OINTMENT	BETAMETHAS ONE DIPROPIONAT E + 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

2924	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,1.0X1 00.0 ML BOTTLE	11/29/2017
2925	NDA/MAL/HDP/7594	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROCHLOR OTHIAZIDE 25MG TABLETS	HYDROCHLOR OTHIAZIDE	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
2926	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	OPHTHALMI C VIALS	1.0X2.5 ML VIAL	11/27/2019

2927	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
2928	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
2929	NDA/MAL/HDP/7599	AMRING FARMA S.R.L	ERIS LTD	RITUXIMAB AMRING	RITUXIMAB AMRING	100 MG/10 ML	SINERGium BIOTECH SA-RUTA PANAMERICANA KM 38.7 GARIN BUENOS AIRES, MABXIENCE S.A.U- CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	ARGENTINA	PARENTERAL ORDINARY VIALS	1.0X2.0X10.0 ML VIAL	11/27/2019

2930	NDA/MAL/HDP/7601	AMRING FARMA S.R.L	ERIS LTD	RITUXIMAB AMRING	RITUXIMAB	500 MG/50 ML	SINERGium BIOTECH SA-RUTA PANAMERICANA KM 38.7 GARIN BUENOS AIRES, MABXIENCE S.A.U- CARLOS VILLAGE 5148 MUNRO, BUENOS AIRES B16054XL	ARGENTINA	PARENTERA L ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	11/27/2019
2931	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	OPHTHALMI C LIQUIDS	1.0X1.0X10.0 ML VIAL	11/27/2019
2932	NDA/MAL/HDP/7610	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	TERBIDERM FORTE	TERBINAFINE HYDROCHLORI DE	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

2933	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
2934	NDA/MAL/HDP/7614	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOPCLIN	CLINDAMYCIN PHOSPHATE	1 %W/W	KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE	11/27/2019
2935	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

2936	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
2937	NDA/MAL/HDP/7631	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMADOL 100MG SR TABLET	TRAMADOL HYDROCHLORI DE	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
2938	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

2939	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
2940	NDA/MAL/HDP/7635	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 10MG FILM- COATED TABLETS	BISOPROLOL FUMARATE	10MG	LEK S.A.-95 - 010 STRYKÓW, PODLIPIE 16, POLAND SALUTAS PHARMA GMBH-OTTO-VON- GUERICKE-ALLEE	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER	7/1/2017
2941	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

2942	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
2943	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
2944	NDA/MAL/HDP/7674	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLEVOX	LEVOFLOXACIN HEMIHYDRATE	5G/L	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2017

2945	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
2946	NDA/MAL/HDP/7683	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DES Loratadine	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
2947	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

2948	NDA/MAL/HDP/7688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORI DE	850MG	NKUNZI PHARMACEUTICALS- 259 DAVIDSON ROAD, WADEVILLEGERMIST ON, 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
2949	NDA/MAL/HDP/7695	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	CORTUM 500	CEFUROXIME AXETIL	500MG	MALIK LIFESCIENCES PRIVATE LIMITED- PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017
2950	NDA/MAL/HDP/7701	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	FLUCONAZOLE TABLETS 200 MG	FLUCONAZOLE	200 MG	MYLAN LABORATORIES LIMITED, V-PLOT NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA AURANGABBAD- 431136 MAHARAstra STATE, INDIA. V	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	7/1/2017

2951	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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER,1.0X1 0.0 TABLET BLISTER	7/1/2017
2952	NDA/MAL/HDP/7708	LEBEN LABORATORIES PVT.LTD	MALIX PHARMA (U) LIMITED	LAMPYKLOX CAPSULES	AMPICILLIN TRIHYDRATE+ CLOXACILLIN SODIUM	250MG+250M G	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
2953	NDA/MAL/HDP/7709	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	DEXAMETHAS ONE SODIUM PHOSPHATE	DEXAMETHAS ONE SODIUM PHOSPHATE	8MG/2ML	NITIN LIFESCIENCES LTD--RAMPUR ROAD PAONTA SAHIB DIST. SIRMOUR (H.P) 173 025	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X50.0X2.0 ML AMPOULE	7/1/2017

2954	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
2955	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,	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	
2956	NDA/MAL/HDP/7716	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DES Loratidine	2.5 MG / 5 ML	NOBEL İLAÇ SAN. VE TİC. A.Ş-SANCAKLAR, DÜZCE, 81100	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	11/29/2017

2957	NDA/MAL/HDP/7724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE	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
2958	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
2959	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 SUSPENSION S/SYRUPS/DROPS	1.0X500.0 ML BOTTLE	7/1/2017

2960	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
2961	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
2962	NDA/MAL/HDP/7745	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	TAZOGARD	PIPERACILLIN +TAZOBACTAM	4G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL ,2X10ML LDPE AMPOULES OF WFI	7/1/2017

2963	NDA/MAL/HDP/7747	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	THERMODOL	PARACETAMOL	1.0%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	7/1/2017
2964	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
2965	NDA/MAL/HDP/7784	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	LORATOL	LORATADINE	5MG/5ML	NOBEL ILAC DUZCE-SANAYIINVE TICARET A.S SANCAKLAR 81100 DUZCE	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	7/1/2017

2966	NDA/MAL/HDP/7903	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MELMET- 1000SR	METFORMIN HYDROCHLORI DE	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
2967	NDA/MAL/HDP/7905	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ACEFYL	ACEFYLINE PIPERAZINE + DIPHENHYDRA MINE HYDROCHLORI DE	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
2968	NDA/MAL/HDP/7906	AXA PARENTERALS LTD	VITACARE LIMITED	IVMOL	PARACETAMO L	10MG/ML	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKE E 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	7/1/2016

2969	NDA/MAL/HDP/7907	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUCOG 5000 HP	CHORIONIC GONADOTROP HIN	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 NA CL AMBER GLASS AMPOULE	7/1/2017
2970	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
2971	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

2972	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
2973	NDA/MAL/HDP/8015	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	D-FEN	DICLOFENAC SODIUM	25MG/ML	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL 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
2974	NDA/MAL/HDP/8023	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AMOXICLAV-DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBH- BRITENBACHSTRASSE 13 D-13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	7/1/2011

2975	NDA/MAL/HDP/8032	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ABACAVIR SULFATE/LAMI VUDINE	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
2976	NDA/MAL/HDP/8043	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BİLİM PHARMACEUTICALS- GOSB 41480 GEBZE- KOCAELİ/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	7/1/2017
2977	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

2978	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
2979	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
2980	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

2981	NDA/MAL/HDP/8089	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMOXY	AMOXYCILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - - STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1. 0X100.0X10.0 CAPSULE BLISTER,1.0X5 00.0 CAPSULE CONTAINER,1. 0X250.0 CAPSULE CONTAINER	7/1/1997
2982	NDA/MAL/HDP/8091	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL SUSPENSION	ALUMINIUM HYDROXIDE+ MAGNESIUM TRISILICATE	120MG+250M G	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X100.0 ML BOTTLE	7/1/2001
2983	NDA/MAL/HDP/8092	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL 250MG	AMOXYCILLIN	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1. 0X10.0X10.0 CAPSULE BLISTER	7/1/1997

2984	NDA/MAL/HDP/8093	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ ZIDOVUDINE/ NEVIRAPINE TABLETS 150MG/300M G/200MG	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
2985	NDA/MAL/HDP/8095	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	COLOSAR- DENK 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	100MG + 12.5MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.7 9.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	7/1/2016
2986	NDA/MAL/HDP/8096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYLPENICI LLIN SODIUM	2.4MEGA/ VIAL	REYOUNG PHARMACEUTICAL CO. LIMITED-NO. 1 RUIYANG ROAD YIYUAN COUNTY, SHANDONG PROVINCE, P. R. CHINA	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON,1.0X1 00.0X2.4 VIAL CARTON,1.0X1 0.0X2.4 VIAL CARTON	7/1/2011

2987	NDA/MAL/HDP/8097	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN 5000	ERYTHROPOIE TIN	5000IU/ 0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X0.5 ML PRE-FILLED SYRINGE	7/1/2016
2988	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
2989	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

2990	NDA/MAL/HDP/8107	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	WELRAB 20	RABEPRAZOLE SODIUM	20MG	AKUMS DRUGS & PHARMACEUTICALS LTD --19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017
2991	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,100.0 X10.0 TABLET BLISTER,1.0X1000.0 TABLET JAR	7/1/2017
2992	NDA/MAL/HDP/8112	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MOXICLAV	AMOXICILLIN + CLAVULANIC ACID	156.25MG/5ML	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	7/1/2016

2993	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
2994	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
2995	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

2996	NDA/MAL/HDP/8116	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EMTRICITABIN E + TENOFIVIR DISOPROXIL FUMARATE	EMTRICITABIN E + TENOFIVIR 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
2997	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
2998	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0 X10.0X1.0 ML AMPOULE	7/1/2017

2999	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
3000	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
3001	NDA/MAL/HDP/8133	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP	SOFOSBUVIR	400MG	MYLAN LABORATORIES LIMITEDD ,-F-4 & F-12,MIDC, MALEGAON,SIRRRRA R, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE	7/1/2017

3002	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
3003	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
3004	NDA/MAL/HDP/8143	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LYDIA POSTPIL	LEVONORGEST REL	1.5MG	NAARI PHARMA PRIVATE LIMITED- PLOT NO. 14-16, 55- 57, SECTOR-5, IIE, PANT NAGAR RUDRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	7/1/2013

