

NATIONAL DUG REGISTER OF UGANDA HUMAN MEDICINES JANUARY 2020

S/N	NDA REGISTRATIO N NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	GENERIC NAME OF DRUG	STRENGTH OF DRUG	MANUFACTURER	COUNTRY OF MANUFACTU RE	DOSAGE FORM	PACK SIZE	REGISTRATION DATE
1	NDA/MAL/HD P/0001	INGELHEIM PHARMACEUTICAL LTD	SURGIPHARM (U) LIMITED	MICARDIS 40	TELMISARTAN	40MG	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/1997
2	NDA/MAL/HD P/0002	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	X-SONE-N	DEXAMETHAS ONE+NEOMYC IN	0.1W/V+ 0.35W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2011
3	NDA/MAL/HD P/0003	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOXIL CLAV 625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	UNI MEDICOLABS-21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2015

4	NDA/MAL/HD P/0006	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIAMIDE	GLIBENCLAMI DE + METFORMIN HYDROCHLORI DE	5MG + 500MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X12.0 TABLET BLISTER	01/07/2014
5	NDA/MAL/HD P/0007	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROCIP SYRUP	CYPROHEPTA DINE HYDROCHLORI DE	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	01/07/2013
6	NDA/MAL/HD P/0010	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	02-LON	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	ACME FORMULATION PVT LTD.-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

7	NDA/MAL/HD P/0011	INGELHEIM PHARMACEUTICAL LTD	SURGIPHARM (U) LIMITED	MICARDIS 80	TELMISARTAN	80MG	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
8	NDA/MAL/HD P/0012	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENGESIC SR	TRAMADOL HYDROCHLORI DE SR	100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
9	NDA/MAL/HD P/0014	PLOUGH	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 10MG TABLET	MONTELUKAS T	10MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
10	NDA/MAL/HD P/0016	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CODIMEX-CT TABLETS	CETIRIZINE DIHYDROCHLO RIDE	10MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2014

11	NDA/MAL/HD P/0017	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	HYCORT	HYDROCORTIS ONE	100MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X7.5 ML VIAL	01/07/2011
12	NDA/MAL/HD P/0018	INGELHEIM PHARMACEUTICAL LTD	SURGIPHARM (U) LIMITED	CO-MICARDIS	TELMISARTAN + HYDROCHLOR OTHIAZIDE	40MG + 12.5MG	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/1997
13	NDA/MAL/HD P/0021	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	QUINS	QUININE DIHYDROCHLO RIDE	300MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJURAT,INDI A	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE,1.0X2. 0X5.0X2.0 ML AMPOULE	01/07/2013

14	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2009
15	NDA/MAL/HD P/0024	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPICLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
16	NDA/MAL/HD P/0025	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AMLOAS-5	AMLODIPINE	5MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220,TALUKA BAVLA DIST AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

17	NDA/MAL/HD P/0026	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AMLOAS-10	AMLODIPINE	10MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
18	NDA/MAL/HD P/0028	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	HYPERLOK-50	ATENOLOL	50MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
19	NDA/MAL/HD P/0029	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	HYPERLOK- 100	ATENOLOL	100MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

20	NDA/MAL/HD P/0030	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TRADMIN	TRAMADOL HYDROCHLORI DE	50MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2015
21	NDA/MAL/HD P/0031	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFTATIME-SB 1.5	CEFTRIAZONE +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	01/07/2015
22	NDA/MAL/HD P/0032	INGELHEIM PHARMACEUTICAL LTD	SURGIPHARM (U) LIMITED	CO-MICARDIS	TELMISARTAN + HYDROCHLOR OTHIZIDE	80MG + 12.5MG	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2013

23	NDA/MAL/HD P/0033	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELVATE CREAM	BETAMETHAS ONE VALERATE	0.1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
24	NDA/MAL/HD P/0041	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECIM	CIMETIDINE	200MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
25	NDA/MAL/HD P/0043	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL JUNIOR	PARACETAMO L	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
26	NDA/MAL/HD P/0045	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	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,1.0X 100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2007

27	NDA/MAL/HD P/0047	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAMIHOPE ET	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	600MG + 300MG + 300MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET CONTAINER,1.0X 180.0 TABLET CONTAINER	01/07/2015
28	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015
29	NDA/MAL/HD P/0052	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DISPERCAM	PIROXICAM	0.5%W/V	MEDICAL UNION PHARMACEUTICALS CO -36 DR MOHAMED HASSAN EL GAMAL ST. 6TH DISTRICT NASR CITY, CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2014
30	NDA/MAL/HD P/0053	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUANXOL DEPOT	FLUPENTIXOL DECANOATE	20MG/ML	H. LUNDBECK A/S ,,- OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN	DENMARK	PARENTERAL RETARD AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015

31	NDA/MAL/HD P/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	01/07/2013
32	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2015

33	NDA/MAL/HD P/0056	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR QPS	DICLOFENAC	4%W/V	TROIKAA PHARMACEUTICALS LTD- THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA TROIKAA PHARMACEUTICALS LTD- BLOCK NO. 2019, 2020, 2023, VILLAGE VIROCHANNAGAR, TAL- SANAND CITY: AHMEDABAD, DIST. AHMEDABAD-382170, GUJARAT STATE	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/2015
34	NDA/MAL/HD P/0058	NIRMA LIMITED.	LIFE PHARMA AFRICA 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,1.0X1 0.0 ML AMPOULE	01/07/1997

35	NDA/MAL/HD P/0059	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	VAGIBACT CREAM	CLINDAMYCIN PHOSPHATE	2%W/W	NABIQASIM INDUSTRIES (PVT) LTDv-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE + 1 APPLICATOR	01/07/2006
36	NDA/MAL/HD P/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 SPA (BARI)- VIA DELLE MAGNOLIE, 15 (LOC FRAZ ZONA INDUSTRIALE) 70026, MODUGNO, BARI	SWITZERLAND ITALY	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION	01/07/2015
37	NDA/MAL/HD P/0063	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE + LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600MG + 300MG	HETERO LABS LTD. UNIT (V)- 439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015

38	NDA/MAL/HD P/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	SWITZERLAND	PARENTERAL ORDINARY CARTRIDGES	1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION	01/07/2015
39	NDA/MAL/HD P/0065	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	ALENDRONAT E 70MG	ALENDRONAT E SODIUM	70MG	HOVID BHD-LOT 56442 7 1/2 MILES JALAN IPOH / CHEMOR 31200 CHEMOR	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2015
40	NDA/MAL/HD P/0067	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ARTEES	A-B ARTEETHER	75MG/ML	SAKAR HEALTHCARE PVT LTD --406, SILVER OAKS COMMERCIAL COMPLEX,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.2 ML AMPOULE	01/07/2013
41	NDA/MAL/HD P/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	01/07/1999

42	NDA/MAL/HD P/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	01/07/1999
43	NDA/MAL/HD P/0072	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	AMTERICIN	AMPHOTERICI N	50MG	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUHRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 MG VIAL	01/07/2013
44	NDA/MAL/HD P/0073	NAARI LTD	ECHO PHARMACY (U) LIMITED	FASILE-ONE	LEVONORGEST REL TABLETS BP	1.5MG	NAARI PHARMA PRIVATE LIMITED-PLOT NO. 14-16, 55- 57, SECTOR-5, IIE, PANT NAGAR RUHRAPUR-263153 DIST-U.S. NAGAR UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2013

45	NDA/MAL/HD P/0075	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	SYNRIAM	ARTEROLANE MALEATE + PIPERAQUINE PHOSPHATE	150 MG + 750 MG	SUN PHARMACEUTICALS IND. LTD-B-2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA-403404, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014
46	NDA/MAL/HD P/0077	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	X-SONE	DEXAMETHAS ONE SODIUM PHOSPHATE	0.1 % W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2015

47	NDA/MAL/HD P/0079	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	REVOKE 72	LEVONORGEST REL	750MCG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2014

48	NDA/MAL/HD P/0083	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	ZINNIA-F	LEVONORGEST REL & ETHINYLESTRA DIOL + FERROUS FUMARATE	150MCG + 30MCG + 75MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2014

49	NDA/MAL/HD P/0088	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	D-LYTE CO- PACK	ANHYDROUS GLUCOSE/SODIUM CHLORIDE/TRISODIUM CITRATE/POTASSIUM CHLORIDE	(2.7G/0.52G/0.58G/0.3G)/20 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 COMBINATION PACK POWDERS/GRANULES	4.0X500.0 ML SACHET + 1*10 BLISTERS,10.0X200.0 ML SACHET + 1*10 BLISTERS,2.0X1000.0 ML SACHET + 1*10 BLISTERS	01/07/2015
50	NDA/MAL/HD P/0093	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	LORAS	LORATADINE	10MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER	01/07/2013
51	NDA/MAL/HD P/0096	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	LIPOR	ATORVASTATIN	20MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2015

52	NDA/MAL/HD P/0097	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	SAFELEVO 750	LEVOFLOXACI N	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	01/07/2013
53	NDA/MAL/HD P/0098	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	ATOREM 10	ATORVASTATI N	10MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
54	NDA/MAL/HD P/0099	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	CARBAS	CARBAMAZEPI NE	200MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2014

55	NDA/MAL/HD P/0101	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTETRA CAPSULES (THANE)	TETRACYCLINE HYDROCHLORI DE	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,1.0X 1000.0 CAPSULE CONTAINER,1.0X 100.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/1998
56	NDA/MAL/HD P/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	01/07/2014
57	NDA/MAL/HD P/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	01/07/2013

58	NDA/MAL/HD P/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	01/07/2014
59	NDA/MAL/HD P/0105	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOSPRIN TABLETS	ACETYL SALICYLIC ACID	300MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1998
60	NDA/MAL/HD P/0110	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI 40	TELMISARTAN	40MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

61	NDA/MAL/HD P/0111	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI 80	TELMISARTAN	80MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
62	NDA/MAL/HD P/0112	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 5MG/160MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERTRASSE NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007
63	NDA/MAL/HD P/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	01/07/2013

64	NDA/MAL/HD P/0116	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY CW 5	MONTELUKAS T SODIUM	5MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
65	NDA/MAL/HD P/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	01/07/2013
66	NDA/MAL/HD P/0121	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	PEDZINC	ZINC SULPHATE	20MG	SHELYS PHAMACEUTICALS LTD .-NEW BAGAMOYO RD, MWENGE, PLOT 696, DAR ES SALAAM BETA HEALTH CARE INTERNATIONAL LIMITED/- PLOT NO. LR 209/ 6534 MOGADISHU ROAD, KENYA	TANZANIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015

67	NDA/MAL/HD P/0124	DAWA LIMITED	SUPER MEDIC LTD	AMPECIN	AMPICILLIN TRIHYDRATE	125MG/5ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
68	NDA/MAL/HD P/0125	DAWA LIMITED	SUPER MEDIC LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2013
69	NDA/MAL/HD P/0126	DAWA LIMITED	SUPER MEDIC LTD	WHITFIELD'S	BENZOIC ACID + SALICYLIC ACID	6.0%W/W +3.0%W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2014
70	NDA/MAL/HD P/0127	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOR OTHIAZIDE	300MG + 12.5MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD- XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

71	NDA/MAL/HD P/0128	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOR OTHIAZIDE	150MG + 12.5MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD- XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
72	NDA/MAL/HD P/0130	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TRIGAN -D	DICYCLOMINE HYDROCHLORI DE	10MG/ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2015
73	NDA/MAL/HD P/0131	ABBOT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID P125	CLARITHROMY CIN	125MG/5ML	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE,CONSTANTIA KLOOF 1709 P.O BOX 7208 WELTEVREDENPARK 1715	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X50.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1998

74	NDA/MAL/HD P/0132	ABBOT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID 500MG	CLARITHROMY CIN	500MG	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE,CONSTANTIA KLOOF 1709 P.O BOX 7208 WELTEVREDENPARK 1715	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X14.0 TABLET BLISTER	01/07/1998
75	NDA/MAL/HD P/0133	ABBOT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID P250	CLARITHROMY CIN	250MG/5ML	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE,CONSTANTIA KLOOF 1709 P.O BOX 7208 WELTEVREDENPARK 1715	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X50.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1998

76	NDA/MAL/HD P/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	01/07/2013
77	NDA/MAL/HD P/0139	ANGLIAN NUTRITION PRODUCTS COMPANY	SUPER MEDIC LTD	MOXAFORTE	FLUCLOXACILL IN SODIUM + AMOXICILLIN TRIHYDRATE	250MG + 250MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014
78	NDA/MAL/HD P/0141	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT SUSPENSION	NYSTATIN	100,000 I.U./ML	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/1998

79	NDA/MAL/HD P/0142	PFIZER LAB LTD	LABOREX UGANDA LIMITED	PREVENAR 13	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13- VALENT.ADSORBED)	2.2MCG OF POLYSACCHARIDE FOR SEROTYPES 1,3,4,5,6A,7F, 9V,14,18C,19A, 19F,23F,AND 4.4MCG FOR SEROTYPE 6B	WYETH PHARMACEUTICALS INC-401 N MIDDLETOWN RD PEARL RIVER NY 10965	UNITED STATES	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2011
80	NDA/MAL/HD P/0144	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	NEXQUIN 500	LEVOFLOXACIN	500MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
81	NDA/MAL/HD P/0145	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 10	MONTELUKAST SODIUM	10MG	MSN LABORATORIES LTD - PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

82	NDA/MAL/HD P/0148	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SYNCLAV 1000	AMOXICILLIN + CLAVULANATE POTASSIUM	875 MG + 125 MG	MEDREICH LIMITED UNIT 1- 12TH MILE, OLD MADRAS ROAD, VIRGONAGAR, BANGOLORE-560049 MEDOPHARM PVT LTD -NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY-603203 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2013
83	NDA/MAL/HD P/0149	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SYNCLAV 625	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDREICH LIMITED –UNIT I- 12TH MILE, OLD MADRAS ROAD, VIRGONAGAR BANGALORE- 560 049, INDIA MEDOPHARM PVT LTD -NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY-603203 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2013

84	NDA/MAL/HD P/0150	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SYNCLAV 228	AMOXYCILLIN + CLAVULANATE POTASSIUM	200 MG + 28.5 MG	MEDREICH LIMITED –UNIT I- 12TH MILE, OLD MADRAS ROAD, VIRGONAGAR BANGALORE- 560 049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2013
85	NDA/MAL/HD P/0151	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CARDITEL 80	TELMISARTAN	80MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

86	NDA/MAL/HD P/0152	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	RYCARDON 150	IRBESARTAN	150MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD- XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA 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	01/07/2013

87	NDA/MAL/HD P/0153	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	RYCARDON 300	IRBESARTAN	300MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD- XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA 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	01/07/2013
88	NDA/MAL/HD P/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	01/07/2013

89	NDA/MAL/HD P/0157	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECODIN	CODEINE PHOSPHATE + CHLORPHENIR AMINE MALEATE	10MG + 4MG /5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015
90	NDA/MAL/HD P/0158	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 10	MONTELUKAS T SODIUM	10MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
91	NDA/MAL/HD P/0160	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	TIZIGESIC	TIZANIDINE HYDROCHLORI DE	2MG	UNICHEM LABORATORIES LIMITED-C-31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
92	NDA/MAL/HD P/0162	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETH ORPHAN HYDROBROMI DE + CHLORPHENA MINE MALEATE	10MG +4MG /5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2015
93	NDA/MAL/HD P/0163	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PHENAREN	PROMETHAZI NE HYDROCHLORI DE	5MG/5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2015

94	NDA/MAL/HD P/0164	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENPRESS	PROPRANOLO L	40MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
95	NDA/MAL/HD P/0165	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TOLANZ 5	OLANZAPINE ORODISPERSIB LE TABLETS	5MG	TORRENT PHARMACEUTICALS LTD .,- AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
96	NDA/MAL/HD P/0166	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOL E	100MG/5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2015
97	NDA/MAL/HD P/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 DISINTEGRATING TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

98	NDA/MAL/HD P/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	01/07/2014
99	NDA/MAL/HD P/0169	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ROSUVAX 10	ROSUVASTATI N	10MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2015
100	NDA/MAL/HD P/0175	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	XARELTO 10MG	RIVAROXABAN	10MG	BAYER HEALTHCARE AG,-D- 51368, LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013

101	NDA/MAL/HD P/0178	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAYTIME AND NIGHT TIME CAPSULE	DAY TIME(PARACE TAMOL +CAFFEINE ANHYDROUS+ PSEUDOEPHE DRINE HCL) AND NIGHT TIME(PARACE TAMOL +CHLORPHENI RAMINE MALEATE)	DAY TIME (500MG + 30MG + 30MG) AND NIGHT TIME (500MG +2MG)	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0 CAPSULE BLISTER	01/07/2013
102	NDA/MAL/HD P/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	01/07/2014
103	NDA/MAL/HD P/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	01/07/2014
104	NDA/MAL/HD P/0187	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON TABLET	TRANEXAMIC ACID	500 MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

105	NDA/MAL/HD P/0188	AMOUN PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	LEVOXIN	LEVOFLOXACIN	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
106	NDA/MAL/HD P/0189	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NEVIMUNE TABLETS	NEVIRAPINE	200MG	CIPLA LTD--PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA-403 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X60.0 TABLET CONTAINER	01/07/2001
107	NDA/MAL/HD P/0191	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	CLEDOMOX 228.5	AMOXICILLIN + CLAVULANATE	200 MG + 28.5 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2013
108	NDA/MAL/HD P/0193	MEDOPHARM PRIVATE LIMITED	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	01/07/2013

109	NDA/MAL/HD P/0196	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DUOVIR	LAMIVUDINE/ ZIDOVUDINE	150MG/300M G	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
110	NDA/MAL/HD P/0197	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	EFAVIR-600	EFAVIRENZ	600MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2004
111	NDA/MAL/HD P/0198	CIPLA LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	NEVIRAPINE TABLETS 200 MG	NEVIRAPINE	200MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013

112	NDA/MAL/HD P/0203	GLAXOSMITHLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER 250	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 250MCG	GLAXO WELLCOME- PRODUCTION ZONE INDUSTRIELLE NO. 2 23, RUE LAVOISIER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2015
113	NDA/MAL/HD P/0204	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TIVICAY	DOLUTEGRAVI R SODIUM	50MG	GLAXO OPERATIONS UK LTD- WARE SG120DJ UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015
114	NDA/MAL/HD P/0206	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CARDITEL 40	TELMISARTAN	40MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

115	NDA/MAL/HD P/0207	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE	LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	300MG +300MG	MACLEODS PHARMACEUTICALS LTD--- PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401 MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	10/07/2013
116	NDA/MAL/HD P/0209	HETERO LABS LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE ORAL SOLUTION	ABACAVIR SULPHATE	20MG/ML	HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2013

117	NDA/MAL/HD P/0210	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HEPATICUM	SILYMARIN	140MG	MEDICAL UNION PHARMACEUTICALS-36 DR MOHAMED HASSAN EL- GAMAL ST.6TH DISTRICT NASR CITY EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
118	NDA/MAL/HD P/0212	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HEPATICUM	SILYMARIN	1G/100ML	MEDICAL UNION PHARMACEUTICALS-36 DR MOHAMED HASSAN EL- GAMAL ST.6TH DISTRICT NASR CITY EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2012
119	NDA/MAL/HD P/0213	AUROBINDO PHARMA LTD (UNIT VI)	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROPODOX 200	CEFPODOXIME	200MG	AUROBINDO PHARMA LTD (UNIT VI) ,,,,-SURVEY NOS. 329/39 & 329/47, CHITKUL VILLAGE, PATANCHERU MANDAL, MEDAK DISTRICT PIN CODE 502307, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013

120	NDA/MAL/HD P/0217	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PALETHAR	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD .- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. BOX KHATRAJ 382721 TA: KALOL DIST. GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY I M AMPOULES	2.0X3.0X1.0 ML AMPOULE	01/07/2014
121	NDA/MAL/HD P/0221	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO- DAWA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
122	NDA/MAL/HD P/0226	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	ULTRASOLV SYRUP	OXOMEMAZIN E HCL & CARBOCYSTEI NE & GUAIFENESIN	2MG+125MG+ 100MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2014
123	NDA/MAL/HD P/0227	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	CYRINOL SYRUP	PHOLCODINE+ EPHEDRINE HCL +CARBINOXA MINE MALEATE	4MG+7MG+2 MG /5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014

124	NDA/MAL/HD P/0228	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-960	TRIMETHOPRI M/SULFAMET HOXAZOLE	160MG/800M G	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2014
125	NDA/MAL/HD P/0230	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART	ARTHEMETHE R + LUMEFANTRIN E	20MG +120MG	STRIDES SHASUN LIMITED- NO. 36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BENGALURU, KARNATAKA, 562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X6.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER,1.0X1.0X 18.0 TABLET BLISTER,1.0X1.0X 24.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER	01/07/2013
126	NDA/MAL/HD P/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	01/07/2013
127	NDA/MAL/HD P/0236	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CLOB	CLOTRIMAZOL E	1%W/W	INDOCO REMEDIES LIMITED- L-14 VERNA INDUSTRIAL AREA VERNA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X15.0 G TUBE	01/07/2004

128	NDA/MAL/HD P/0237	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 280	ARTEMETHER + LUMEFANTRIN E	40 MG + 240 MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET BLISTER	01/07/2014
129	NDA/MAL/HD P/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,1.0X18.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER	01/07/2014
130	NDA/MAL/HD P/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	01/07/2014

131	NDA/MAL/HD P/0248	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PANTONEX DR- 40	PANTOPRAZO LE	40 MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
132	NDA/MAL/HD P/0254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARA TE	5MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250- 64293 DARMSTADT WINTHROP PHARMACEUTICALS(PTY) LTD,-315 WATLOO ROAD,WATLOO,PRETORIA,S OUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE)	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

133	NDA/MAL/HD P/0256	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	CAPETERO 500	CAPECITABINE	500MG	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOONAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2015
134	NDA/MAL/HD P/0257	SANOFI AVENTS FRANCE	LABOREX UGANDA LIMITED	CORDARONE	AMIODARONE HYDROCHLORI DE	200MG	SANOFI WINTHROP INDUSTRIE-LAGRAGE 33565 CARBON BLANC CEDEX FRANCE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X 15.0 TABLET BLISTER	01/07/1998
135	NDA/MAL/HD P/0266	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2.400.000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2001

136	NDA/MAL/HD P/0270	BYANSI SERVICES 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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2001
137	NDA/MAL/HD P/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,1.0X2 4.0X10.0 ML AMPOULE,1.0X5. 0 ML VIAL (10 DOSES)	01/07/2001

138	NDA/MAL/HD P/0272	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	LEVIN 250	LEVOFLOXACIN	250MG	HETERO LABS LTD. UNIT (V)- 439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2019
139	NDA/MAL/HD P/0275	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	400MG	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD-39 HAWKINS AVENUE, EPPING INDUSTRIAL, CAPE TOWN, 7460, SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2011
140	NDA/MAL/HD P/0276	MICRO LABS LTD	LABOREX UGANDA LIMITED	MELANOV 80	GLICLAZIDE	80MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

141	NDA/MAL/HD P/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,1.0X 100.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER	01/07/1998
142	NDA/MAL/HD P/0283	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO- DAWA	AMPICILLIN + CLOXACILLIN	125 MG + 125 MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013
143	NDA/MAL/HD P/0284	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	PARENTERAL ORDINARY DRY VIALS	10.0X1.2 G VIAL	01/07/2009
144	NDA/MAL/HD P/0286	GUILIN PHARMACEUTICAL CO.LTD	STAR PHARMACEUTICALS LTD	GLUMAC	ARTEMETHER +LUMEFANTRI NE	20MG+120MG	GUILIN PHARMACEUTICAL CO. LTD-NO. 17 SHANGHAI ROAD, GUILIN 541002, GUANXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X18.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER	01/07/2014

145	NDA/MAL/HD P/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	01/07/2013
146	NDA/MAL/HD P/0288	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	DUXCOSPAN	HYOSCINE BUTYL BROMIDE	10MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
147	NDA/MAL/HD P/0290	LABORATORY AND 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,1.0X100 0.0 TABLET CONTAINER	01/07/1997

148	NDA/MAL/HD P/0296	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PRAZITEL TABLETS	PRAZQUANTEL	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1998
149	NDA/MAL/HD P/0298	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	SEFIXI-50 DRY SYRUP	CEFIXIME	50MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X60.0 ML BOTTLE	01/07/2013

150	NDA/MAL/HD P/0301	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	MONAST 10	MONTELUKAS T 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	01/07/2013
151	NDA/MAL/HD P/0303	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ABACAVIR SULPHATE	ABACAVIR SULPHATE	300MG	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEDIMETLA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2014
152	NDA/MAL/HD P/0304	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	DARUNAVIR	DARUNAVIR	400MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2014

153	NDA/MAL/HD P/0305	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250 DRY SYRUP	CEFALEXIN	250MG/5ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2013
154	NDA/MAL/HD P/0307	HETERO DRUGS LTD	AIVEEN (U) LIMITED	LAMIVUDINE ORAL SOLUTION	LAMIVUDINE	10MG/ML	HETERO DRUGS LTD, UNIT III 22-110, IDA, JEEDIMETLA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X240.0 ML CONTAINER	01/07/2013
155	NDA/MAL/HD P/0308	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250	CEFALEXIN	250MG	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 CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013

156	NDA/MAL/HD P/0311	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	FENTANYL	FENTANYL CITRATE	50MCG/ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
157	NDA/MAL/HD P/0312	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA ORAL SOLUTION 125	CLOXACILLIN	125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR- 361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013
158	NDA/MAL/HD P/0314	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	SUXAMETHON IUM CHLORIDE SOLUTION FOR INJECTION	SUXAMETHON IUM CHLORIDE	50MG/ML	MARTINDALE PHARMA - BAMPTON ROAD, HAROLD HILL,ROMFORD,RM3844	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2013
159	NDA/MAL/HD P/0318	DAWA LIMITED	SUPER MEDIC LTD	SABULIN	SALBUTAMOL	4MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
160	NDA/MAL/HD P/0320	DAWA LIMITED	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOL E	1%W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2013

161	NDA/MAL/HD P/0322	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
162	NDA/MAL/HD P/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 SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2014
163	NDA/MAL/HD P/0332	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ROSUVAX 20	ROSUVASTATI N CALCIUM	20MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2015

164	NDA/MAL/HD P/0333	KOPRAN LIMITED	TATA UGANDA LIMITED	CLAVAMYN- 625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG +125MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014
165	NDA/MAL/HD P/0335	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	NEOMYCIN SULPHATE CREAM USP	NEOMYCIN SULPHATE CREAM USP	0.5%WW	KREMOINT PHARMA PVT LTD-B-8,ADDITIONAL AMBERNATH MIDC, AMBERNATH (E),DIST: THANE 421506, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2013
166	NDA/MAL/HD P/0336	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AS-DP TABLETS	DICYCLOMINE HCL + PARACETAMO L	20MG+500MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013

167	NDA/MAL/HD P/0337	IND-SWIFT	PLANET PHARMACEUTICALS UGANDA LTD	SWAZI *500	AZITHROMYCI N	500MG	IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014
168	NDA/MAL/HD P/0338	KOPRAN LIMITED	TATA UGANDA LIMITED	KORAB 20	RABEPRAZOLE SODIUM	20MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
169	NDA/MAL/HD P/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	01/07/2014