3005	NDA/MAL/HDP/8144	NAARI LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MA KARE	MIFEPRISTON E + 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
3006	NDA/MAL/HDP/8145	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR 10	MONTELUKAS T 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
3007	NDA/MAL/HDP/8146	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 4	MONTELUKAS T 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

3008	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
3009	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
3010	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

3011	NDA/MAL/HDP/8151	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-C	VITAMIN C	100MG	AGOG PHARMA LTD- PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET STRIP	7/1/2005
3012	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
3013	NDA/MAL/HDP/8154	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOGCORT	HYDROCORTIS ONE 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

3014	NDA/MAL/HDP/8155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	7/1/2017
3015	NDA/MAL/HDP/8156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+11MCG	BIOLOGICAL E LTD- PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLThER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0 X5.0 ML VIAL (10 DOSE VIAL)	7/1/2014
3016	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

3017	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
3018	NDA/MAL/HDP/8160	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+250MG+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
3019	NDA/MAL/HDP/8162	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUMOG 75 HP	HIGHLY PURIFIED MENOTROPIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE	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

3020	NDA/MAL/HDP/8170	PRISMA PHARMA FZE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+250MG+125MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X200.0 ML BOTTLE	7/1/2017
3021	NDA/MAL/HDP/8177	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC PLUS	TELMISARTAN + HYDROCHLOR OTHIAZIDE	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
3022	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,1.0X1 00.0 TABLET BOTTLE,1.0X1 0.0X10.0 TABLET BLISTER	7/1/2005

3023	NDA/MAL/HDP/8185	AFRICURE PHARMACEUTICALS (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	INDOSIM	INDOMETHACI N	25MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1 000.0 CAPSULE CONTAINER	
3024	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,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	7/1/2005
3025	NDA/MAL/HDP/8194	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	SOLONEX-100	ISONIAZID	100MG	OXALIS LAB-VILLAGE THEDA, P.O. LODHIMAJRA, TEHSIL BADDI, DIST. SOLAN (HP) PIN CODE 174101 MACLEODS PHARMACEUTICALS LTD.-PLOT 1 & 2 MAHIM ROAD NEAR KULDEEP NAGAR, PALGHAR (W) 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER,1. 0X24.0X28.0 TABLET BLISTER	7/1/2005

3026	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
3027	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	PARENTERA L ORDINARY VIALS	1.0X2.0 ML VIAL	7/1/2017
3028	NDA/MAL/HDP/8198	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX DROPS	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	7/1/1999

3029	NDA/MAL/HDP/8199	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX SYRUP	MULTIVITAMIN/ DIASTASE/PEP SIN	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
3030	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
3031	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.LODHIM AJRA ,TEHSIL	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

3032	NDA/MAL/HDP/8204	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	DOPAMINE HCL FRESENIUS	DOPAMINE HYDROCHLORI DE	200MG/5ML	FRESNIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD KORSTEN PORT ELIZABETH 6020	SOUTH AFRICA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	7/1/2017
3033	NDA/MAL/HDP/8206	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRULEXIN	CEFALEXIN MONOHYDRA TE	125MG/5ML	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD- 121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
3034	NDA/MAL/HDP/8207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;- SCHAFFHAUSERSTRA SSE CH 4332 STEIN- SWITZERLAND	SWITZERLAND	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0 VIAL CARTON	7/1/2017

3035	NDA/MAL/HDP/8210	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTISONE	100MG	CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	7/1/2007
3036	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,MOGA DISHU 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
3037	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

3038	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
3039	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
3040	NDA/MAL/HDP/8224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT OINTMENT	GENTAMICIN SULFATE	0.3%W/W	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	7/1/2017

3041	NDA/MAL/HDP/8225	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	ARTELIN 60	ARTESUNATE	60MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*1 ML AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION B.P + 1*5 ML AMPOULE OF 0.9%W/V NACL	7/1/2017
3042	NDA/MAL/HDP/8228	AFRICURE PHARMACEUTICALS (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	VITAMIN B-COMPLEX (BEEKO)	VITAMINS B1 + B2 + B6 + NIACINAMIDE	1MG +1MG +1MG +15MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)-PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2017
3043	NDA/MAL/HDP/8231	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ANASTROZOLE DENK	ANASTROZOLE	1MG	HAUPT PHARMA GMBH & CO KG-SCHLEEBRUGGENKA MP 15, 48159 MUNSTER, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/1/2017

3044	NDA/MAL/HDP/8232	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MOMATE	MOMETASON E FUROATE MONOHYDRA TE	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
3045	NDA/MAL/HDP/8235	DAWA LIMITED-	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + SERRATIOPEPT IDASE + PARACETAMO L	100MG + 15MG + 500MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	7/1/2017
3046	NDA/MAL/HDP/8238	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	METROSUPP 500	METRONIDAZ OLE	500MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITOR IES	1.0X2.0X5.0 SUPPOSITORY STRIP	7/1/2017

3047	NDA/MAL/HDP/8242	MACLEODS PHARMACEUTICALS LTD	KIMSY MEDS LTD	TETRACYCLINE HYDROCHLORI DE	TETRACYCLINE HYDROCHLORI DE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMI C OINTMENTS	1.0X50.0X5.0 G TUBE,1.0X50.0 X3.5 G TUBE	7/1/2017
3048	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
3049	NDA/MAL/HDP/8247	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	E-DOL	TRAMADOL HYDROCHLORI DE	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	PARENTERA L ORDINARY AMPOULES	1.0X2.0X5.0X2 .0 ML AMPOULE	

3050	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	7/1/2017
3051	NDA/MAL/HDP/8250	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM DT	ARTEMETHER +LUMEFANTRI NE	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,1.0X3 0.0X6.0 TABLET BLISTER,1.0X3 0.0X12.0 TABLET BLISTER	7/1/2017
3052	NDA/MAL/HDP/8252	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	PARACETAMO L FRESENIUS	PARACETAMO L	10MG/ML	FRESENIUS KABI AUSTRIA GMBH- AUSTRIA GMBH HAFNERSTRASSEM 36 8055 GRAZ FRESENIUS KABI DEUTSCHLAND GMBH- FRESENIUSSTRASSE 1, D-61169, FRIEDBERG	GERMANY AUSTRIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X10.0X50.0 ML VIAL,1.0X10.0 X100.0 ML VIAL	7/1/2017

3053	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	PARENTERA L ORDINARY AMPOULES	10.0X10.0X3.0 ML AMPOULE	7/1/2017
3054	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
3055	NDA/MAL/HDP/8264	CACHET PHARMA PVT LTD	ASTRA PHARMA (U) LIMITED	EMITINO ORAL SOLUTION	ONDANSETRO N	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

3056	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	PARENTERA L ORDINARY AMPOULES	1.0X2.0X6.0X2 .0 ML AMPOULE IN BLISTERS	7/1/2013
3057	NDA/MAL/HDP/8293	NAARI LTD	PHARMA VILLE LIMITED	DIVABO	MIFEPRISTON E + 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 COMBINATI ON PACK TABLETS	1.0X1.0 TABLET BLISTER + 1.0X4.0 TABLETS OF MISOPROSTOL	8/28/2019
3058	NDA/MAL/HDP/8299	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	DICLOFENAC TABLETS BP	DICLOFENAC SODIUM	50MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR- 401404. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	7/1/2007

3059	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
3060	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
3061	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

3062	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
3063	NDA/MAL/HDP/8316	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVI R 50 MG/ LAMIVUDINE 300 MG/ TENOFVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	"AUROBINDO PHARMA LIMITED- UNIT -VII, SEZ, TSIC, 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	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE,1.0X9 0.0 TABLET BOTTLE	5/30/2018
3064	NDA/MAL/HDP/8318	ACULIFE HEALTHCARE PVT LTD	ASTRA PHARMA (U) LIMITED	B-CANE HEAVY	BUPIVACAINE HYDROCHLORI DE BP	5 MG/ML	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X4.0 ML AMPOULE	11/29/2017

3065	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
3066	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
3067	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

3068	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
3069	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,1.0X1 0.0X10.0 TABLET BLISTER (EMBOSSSED WITH "GOU NOT FOR SALE" & NON- EMBOSSSED)	11/29/2017
3070	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

3071	NDA/MAL/HDP/8333	MICRO LABS LTD 92 SIPCOT INDUSTRIAL	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AVAS-20	ATORVASTATI N	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
3072	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
3073	NDA/MAL/HDP/8340	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	MONTEMAC 5	MONTELUKAS T 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

3074	NDA/MAL/HDP/8341	GILEAD SCIENCES INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR +COBICISTAT+ EMTRICISTABINE+TENOFVIR 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
3075	NDA/MAL/HDP/8343	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE)	325MG+675MG	TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	11/28/2019
3076	NDA/MAL/HDP/8344	CACHET PHARMACEUTICALS 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 SUSPENSION S/SYRUPS/DROPS	1.0X50.0 ML BOTTLE	11/29/2017

3077	NDA/MAL/HDP/8345	CACHET PHARMACEUTICALS 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
3078	NDA/MAL/HDP/8346	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 8	CANDESARTA N 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
3079	NDA/MAL/HDP/8348	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5M G	IRBESARTAN + HYDROCHLOR OTHIAZIDE	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

3080	NDA/MAL/HDP/8350	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.- NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	5/30/2018
3081	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,1.0X2 0.0 AMPOULE CARTON,1.0X5 .0 AMPOULE CARTON	11/26/2019
3082	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	11/29/2017

3083	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X100.0 ML BOTTLE	11/29/2017
3084	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
3085	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	PARENTERA L ORDINARY OTHER INFUSIONS	1.0X10.0X20.0 ML VIAL,1.0X10.0 X50.0 ML VIAL,1.0X10.0 X100.0 ML VIAL	11/29/2017