170	NDA/MAL/HD P/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	01/07/2013
171	NDA/MAL/HD P/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	01/07/2014
172	NDA/MAL/HD P/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	01/07/2014

173	NDA/MAL/HD P/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	01/07/2013
174	NDA/MAL/HD P/0348	PHARMACIE BETHEL	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	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2015
175	NDA/MAL/HD P/0350	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CETRIREN	CETIRIZINE HYDROCHLORI DE	10MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

176	NDA/MAL/HD P/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	01/07/2014
177	NDA/MAL/HD P/0353	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-10	AMLODIPINE BESILATE	10MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X3.0X 1.0X10.0 TABLET BLISTER	01/07/2015
178	NDA/MAL/HD P/0354	KOPRAN LIMITED	TATA UGANDA LIMITED	LEVOKOP	LEVOFLOXACI N	500MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
179	NDA/MAL/HD P/0355	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	BICO VITA	THIAMINE HCL + RIBOFLAVIN + PYRIDOXINE HCL + NICOTINAMID E	10MG + 0.1MG + 1MG + 10MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2015

180	NDA/MAL/HD P/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,1.0X1.0X 10.0 TABLET BLISTER	01/07/2014
181	NDA/MAL/HD P/0360	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 20MG	ESOMEPRAZOLE	20MG	ASTRA ZENECA AB, SODERTALJE- GARTUNAYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER,1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON	01/07/2001
182	NDA/MAL/HD P/0362	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	BUPI	BUPIVACAINE	5 MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2015

183	NDA/MAL/HD P/0363	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	AGYCIN	AZITHROMYCI N	250MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
184	NDA/MAL/HD P/0366	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	AGYCIN 500	AZITHROMYCI N	500MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2014
185	NDA/MAL/HD P/0368	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	QUININE DI HYDROCHLORI DE INJECTION	QUININE DIHYDROCHLO RIDE	300MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/1997

186	NDA/MAL/HD P/0369	ABBOT LABORATORIES S.A. (PTY) LTD	HARLEYS UGANDA LIMITED	KLACID 250MG	CLARITHROMY CIN	250MG	ABBOTT LABORATORIES S.A (PTY) LTD-ABBOTT PLACE,219 GOLF CLUB TERRACE,CONSTANTIA KLOOF 1709 P.O BOX 7208 WELTEVREDENPARK 1715	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/1998
187	NDA/MAL/HD P/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOR OTHIAZIDE	5MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
188	NDA/MAL/HD P/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,5.0X2.0X 10.0 TABLET BLISTER	01/07/2009

189	NDA/MAL/HD P/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	01/07/2014
190	NDA/MAL/HD P/0385	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASFORMIN	METFORMIN HYDROCHLORI DE	500MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
191	NDA/MAL/HD P/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	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	01/07/2014

192	NDA/MAL/HD P/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,1.0X 1000.0 CAPSULE CONTAINER,1.0X 500.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/1997
193	NDA/MAL/HD P/0389	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANMOL INFUSION IV	PARACETAMO L	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	01/07/2014
194	NDA/MAL/HD P/0394	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	DOXYLEB	DOXYCYCLINE	100MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2014

195	NDA/MAL/HD P/0397	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-LT	AMLODIPINE + LOSARTAN POTASSIUM	2.5 MG + 50 MG	EMCURE PHARMACEUTICALS LTD- LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0X10. 0 TABLET BLISTER	01/07/2013
196	NDA/MAL/HD P/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	01/07/2013
197	NDA/MAL/HD P/0403	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	SUPRIDOL	TRAMADOL HYDROCHLORI DE	50MG/ML	NEON LABORATORIES LTD -- PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2013

198	NDA/MAL/HD P/0404	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED WET COUGH & COLD	TRIPLORIDINE HCL/PSEUDOE PHEDRINE/GU AIPHENESIN	1.25MG/30M G/100MG	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L JERRYCAN	01/07/1997
199	NDA/MAL/HD P/0405	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	CHEMLET	LETROZOLE	2.5MG	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
200	NDA/MAL/HD P/0406	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	EVATOCIN	OXYTOCIN	10 I.U./ ML	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2015

201	NDA/MAL/HD P/0407	NEON LABORATORIES LTD	AIVEEN (U) 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 I V AMPOULES	1.0X20.0 ML AMPOULE	01/07/2013
202	NDA/MAL/HD P/0408	MSN LABORATORIES LTD	METRO PHARMACEUTICALS LIMITED	ALGIC - P	ACECLOFENAC + PARACETAMO L	100 MG + 500 MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

203	NDA/MAL/HD P/0409	NEON LABORATORIES LTD	AIVEEN (U) 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	01/07/2013
204	NDA/MAL/HD P/0410	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 20	ROSUVASTATI N CALCIUM	20MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
205	NDA/MAL/HD P/0411	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	JADELLE SINE	LEVONORGEST REL	150MG	BAYER OY-PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X10.0X1.0X2. 0X75.0 MG IMPLANT	01/07/2003
206	NDA/MAL/HD P/0412	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LDNIL 5	ROSUVASTATI N CALCIUM	5MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

207	NDA/MAL/HD P/0413	NEON LABORATORIES LTD	AIVEEN (U) LIMITED	XSPAS	HYOSCINE BUTYLBROMID E	20MG/ML	NEON LABORATORIES LTD -- PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2013
208	NDA/MAL/HD P/0415	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRA MINE HYDROCHLORI DE+AMMONI UM CHLORIDE+SO DIUM CITRATE+MEN THOL	14.03MG+138 MG+57.03MG +0.90MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
209	NDA/MAL/HD P/0416	NOVARTIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	RAMIZID 5	RAMIPRIL	5MG	LEK S.A-95 - 010 STRYKÓW, PODLPIE 16, POLAND	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
210	NDA/MAL/HD P/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	01/07/2013

211	NDA/MAL/HD P/0419	ASTRAZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 2.5MG/1000M G	SAXAGLIPTIN + METFORMIN	2.5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.- 4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
212	NDA/MAL/HD P/0421	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	PREGASAFE 150	PREGABALIN	150MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
213	NDA/MAL/HD P/0422	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PARAFLAM	IBUPROFEN + PARACETAMO L	100MG + 162.5MG /5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2013

214	NDA/MAL/HD P/0423	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTRAM	TRAMADOL	50MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2013
215	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER	01/07/1998
216	NDA/MAL/HD P/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	01/07/2015
217	NDA/MAL/HD P/0428	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROMOX- 400	MOXIFLOXACI N	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	01/07/2013

218	NDA/MAL/HD P/0429	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FLEXON MR	IBUPROFEN + PARACETAMO L + CHLORZOXAZ ONE	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	01/07/2014
219	NDA/MAL/HD P/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC +PARACETAM OL	100MG+500M G	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2013
220	NDA/MAL/HD P/0433	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PROANES MCT/LCT	PROPOFOL	1%W/V	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY I V AMPOULES	1.0X5.0X20.0 ML AMPOULE	01/07/2014

221	NDA/MAL/HD P/0434	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	PROHIBIN	OMEPRAZOLE	20MG	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,1.0X10.0 X10.0 CAPSULE STRIP	01/07/2010
222	NDA/MAL/HD P/0436	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANBE HEST 130	POLY (0-2- HYDROXYETHY L) STARCH	30G	PT SANBE FARMA-JI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2014
223	NDA/MAL/HD P/0438	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANBE HEST 200	POLY (0-2- HYDROXYETHY L) STARCH	MW 200,000	PT SANBE FARMA-JI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2014
224	NDA/MAL/HD P/0447	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®125	METHYLPRED NISOLONE SODIUM SUCCINATE	125MG/VIAL	PT.CAPRIFARMINDO LABORATORIES-JI.INDUSTRI NO.8,KOMPLEKS INDUSTRI CIMAREME DESA CIMAREME,KEC PADALARANG,KAB BANDUNG	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X125.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2014

225	NDA/MAL/HD P/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	01/07/2013
226	NDA/MAL/HD P/0451	PT SANBE FARMA	MEDVIN PHARMA LIMITED	SANEXON®500	METHYLPRED NISOLONE SODIUM SUCCINATE	500MG/VIAL	PT.CAPRIFARMINDO LABORATORIES-JI.INDUSTRI NO.8,KOMPLEKS INDUSTRI CIMAREME DESA CIMAREME,KEC PADALARANG,KAB BANDUNG	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*8ML AMPOULE OF WFI	01/07/2014

227	NDA/MAL/HD P/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	01/07/2013
228	NDA/MAL/HD P/0454	PT SANBE FARMA	MEDVIN PHARMA LIMITED	LEVOCIN INFUSION	LEVOFLOXACI N HEMIHYDRATE	500 MG	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014
229	NDA/MAL/HD P/0456	LEBEN LABORATORIES PVT. LTD	ANDYCO PHARMACY (UGANDA) LTD	METROLEB	METRONIDAZ OLE	125MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014
230	NDA/MAL/HD P/0457	UNIVERSAL CORPORATION LTD	DELMAN ENTERPRISES LIMITED	UNIBROL 250MG	AMINOSIDINE	250MG	UNIVERSAL CORPORATION LTD-UNIVERSAL CORPORATION LTD	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X4.0X 6.0 TABLET BLISTER	01/07/2012

231	NDA/MAL/HD P/0460	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORI DE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE	01/07/2009
232	NDA/MAL/HD P/0463	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TOPHEN	PHENYTOIN	100MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/2011
233	NDA/MAL/HD P/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	01/07/1997
234	NDA/MAL/HD P/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	DENMARK	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
235	NDA/MAL/HD P/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	DENMARK	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014

236	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL,1.0X0.5 ML VIAL	01/07/2015
237	NDA/MAL/HD P/0480	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ, LAMIVUDINE & TENOFOVIR DISOPROXIL FUMERATE 600/300/300 MG	EFAVIRENZ + LAMIVUDINE + TENFOVIR DISOPROXIL FUMARATE	600MG+300M G+300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA CIPLA L.T.D -MIDC PATALGANGA MAHARASHTRA 410 220 CIPLA LTD UNIT VII PD II-S- 103 TO S-105, S-107 TO S- 112, L-138, L-147/1 TO L- 147/3, L-147A, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA 403722, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2014

238	NDA/MAL/HD P/0482	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	AZILEB-500	AZITHROMYCI N	500MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X3.0 TABLET BLISTER	01/07/2014
239	NDA/MAL/HD P/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, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
240	NDA/MAL/HD P/0484	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	PILPLAN PLUS	ETHINYL ESTRADIOL + LEVONORGEST REL / FERROUS FUMARATE	0.03MG+0.15 MG/75MG	BAYER SCHERING PHARMA AG.-13342, BERLIN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X28 .0 TABLET BLISTER	01/07/2014
241	NDA/MAL/HD P/0489	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	CEBAY-200 DT	CEFIXIME	200MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014

242	NDA/MAL/HD P/0490	SANOFI	LABOREX UGANDA LIMITED	ORELOX	CEFPODOXIME	200MG	SANOFI WINTHROP INDUSTRIE-SANOFI WINTHROP INDUSTRIE 56, RUE DE CHOISY AU BAC 60205 COMPIÈGNE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
243	NDA/MAL/HD P/0491	PHARMACIE BETHEL	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	01/07/2013
244	NDA/MAL/HD P/0493	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 10	PRASUGREL	10MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

245	NDA/MAL/HD P/0496	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MYPRODOL	PARACETAMO L + IBUPROFEN + CODEINE PHOSPHATE	250MG + 200MG + 10MG	ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER, 1.0X3.0X 10.0 CAPSULE BLISTER	01/07/2014
246	NDA/MAL/HD P/0497	LABORATORY&ALLIE D LTD	HARLEYS UGANDA LIMITED	KEMOXYL DRY SUSPENSION	AMOXICILLIN TRIHYDRATE	125MG/5ML	LABORATORY & ALLIED LTD- PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
247	NDA/MAL/HD P/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	01/07/2001
248	NDA/MAL/HD P/0510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	LIZOLID-600	LINEZOLID	600MG	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET STRIP	01/07/2004

249	NDA/MAL/HD P/0517	SANOFI AVENTIS KENYA LTD	LABOREX UGANDA LIMITED	SHANVAC -B	R- DNA HEPATITIS -B SURFACE ANTIGEN PURIFIED	20MCG/ML	SHANTHA BIOTECHNICS LTD - SURVEY NO. 274, ATHVELLI VILLAGE, MEDCHAL MANDAL – 501401, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 ADULT DOSE), 1.0X35.0X 0.5 ML VIAL (1 PEDIATRIC DOSE)	01/07/2015
250	NDA/MAL/HD P/0518	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CYCLOREN	ACICLOVIR	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2006
251	NDA/MAL/HD P/0522	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	VAZORTAN 50	LOSARTAN POTASSIUM	50MG	MEDLEY PHARMACEUTICALS LTD -PLOT NO. 18 AND 19, SURVEY NO. 378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM , DAMAN-396 210, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

252	NDA/MAL/HD P/0526	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	AMILEB- 25	AMITRIPTYLIN E	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
253	NDA/MAL/HD P/0531	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	ENDERM-GM	CLOBETASOL PROPIONATE + GENTAMYCIN + MICONAZOLE NITRATE	0.05%W/W + 0.10%W/W + 2.0%W/W	LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2014
254	NDA/MAL/HD P/0533	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 5	MONTELUKAS T SODIUM	5MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
255	NDA/MAL/HD P/0538	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 180	FEXOFENADIN E HYDROCHLORI DE	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,1.0X1.0X 10.0 TABLET BLISTER	01/07/2013