3086	NDA/MAL/HDP/8392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5M G	IRBESARTAN + HYDROCHLOR OTHIAZIDE	150MG + 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
3087	NDA/MAL/HDP/8394	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMID E 150 MG DISPERSIBLE TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMID E	75MG + 50MG + 150MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27- PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER,1. 0X3.0X28.0 TABLET BLISTER,1.0X2 4.0X28.0 TABLET BLISTER	11/29/2017
3088	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	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER,1. 0X3.0X28.0 TABLET BLISTER	11/29/2017

3089	NDA/MAL/HDP/8396	MARIE STOPES INTERNATIONAL	MARIE STOPES UGANDA LIMITED	BACK-UP	LEVONORGEST REL	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
3090	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
3091	NDA/MAL/HDP/8410	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	AMOXICILLIN & POTASSIUM CLAVULANATE	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	1.2G	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	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	1/13/2020

3092	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
3093	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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0 X100.0X2.0 ML AMPOULE	
3094	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

3095	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
3096	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
3097	NDA/MAL/HDP/8476	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AURODANZ 8	ONDANSETRO N HYDROCHLORI DE 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

3098	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	PARENTERA L ORDINARY CARTRIDGES	1.0X3.0 ML CARTRIDGE	1/31/2018
3099	NDA/MAL/HDP/8481	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	PARACETAMO L BP INJECTION	PARACETAMO L	150MG/ML	LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	1/31/2018
3100	NDA/MAL/HDP/8483	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE 2MG	GLIMEPIRIDE	2MG	LEK S.A--U1, PODLPIE 16, 95- 0140 STRYKOW POLAND	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	1/31/2018

3101	NDA/MAL/HDP/8485	CACHET PHARMACEUTICALS 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
3102	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
3103	NDA/MAL/HDP/8489	SWISS PARENTERALS LTD	SHREEJI CARE LIMITED	MEDOL	TRAMADOL HYDROCHLORI DE	100 MG / 2 ML	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERA L ORDINARY AMPOULES	1.0X2.0 ML AMPOULE,1.0 X5.0X2.0 ML AMPOULE	1/31/2018

3104	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
3105	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
3106	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 STRAÙE 51-61,59320 ENNIGERLOH,GERMANY	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	1/31/2018

3107	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 SUSPENSION S/SYRUPS/D ROPS	1.0X30.0 ML BOTTLE	1/31/2018
3108	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
3109	NDA/MAL/HDP/8498	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	OMASI MED LIMITED	TRIAZONE 0.5G	CEFTRIAZONE	0.5G	GULF PHARMACEUTICALS INDUSTRIES"JULPHA R"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 5 ML AMPOULE OF WATER FOR INJECTION	1/31/2018

3110	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 SUSPENSION S/SYRUPS/D ROPS	1.0X70.0 ML BOTTLE	7/1/2009
3111	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
3112	NDA/MAL/HDP/8522	PLANET PHARMACEUTICALS 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

3113	NDA/MAL/HDP/8566	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	AZINOWEL	AZITHROMYCIN	200MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD-PLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT.: HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	11/29/2019
3114	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
3115	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 SUSPENSION S/SYRUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	3/28/2018

3116	NDA/MAL/HDP/8641	CADILA PHARMACEUTICALS LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	TELI H	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/28/2018
3117	NDA/MAL/HDP/8642	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORAFAST	DESLOTRADINE	2.5MG/5ML	EGYPHAR FACTORY- OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	1/13/2020
3118	NDA/MAL/HDP/8643	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	BLISS INDAS LIFESCIENCE P. LTD.- PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3	3/28/2018

3119	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 SUSPENSION S	1.0X1.0X30.0 ML BOTTLE	3/28/2018
3120	NDA/MAL/HDP/8645	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MODAZAR	LOSARTAN + HYDROCHLOR OTHIAZIDE	100MG + 25MG	EGYPHAR FACTORY- OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X4.0 TABLET STRIP	1/13/2020
3121	NDA/MAL/HDP/8647	EGYPHAR	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZISROCIN	AZITHROMYCI N DIHYDRATE	100MG/5ML	EGYPHAR FACTORY- OBOUR CITY- INDUSTRIAL ZONE (A), BLOCK NO 13026. PIECE NO 9,0- EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSION S	1.0X30.0 ML BOTTLE	1/13/2020

3122	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	PARENTERA L ORDINARY VIALS	1.0X10.0 ML VIAL	1/31/2018
3123	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 SANCAKLAR, DÜZCE- TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER,1.0X2. 0X1.0X5.0 TABLET BLISTER	3/28/2018
3124	NDA/MAL/HDP/8655	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 1000MG	METFORMIN HYDROCHLORI DE	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

3125	NDA/MAL/HDP/8658	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 1000MG	METFORMIN HYDROCHLORI DE	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
3126	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
3127	NDA/MAL/HDP/8661	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVI R TABLETS 50MG	DOLUTEGRAVI R 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

3128	NDA/MAL/HDP/8665	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	PAMAGIN-C	CETIRIZINE HYDROCHLORI DE + DEXTROMETH ORPHAN HYDROBROMI DE + ACETAMINOP HEN + PHENYLEPHRI NE HYDROCHLORI DE + ZINC	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
3129	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
3130	NDA/MAL/HDP/8688	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 600	DARUNAVIR	600 MG	MYLAN LABORATORIES LTD -- H-12 & H-13, MIDC, WALUJ,AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	5/30/2018

3131	NDA/MAL/HDP/8689	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD -- H-12 & H-13, MIDC, WALUJ,AURANGABA D- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	5/30/2018
3132	NDA/MAL/HDP/8692	GOODMAN INTERNATIONAL (U) LTD	GOODMAN INTERNATIONAL LTD	PARAFUSIV	PARACETAMO L	10 MG/ML	S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO- POTENZA (PZ) ITALY	ITALY	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X50.0 ML VIAL,1.0X100. 0 ML VIAL	5/30/2018
3133	NDA/MAL/HDP/8693	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 100MG/ML	LEVETIRACETA M	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

3134	NDA/MAL/HDP/8694	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ERBITUX	CETUXIMAB	5MG/ML	MERCK KGAA-250 FRANKFURTERSTRAS SE, D-6100 DARMSTADT	GERMANY	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X20.0 ML VIAL	
3135	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
3136	NDA/MAL/HDP/8699	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ACETAZOLAMI DE	ACETAZOLAMI DE	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

3137	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
3138	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
3139	NDA/MAL/HDP/8779	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	STATINOR 20	ROSUVASTATI N	20MG	HETERO LABS LIMITED UNIT V- TSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) –509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	5/29/2019

3140	NDA/MAL/HDP/8780	HETERO DRUGS LTD	AIVEEN (U) LIMITED	STATINOR 10	ROSUVASTATIN CALCIUM	10 MG	HETERO LABS LIMITED UNIT V-TSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) -509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/27/2019
3141	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
3142	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

3143	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
3144	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 SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	11/26/2019
3145	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

3146	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
3147	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
3148	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

3149	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
3150	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
3151	NDA/MAL/HDP/8816	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABPARA	PARACETAMOL	1%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BOTTLE	5/30/2018

3152	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
3153	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
3154	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

3155	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
3156	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
3157	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

3158	NDA/MAL/HDP/8829	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301 HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO.	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
3159	NDA/MAL/HDP/8830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOROTHIAZIDE	300MG + 12.5MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/26/2019
3160	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

3161	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
3162	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,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	11/26/2019
3163	NDA/MAL/HDP/8839	SHIJIAZHUANG AOSUO INTERNATIONAL TRADE CO. 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

3164	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
3165	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
3166	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

3167	NDA/MAL/HDP/8916	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	TAMSUMAC 0.4	TAMSULOSIN HYDROCHLORI DE	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
3168	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
3169	NDA/MAL/HDP/8918	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-3 LLW TABLETS	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORI DE	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

3170	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
3171	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
3172	NDA/MAL/HDP/8921	SUN PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	VESIZEN 5	SOLIFENACIN SUCCINATE	5 MG	SUN PHARMACEUTICALS LTD-,-SEZ UNIT -I, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	7/25/2018

3173	NDA/MAL/HDP/8927	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA AND TETANUS VACCINE (ADSORBED REDUCED ANTIGEN(S) CONTENT)	DIPHThERIA TOXOID + TETANUS TOXOID	2 LF (NOT LESS THAN 2 IU) + 8.8 LF (NOT LESS THAN 20 IU)/ 0.5ML	BIOLOGICAL E. LIMITED--PLOT NO.1 SHAPOORJI PALLONJI BIOTECH PARK PHASE II, KOLTHUR VILLAGE, SHAMEERPET, MANDAL, R.R. DISTRICT, ANDRA PRADESH 500078, INDIA	INDIA	PARENTERA L ORDINARY VIALS	1.0X24.0X1.0X 10.0 DOSE VIAL,1.0X48.0 X1.0 DOSE VIAL	7/25/2018
3174	NDA/MAL/HDP/8929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESEL LSCHAFT DEUTSCHLAND MBH- -WOLFGANG- MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY	GERMANY	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X50.0 ML BOTTLE,1.0X1. 0X100.0 ML BOTTLE	7/1/2018
3175	NDA/MAL/HDP/8933	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	Q-TIB	SULFAMETHO XAZOLE + TRIMETHOPRI M + ISONIAZID + PYRIDOXINE HYDROCHLORI DE	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

3176	NDA/MAL/HDP/8934	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CYCLO P EYE DROPS	CYCLOPENTOLATE HYDROCHLORIDE	1.0%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	7/25/2018
3177	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
3178	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