256	NDA/MAL/HD P/0539	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 4	MONTELUKAS T SODIUM	4MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
257	NDA/MAL/HD P/0540	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	HYDRICORT	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	01/07/2014
258	NDA/MAL/HD P/0541	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 120	FEXOFENADIN E HYDROCHLORI DE	120MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
259	NDA/MAL/HD P/0542	DAWA LIMITED	SUPER MEDIC LTD	PHENBITAL	PHENOBARBIT AL	30MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

260	NDA/MAL/HD P/0543	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 2	GLIMEPIRIDE	2MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
261	NDA/MAL/HD P/0544	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN PLUS	ACECLOFENAC + PARACETAMO L	100 MG + 500 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
262	NDA/MAL/HD P/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	01/07/2012

263	NDA/MAL/HD P/0549	ABBOTT LABORATORIES S.A (PTY) LTD	HARLEYS UGANDA LIMITED	HIDRASEC	RACECADOTRI L	100 MG	LABORATOIRES SOPHARTEX- 21 RUE DU PRESOIR, 28500 VERNOUILLET, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2014
264	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2014
265	NDA/MAL/HD P/0551	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	REDAMOX	AMOXICILLIN + CLAVULANIC ACID	125 MG/ 5 ML + 31.25 MG/ 5 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	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
266	NDA/MAL/HD P/0552	ABBOTT LABORATORIES S.A (PTY) LIMITED	HARLEYS UGANDA LIMITED	HIDRASEC INFANTS	RACECADOTRI L	10 MG	LABORATOIRES SOPHARTEX- 21 RUE DU PRESOIR, 28500 VERNOUILLET, FRANCE	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X16.0 SACHET CARTON	01/07/2014

267	NDA/MAL/HD P/0553	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	EQUIRAB	RABIES ANTISERUM	1000IU/ 5ML	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL (5 DOSE VIAL)	01/07/2013
268	NDA/MAL/HD P/0555	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CARZEPIN	CARBAMAZEPI NE	200MG	HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
269	NDA/MAL/HD P/0556	ABOTT LABORATORIES S.A (PTY) LTD	HARLEYS UGANDA LIMITED	HIDRASEC CHILDREN	RACECADOTRI L	30 MG	LABORATOIRES SOPHARTEX- 21 RUE DU PRESSEIR, 28500 VERNOUILLET, FRANCE	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X30.0 SACHET CARTON	01/07/2014

270	NDA/MAL/HD P/0557	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	REDAMOX 312.5	AMOXICILLIN + POTASSIUM CLAVULANATE	250 MG/5 ML + 62.5 MG/5 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	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2013
271	NDA/MAL/HD P/0558	PHARMACIE BETHEL	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	01/07/2014
272	NDA/MAL/HD P/0559	HOVID BHD	MEDICAL ACCESS (UGANDA) LIMITED	DIABETMIN RETARD	METFORMIN HYDROCHLORI DE	850MG	HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

273	NDA/MAL/HD P/0560	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 1	GLIMEPIRIDE	1MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .--P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
274	NDA/MAL/HD P/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	01/07/2013
275	NDA/MAL/HD P/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,GUJRAT,INDI A	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE	01/07/2013

276	NDA/MAL/HD P/0567	KOTRA PHARMA SDN BDN	ABACUS PHARMA (AFRICA) LIMITED	VAXCEL CEFTRIAZONE 500MG	CEFTRIAZONE	500MG	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013
277	NDA/MAL/HD P/0568	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUOXIREN	FLUOXETINE	20MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
278	NDA/MAL/HD P/0569	KOTRA PHARMA SDN BDN	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	01/07/2014
279	NDA/MAL/HD P/0570	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	TETGLOB 250 I.U	HUMAN TETANUS IMMUNOGLO BULIN	250IU	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0X2.0 ML VIAL (1 DOSE VIAL)	01/07/2013

280	NDA/MAL/HD P/0571	KOTRA PHARMA (M) SDN BHD	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 MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2015
281	NDA/MAL/HD P/0573	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL PARACETAMO L-250	PARACETAMO L	250MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2014
282	NDA/MAL/HD P/0574	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUIN E TABLETS 100/270	ARTESUNATE AND AMODIAQUIN E	100MG+270M G	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER	01/07/2013
283	NDA/MAL/HD P/0576	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	DUODART	DUTASTERIDE + TAMSULOSIN	0.5MG + 0.4MG	CATALENT GERMANY SCHONDORF GMBH - STEINBEISSTRASSE 1-2, 73614 SCHORNDORF, GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2015

284	NDA/MAL/HD P/0577	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTENDED	PARACETAMO L	650MG	TROIKAA PHARMACUETICALS LIMITED- C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
285	NDA/MAL/HD P/0580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDI ENT	MULTINGREDI ENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
286	NDA/MAL/HD P/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC +PARACETAM OL+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, 1.0X10.0 X10.0 TABLET BLISTER	01/07/2015

287	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
288	NDA/MAL/HD P/0586	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ONSETT	ONDANSETRO N	2MG/ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE,1.0X5. 0X4.0 ML AMPOULE	01/07/2013
289	NDA/MAL/HD P/0587	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CADIGREL	CLOPIDOGREL	75MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

290	NDA/MAL/HD P/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	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2013
291	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
292	NDA/MAL/HD P/0590	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	ASNA ANTIVENOM C	B.GABONICA/ B.ARIENTANS/ B.NASICORNIS / DENDROASPIS / POLYEPIS/D.A NGUSTICEPS/ N.NIVEA /N.NLGRCOLLI S/N.HAJE	25/25/20/25/ 25/25/25/25/ 20/25/20/25 I.U	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X10.0 ML VIAL	01/07/2012

293	NDA/MAL/HD P/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	OPHTHALMIC LIQUIDS	1.0X10.0 ML CONTAINER	01/07/2013
294	NDA/MAL/HD P/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,1.0X3.0X1 0.0 CAPSULE STRIP	01/07/2014
295	NDA/MAL/HD P/0594	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROVISC- 2ML PFS	HYPROMELLO SE OPHTHALMIC SOLUTION USP	2%W/V	AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	01/07/2013
296	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2015

297	NDA/MAL/HD P/0596	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN /HYDROCHLO ROTHIAZIDE	40MG/12.5M G	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
298	NDA/MAL/HD P/0598	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LIPICURE-20	ATORVASTATI N	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003
299	NDA/MAL/HD P/0599	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	GRAMOCEF-O- 400	CEFIXIME	400MG	MICROLABS LIMITED-PLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/2013
300	NDA/MAL/HD P/0600	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	CARVEDI- DENK 6.25	CARVEDIOL	6.25MG	ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

301	NDA/MAL/HD P/0603	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	GROMIN SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/1999
302	NDA/MAL/HD P/0604	DAWA PHARMACEUTICALS LIMITED	SUPER MEDIC LTD- MBARARA	TRIMOXOL	CO- TRIMOXAZOLE	480MG	DAWA LIMITED -16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/1997
303	NDA/MAL/HD P/0605	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	CARVEDI- DENK 25	CARVEDILOL	25MG	ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
304	NDA/MAL/HD P/0608	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LOPINAVIR AND RITONAVIR TABLETS 200MG/50MG	LOPINAVIR + RITONAVIR	200MG + 50MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2012

305	NDA/MAL/HD P/0609	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	CLOPI-DENK 75	CLOPIDOGREL BESYLATE	75MG	ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
306	NDA/MAL/HD P/0611	GALPHAR LABORATORIES LTD	AIVEEN (U) LIMITED	GALCIPRO 500	CIPROFLOXACI N HYDROCHLORI DE	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	01/07/2015
307	NDA/MAL/HD P/0614	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	126 MG/ 5 ML + 31.25 MG/ 5 ML	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1998

308	NDA/MAL/HD P/0615	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	VALSAR 80	VALSARTAN	80MG	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 FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
309	NDA/MAL/HD P/0618	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	VALSAR 160	VALSARTAN	160MG	HETERO LABS LTD. UNIT (V)- 439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015

310	NDA/MAL/HD P/0619	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	D10	GLUCOSE	10%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2013
311	NDA/MAL/HD P/0621	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ALZER	DONEPEZIL HYDROCHLORI DE	10MG	HETERO LABS LTD. UNIT (V)- 439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
312	NDA/MAL/HD P/0625	SANOFI PASTEUR	LABOREX UGANDA LIMITED	VERORAB	RABIES VACCINE	1 DOSE	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 DOSE VIAL,1.0X5.0X1.0 DOSE VIAL + 1.0X5.0X0.5ML GLASS AMPOULES OF 0.9% SODIUM CHLORIDE	01/07/1997

313	NDA/MAL/HD P/0626	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC-10	AMLODIPINE BESILATE	10MG	KPI INDUSTRIES (1996) LTD- PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0X10 .0 TABLET BLISTER	01/07/2015
314	NDA/MAL/HD P/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,1.0X2.0X1 0.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2015
315	NDA/MAL/HD P/0630	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEO LORIDIN	DESLOTRADIN E	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2011
316	NDA/MAL/HD P/0633	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	CIPROCIN	CIPROFLOXACI N	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	01/07/2013

317	NDA/MAL/HD P/0634	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	TRISOLIV	ANDROGRAPH OLIDES/TRICH OLINE CITRATE	50MCG+50MG /ML	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2014
318	NDA/MAL/HD P/0635	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-AMIN	AMINOPHYLLI NE	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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2009

319	NDA/MAL/HD P/0636	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	REVOKE-1.5	LEVONORGEST REL	1.5MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER	01/07/2014

320	NDA/MAL/HD P/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	01/07/2014
321	NDA/MAL/HD P/0638	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABLOL-5 EYE DROPS	TIMOLOL MALEATE	0.5% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2013
322	NDA/MAL/HD P/0639	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	RHEUMATIC CREAM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

323	NDA/MAL/HD P/0643	NAARI AG	ECHO PHARMACY (U) 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,25.0X1.0 X4.0 TABLET BLISTER	01/07/2013
324	NDA/MAL/HD P/0652	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS	VILDAGLIPTIN	50MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS BARBERA -SPAIN	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2014
325	NDA/MAL/HD P/0654	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG/500MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013
326	NDA/MAL/HD P/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,1.0X6.0X 10.0 TABLET BLISTER	01/07/2013

327	NDA/MAL/HD P/0658	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN/ METFORMIN	50MG/1000M G	NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X 10.0 TABLET BLISTER	01/07/2013
328	NDA/MAL/HD P/0665	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	IRBIS 150	IRBESARTAN	150MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2013
329	NDA/MAL/HD P/0666	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	IRBIS-H 300	IRBESARTAN	300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	01/07/2013

330	NDA/MAL/HD P/0667	KOTRA PHARMA (M) SDN,BHD	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 MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE	01/07/2013
331	NDA/MAL/HD P/0668	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TELI 40	TELMISARTAN	40MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
332	NDA/MAL/HD P/0669	KOTRA PHARMA (M) SDN,BHD	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	01/07/2013
333	NDA/MAL/HD P/0670	AGOG PHARMA LTD	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,1.0X5.0X 4.0 CAPSULE BLISTER	01/07/2014

334	NDA/MAL/HD P/0671	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL LIGNOCAINE	LIDOCAINE	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2014
335	NDA/MAL/HD P/0672	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGONOR TABLETS	NORFLOXACIN	400MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2013
336	NDA/MAL/HD P/0673	MIRACLE CENTRE KAWEMPE	KARURI PHARMACEUTICALS LTD.	ONSETT 8	ONDANSETRO N	8MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

337	NDA/MAL/HD P/0674	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2013
338	NDA/MAL/HD P/0675	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL METRONIDAZ OLE 400	METRONIDAZ OLE	400MG	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
339	NDA/MAL/HD P/0676	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ONSETT 4	ONDANSETRO N	4MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

340	NDA/MAL/HD P/0677	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DOPAMET	METHYLDOPA	250MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
341	NDA/MAL/HD P/0678	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL HYDROCORTIS ONE CREAM	HYDROCORTIS ONE	1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/2014
342	NDA/MAL/HD P/0679	AGOG PHARMA	GITTOES PHARMACEUTICALS LIMITED	MEFENA-250 CAPSULES	MEFENAMIC ACID	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2013
343	NDA/MAL/HD P/0681	GENNOVA BIOPHARMACEUTICA LS LTD	HARLEYS UGANDA LIMITED	ELAXIM 40	TENECTEPLAS E (RECOMBINAN T TISSUE PLASMINOGE N ACTIVATOR)	40MG/VIAL	EMCURE PHARMACEUTICALS LTD .- PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X40.0 MG VIAL , 1*8 ML VIAL OF WFI	01/07/2013

344	NDA/MAL/HD P/0684	TROGE MEDICAL GMBH	ECHO PHARMACY (U) LIMITED	TRO-CEFTRIAX 1G	CEFTRIAXONE	1G	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	G VIAL	01/07/2014
345	NDA/MAL/HD P/0685	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	SOMAZINA	CITICOLINE	1000MG	FERRER INTERNACIONAL S.A - -GRAN VIA CARLOS III 94 08028 BARCELONA	SPAIN	PARENTERAL RETARD I M AMPOULES	1.0X5.0X4.0 ML AMPOULE	01/07/2015
346	NDA/MAL/HD P/0687	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	SOMAZINA	CITICOLINE	1000MG	FERRER INTERNACIONAL S.A - -GRAN VIA CARLOS III 94 08028 BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X6.0X10.0 ML SACHET	01/07/2015
347	NDA/MAL/HD P/0688	AGOG PHARMA LTD	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	01/07/2014

348	NDA/MAL/HD P/0689	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGONAL	NALIDIXIC ACID	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
349	NDA/MAL/HD P/0690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHEASE CREAM	BECLOMETHA SONE DIPROPIONA 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	01/07/2014
350	NDA/MAL/HD P/0691	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-20	OLMESARTAN MEDOXOMIL	20 MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
351	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/2015
352	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/2014