3179	NDA/MAL/HDP/8939	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	RHINOCOLD	PARACETAMO L + PHENYLEPHRI NE HYDROCHLORI DE + CHLORPHENIR AMINE 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	1.0X50.0X1.0X 4.0 TABLET BLISTER	7/25/2018
3180	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
3181	NDA/MAL/HDP/8941	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	LIVERCOL 20MG	ROSUVASTATI N 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

3182	NDA/MAL/HDP/8943	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT 150/12.5	IRBESARTAN + HYDROCHLOR OTHIAZIDE	150MG + 12.5MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOONAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	11/26/2019
3183	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
3184	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	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X0.6 G VIAL	7/25/2018

3185	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	PARENTERA L ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	7/25/2018
3186	NDA/MAL/HDP/8948	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	OMASI MED LIMITED	JULMENTIN ES	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	600 MG / 5 ML + 42.9 MG / 5 ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR) -- DIGDAGA, AIRPORT STREET RAS AL KHAIMAH UNITED ARAB EMIRATES	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X100.0 ML BOTTLE	7/25/2018
3187	NDA/MAL/HDP/8949	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CETAL SUPOSITORIES	PARACETAMO L	120MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	RECTAL SYSTEMIC SUPPOSITOR IES	1.0X1.0X5.0 SUPPOSITORY BLISTER	7/1/2018

3188	NDA/MAL/HDP/8952	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFLEX - 500	CEFALEXIN MONOHYDRA TE	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
3189	NDA/MAL/HDP/8953	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN CHILDREN'S WET COUGH	GUAIFENESIN	100MG PER 10ML	JOHNSON&JOHNSO N 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
3190	NDA/MAL/HDP/8954	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN WET COUGH	GUAIFENESIN	200MG PER 10ML	JOHNSON&JOHNSO N 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

3191	NDA/MAL/HDP/9051	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	SULFAMETHO XAZOLE/ TRIMETHOPRI M TABLETS USP	SULFAMETHO XAZOLE + TRIMETHOPRI M	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
3192	NDA/MAL/HDP/9052	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	SULFAMETHO XAZOLE/ TRIMETHOPRI M TABLETS USP	SULFAMETHO XAZOLE + TRIMETHOPRI M	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
3193	NDA/MAL/HDP/9057	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP®	DIHYDROARTE MISININ + 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

3194	NDA/MAL/HDP/9058	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	D-ARTEPP® DISPERSIBLE	DIHYDROARTE MISININ + 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
3195	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 SUSPENSION S/SYRUPS/D ROPS	1.0X10.0 ML BOTTLE	9/26/2018
3196	NDA/MAL/HDP/9062	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 32	CANDESARTA N 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

3197	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
3198	NDA/MAL/HDP/9064	THEON PHARMACEUTICALS 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
3199	NDA/MAL/HDP/9065	THEON PHARMACEUTICALS 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

3200	NDA/MAL/HDP/9066	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFIX-200	CEFIXIME 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
3201	NDA/MAL/HDP/9129	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOXAMOX	LEVOFLOXACIN HEMIHYDRATE S	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
3202	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

3203	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
3204	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
3205	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

3206	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
3207	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
3208	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 SUSPENSION S/SYRUPS/D ROPS	1.0X60.0 ML BOTTLE	11/26/2019

3209	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
3210	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
3211	NDA/MAL/HDP/9165	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-100	CLOTRIMAZOLE	100 MG	M/S BLISS GVS PHARMA LIMITED - PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X7.0 PESSARY BLISTER,1.0X1.0X6.0 PESSARY BLISTER	11/27/2019

3212	NDA/MAL/HDP/9172	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	DOXYDERMA	DOXYCYCLINE MONOHYDRA TE	100MG	PROFARMA SH.A- MYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	1/10/2020
3213	NDA/MAL/HDP/9173	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	PRODEXA-T	DEXAMETHAS ONE	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
3214	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

3215	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
3216	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
3217	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

3218	NDA/MAL/HDP/9178	PROFARMA .SH.A	JOINT MEDICAL STORE (UPMB - UCMB)	LORADE	LORATIDINE,L ORATIDINE	10MG,10MG	PROFARMA SH.A- MYSLYM KETA,TIRANA	ALBANIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	1/13/2020
3219	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	PARENTERA L ORDINARY DRY VIALS	1.0X20.0 MG VIAL + 1*5ML WFI IN LDPE	9/28/2020
3220	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 SUSPENSION S/SYRUPS/D ROPS	1.0X100.0 ML BOTTLE	9/28/2020

3221	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
3222	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
3223	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

3224	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
3225	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
3226	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

3227	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/G RANULES	1.0X15.0 G SACHET	9/28/2020
3228	NDA/MAL/HDP/9200	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 250	LEVETIRACETA M	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
3229	NDA/MAL/HDP/9201	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	LEVIGRESS 500	LEVETIRACETA M	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

3230	NDA/MAL/HDP/9202	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 5	ESCITALOPRA M 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
3231	NDA/MAL/HDP/9203	LA RENON HEALTHCARE PRIVATE LIMITED	AIVEEN (U) LIMITED	ESCIGRESS 10	ESCITALOPRA M 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
3232	NDA/MAL/HDP/9204	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS LTD	CHERIFLU PLUS WITH VITAMIN C	CHLORPHENA MINE MALEATE + PARACETAMO L + PHENYLEPHRI NE HYDROCHLORI DE +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

3233	NDA/MAL/HDP/9205	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GASTROSYN	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	250 MG + 250 MG + 50 MG / 5ML	SYNOKEM PHARMACEUTICALS LIMITED -PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X200.0 ML BOTTLE	9/28/2020
3234	NDA/MAL/HDP/9207	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	FLIPTOR 10	ROSUVASTATI N 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
3235	NDA/MAL/HDP/9209	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	NOFONG	TERBINAFINE HYDROCHLORI DE	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

3236	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
3237	NDA/MAL/HDP/9211	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 10000 IU	CHOLECALCIFE ROL	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
3238	NDA/MAL/HDP/9212	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HI DEE 50000 IU	CHOLECALCIFE ROL	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

3239	NDA/MAL/HDP/9213	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART SUSPENSION	ARTEMETHER + LUMEFANTRINE	15 MG + 90 MG/5ML	MADRAS PHARMACEUTICALS - 137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/DROPS	1.0X60.0 ML BOTTLE	9/28/2020
3240	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
3241	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

3242	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
3243	NDA/MAL/HDP/9219	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TESS	TRIAMCINOLONE ACETONIDE	0.1% W/W	TROIKAA PHARMACEUTICALS LTD-BLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL-SANAND CITY: AHMEDABAD, DIST. AHMEDABAD-382170, GUJARAT STATE	INDIA	TOPICAL EXTERNAL PASTES	1.0X1.0X5.0 G TUBE	9/28/2020
3244	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

3245	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
3246	NDA/MAL/HDP/9229	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	TRADMIN	TRAMADOL HYDROCHLORIDE	50MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19-20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR-249403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	9/25/2020
3247	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

3248	NDA/MAL/HDP/9236	LUPIN LTD	AIVEEN (U) LIMITED	RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORI DE TABLETS	RIFAMPIN + ISONIAZID + ETHAMBUTOL HYDROCHLORI DE	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
3249	NDA/MAL/HDP/9237	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	AZITHRO- DENK 250 MG	AZITHROMYCI N MONOHYDRA TE	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
3250	NDA/MAL/HDP/9238	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AZITHRO- DENK 500 MG	AZITHROMYCI N MONOHYDRA TE	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

3251	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
3252	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
3253	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

3254	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
3255	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
3256	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

3257	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
3258	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
3259	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

3260	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
3261	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	UNITED STATES GERMANY	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON	9/28/2020
3262	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	9/28/2020

3263	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 &	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1. 0X60.0 TABLET CONTAINER	9/28/2020
3264	NDA/MAL/HDP/9275	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	GENTACIN	GENTAMICIN SULPHATE	0.3% W/V	NITIN LIFE SCIENCES LIMITED.-RAMPUR ROAD, PAONTA SAHIB, SIRMOUR- 173025, H.P,	INDIA	OPHTHALMI C LIQUIDS	1.0X1.0X10.0 ML BOTTLE	9/28/2020
3265	NDA/MAL/HDP/9276	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZYLODINE	LIDOCAINE HYDROCHLORI DE	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	PARENTERA L ORDINARY VIALS	1.0X25.0X50.0 ML VIAL	9/28/2020

3266	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
3267	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
3268	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

3269	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
3270	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
3271	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

3272	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
3273	NDA/MAL/HDP/9296	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-CL	CLINDAMYCIN + CLOTRIMAZOLE	100 MG + 200 MG	BLISS GVS PHARMA LIMITED-10,11 & 12,DEWAN UDYOG NAGAR,ALIYALI,PAL GHAR,MAHARASHTRA 401404,INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 SUPPOSITORY STRIP	9/25/2020
3274	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

3275	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
3276	NDA/MAL/HDP/9306	BLISS GVS PHARMA LIMITED	MEDVIN PHARMA LIMITED	FUNBACT-A	CLOTRIMAZOL E + BETAMETHAS ONE DIPROPIONAT E + 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
3277	NDA/MAL/HDP/9315	CENTAUR PHARMACEUTICALS PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	ACETAMOX	ACETAZOLAMI DE	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

3278	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
3279	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
3280	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