353	NDA/MAL/HD P/0694	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	DT ZINC-20 TABLETS	ZINC SULPHATE	20MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER, 1.0X10.0 X10.0 TABLET CARTON	01/07/2013
354	NDA/MAL/HD P/0698	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	WHITFIELD'S OINTMENT	BENZOIC ACID+SALICYLI C CID	6%W/W + 3%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/2003
355	NDA/MAL/HD P/0700	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	VAXIRAB N	INACTIVATED RABIES VIRUS(PITMA N MOORE STRAIN)	>2.5 I.U	CADILA HEALTHCARE LTD--- SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL + 1ML AMPOULE OF WFI(1 DOSE VIAL)	01/07/2015
356	NDA/MAL/HD P/0702	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEPTOCIN	STREPTOMYCI N SULPHATE	1GM	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL	01/07/2014

357	NDA/MAL/HD P/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	01/07/2013
358	NDA/MAL/HD P/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 SOLAN H.P	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,10.0X1.0 X5.0 TABLET BLISTER	01/07/2013

359	NDA/MAL/HD P/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	01/07/2013
360	NDA/MAL/HD P/0707	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	PENVIR 500	FAMCICLOVIR	500MG	HETERO LABS LTD(UNIT V).- JADCHERLA (M),MAHABOONNAGAR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
361	NDA/MAL/HD P/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	01/07/2013
362	NDA/MAL/HD P/0712	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZENTEL	ALBENDAZOLE	100MG/5ML	FARMACLAIR -440 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/1997

363	NDA/MAL/HD P/0713	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 20	PANTOPRAZO LE SODIUM SESQUIHYDRA TE	20MG	ADVANCE PHARMA GMBH..- WALLENRODER STR.12-14, 13435 BERLIN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2015
364	NDA/MAL/HD P/0715	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 40	PANTOPRAZO LE SODIUM SESQUIHYDRA TE	40MG	ADVANCE PHARMA GMBH..- WALLENRODER STR.12-14, 13435 BERLIN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2015
365	NDA/MAL/HD P/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	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.4 ML PRE- FILLED SYRINGE	01/07/2011
366	NDA/MAL/HD P/0721	MISSION PHARMA	METRO PHARMACEUTICALS LIMITED	ARH-A	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE,1.0X1. 0X6.0 ML AMPOULE	01/07/2014

367	NDA/MAL/HD P/0722	FDC LTD	AIVEEN (U) LIMITED	IOTIM 0.5%	TIMOLOL MALEATE	0.5% W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014
368	NDA/MAL/HD P/0726	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T DOL RAPID	TRAMADOL HYDROCHLORI DE	50MG	TROIKAA PHARMACEUTICALS LTD- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2014
369	NDA/MAL/HD P/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	01/07/2005
370	NDA/MAL/HD P/0728	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ARTESUNATE AND AMODIAQUIN E 25/67.5	ARTESUNATE+ AMODIAQUIN E	25MG+67.5M G	IPCA LABORATORIES LIMITED -SEJAVTA VILLAGE, DIST. RATLAM (M.P) 457002 ☐ INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2013

371	NDA/MAL/HD P/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	01/07/2013
372	NDA/MAL/HD P/0732	ANHIU	MAISHA MEDICAL SUPPLIES LIMITED	VOLTAMED- 100	DICLOFENAC	100 MG	MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
373	NDA/MAL/HD P/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	01/07/2013

374	NDA/MAL/HD P/0745	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TELI 80	TELMISARTAN	80MG	B. BRAUN MELSUNGEN - MISTELWEG-1389, TRABAD ROAD, DHOLKA 387 810, DISTRICT AHMEDABAD, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
375	NDA/MAL/HD P/0746	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DTS-Z KIT	TABLET-ZINC, SACHET-NACL + KCL + TRISODIUM CITRATE + ANHYDROUS GLUCOSE	TABLET- 54.89MG , SACHET 1.3G + 0.75G + 1.45G + 6.75G	COSMOS LIMITED, KENYA- RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X4.0X10.3 G SACHET + 1.0X10.0 TABLET BLISTER	01/07/2013
376	NDA/MAL/HD P/0747	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE ORANGE CO- PACK	GLUCOSE ANHYDROUS + SODIUM CHLORIDE + TRISSODIUM CITRATE DEHYDRATE + POTASSIUM CHLORIDE / ZINC SULPHATE	13.5G + 2.6G + 2.9G + 1.5G/ SACHET + 27.43MG/5ML	: MEDIPHARM INDUSTRIES LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY OTHER SOLID SPECIAL FORMS	1.0X20.8 G SACHET + 60 ML BOTTLE	01/07/2013

377	NDA/MAL/HD P/0748	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 15MG	RIVAROXABAN	15MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013
378	NDA/MAL/HD P/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	01/07/2014
379	NDA/MAL/HD P/0750	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 20MG	RIVAROXABAN	20MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER	01/07/2013
380	NDA/MAL/HD P/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	01/07/2013

381	NDA/MAL/HD P/0754	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TORAS DENK 10	TORASEMIDE	10MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
382	NDA/MAL/HD P/0755	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T- DOL	TRAMADOL HYDROCHLORI DE	50MG/ML	TROIKAA PHARMACEUTICALS LIMITED..-THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2014
383	NDA/MAL/HD P/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	01/07/2014
384	NDA/MAL/HD P/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	01/07/2014

385	NDA/MAL/HD P/0759	MICRO LABS LTD	PHARMA VILLE LIMITED	COTRIMOXAZ OLE	COTRIMOXAZ OLE	960MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2011
386	NDA/MAL/HD P/0764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 5	AMLODIPINE	5MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2011
387	NDA/MAL/HD P/0765	PHARM ACCESS AFRICA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LEVOPLANT	LEVONORGEST REL	75MG	SHANGHAI DAHUA PHARMACEUTICAL CO. LTD- CHANG ZENG FARM, CHONGMING COUNTY, SHANGHAI	CHINA	PARENTERAL RETARD IMPLANTS	1.0X10.0X2.0 ROD IMPLANT	01/07/2010
388	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1999

389	NDA/MAL/HD P/0772	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 150	PREGABALIN	150MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
390	NDA/MAL/HD P/0775	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 75	PREGABALIN	75MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
391	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/1999

392	NDA/MAL/HD P/0780	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ATORVA TABLETS	ATORVASTATI N	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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2001
393	NDA/MAL/HD P/0781	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRICOLD	PARACETAMO L/PHENYLEPH RINE HYDROCHLORI DE/CAFFEINE ANHYDROUS/ CHLORPHENIR AMINE	500MG/10MG /30MG/2MG	TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62- 64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0 X4.0 TABLET BLISTER	01/07/2013
394	NDA/MAL/HD P/0783	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	CYPOLIVE	CYPROHEPTA DINE HYDROCHLORI DE	4 MG	TRIVENI FORMULATIONS LIMITED--PLOT NO: 52,53,54, 62,63 & 64 ALEAP INDUSTRIAL ESTATE SURAMPALI VILLAGE, GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET BLISTER	01/07/2013

395	NDA/MAL/HD P/0784	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HEMOSAN	FERROUS FUMERATE	300MG	COSMOS LIMITED, KENYA- RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
396	NDA/MAL/HD P/0788	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRIDANTIN	NITROFURANT OIN	100 MG	TRIVENI FORMULATIONS LIMITED .- PLOT NO 52,53- 54,63-64 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAN MANDAL KRISHNA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
397	NDA/MAL/HD P/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGDEX	TOBRAMYCIN/ DEXAMETHAS ONE	3MG+1MG/M L	REMINGTON PHARMACEUTICALS (PVT) LTD-18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2014

398	NDA/MAL/HD P/0795	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMET HYL PENICILLIN POTASSIUM	250MG	MILAN LABORATORIES (INDIA) PVT LTD .-PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2013
399	NDA/MAL/HD P/0796	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	AMLO-H 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	01/07/2013
400	NDA/MAL/HD P/0797	NVS KENYA LTD	SURGIPHARM (U) LIMITED	AFINITOR 5MG	EVEROLIMUS	5MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2015

401	NDA/MAL/HD P/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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2013
402	NDA/MAL/HD P/0799	NVS KENYA LTD	SURGIPHARM (U) LIMITED	AFINITOR 10MG	EVEROLIMUS	10MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2015

403	NDA/MAL/HD P/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-SCHAFFHARVSETRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E- 08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
404	NDA/MAL/HD P/0808	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	ISOFLURANE	ISOFLURANE	250ML	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2005
405	NDA/MAL/HD P/0809	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	PARAPAED	PARACETAMO L	120MG/5ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013

406	NDA/MAL/HD P/0811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
407	NDA/MAL/HD P/0812	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	FENPAED	IBUPROFEN	100MG/5ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
408	NDA/MAL/HD P/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	01/07/2012
409	NDA/MAL/HD P/0820	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FIXIME 400MG	CEFIXIME	400MG	NKUNZI PHARMACEUTICALS- 259 DAVIDSON ROAD, WADEVILLEGERMISTON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER, 1.0X1.0 TABLET BLISTER, 1.0X1.0X 10.0 TABLET BLISTER	01/07/2015
410	NDA/MAL/HD P/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	01/07/2012

411	NDA/MAL/HD P/0822	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXCIN-500	CLOXACILLIN SODIUM	500MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X0.5 G VIAL	01/07/2014
412	NDA/MAL/HD P/0823	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAP TABLETS	TRAMADOL HCL + PARACETAMO L	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	01/07/2013
413	NDA/MAL/HD P/0824	I CARE PHARMA LIMITED	VITACARE LTD	CLOXACILLIN	CLOXACILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2013
414	NDA/MAL/HD P/0826	I CARE PHARMA LIMITED	VITACARE LTD	AMOXYCILLIN	AMOXYCILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2013

415	NDA/MAL/HD P/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,1.0X4.0X 25.0 TABLET BLISTER	01/07/2015
416	NDA/MAL/HD P/0831	I CARE PHARMA LIMITED	VITACARE LTD	AMPICILLIN CAPSULES	AMPICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2013
417	NDA/MAL/HD P/0832	MERCK (PTY) LTD	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,1.0X1.0X 30.0 TABLET BLISTER	01/07/2015
418	NDA/MAL/HD P/0835	AGOG PHARMA LTD.	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,1.0X100 0.0 TABLET CONTAINER	01/07/2013

419	NDA/MAL/HD P/0846	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MOXIMAC	MOXIFLOXACI N	400MG	MACLEODS PHARMACEUTICALS LTD-- PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2014
420	NDA/MAL/HD P/0848	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MACROZIDE 500	PYRAZINAMID E	500MG	MACLEODS PHARMACEUTICALS LTD--- PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER	01/07/2014
421	NDA/MAL/HD P/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	G CONTAINER	01/07/2012
422	NDA/MAL/HD P/0855	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	LAZINE	LEVOCETIRIZIN E DIHYDROCHLO RIDE	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	01/07/2013

423	NDA/MAL/HD P/0857	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID-V6 VAGINAL TABLETS	CLOTRIMAZOL E	100MG	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2000
424	NDA/MAL/HD P/0858	ASTRAZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001
425	NDA/MAL/HD P/0860	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	FLOXSAFE 400	MOXIFLOXACI N HYDROCHLORI DE	400MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0 TABLET BLISTER	01/07/2012
426	NDA/MAL/HD P/0861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZI NE	25MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJRAT,INDI A	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE	01/07/2013

427	NDA/MAL/HD P/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 BOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
428	NDA/MAL/HD P/0866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	LIZOLID	LINEZOLID	2MG/ML	AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X300.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2013

429	NDA/MAL/HD P/0867	HETERO LABS LTD UNIT IX	AIVEEN (U) LIMITED	PANTIN-20	PANTOPRAZO LE SODIUM	20MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 BOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
430	NDA/MAL/HD P/0868	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	VARMIKA-500	AMIKACIN	500MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013

431	NDA/MAL/HD P/0869	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	LARTRM	ARTEMETHER	80MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2013
432	NDA/MAL/HD P/0870	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENAD IONE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED- THOL, DIST. MEHSANA- 382728, GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2010

433	NDA/MAL/HD P/0871	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	DEXA	DEXAMETHAS ONE SODIUM	4MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	2.0X6.0X2.0 ML VIAL	01/07/2013
434	NDA/MAL/HD P/0873	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	OXYTOCIN INJECTION	OXYTOCIN	10I.U/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
435	NDA/MAL/HD P/0874	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014

436	NDA/MAL/HD P/0877	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	ANTAGIT DS GEL MINT FLAVOUR	DRIED ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	400MG + 400MG + 50MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X170.0 ML BOTTLE	01/07/2007
437	NDA/MAL/HD P/0879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBEES 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	01/07/2012
438	NDA/MAL/HD P/0882	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/2.5M G	METFORMIN + GLIBENCLAMI DE	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,1.0X4.0X 15.0 TABLET BLISTER	01/07/2012
439	NDA/MAL/HD P/0883	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/5MG	METFORMIN + GLIBENCLAMI DE	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,1.0X4.0X 15.0 TABLET BLISTER	01/07/2012

440	NDA/MAL/HD P/0889	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500. 0 ML BOTTLE	01/07/2012
441	NDA/MAL/HD P/0892	ASTRA ZENECA	MACNAUGHTON LIMITED	ONGLYZA	SAXAGLIPTIN	2.5MG	BRISTOL-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
442	NDA/MAL/HD P/0894	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	GIAGRA 100	SILDENAFIL CITRATE	100MG	HETERO LABS LTD. UNIT (V)- 439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	01/07/2014

443	NDA/MAL/HD P/0895	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH	SODIUM HYALURONAT E	10MG/1ML	VIRCHOW BIOTECH PVT, LTD- SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	01/07/2015
444	NDA/MAL/HD P/0897	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+ 100MG/G	VIRCHOW BIOTECH PVT, - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2015
445	NDA/MAL/HD P/0899	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE	CEFTRIAZONE	1G	INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML VIAL WFI	01/07/2013
446	NDA/MAL/HD P/0902	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOPINE SR	NIFEDIPINE	20MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