3281	NDA/MAL/HDP/9322	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVI R, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50 MG + 300 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	9/25/2020
3282	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
3283	NDA/MAL/HDP/9327	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	OXICIN-D	MOXIFLOXACI N + DEXAMETHAS ONE SODIUM PHOSPHATE	0.5%W/V + 0.1% W/V	ATCO LABS LTD,-B- 18, S.I.T.E, KARACHI	PAKISTAN	OPHTHALMI C DROPS	1.0X1.0X5.0 ML CONTAINER	9/25/2020

3284	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
3285	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
3286	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

3287	NDA/MAL/HDP/9352	HEALTHCARE LTD.	HEALTHCARE LTD.	NEFZONE-S	CEFTRIAXONE SODIUM + SULBACTAM SODIUM	1000MG + 500MG	NITIN LIFE SCIENCES LIMITED.-RAMPUR ROAD, PAONTA SAHIB, SIRMOUR- 173025, H.P,	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL	12/22/2020
3288	NDA/MAL/HDP/9353	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	LUMITER DT	ARTEMETHER + LUMEFANTRIN E	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,1.0X3 0.0X6.0 TABLET BLISTER,1.0X3 0.0X2.0X6.0 TABLET BLISTER	12/22/2020
3289	NDA/MAL/HDP/9356	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IRIS	DES Loratadine	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

3290	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
3291	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, MAHABOOB NAGAR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER	12/22/2020
3292	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,1.0X3.0X6.0 TABLET BLISTER,1.0X3.0X1.0X6.0 TABLET BLISTER	12/22/2020

3293	NDA/MAL/HDP/9365	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 100	BEVACIZUMAB	100MG/4ML	HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOONNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	12/22/2020
3294	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
3295	NDA/MAL/HDP/9367	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XENAMEX	TRANEXAMIC ACID	100MG/ML	MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY VIALS	1.0X10.0X5.0 ML VIAL	12/18/2020

3296	NDA/MAL/HDP/9368	HETERO BIOPHARMA LIMITED,	AIVEEN (U) LIMITED	BEVAAS 400	BEVACIZUMAB	400MG/16ML	HETERO BIOPHARMA LIMITED-SY. NO. 458 (PART), TSIIC-FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL MAHABOBNAGAR DISTRICT – 509 301, TELANGANA STATE, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.0 ML VIAL	12/22/2020
3297	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
3298	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

3299	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
3300	NDA/MAL/HDP/9377	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN DT 250	AMOXICILLIN 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
3301	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

3302	NDA/MAL/HDP/9383	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS LTD	DOLUTEGRAVI R, LAMIVUDINE, TENOFVIR DISOPROXIL FUMARATE TABLETS	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR 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
3303	NDA/MAL/HDP/9385	BRAWN LABORATORIES LTD	TATA UGANDA LIMITED	BRUZOLIN	XYLOMETAZOL INE HYDROCHLORI DE	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
3304	NDA/MAL/HDP/9386	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	PROXYVON PLUS	TRAMADOL HYDROCHLORI DE + PARACETAMO L	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

3305	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
3306	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
3307	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

3308	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
3309	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 AJANTA PHARMA LIMITED-MIRZA-PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML BOTTLE	12/22/2020
3310	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

3311	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
3312	NDA/MAL/HDP/9427	SANOVI 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
3313	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

3314	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
3315	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
3316	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

3317	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
3318	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
3319	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

3320	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	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X0.6 ML PRE- FILLED SYRINGE	12/22/2020
3321	NDA/MAL/HDP/9480	TROIKAA PHARMACEUTICALS 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
3322	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X100.0 ML BOTTLE	12/18/2020

3323	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
3324	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
3325	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

3326	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
3327	NDA/MAL/HDP/9497	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ETOHOPE 60	ETORICOXIB	60 MG	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 FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/4/2021
3328	NDA/MAL/HDP/9498	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ETOHOPE 90	ETORICOXIB	90 MG	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 FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/4/2021

3329	NDA/MAL/HDP/9499	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ETOHOPE 120	ETORICOXIB	120 MG	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 FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/4/2021
3330	NDA/MAL/HDP/9500	POPULATION SERVICES INTERNATIONAL, UGANDA (PSIU)	POPULATION SERVICES INTERNATIONAL - UGANDA	MEURI	DESOGESTREL + ETHINYLESTRA DIOL	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
3331	NDA/MAL/HDP/9501	BESINS HEALTHCARE SA	SURGIPHARM (U) LIMITED	UTROGESTAN VAGINAL 100 MG	PROGESTERO NE	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

3332	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
3333	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
3334	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

3335	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
3336	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	1.0X20.0X1.0X 2.0 TABLET BLISTER	3/4/2021
3337	NDA/MAL/HDP/9509	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	TOBIDERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + TOLNAFTATE + IODOCHLORHYDROXYQUINOLINE	(0.643 MG + 1.0 MG + 10 MG + 10 MG)/G	KREMOINT PHARMA PVT LTD PLANT II-B- 8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	3/4/2021

3338	NDA/MAL/HDP/9510	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	GEODERM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	(0.5 MG + 1.0 MG + 10.0 MG)/G	KREMOINT PHARMA PVT LTD PLANT II-B-8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE, 1.0X30.0 G TUBE	3/4/2021
3339	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
3340	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

3341	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
3342	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
3343	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

3344	NDA/MAL/HDP/9516	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FORTYMOX	MOXIFLOXACI N HYDROCHLORI DE	0.5%W/V	ORCHIDIA PHARMACEUTICAL INDUSTRIES-AL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMI C LIQUIDS	1.0X1.0X10.0 ML CONTAINER	3/4/2021
3345	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	OPHTHALMI C SUSPENSION S	1.0X1.0X5.0 ML CONTAINER	3/4/2021
3346	NDA/MAL/HDP/9523	KOTRA PHARMA (M) SDN. BHD	ABACUS PHARMA (AFRICA) LIMITED	CEFACLO-125	CEFACLO MONOHYDRA TE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD,-NO. 1, 2 & 3, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA.	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X60.0 ML BOTTLE	3/4/2021

3347	NDA/MAL/HDP/9524	STRIDES PHARMA SCIENCE LIMITED	DELMAW ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ DOLUTEGRAVI R TABLETS	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE + DOLUTEGRAVI R SODIUM	300 MG + 300 MG + 50 MG	STRIDES SHASUN LIMITED-NO. 36/7, SURAGAJAKKANAH LLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	3/4/2021
3348	NDA/MAL/HDP/9525	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMI NE) + AMODIAQUIN E HYDROCHLORI DE	(250 MG + 12.5 MG) +76.5 MG	GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X 4.0 TABLET BLISTER	3/4/2021
3349	NDA/MAL/HDP/9526	SHANGHAI FOSUN PHARMACEUTICAL DEVELOPMENT CO. LTD	TRIDEM PHARMA UGANDA LIMITED	SPAQ-CO DISP	(SULFADOXINE + PYRIMETHAMI NE) + AMODIAQUIN E HYDROCHLORI DE	(500 MG + 25 MG) +153 MG	GUILIN PHARMACEUTICAL CO LTD .-NO. 43, QULIDIAN ROAD, GUILIN 541004	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X 4.0 TABLET BLISTER	3/4/2021

3350	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
3351	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
3352	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

3353	NDA/MAL/HDP/9535	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO DURATAZ INJECTION 4.5 G	PIPERACILLIN + TAZOBACTAM	(4 G + 0.5 G)/VIAL	ARISTO PHARMACEUTICALS PVT LTD-PLOT 208, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP 462046 DIST. RAISEN (MP)	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL	3/4/2021
3354	NDA/MAL/HDP/9537	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	SENSOCAIN SPINAL 0.5% INJECTION	BUPIVACAINE HYDROCHLORI DE	5MG/ML	BROOKES PHARMA (PRIVATE) LIMITED- 58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	PARENTERA L ORDINARY AMPOULES	1.0X5.0X4.0 ML AMPOULE	3/4/2021
3355	NDA/MAL/HDP/9538	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	ECZEMUS 0.1 % OINTMENT	TACROLIMUS MONOHYDRA TE	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

3356	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	PARENTERA L ORDINARY VIALS	1.0X1.0X20.0 MG VIAL + 1*1*1.5 ML DILUENT	3/4/2021
3357	NDA/MAL/HDP/9540	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TENGLYN	TENELIGLIPTIN HEMIPENTAH YDROBROMID E 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
3358	NDA/MAL/HDP/9541	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ERLOCIP 25	ERLOTINIB HYDROCHLORI DE	25MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/4/2021

3359	NDA/MAL/HDP/9542	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ERLOCIP 100	ERLOTINIB HYDROCHLORI DE	100MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	3/4/2021
3360	NDA/MAL/HDP/9543	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ERLOCIP 150	ERLOTINIB HYDROCHLORI DE	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
3361	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	1.0X10.0X10.0 TABLET BLISTER	3/4/2021

3362	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	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	3/4/2021
3363	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
3364	NDA/MAL/HDP/9547	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LIMITED-	SWASTIK PHARMACEUTICAL LTD	TRYCLOR 125 DS	CEFACLOX	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 SUSPENSION S/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	3/4/2021

3365	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
3366	NDA/MAL/HDP/9550	OCTOBER PHARMA-	ABACUS PHARMA (AFRICA) LIMITED	BRONCHOPRO	AMBROXOL HYDROCHLORI DE	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
3367	NDA/MAL/HDP/9555	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TRAMADOL DENK 200MG RETARD	TRAMADOL HYDROCHLORI DE	200 MG	GRUNENTHAL GMBH ZIEGLERSTR. 6, 52078 AACHEN - GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	3/5/2021

3368	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
3369	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
3370	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

3371	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
3372	NDA/MAL/HDP/9576	SAVA HEALTHCARE LIMITED -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUTIAIR 0.05%	FLUTICASON 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
3373	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 SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X100.0 ML BOTTLE	6/4/2021

3374	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
3375	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
3376	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

3377	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
3378	NDA/MAL/HDP/9589	MACLEODS PHARMACEUTICALS 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
3379	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

3380	NDA/MAL/HDP/9591	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	AZITOZ-500	AZITHROMYCIN DIHYDRATE	500 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	1.0X1.0X3.0 TABLET BLISTER	6/4/2021
3381	NDA/MAL/HDP/9592	JAMJOOM PHARMACEUTICALS 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
3382	NDA/MAL/HDP/9593	AUROBINDO 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 TELEGANA (STATE)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/4/2021

3383	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
3384	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
3385	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

3386	NDA/MAL/HDP/9599	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	VORICONA-DENK 200MG	VORICONAZOLE	200 MG	ACTAVIS LTD-BLB015016, BULEBEL INDUSTRIAL ESTATE, ZEJTUN ZTN3000	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/3/2021
3387	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
3388	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

3389	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
3390	NDA/MAL/HDP/9603	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOCITAF	DOLUTEGRAVI R SODIUM + EMTRICITABIN E + TENOFVIR 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
3391	NDA/MAL/HDP/9604	AMRING FARMA S.R.L	ERIS LTD	PROPOFOL AMRING	PROPOFOL	10 MG/ML	BAXTER (I) PVT. LTD- B-15/2, MIDC AREA, WAVUJ, AURANGABAD- 431136	INDIA	PARENTERA L ORDINARY OTHER INFUSIONS	1.0X5.0X20.0 ML VIAL	6/3/2021

3392	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	PARENTERA L ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	6/3/2021
3393	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, PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	6/3/2021
3394	NDA/MAL/HDP/9614	CIPLA LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	IVABEAT 7.5	IVABRADINE HYDROCHLORI DE	7.5 MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S-103 TO S-105, S-107 TO S- 112, L-147/1 TO L- 147/3, L-138, L- 147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE- GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER	6/3/2021

3395	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
3396	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
3397	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

3398	NDA/MAL/HDP/9618	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EMCAP 500	CAPECITABINE	500 MG	MSN LABORATORIES PRIVATE LIMITED- UNIT II, SY. NO. 1277 & 1319 TO 1324, NANDIGAMA (VILLAGE & MANDAL), RANDAREDDY DISTRICT, PIN CODE, 509 228, TELENGANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	6/3/2021
3399	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
3400	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, SANCET, GOA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X10.0 TABLET BLISTER,1.0X2.0X21.8 G SACHET COMBIPACK	6/3/2021

3401	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
3402	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
3403	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

3404	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
3405	NDA/MAL/HDP/9628	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	MPLIFY 20	TADALAFIL	20 MG	UNICHEM LABORATORIES LTD- PLOT NO. 15,16,17,17A & 18, PILERNE INDUSTRIAL ESTATE, PILERNE, BARDEZ, GOA- 403511	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X1.0 TABLET BLISTER	6/3/2021
3406	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

3407	NDA/MAL/HDP/9630	NEOMI PHARMACEUTICALS 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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	6/3/2021
3408	NDA/MAL/HDP/9631	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLON E 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
3409	NDA/MAL/HDP/9632	AGIO PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	CANISON VAGINAL 100	CLOTRIMAZOL E	100 MG	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE- 411026, MAHARASHTRA	INDIA	VAGINAL TABLETS	1.0X1.0X6.0 TABLET STRIP	6/3/2021

3410	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
3411	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
3412	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

3413	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
3414	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
3415	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

3416	NDA/MAL/HDP/9641	BERLIN-CHEMIE AG -	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PRILIGY 60 MG	DAPOXETINE HYDROCHLORI DE	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
3417	NDA/MAL/HDP/9642	GLENMARK PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLOMIL	AMOROLFINE HYDROCHLORI DE	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
3418	NDA/MAL/HDP/9644	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	HYDROMAX	HYDROCORTIS ONE	1.0 % W/W	KREMOINT PHARMA PVT LTD PLANT II-B- 8, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST) DIST. THANE 421506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	6/3/2021

3419	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, 1.0 X10.0X1.0 ML AMPOULE	6/4/2021
3420	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
3421	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

3422	NDA/MAL/HDP/9650	AGIO PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	SILVEX PLUS CREAM	SILVER SULFADIAZINE + CHLORHEXIDI NE 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
3423	NDA/MAL/HDP/9651	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANTOCYN	OXYTOCIN	10 IU/ML	PT SANBE FARMA UNIT 3.-JL INDUSTRI CIMAREME NO.8 PADALARANG 40533 BANDUNG	INDONESIA	PARENTERA L ORDINARY AMPOULES	1.0X2.0X5.0X1 .0 ML AMPOULE	6/4/2021
3424	NDA/MAL/HDP/9652	SUN PHARMACEUTICAL INDUSTRIES LIMITED -	STAR PHARMACEUTICALS LTD	LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE 300 MG/300 MG TABLETS	LAMIVUDINE + TENOFVIR 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

3425	NDA/MAL/HDP/9653	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	FERROUS SULPHATE WITH FOLIC ACID TABLETS	FERROUS SULPHATE + FOLIC ACID	60 MG + 0.6 MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	6/4/2021
3426	NDA/MAL/HDP/9654	THEON PHARMACEUTICALS LIMITED	AIVEEN (U) LIMITED	THEOTAX-1G	CEFOTAXIME SODIUM	1 G/VIAL	THEON PHARMACEUTICALS LTD ,-VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL	6/4/2021
3427	NDA/MAL/HDP/9657	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEMONT-IR 10	MONTELUKAS T SODIUM	10 MG	GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. S- 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	6/4/2021

3428	NDA/MAL/HDP/9658	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	TELMA 40	TELMISARTAN	40MG	GLENMARK PHARMACEUTICALS LIMITED-PLOT NO. S- 7, COLVALE, INDUSTRIAL ESTATE COLVALE, BARDEZ 403513, GOA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	6/4/2021
3429	NDA/MAL/HDP/9659	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	VOLUVEN	POLY (O-2- HYDROXYETHY L) 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	SOUTH AFRICA GERMANY	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X500.0 ML BAG	6/4/2021
3430	NDA/MAL/HDP/9660	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	TELMA 80H	TELMISARTAN + HYDROCHLOR OTHIAZIDE	80 MG + 12.5 MG	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	6/4/2021

3431	NDA/MAL/HDP/9661	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	TELMA H	TELMISARTAN + HYDROCHLOR OTHIAZIDE	40 MG + 12.5 MG	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	1.0X2.0X14.0 TABLET BLISTER	6/4/2021
3432	NDA/MAL/HDP/9662	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	IMOX 250 DT	AMOXICILLIN TRIHYDRATE	250MG	IPCA LABORATORIES LIMITED-PLOT NO. 69-72(B), SECTOR-II KASEZ, GANDHIDHAM- GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X2.0 X10.0 TABLET STRIP	6/4/2021
3433	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,1.0X1 000.0 ML BOTTLE	6/4/2021

3434	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
3435	NDA/MAL/HDP/9665	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC-SP	ACECLOFENAC + PARACETAMO L + SERRATIOPEPT IDASE	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
3436	NDA/MAL/HDP/9666	SCOTT-EDIL PHARMACIA LTD.,	ESCORTS PHARMACEUTICALS LIMITED	VOLIGESIC- GEL	DICLOFENAC DIETHYLAMIN E	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

3437	NDA/MAL/HDP/9668	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	AZILAB-200	AZITHROMYCI N DIHYDRATE	200MG/5ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X30.0 ML CONTAINER + 30 ML WFI IN LDPE CONTAINER	6/4/2021
3438	NDA/MAL/HDP/9669	ZOTA HEALTHCARE LTD	REDDYS PHARMA LIMITED	ZOCOLD	PARACETAMO L + CHLORPHENA MINE MALEATE + PHENYLEPHRI NE HYDROCHLORI DE	500 MG + 2 MG + 5 MG	ZOTA HEALTHCARE LIMITED-PLOT NO. 169, SURAT SPECIAL ECONOMIC ZONE, NR. SACHIN RAILWAY SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	6/4/2021
3439	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 SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	6/4/2021

3440	NDA/MAL/HDP/9671	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	RISOPINE	CARBAMAZEPI NE	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
3441	NDA/MAL/HDP/9672	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NASO B12	METHYLCOBA LAMIN	250 MCG/ACTUATI ON	TROIKAA PHARMACEUTICALS LIMITED...THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X2.3 ML BOTTLE	6/4/2021
3442	NDA/MAL/HDP/9673	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 100 MG/50ML	DOXORUBICIN HYDROCHLORI DE	100 MG/50ML	EBEWE PHARMA GES.M.B.H. NFG.KG- MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	AUSTRIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X50.0 ML VIAL	6/4/2021

3443	NDA/MAL/HDP/9674	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 50 MG/25ML	DOXORUBICIN HYDROCHLORI DE	50 MG/25ML	EBEWE PHARMA GES.M.B.H. NFG.KG- MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	AUSTRIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X25.0 ML VIAL	6/4/2021
3444	NDA/MAL/HDP/9675	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OD-TAM 0.4	TAMSULOSIN HYDROCHLORI DE	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), TSIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHRLA MANDAL, MAHABOOB NAGA DISTRICT, PIN CODE:	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	6/4/2021
3445	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X8.0 ML VIAL	6/4/2021