447	NDA/MAL/HD P/0904	ASTRA ZENECA	MACNAUGHTON LIMITED	ONGLYZA	SAXAGLIPTIN	5MG	BRISTOL-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
448	NDA/MAL/HD P/0905	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECPOD	CEFPODOXIME PROXETIL	200MG	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
449	NDA/MAL/HD P/0906	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	IONSIL	SILVER NITRATE	0.2%W/W	VIRCHOW BIOTECH PVT, - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R., DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2015

450	NDA/MAL/HD P/0907	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	CEFUXIT	CEFUROXIME AXETIL	250MG	NECTAR LIFE SCIENCES LTD-- UNIT VI BHATOLIKALAN DIST SOLAN H.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP	01/07/2013
451	NDA/MAL/HD P/0909	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	FIXINECT	CEFIXIME	100MG	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2013
452	NDA/MAL/HD P/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	01/07/2015
453	NDA/MAL/HD P/0913	NOVARTIS PHARMA	SURGIPHARM (U) LIMITED	FEMARA	LETROZOLE	2.5MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

454	NDA/MAL/HD P/0914	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	OSTEOTIDE	TERIPARATIDE [RECOMBINANT HUMAN PARATHYROID HORMONE (1- 34)] INJECTION	250MCG/ML	VIRCHOW BIOTECH PVT LTD - SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X3.0 ML VIAL	01/07/2015
455	NDA/MAL/HD P/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	01/07/2014
456	NDA/MAL/HD P/0920	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY HEAVY	BUPIVACAINE HYDROCHLORI DE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X4.0 ML VIAL	01/07/2012
457	NDA/MAL/HD P/0926	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV- 375	AMOXICILLIN +CLAVULANAT E 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,1.0X2.0X1 0.0 TABLET STRIP	01/07/2004

458	NDA/MAL/HD P/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	01/07/2013
459	NDA/MAL/HD P/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,10.0X1.0 X8.0 TABLET BLISTER	01/07/2012
460	NDA/MAL/HD P/0931	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ARH JUNIOR	ALPHA-BETA ARTEETHER	75MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJRAT,INDI A	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X1.0 ML AMPOULE	01/07/2012

461	NDA/MAL/HD P/0934	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 4	MONTELUKAS T	4MG	CADILA HEALTHCARE LTD SARKHEJ-BAVLA NH NO.8A MORAIYA TAL SANAND DISTRICT AHMEDABAD 382210	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
462	NDA/MAL/HD P/0939	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ARH	ALPHA -BETA ARTEETHER	150MG /2ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJURAT,INDI A	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE	01/07/2012
463	NDA/MAL/HD P/0941	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA	AZITHROMYCI N	200MG/5ML	AJANTA PHARMA LIMITED- 31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/2013
464	NDA/MAL/HD P/0942	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ARH FORTE	ALPHA -BETA ARTEETHER	225MG/ 3ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ- BAVLA ROAD, AHMEDABAD,GUJURAT,INDI A	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X3.0 ML AMPOULE	01/07/2012

465	NDA/MAL/HD P/0946	ASTRAZENECA	MACNAUGHTON LIMITED	TENORETIC	ATENOLOL + CHLORTHALID ONE	100 MG + 25 MG	ASTRA ZENECA UK LIMITED- SILK ROAD BUSINESS PARK,MACCLESFIELD,CHESHI RE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/1997
466	NDA/MAL/HD P/0948	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA SYRUP 5MG/5ML	LORATADINE	5MG/5ML	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2013
467	NDA/MAL/HD P/0951	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	NORAD	STERILE NORADRENALI NE CONCENTRAT E	2MG/2ML	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY S C AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2013
468	NDA/MAL/HD P/0952	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	EFECATAL	CEFTRIAXONE	1G	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013

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

472	NDA/MAL/HD P/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, 1.0X30.0 X6.0 TABLET BLISTER, 1.0X30.0 X12.0 TABLET BLISTER	01/07/2013
473	NDA/MAL/HD P/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	01/07/2013
474	NDA/MAL/HD P/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	01/07/2013

475	NDA/MAL/HD P/0969	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-2.5	AMLODIPINE BESILATE	2.5MG	EMCURE PHARMACEUTICALS LTD - LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005
476	NDA/MAL/HD P/0972	PHARCO PHARMACEUTICALS COMPANY LTD	ECHO PHARMACY (U) LIMITED	AZOMYCIN	AZITHROMYCI N DIHYDRATE	200 MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	01/07/2013
477	NDA/MAL/HD P/0975	PHARCO PHARMACEUTICALS	ECHO PHARMACY (U) LIMITED	CETRAK SYRUP	CETIRIZINE DIHYDROCHLO RIDE	5MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2013

478	NDA/MAL/HD P/0980	PHARCO PHARMACEUTICALS	ECHO PHARMACY (U) LIMITED	AZOMYCIN	AZITHROMYCI N	250MG	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	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2013
479	NDA/MAL/HD P/0981	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC SR TABLETS	DICLOFENAC SODIUM	100MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
480	NDA/MAL/HD P/0982	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASMETO-10	METOCLOPRA MIDE	10MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2014

481	NDA/MAL/HD P/0984	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	JOVAN T20	TADALAFIL	20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
482	NDA/MAL/HD P/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	01/07/2013
483	NDA/MAL/HD P/0988	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS 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	01/07/2013

484	NDA/MAL/HD P/0990	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUSIDERM CREAM	FUSIDIC ACID	2%W/W	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
485	NDA/MAL/HD P/0997	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GENUPHIL	GLUCOSAMIN E SULPHATE SODIUM CHLORIDE+ME THYLSULPHON YLMETHANE+ CHONDROITIN SULPHATE	375MG+375M G+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	01/07/2013
486	NDA/MAL/HD P/0999	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	THIOEVA	THIOTIC ACID	600MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014

487	NDA/MAL/HD P/1000	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TROYCURIUM	ATRACURIUM	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED- THOL, DIST. MEHSANA- 382728, GUJARAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE,1.0X5. 0X2.5 ML AMPOULE	01/07/2012
488	NDA/MAL/HD P/1001	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	THIOEVA	THIOTIC ACID	300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
489	NDA/MAL/HD P/1003	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZEFICAM	LORNOXICAM	8MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2013
490	NDA/MAL/HD P/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	01/07/2012

491	NDA/MAL/HD P/1007	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZINCOS DISPERSIBLE TABLETS 20MG	ZINC SULPHATE	20MG	COSMOS LIMITED, KENYA- RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
492	NDA/MAL/HD P/1009	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY 0.5%	BUPIVACAINE	5MG/ML	TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2012
493	NDA/MAL/HD P/1011	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DABORAL SYRUP	AMINOSIDINE	125MG/5ML	COSMOS LIMITED, KENYA- RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2012

494	NDA/MAL/HD P/1012	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	LOX 2%	LIDOCAINE	2% W/V	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	01/07/2013
495	NDA/MAL/HD P/1013	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	THIOSOL	THIOPENTAL SODIUM	500MG	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X20.0 ML VIAL	01/07/2013
496	NDA/MAL/HD P/1015	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN	250MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
497	NDA/MAL/HD P/1017	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYCLOX	AMPICILLIN/C LOXACILLIN	125MG/125M G	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015

498	NDA/MAL/HD P/1022	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013

499	NDA/MAL/HD P/1023	MYLAN LABORATORIES LIMITED	NORVIK ENTERPRISES LIMITED	ZINNIA P	LEVONORGEST REL + ETHINYLESTRA DIOL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER,3.0X28.0 TABLET BLISTER	01/07/2013

500	NDA/MAL/HD P/1026	BIOCON LTD	ABACUS PHARMA (AFRICA) LIMITED	INSUGEN R (REGULAR)	INSULIN HUMAN	100 IU/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE PLOT 204 PHASE IV BOMMASANDRA JIGANI LINK ROAD	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X1.0X5.0 X3.0 ML CARTRIDGE	01/07/2012
501	NDA/MAL/HD P/1027	BIOCON LTD	ABACUS PHARMA (AFRICA) LIMITED	INSUGEN-N (NPH)	INSULIN HUMAN	100 IU/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE PLOT 204 PHASE IV BOMMASANDRA JIGANI LINK ROAD	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X1.0X5.0 X3.0 ML CARTRIDGE	01/07/2012
502	NDA/MAL/HD P/1028	BIOCON LTD	ABACUS PHARMA (AFRICA) LIMITED	INSUGEN - 30/70 (BIPHASIC)	INSULIN HUMAN	30/70I.U/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE PLOT 204 PHASE IV BOMMASANDRA JIGANI LINK ROAD	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X1.0X5.0 X3.0 ML CARTRIDGE	01/07/2012
503	NDA/MAL/HD P/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	01/07/2013

504	NDA/MAL/HD P/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, 1.0X3.0X 10.0 TABLET BLISTER	01/07/2013
505	NDA/MAL/HD P/1035	GUILIN PHARMACEUTICAL CO.LTD	STAR PHARMACEUTICALS LTD	G-CIPROX	CIPROFLOXACIN	500MG	GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
506	NDA/MAL/HD P/1041	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN	RECOMBINANT HUMAN ERYTHROPOIETIN	4000 I.U/1ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0X1.0 ML PRE- FILLED SYRINGE, 1.0X1.0 X1.0 ML VIAL	01/07/2013

507	NDA/MAL/HD P/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,1.0X3.0X1 0.0 TABLET STRIP	01/07/2013
508	NDA/MAL/HD P/1044	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 80MG	VALSARTAN	80MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

509	NDA/MAL/HD P/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	01/07/2013
510	NDA/MAL/HD P/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	01/07/2013
511	NDA/MAL/HD P/1049	AGOG PHARMA LTD.	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	01/07/2012

512	NDA/MAL/HD P/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	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER,10.0X10. 0 TABLET BLISTER	01/07/2013
513	NDA/MAL/HD P/1051	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIVAL 300MG	SODIUM VALPROATE	300MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X50.0 TABLET CONTAINER	01/07/2013

514	NDA/MAL/HD P/1052	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	MICLOGEN	MICONAZOLE NITRATE+NEO MYCIN SULPHATE+CL OBETASOL PROPIONATE	2.0%W/W+0.5 %W/W+0.05% W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
515	NDA/MAL/HD P/1053	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .-PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2013
516	NDA/MAL/HD P/1054	AGOG PHARMA 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	01/07/2011

517	NDA/MAL/HD P/1055	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 40	ROSUVASTATI N CALCIUM	40MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
518	NDA/MAL/HD P/1056	AGOG PHARMA LTD.	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	01/07/2013
519	NDA/MAL/HD P/1057	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	FIXINECT- 200MG	CEFIXIME	200MG	NECTAR LIFE SCIENCES LTD- VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
520	NDA/MAL/HD P/1061	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	BISALAX	BISACODYL	5MG	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2010

521	NDA/MAL/HD P/1062	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	VANCONEX-CP	VANCOMYCIN	500MG	VENUS REMEDIES LIMITED- UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI BADDI (HP) 173205 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2013
522	NDA/MAL/HD P/1063	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VIRECTA	SILDENAFIL CITRATE	100MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0 TABLET BLISTER	01/07/2013
523	NDA/MAL/HD P/1064	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	OXOL	OXALIPLATIN	2MG/ML	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	01/07/2012

524	NDA/MAL/HD P/1065	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM-5	DIAZEPAM	5MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
525	NDA/MAL/HD P/1067	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+P ARACETAMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010
526	NDA/MAL/HD P/1068	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AROFF 100	ACECLOFENAC	100MG	UNICHEM LABORATORIES LIMITED-C-31,32 & D-10, INDUSTRIAL AREA, MEERUT ROAD, GHAZIABAD, U.P.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

527	NDA/MAL/HD P/1069	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	K-ONE INJECTION	PHYTOMENAD IONE	10MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1 .0 ML AMPOULE	01/07/2014
528	NDA/MAL/HD P/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	01/07/2013
529	NDA/MAL/HD P/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	01/07/2013

530	NDA/MAL/HD P/1074	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	CEFUAXIT	CEFUROXIME	500MG	NECTAR LIFE SCIENCES LTD- VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2013
531	NDA/MAL/HD P/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	01/07/2013
532	NDA/MAL/HD P/1077	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECTRAM	CEFTRIAXONE	1G	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*10 ML WFI AMPOULE	01/07/2013

533	NDA/MAL/HD P/1078	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT INFUSION	LEVOFLOXACI N HEMIHYDRATE	500MG	AHLCON PARENTERALS (INDIA) LTD-SP-917-918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2013
534	NDA/MAL/HD P/1079	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOG- QUININE SYRUP	QUININE HYDROCHLORI DE	100MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
535	NDA/MAL/HD P/1081	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	ACIDEX	SODIUM BICARBONATE + SODIUM ALGINATE + CALCIUM CARBONATE	267MG + 500MG + 160MG /10ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2013
536	NDA/MAL/HD P/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	01/07/2013

537	NDA/MAL/HD P/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	01/07/2013
538	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2013
539	NDA/MAL/HD P/1086	NEM LABORATORIES PRIVATE LIMITED	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	01/07/2012
540	NDA/MAL/HD P/1087	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCYCLINE	TETRACYCLINE	3%W/W	AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2013

541	NDA/MAL/HD P/1094	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O- 100	CEFIXIME	100MG/5ML	MICRO LABS LTD--NO. 121- 124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013
542	NDA/MAL/HD P/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	01/07/2012
543	NDA/MAL/HD P/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	01/07/2012