3446	NDA/MAL/HDP/9677	SANDOZ GMBH, KUNDL	KIMSY MEDS LTD	DOXORUBICIN 200 MG / 100 ML	DOXORUBICIN HYDROCHLORI DE	200 MG / 100 ML	EBEWE PHARMA GES.M.B.H. NFG.KG- MONDSEESTRABE 11 4866 UNTERACH AM ATTERSEE - AUSTRIA	AUSTRIA	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X100.0 ML VIAL	6/4/2021
3447	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
3448	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

3449	NDA/MAL/HDP/9681	SYNOKEM PHARMACEUTICALS 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
3450	NDA/MAL/HDP/9682	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	ROTRAMIC	TRANEXAMIC ACID	500 MG	SYNOKEM PHARMACEUTICALS LIMITED -PLOT NO.- 35-36, SECTOR-6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	6/23/2021
3451	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

3452	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
3453	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-	SOUTH KOREA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER, 1.0X90.0 TABLET CONTAINER	7/2/2021
3454	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	1.0X10.0X10.0 X2.0 ML AMPOULE	9/13/2021

3455	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
3456	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
3457	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

3458	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
3459	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
3460	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

3461	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
3462	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
3463	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

3464	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
3465	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
3466	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

3467	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
3468	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
3469	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

3470	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
3471	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
3472	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

3473	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
3474	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
3475	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

3476	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
3477	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
3478	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

3479	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	10/11/2021
3480	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X30.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	10/11/2021
3481	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X120.0 MG VIAL 1 CLEAR GLASS AMPOULE OF SODIUM BICARBONATE	10/11/2021

3482	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
3483	NDA/MAL/HDP/9751	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	GOODMAN INTERNATIONAL LTD	VAXATO 20 MG	RIVAROXABAN	20 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
3484	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

3485	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
3486	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
3487	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

3488	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
3489	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
3490	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

3491	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
3492	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
3493	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

3494	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
3495	NDA/MAL/HDP/9763	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DPIRIV 40/320 TABLET	DIHYDROARTERISININ + 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
3496	NDA/MAL/HDP/9764	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	DPIRIV 90/720	DIHYDROARTERISININ + 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 SUSPENSION S/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	10/12/2021

3497	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
3498	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
3499	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

3500	NDA/MAL/HDP/9768	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	MALAREST	QUININE DIHYDROCHLO RIDE	600MG/2ML	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	FRANCE	PARENTERA L ORDINARY AMPOULES	1.0X1.0X10.0X 2.0 ML AMPOULE	10/11/2021
3501	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	PARENTERA L ORDINARY AMPOULES	1.0X1.0X10.0X 1.0 ML AMPOULE	10/11/2021
3502	NDA/MAL/HDP/9770	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SARANTO-H 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	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

3503	NDA/MAL/HDP/9771	AUROBINDOM 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
3504	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
3505	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

3506	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
3507	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
3508	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

3509	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
3510	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
3511	NDA/MAL/HDP/9779	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	EYLEA			BAYER AG, BERLIN- MULLERSTRABE 178, 13353 BERLIN - GERMANY	GERMANY	PARENTERA L ORDINARY VIALS	1.0X1.0 ML VIAL	10/11/2021

3512	NDA/MAL/HDP/9780	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE DS 125	CLARITHROMY CIN	125 MG/5 ML	IND-SWIFT LIMITED ,-PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X50.0 ML BOTTLE	10/12/2021
3513	NDA/MAL/HDP/9781	IND SWIFT LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE DS 250	CLARITHROMY CIN	250 MG/5 ML	IND-SWIFT LIMITED ,-PHASE 1, INDUSTRIAL GROWTH CENTRE, SAMBA-184121, JAMMU & KASHMIR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSION S/SYRUPS/D ROPS	1.0X1.0X50.0 ML BOTTLE	10/12/2021
3514	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

3515	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/INSTANB UL, TURKEY	TURKEY	OPHTHALMI C DROPS	1.0X1.0X2.5 ML BOTTLE	10/12/2021
3516	NDA/MAL/HDP/9784	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	BRINZOL	BRINZOLAMID E + 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/INSTANB UL, TURKEY	TURKEY	OPHTHALMI C DROPS	1.0X1.0X5.0 ML BOTTLE	10/12/2021
3517	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

3518	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
3519	NDA/MAL/HDP/9787	SYNOKEM PHARMACEUTICALS LIMITED	ROYAL PHARMA 2011 LIMITED	SURE-72	LEVONORGEST REL	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
3520	NDA/MAL/HDP/9788	AFRICURE PHARMACEUTICALS (INDIA) PVT. LTD	ROYAL PHARMA 2011 LIMITED	CHLOROSIM- 250	CHLORAMPHE NICOL	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

3521	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
3522	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	1.0X5.0X2.0X1 0.0 TABLET BLISTER	10/12/2021
3523	NDA/MAL/HDP/9791	IMPACT RH360	UNITED HEALTHCARE DISTRIBUTORS LTD	AVIBELA	LEVONORGEST REL	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

3524	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	PARENTERA L ORDINARY DRY VIALS	1.0X1.0X500.0 MG VIAL	10/12/2021
3525	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	PARENTERA L ORDINARY INFUSION DRY VIALS/BOTT LES	1.0X1.0X1000. 0 MG VIAL	10/12/2021
3526	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	PARENTERA L ORDINARY AMPOULES	1.0X10.0X10.0 X1.0 ML AMPOULE	10/12/2021

3527	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 CUAUHEMOC MEXICO D.F, MEXICO	MEXICO	PARENTERAL RETARD DRY VIALS	1.0X1.0 VIAL PACK	10/12/2021
3528	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
3529	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

3530	NDA/MAL/HDP/9798	ORCHIDIA PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OZOLAMIDE	DORZOLAMID E HYDROCHLORI DE	22.26 MG/ML	ORCHIDIA PHARMACEUTICAL INDUSTRIES-AL OBOUR CITY INDUSTRIAL ZONE, AREA 14, 15 - PLOT NO. 12011 - CAIRO - EGYPT	EGYPT	OPHTHALMI C DROPS	1.0X1.0X5.0 ML BOTTLE	10/12/2021
3531	NDA/MAL/HDP/9799	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VOMIRAN 8 MG/ 4ML	ONDANSETRO N HYDROCHLORI DE 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	PARENTERA L ORDINARY VIALS	1.0X5.0X4.0 ML VIAL	10/12/2021
3532	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

3533	NDA/MAL/HDP/9801	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LENOSIDE 10	LENALIDOMID E	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
3534	NDA/MAL/HDP/9802	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LENOSIDE 15	LENALIDOMID E	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
3535	NDA/MAL/HDP/9803	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LENOSIDE 25	LENALIDOMID E	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

3536	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	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X10.0X5.0 ML PRE- FILLED SYRINGE	10/11/2021
3537	NDA/MAL/HDP/9805	INTERNATIONAL PARTNERSHIP FOR MICROBICIDES SOUTH AFRICA NON-PROFIT COMPANY	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DAPIRING	DAPIVIRINE	25MG/RING	QPHARMA AB- AGNESLUNDSVAGEN 27, MALMO, 21215 - SWEDEN	SWEDEN	VAGINAL OTHER SPECIAL FORMS	1.0X1.0X25.0 MG RING	10/12/2021
3538	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X16.0 ML VIAL	10/11/2021

3539	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
3540	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
3541	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

3542	NDA/MAL/HDP/9810	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	MONTIGET	MONTELUKAS T 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
3543	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
3544	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

3545	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
3546	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
3547	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

3548	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
3549	NDA/MAL/HDP/9817	GETZ PHARMA PVT LIMITED	MU PHARMA CO - SMC LIMITED	LARINEX	DESLOTRATIDINE	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
3550	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

3551	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
3552	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
3553	NDA/MAL/HDP/9821	JERUSALEM PHARMACEUTICALS 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

3554	NDA/MAL/HDP/9822	CIPLA LTD.	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ONDANSETRO N ORAL DISPERSIBLE TABLETS	ONDANSETRO N	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
3555	NDA/MAL/HDP/9823	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	HEDON PLUS	PARACETAMO L + 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	1.0X50.0X1.0X 2.0 TABLET STRIP	10/11/2021
3556	NDA/MAL/HDP/9824	AVACARE GLOBAL	GOODMAN INTERNATIONAL LTD	AVADEX	DEXAMETHAS ONE 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, GÜNEŞİL- BAĞCILAR/İSTANB UL, TURKEY	TURKEY	OPHTHALMI C DROPS	1.0X1.0X5.0 ML BOTTLE	10/11/2021

3557	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
3558	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, GUNESIL-BAGCILAR/INSTANBUL, TURKEY	TURKEY	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	10/11/2021
3559	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

3560	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	1.0X1.0X10.0X 1.0 ML AMPOULE	10/11/2021
3561	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
3562	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	1.0X10.0X10.0 TABLET BLISTER	10/11/2021

3563	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
3564	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
3565	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	OPHTHALMI C DROPS	1.0X1.0X5.0 ML VIAL	12/16/2021

3566	NDA/MAL/HDP/9835	PINNACLE LIFE SCIENCE PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	METAPROMID E	METOCLOPRA MIDE HYDROCHLORI DE	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
3567	NDA/MAL/HDP/9838	AGIO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AZIAGIO 100	AZITHROMYCI N DIHYDRATE	100MG/5ML	AGIO PHARMACEUTICALS LIMITED.-T-82 MIDC BHOSARI, PUNE- 411026, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X30.0 ML BOTTLE	12/16/2021
3568	NDA/MAL/HDP/9843	DAFRA PHARMA GMBH	MULTIPHAR UGANDA LIMITED	HACTOSEC	LEVODROPRO PIZINE	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

3569	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
3570	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
3571	NDA/MAL/HDP/9846	GLOBELA PHARMA PVT. LTD.	TATA UGANDA LIMITED	SQUAM	DIHYDROARTHEMISININ + 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

3572	NDA/MAL/HDP/9847	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICALS (U) LIMITED	PROCTOHEAL NEW® SUPPOSITORIE S	LIDOCAINE HYDROCHLORI DE + FLUOCINOLON E 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	SUPPOSITOR IES	1.0X2.0X10.0 SUPPOSITORY BLISTER	12/16/2021
3573	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	PARENTERA L ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE	12/16/2021
3574	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	PARENTERA L ORDINARY PRE-FILLED SYRINGES	1.0X1.0X0.8 ML SYRINGE	12/16/2021

3575	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 SATTION, SACHIN - 394230, SURAT, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	12/16/2021
3576	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
3577	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-MALKAJIRI DISTRICT, TELANGANA, INDIA, 500078	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X25.0 ML VIAL	12/16/2021

3578	NDA/MAL/HDP/9853	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MYCOREN V	NYSTATIN	100,000 IU	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	PESSARIES	1.0X1.0X15.0 PESSARY BLISTER	12/16/2021
3579	NDA/MAL/HDP/9854	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUZOLE	FLUCONAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X4.0 CAPSULE STRIP	12/16/2021
3580	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

3581	NDA/MAL/HDP/9856	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARTEM DISPERSIBLE	ARTEMETHER + LUMEFANTRIN E	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
3582	NDA/MAL/HDP/9857	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	ANLEPTIC	CARBAMAZEPI NE	100 MG/5 ML	SQUARE PHARMACEUTICALS LTD.-SQUARE ROAD SALGARIA PABNA	BANGLADESH	ORAL LIQUID ORDINARY SUSPENSION S	1.0X1.0X100.0 ML BOTTLE	12/16/2021
3583	NDA/MAL/HDP/9858	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	TIVICAY 25MG	DOLUTEGRAVI R SODIUM	25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)- PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	12/16/2021

3584	NDA/MAL/HDP/9859	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	TIVICAY 10MG	DOLUTEGRAVI R 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	UNITED KINGDOM SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	12/16/2021
3585	NDA/MAL/HDP/9860	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CLINDACIN 300 MG	CLINDAMYCIN HYDROCHLORI DE	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
3586	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	1.0X20.0X5.0X 10.0 TABLET BLISTER,1.0X1 0.0X10.0 TABLET BLISTER,1.0X1 000.0 TABLET CONTAINER	12/16/2021

3587	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
3588	NDA/MAL/HDP/9863	LABORATE PHARMACEUTICALS INDIA LIMITED	HEALTHCARE LTD.	LABDIC RELIEF TABLETS	DICLOFENAC SODIUM + PARACETAMO L + MAGNESIUM TRISILCATE + CHLORPHENIR AMINE MALEATE	50MG + 325MG + 100MG + 4MG	LABORATE PHARMACEUTICAL INDIA LIMITED UNIT II-31, RAJBAN ROAD, NARIWALA, PAONTA SAHIB, DISTT., SIRMOUR, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X 10.0 TABLET BLISTER	1/19/2022
3589	NDA/MAL/HDP/9864	MACLEODS PHARMACEUTICALS LTD	VITACARE LIMITED	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS, 400 MG / 300 MG / 300 MG	EFAVIRENZ, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE	400MG+300M G+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,1.0X3 0.0 TABLET BOTTLE	12/21/2021

3590	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
3591	NDA/MAL/HDP/9866	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	JULUCA 50MG/25MG	DOLUTEGRAVI R SODIUM + RILPIVIRINE HYDROCHLORI DE	50MG + 25MG	GLAXO OPERATIONS UK LTD (TRADING AS GLAXO WELLCOME OPERATIONS)- PRIORY STREET, WARE, SG12 ODJ	UNITED KINGDOM SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	12/21/2021
3592	NDA/MAL/HDP/9867	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.	ASTRA PHARMA (U) LIMITED	CEFTRIAXONE	CEFTRIAXONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD-NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, (WORKSHOP 402)CHINA	CHINA	PARENTERA L ORDINARY DRY VIALS	1.0X1.0 G VIAL	12/21/2021

3593	NDA/MAL/HDP/9868	PHARMA BAVARIA INTERNACIONAL PORTUGAL	GOODMAN INTERNATIONAL LTD	CADEN 6MG/2ML	ADENOSINE	6MG/2ML	VALDEPHARM-PARC INDUSTRIEL D'INCARVILLE, PARC DE LA FRINGALE, CS10606, 27100 VAL DE REUIL - FRANCE	FRANCE	PARENTERA L ORDINARY VIALS	1.0X1.0X6.0X2 .0 ML VIAL	12/21/2021
3594	NDA/MAL/HDP/9869	PHARMA BAVARIA INTERNACIONAL GMBH -	GOODMAN INTERNATIONAL LTD	FOSMOL	FOSFOMYCINT ROMETAMOL	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
3595	NDA/MAL/HDP/9870	PHARMA BAVARIA INTERNACIONAL GMBH -	GOODMAN INTERNATIONAL LTD	TAFIXYL	TRANEXAMIC ACID	500MG/5ML	LABIANA PHARMACEUTICALS, S.L.U.-C/CASANOVA, 27-31, 08757 CORBERA DE LLOBREGAT (BARCELONA)	SPAIN	PARENTERA L ORDINARY I V AMPOULES	1.0X1.0X5.0X5 .0 ML AMPOULE	12/21/2021

3596	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
3597	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
3598	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, 1.0X5.0X 40.0 MG VIAL	12/21/2021

3599	NDA/MAL/HDP/9874	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OCTANATE 500 IU	HUMAN COAGULATIO N FACTOR VIII	500IU PER VIAL	OCTAPHARMA DESSAU GMBH- OTTO-REUTER-STR.3 06847 DESSAU, ROSSLAU	SWEDEN GERMANY	PARENTERA L 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
3600	NDA/MAL/HDP/9875	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TALIMUS 0.1%	TACROLIMUS	0.1% W/W	AJANTA PHARMA LIMITED-MIRZA- PALASHBARI ROAD, VILLAGE-KOKJHAR, PALASHBARI 781128 KAMRUP(R.ASSAM)	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0G TUBE	12/21/2021
3601	NDA/MAL/HDP/9876	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	LENIOL	PARACETAMO L	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	PARENTERA L ORDINARY INFUSION VIALS/BOTT LES	1.0X1.0X100.0 ML BAG	12/21/2021

3602	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
3603	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
3604	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

3605	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,PA LGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BOTTLE	12/21/2021
3606	NDA/MAL/HDP/9881	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVIR, EMTRICITABINE AND TENOFIVIR ALAFENAMIDE TABLETS 50MG/200MG /25MG	DOLUTEGRAVIR SODIUM + EMTRICITABINE + TENOFIVIR 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
3607	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

3608	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	1.0X10.0X10.0 TABLET BLISTER	12/21/2021
3609	NDA/MAL/HDP/9885	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BECLOCORT	BECLOMETHA SONE DIPROPIONAT E	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
3610	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

3611	NDA/MAL/HDP/9888	GLOBELA PHARMA PVT. LTD.	SHREEJI CARE LIMITED	GLOMET 200	METRONIDAZ OLE	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,1.0X1 000.0 TABLET CONTAINER	12/21/2021
3612	NDA/MAL/HDP/9889	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MOMADERM	MOMETASON E 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
3613	NDA/MAL/HDP/9899	MEDICAL UNION PHARMACEUTICALS.	KARURI PHARMACEUTICALS LTD.	MUCOSOL ADULT SYRUP	CARBOCYSTEI NE	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

3614	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
3615	NDA/MAL/HDP/9905	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BISOLOL H 10/6.25	BISOPROLOL FUMARATE + HYDROCHLOR OTHIAZIDE	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
3616	NDA/MAL/HDP/9906	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	NEBTAS-5	NEBIVOLOL HYDROCHLORI DE	5MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197, DEHRADUN (UTTARAKHAND)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	12/11/2021

3617	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
3618	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
3619	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

3620	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
3621	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
3622	NDA/MAL/HDP/9922	CIPLA LTD.	QUALITY CHEMICALS LTD	PALONOSETR ON HYDROCHLORI DE INJECTION	PALONOSETR ON HYDROCHLORI DE	0.25MG/5ML	CIPLA LIMITED.-PLOT NO. L-139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	PARENTERA L ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	12/11/2021

3623	NDA/MAL/HDP/9926	UNIVERSAL CORPORATION LTD	PHARMA VILLE LIMITED	UNILYTE-N	DEXTROSE + POTASSIUM CHLORIDE + TRI SODIUM CITRATE + SODIUM CHLORIDE	13.5G + 1.5G + 2.9G + 2.6G	UNIVERSAL CORPORATION LIMITED-PLOT NO 13777, P. O. BOX 1748-00902 KIKUYU CLUB ROAD.	KENYA	ORAL SOLID ORDINARY POWDERS	1.0X20.56 G SACHET,1.0X1 0.28 G SACHET	1/27/2022
3624	NDA/MAL/HDP/9927	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN	NYSTATIN	500,000 I.U	MEDICAMEN BIOTECH LTD .-SP- 1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) LINCOLN PHARMACEUTICALS LTD-10, 12, 13, TRIMUL ESTATE, AFTER VADSAR VILLAGE, NEAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1. 0X10.0X10.0 TABLET BLISTER	2/2/2022