544	NDA/MAL/HD P/1100	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOVIR SKIN CREAM	ACICLOVIR	5% W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X5.0 G TUBE	01/07/2013
545	NDA/MAL/HD P/1103	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCIN CREAM	NEOMYCIN SULPHATE	0.5% W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014
546	NDA/MAL/HD P/1104	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	LIPIDUCE 10	ATORVASTATI N	10MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2014
547	NDA/MAL/HD P/1105	DAWA LIMITED	SUPER MEDIC LTD	DERMAZINE PLUS	SILVER SULPHADIAZIN E AND CHLORHEXIDI NE GLUCONATE	1%W/W / 10.0%W/W	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2014

548	NDA/MAL/HD P/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,1.0X2.0X 10.0 CAPSULE BLISTER	01/07/2013
549	NDA/MAL/HD P/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),1.0X10.0 X0.5 ML VIAL (1 DOSE)	01/07/2005
550	NDA/MAL/HD P/1109	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIR AMINE MALEATE	2MG/5ML	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2014
551	NDA/MAL/HD P/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	01/07/2013
552	NDA/MAL/HD P/1112	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ZIDOVUDINE CAPSULES	ZIDOVUDINE	100MG	AUROBINDO PHARMA LTD .- UNIT III SURVEY NO.313 BACHU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2008

553	NDA/MAL/HD P/1113	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID- YELLOW	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160. 0 ML BOTTLE	01/07/1997
554	NDA/MAL/HD P/1114	NEM LABORATORIES PRIVATE LIMITED	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	01/07/2012
555	NDA/MAL/HD P/1117	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TETRACYCLINE EYE OINTMENT USP 1%	TETRACYCLINE	1%W/W	NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE	01/07/2013
556	NDA/MAL/HD P/1122	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EAR DROPS	CHLORAMPHE NICOL	5%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 VIAL,1.0X5.0 ML VIAL	01/07/2013

557	NDA/MAL/HD P/1123	AGOG PHARMA 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,1.0X100. 0 TABLET CONTAINER	01/07/2012
558	NDA/MAL/HD P/1124	AGOG PHARMA LTD	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	01/07/2013
559	NDA/MAL/HD P/1125	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROXONE 1000	CEFTRIAXONE	1000MG	API AMMAN PHARMACEUTICAL INDUSTRIES-UNIT VI, SY. NO 329/39, 329/	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
560	NDA/MAL/HD P/1133	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDICOL SUSPENSION	CHLORAMPHE NICOL	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007

561	NDA/MAL/HD P/1136	AGOG PHARMA LTD.	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	01/07/2013
562	NDA/MAL/HD P/1138	AGOG PHARMA LTD	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	01/07/2013
563	NDA/MAL/HD P/1139	AGOG PHARMA LTD.	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	01/07/2013
564	NDA/MAL/HD P/1140	AGOG PHARMA LTD.	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	01/07/2013

565	NDA/MAL/HD P/1142	AGOG PHARMA LTD	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	01/07/2013
566	NDA/MAL/HD P/1145	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	HILAC	LACTULOSE	68%W/V	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2005
567	NDA/MAL/HD P/1148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 10	MONTELUKAS T	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	01/07/2012
568	NDA/MAL/HD P/1149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	UNIVERSAL CORPORATION LTD..-PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2015

569	NDA/MAL/HD P/1156	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FUNGICIP	CLOTRIMAZOL E	1%W/W	CIPLA LTD ----L139 TO L-146 VERNA INDUSTRIAL ESTATE VERNA SALCETTE GOA 403 722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2011
570	NDA/MAL/HD P/1158	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	TRAMADOL	TRAMADOL	50MG	TRIVENI FORMULATIONS LTD . -PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2012
571	NDA/MAL/HD P/1160	DAFRA PHARMA LTD	LABOREX 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	01/07/2011
572	NDA/MAL/HD P/1163	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	FRUSEMIDE	FUROSEMIDE	40MG	NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2013

573	NDA/MAL/HD P/1164	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	PIROXICAM	PIROXICAM	20MG	TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
574	NDA/MAL/HD P/1166	PANACEA BIOTEC LTD	VITACARE LIMITED	DOLZERO	TRAMADOL HYDROCHLORI DE + PARACETAMO L	37.5MG + 325MG	PANACEA BIOTEC LTD- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
575	NDA/MAL/HD P/1167	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	METOCLOPRA MIDE INJECTION	METOCLOPRA MIDE	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2010

576	NDA/MAL/HD P/1168	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CORT CREAM	HYDROCORTIS ONE	1%W/W	DAWA LTD -BABA DOGO ROAD, RUARAKA P.O.BOX 16633-00620, NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
577	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2013
578	NDA/MAL/HD P/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,MANDIDEEP PRADESH	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE	01/07/2013

579	NDA/MAL/HD P/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,INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2010
580	NDA/MAL/HD P/1176	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	FUNGISAFE	TERBINAFINE HYDROCHLORI DE	1%W/W	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL- OBOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2013
581	NDA/MAL/HD P/1178	HETERO DRUGS LTD	AIVEEN (U) LIMITED	TENOFOVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013

582	NDA/MAL/HD P/1179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONA DOTROPIN ALFA	250MCG/0.5ML	MERCK SERONO SA-1170 AUBONNE(SWITZERLAND) MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY	SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON	01/07/2015
583	NDA/MAL/HD P/1180	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ZIF TIMED RELEASED CAPSULES	DRIED FERROUS SULPHATE+ZINC SULPHATE MONOHYDRATE+FOLIC ACID	150MG+61.8 MG+0.5MG	SQUARE PHARMACEUTICALS LIMITED--DHAKA UNIT KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
584	NDA/MAL/HD P/1181	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ASTHATOR 4	MONTELUKAST SODIUM	4 MG	TORRENT PHARMACEUTICALS LTD .,- AHMEDABAD-MEHSANA HIGHWAY, TALUKA-KADI, DIST. MEHSANA, INDRAD- 382721, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

585	NDA/MAL/HD P/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	01/07/2013
586	NDA/MAL/HD P/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	01/07/2013
587	NDA/MAL/HD P/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	01/07/2013
588	NDA/MAL/HD P/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	01/07/2013

589	NDA/MAL/HD P/1194	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PISA	PIPERACILLIN + TAZOBACTAM	4000MG/VIAL + 500MG/VIAL	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL	01/07/2009
590	NDA/MAL/HD P/1195	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	ALTRINE	CETIRIZINE	5MG/5ML	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2013
591	NDA/MAL/HD P/1202	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX SYRUP	QUININE HYDROCHLORI DE	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2003

592	NDA/MAL/HD P/1205	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EFAVIRENZ	EFAVIRENZ	600MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008
593	NDA/MAL/HD P/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,1.0X 15.0 G CONTAINER,1.0X 30.0 G CONTAINER	01/07/2013

594	NDA/MAL/HD P/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	01/07/2011
595	NDA/MAL/HD P/1209	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-80	TELMISARTAN	80MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
596	NDA/MAL/HD P/1211	ASTRA ZENECA	MACNAUGHTON LIMITED	BRILINTA	TICAGRELOR	90MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2011
597	NDA/MAL/HD P/1212	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	01/07/2011

598	NDA/MAL/HD P/1214	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	NUCLEO C.M.P FORTE	CYTIDINE+URI DINE	5MG+3MG	FERRER INTERNACIONAL, S.A- JOAN BUCSALA 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER	01/07/2013
599	NDA/MAL/HD P/1215	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZ OLE+NEOMYCIN SULPHATE+NY STATIN	500MG+65,00 0I.U+100,000I. U	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	VAGINAL SUPPOSITORIES	1.0X10.0 TABLET BLISTER	01/07/2013
600	NDA/MAL/HD P/1218	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE-50	ARTESUNATE	50MG	M/S BLISS GVS PHARMA LIMITED -PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	01/07/2009

601	NDA/MAL/HD P/1219	DENK PHARMA GMBH &CO. KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
602	NDA/MAL/HD P/1220	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRIN E	180 MG + 1080 MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BLISTER	01/07/2008
603	NDA/MAL/HD P/1223	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/1997

604	NDA/MAL/HD P/1224	KOTRAPHARMA (M) SDN.BHD	ABACUS PHARMA (AFRICA) LIMITED	VAXCEL CEFTRIAZONE	CEFTRIAZONE	1G	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
605	NDA/MAL/HD P/1225	AMOUN PHARMACEUTICAL COMPANY	BOOTS PHARMACEUTICALS LIMITED	MOSEDIN PLUS SR	PSEUDOEPHE DRINE HYDROCHLORI DE + LORATADINE	120MG + 5MG	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL- OBOUR CITY, KALYUBIA CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	01/07/2013
606	NDA/MAL/HD P/1228	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	LUMETHER	ARTEMETHER + LUMEFANTRIN E	20 MG + 120 MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X6.0 TABLET BLISTER	01/07/2010

607	NDA/MAL/HD P/1230	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	LOXAMP	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2013
608	NDA/MAL/HD P/1238	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN INJECTION	CO- TRIMOXAZOLE	480MG/5ML	DRAXIS PHARMA INC.- QUEBEC, CANADA	CANADA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/1997
609	NDA/MAL/HD P/1242	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2013
610	NDA/MAL/HD P/1243	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 250	LEVOFLOXACI N HEMIHYDRATE	250MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61 59320 ENNIGERLOH GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
611	NDA/MAL/HD P/1247	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROCIP	CYPROHEPTA DINE	4MG	AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10. 0 TABLET BLISTER	01/07/2012

612	NDA/MAL/HD P/1250	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	STRIMOL EXTRA	PARACETAMO L+CAFFEINE	500MG+30MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAWADICROSS ANEKAL TALUK BANYALURE-562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2014
613	NDA/MAL/HD P/1252	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHAMACEAUTICALS PVT LTD- VILL ISSAPUR P.O DAPPAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2013
614	NDA/MAL/HD P/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,1.0X 100.0 TABLET CONTAINER	01/07/1998
615	NDA/MAL/HD P/1255	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NIFELAT RETARD	NIFEDIPINE	20MG	CIPLA LTD-MIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

616	NDA/MAL/HD P/1259	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ- 6.25	CARVEDILOL	6.25MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013
617	NDA/MAL/HD P/1261	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	CARDOZ-12.5	CARVEDILOL	12.5MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2013
618	NDA/MAL/HD P/1264	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	OCUCYCLINE EYE OINTMENT	TETRACYCLINE HYDROCHLORI DE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE,1.0X3.5 G TUBE	01/07/2000

619	NDA/MAL/HD P/1265	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2008
620	NDA/MAL/HD P/1274	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ROMYCIN	AZITHROMYCI N	250MG	NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER	01/07/2007
621	NDA/MAL/HD P/1275	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 10 F.C TABLETS	NIFEDIPINE	10MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
622	NDA/MAL/HD P/1278	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	01/07/2013

623	NDA/MAL/HD P/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	01/07/2016
624	NDA/MAL/HD P/1285	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR-750	CEFUROXIME	750MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/2012
625	NDA/MAL/HD P/1287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2014

626	NDA/MAL/HD P/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	01/07/2013
627	NDA/MAL/HD P/1291	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST- 300	IOPROMIDE	300MG/ML	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	01/07/2012
628	NDA/MAL/HD P/1293	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEGRA - 100	SILDENAFIL CITRATE	100MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016
629	NDA/MAL/HD P/1294	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST 370	IOPROMIDE	370MG/ML	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL	01/07/2012

630	NDA/MAL/HD P/1298	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FORTE	THIAMINE MONONITRAT E/ PYRIDOXINE/ CYANOCOBAL AMIN	245.5MG/ 250MG/ 1.4MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
631	NDA/MAL/HD P/1300	KOPRAN LIMITED	TATA UGANDA LIMITED	ATENOLOL- 100	ATENOLOL	100MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X16.0X14.0 TABLET BLISTER	01/07/1997
632	NDA/MAL/HD P/1301	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	COSAMINE PLUS	GLUCOSAMIN E SULPHATE + CHONDROITIN SULPHATE	250MG + 200MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
633	NDA/MAL/HD P/1302	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN CAPSULES	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/1997

634	NDA/MAL/HD P/1304	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE PLUS 2	GLIMEPIRIDE+ METFORMIN	1MG + 500MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
635	NDA/MAL/HD P/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	01/07/2013
636	NDA/MAL/HD P/1312	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM- 2.5	DIAZEPAM	2.5MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
637	NDA/MAL/HD P/1319	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ZESTAVAL 200 F.C TABLETS	ALBENDAZOLE	200MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	50.0X2.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1997

638	NDA/MAL/HD P/1324	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TOOTH HEAL	MULTI INGREDIENT	MULTI INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X18.0 ML BOTTLE	01/07/2005
639	NDA/MAL/HD P/1328	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	20MCG/ML	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE),1.0X25.0X 1.0 ML VIAL (1 DOSE)	01/07/1997
640	NDA/MAL/HD P/1330	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	RAPICLAV-625	AMOXYCILLIN +CLAVULANIC ACID	500MG+125M G	IPCA LABORATORIES LTD,- PLOT 69 TO 72 (B), SECTOR II, KASEZ, GANDHIDHAM - 370230, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET STRIP,1.0X7.0X3. 0 TABLET STRIP	01/07/2003
641	NDA/MAL/HD P/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	01/07/1997
642	NDA/MAL/HD P/1335	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	PREGATAS	PREGABALIN	75MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2012

643	NDA/MAL/HD P/1338	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	GRISEBEN 500	GRISEOFULVIN	500 MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
644	NDA/MAL/HD P/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	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	01/07/2016
645	NDA/MAL/HD P/1342	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHELEXIN 250	CEPHELEXIN MONOHYDRA TE	250MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2008

646	NDA/MAL/HD P/1343	MICRO LABS LTD	PHARMA VILLE LIMITED	PRAZIQUANTE L	PRAZIQUANTE 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	01/07/2013
647	NDA/MAL/HD P/1346	ASTRA PHARMA LTD	ASTRA PHARMA (U) LIMITED	ASIX	FUROSEMIDE	40MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2010
648	NDA/MAL/HD P/1347	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010

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

652	NDA/MAL/HD P/1353	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	KITPYLO - C	LANSOPRAZOL E + 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)	01/07/2015
653	NDA/MAL/HD P/1355	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	SEVOFLURANE	SEVOFLURANE	100% V/V	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2010
654	NDA/MAL/HD P/1359	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC-100 SR	DICLOFENAC SODIUM	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2016
655	NDA/MAL/HD P/1360	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ABAMUNE-L BABY	ABACAVIR SULPHATE + LAMIVUDINE	60MG + 30MG	CIPLA LTD-UNIT I & II A-32 & A-42 MIDC PATALGANGA 410220 DIST-RAIGAD, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2016

656	NDA/MAL/HD P/1361	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	FALCI CARE	ARTESUNATE	120MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*5ML OF 0.9%W/V NACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE	01/07/2016
657	NDA/MAL/HD P/1362	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV- 1000	AMOXICILLIN + CLAVULANATE	875 MG + 125 MG	MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET STRIP	01/07/2013
658	NDA/MAL/HD P/1367	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMO L	100 MG + 500 MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
659	NDA/MAL/HD P/1368	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2010

660	NDA/MAL/HD P/1370	PHARMACIE BETHEL	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,1.0X1 0.0 ML AMPOULE,1.0X7. 5 ML AMPOULE	01/07/2010
661	NDA/MAL/HD P/1374	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	VALODIN -125	CEPHADRINE	125MG/5ML	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2003
662	NDA/MAL/HD P/1377	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	WATER FOR INJECTION	WATER FOR INJECTION	N/A	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML AMPOULE	01/07/2014
663	NDA/MAL/HD P/1380	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT CREAM	HYDROCORTIS ONE	1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/1997

664	NDA/MAL/HD P/1381	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE,/ZIDOVUDINE TABLETS	LAMIVUDINE,+ ZIDOVUDINE	150MG+300M G	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	1.0X60.0 TABLET BOTTLE	01/07/2007
665	NDA/MAL/HD P/1382	HOVID BERHAD	UNITED HEALTHCARE DISTRIBUTORS LTD	INOX CAPSULES	ITRACONAZOL E	100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	01/07/2012
666	NDA/MAL/HD P/1383	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOFEN GEL	KETOPROFEN	2.5%W/W	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G CONTAINER	01/07/2013
667	NDA/MAL/HD P/1384	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE AND ZIDOVUDINE TABLETS	LAMIVUDINE + ZIDOVUDINE	30MG + 60MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013

668	NDA/MAL/HD P/1387	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAN-30	LANSOPRAZOL E	30MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0X10. 0 CAPSULE STRIP	01/07/2004
669	NDA/MAL/HD P/1389	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	NELSTAT	NYSTATIN	100000 I.U/ML	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2010
670	NDA/MAL/HD P/1390	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATI N 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	01/07/2010
671	NDA/MAL/HD P/1391	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	UNIVIR 5%	ACYCLOVIR	5%W/W	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	01/07/2010

672	NDA/MAL/HD P/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 REFILLED SYRINGE CARTON	01/07/1997
673	NDA/MAL/HD P/1395	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZO LE	40MG/5ML	ASTRA ZENECA-- KVARNBERGAGATAN12, SE- 151 SODERTALIJE	SWEDEN	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL,1.0X10.0X5. 0 ML VIAL	01/07/2010
674	NDA/MAL/HD P/1397	ASTRAZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2001
675	NDA/MAL/HD P/1399	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ASTHALIN	SALBUTAMOL	100MCG/DOS E	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE -II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2010

676	NDA/MAL/HD P/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	01/07/2015
677	NDA/MAL/HD P/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	01/07/2015

678	NDA/MAL/HD P/1403	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	DOMAXIN-RD 10MG	DOXORUBICIN HCL	10MG	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 MG VIAL	01/07/2010
679	NDA/MAL/HD P/1406	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	CEBAY DRY SYRUP	CEFIXIME TRIHYDRATE	50MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014
680	NDA/MAL/HD P/1407	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	BELIFAX	OMEPRAZOLE	20MG	PHARMATHEN S.A- 6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BOTTLE	01/07/1997
681	NDA/MAL/HD P/1408	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ROSUCOR	ROSUVASTATI N	20MG	TORRENT PHARMACEUTICALS LTD- VILLAGE. BHUD-MAKHNU MAJRA, TEHSIL: BADDI 173205 DIST SOLAN (H.P)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

682	NDA/MAL/HD P/1409	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ROMYCIN	AZITHROMYCI N	200MG/5ML	NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	01/07/2007
683	NDA/MAL/HD P/1411	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	CIPIMUM	CHLORPHENIR AMINE	4MG	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X20.0 TABLET BLISTER	01/07/2011
684	NDA/MAL/HD P/1413	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	PODINE MOUTH WASH	POVIDONE IODINE	0.1%W/V	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/2014

685	NDA/MAL/HD P/1414	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	DICLORAN SR TABLETS	DICLOFENAC SODIUM	100MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
686	NDA/MAL/HD P/1415	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND	CANDESARTA N	32MG	ASTRA ZENECA SWEDEN OPERATIONS-TABLET PRODUCTION SE-151 85, GARTUNAVAGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2011
687	NDA/MAL/HD P/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	01/07/2001
688	NDA/MAL/HD P/1418	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	AMINOPHYLLI NE TABLETS	AMINOPHYLLI NE	100MG	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2011

689	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2005
690	NDA/MAL/HD P/1422	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	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	01/07/2005
691	NDA/MAL/HD P/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	01/07/2016
692	NDA/MAL/HD P/1425	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM	COTRIMOXAZ OLE	240MG/5ML	LEBEN LABORATORIES PVT. LTD-L-4, PHASE –III, M.I.D.C,	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2007
693	NDA/MAL/HD P/1426	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	METROLEB	METRONIDAZ OLE	200MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015

694	NDA/MAL/HD P/1427	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	TENA-50	ATENOLOL	50MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X28.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2011
695	NDA/MAL/HD P/1428	UNIVERSAL CORPORATION LTD	ROYAL PHARMA 2011 LIMITED	DINAC-50	DICLOFENAC SODIUM	50 MG	UNIVERSAL CORPORATION LTD.-CLUB ROAD, PAST KIKUYU POST OFFICE, P.O. BOX 1748-00902 KIKUYU TOWN	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
696	NDA/MAL/HD P/1431	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 10	TORSEMIDE	10MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

697	NDA/MAL/HD P/1432	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORAMPHE NICOL EAR DROPS	CHLORAMPHE NICOL	5%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	OTIC DROPS	1.0X10.0 ML VIAL	01/07/2007
698	NDA/MAL/HD P/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,1.0X10 0.0X1.0 ML VIAL	01/07/1997
699	NDA/MAL/HD P/1436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARA TE	10MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250- 64293 DARMSTADT WINTHROP PHARMACEUTICALS(PTY) LTD,-315 WATLOO ROAD,WATLOO,PRETORIA,S OUTHAFRICA (FPP SECONDARY PACKAGING,FPP RELEASE/QC TESTING SITE)	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

700	NDA/MAL/HD P/1445	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	AXONE 1000	CEFTRIAXONE SODIUM	1000MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2003
701	NDA/MAL/HD P/1446	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN B COMPLEX	VITAMINS B1 + B2 + B6 + NIACINAMIDE	0.5 MG + 0.5MG + 7.5MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2015
702	NDA/MAL/HD P/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	01/07/2014
703	NDA/MAL/HD P/1450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMM ONIUM	1%W/V	NOVARTIS CONSUMER HEALTH SA-CH-1260 NYON SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE,1.0X50.0 G TUBE	01/07/1997

704	NDA/MAL/HD P/1451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1997
705	NDA/MAL/HD P/1452	ASTRA ZENECA	MACNAUGHTON LIMITED	ZESTORETIC	LISINOPRIL/HY DROCHLOROT HIAZIDE	20MG/12.5M G	ASTRAZENECA MACCLESFIELD-CESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997
706	NDA/MAL/HD P/1454	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PAINEX	PARACETAMO L + ASPIRIN + CAFFEINE	500MG + 400MG + 50 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2003
707	NDA/MAL/HD P/1457	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	DYSEN FORTE	SECNIDAZOLE	1000MG	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2006
708	NDA/MAL/HD P/1458	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	CLAVICIN INJECTION	AMOXICILLIN + POTASSIUM CLAVULANATE	1.2G	STRIDES ARCOLAB LTD - BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL	01/07/2013

709	NDA/MAL/HD P/1459	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 200	NILOTINIB	200MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2014
710	NDA/MAL/HD P/1460	VENUS REMEDIES LIMITED	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	1.0X10.0X2.0 ML PRE- FILLED SYRINGE	01/07/2009
711	NDA/MAL/HD P/1463	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ARISTOZYME LIQUID	DIASTASE+PEP SIN	50MG+10MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE	01/07/2015

712	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2014
713	NDA/MAL/HD P/1465	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTFAST 50MG	DICLOFENAC POTASSIUM	50MG	MIPHARM S.P.A -VIA BERNARDO QUARANTA, 12- 20141, MILANO ITALY.	ITALY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X3.0 SACHET CARTON	01/07/2014
714	NDA/MAL/HD P/1468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID CAPSULES	OMEPRAZOLE	20MG	S KANT HEALTHCARE LTD- PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT. CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA- 403 115, INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/1998

715	NDA/MAL/HD P/1471	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	TEMIRAL	ACICLOVIR	30MG/G	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE	01/07/2011
716	NDA/MAL/HD P/1472	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FORTUM INJECTION	CEFTAZIDIME	1GM	GLAXOSMITHKLINE LTD MANUFACTURING SPA- VERONA	ITALY	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/1997
717	NDA/MAL/HD P/1474	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGODIC	DICLOFENAC DIETHYLAMIN E	1%W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016
718	NDA/MAL/HD P/1476	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	SEPTOL	SILVER SULFADIAZINE + CHLORHEXIDI NE GLUCONATE	1%W/W + 0.20W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2016

719	NDA/MAL/HD P/1478	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA	SILDENAFIL	50MG	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARAstra STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2001
720	NDA/MAL/HD P/1481	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTROGYL	METRONIDAZ OLE	200MG	ASTRA LIFE CARE (INDIA) PVT LIMITED-57/P RAJODA 382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER	01/07/1997
721	NDA/MAL/HD P/1482	SANOPI PASTEUR	LABOREX UGANDA LIMITED	STAMARIL PASTEUR	YELLOW FEVER VIRUS 17D-204 STRAIN(LIVE ATTENUATED)	NLT 1000 I.U	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A- 2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF SOLVENT IN PRE- FILLED SYRINGE,1.0X10. 0X10.0 DOSE VIAL + 1*10*10 DOSE AMPOULE OF NS	01/07/1997

722	NDA/MAL/HD P/1485	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DICLOFEN 25	DICLOFENAC	25MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2011
723	NDA/MAL/HD P/1486	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-1	AMPICILLIN	1G	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL	01/07/2011
724	NDA/MAL/HD P/1488	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 100 RECTAL	DICLOFENAC SODIUM	100MG	HAUPT PHARMA WULFING GMBH.-BETHELNER LANDSTR. 18, 31028 GRONAU	GERMANY	RECTAL SYSTEMIC ADULT SUPPOSITORIES	10.0X1.0X2.0X5. 0 SUPPOSITORY STRIP,1.0X5.0 SUPPOSITORY STRIP	01/07/2000

725	NDA/MAL/HD P/1492	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 75 INJECTION	DICLOFENAC SODIUM	25MG/ML	HAUPT PHARMA WULFING GMBH;--BETHELNER LANDSTR. 18, 31028 GRONAULEIRE, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE	01/07/1998
726	NDA/MAL/HD P/1493	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	KOACT 1000	AMOXICILLIN/ CLAVULANATE POTASSIUM	875MG/125M G	AUROBINDO PHARMA LTD- UNIT VII (SEZ), PLOT NO.S1, GREEN INDUSTRIAL PARK, POLEPALLY (V) JEDCHERIA (M), MAHABOOB NAGAR	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2007
727	NDA/MAL/HD P/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	01/07/2013

728	NDA/MAL/HD P/1495	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	PELOX-400	PEFLOXACIN	400MG	WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP	01/07/1997
729	NDA/MAL/HD P/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	01/07/1997
730	NDA/MAL/HD P/1499	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZI NE	PROMETHAZI NE HYDROCHLORI DE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2005
731	NDA/MAL/HD P/1500	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) 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	01/07/2008

732	NDA/MAL/HD P/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	01/07/2003
733	NDA/MAL/HD P/1505	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE EVOHALER	SALMETEROL/ FLUTICASONE PROPIONATE	25/50 MCG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/2007
734	NDA/MAL/HD P/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	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2011
735	NDA/MAL/HD P/1508	IMMUCOR	SUPER MEDIC LTD	WOMNIL	ALBENDAZOLE	200MG/5ML	DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2009

736	NDA/MAL/HD P/1509	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	FEVEREX	PARACETAMO L	500MG	BETA HEALTHCARE INTERNATIONAL LTD-PLOT LR 209/6554 MOGADISHU ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA NAIROBI, 00100,	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2007
737	NDA/MAL/HD P/1510	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LISTERINE ANTISEPTIC	THYMOL + ALCOHOL 95%	12.78MG/20M L + 5.60ML/ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2001
738	NDA/MAL/HD P/1514	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOL E	100MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/1997
739	NDA/MAL/HD P/1515	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	CIPLACEF 1000	CEFTRIAXONE	1000MG	CIPLA LTD C/O OKASA- OKASA PHARMA PVT LTD L-2 ADDITIONAL MIDC SATARA 415004	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X15.0 ML VIAL 1X1 WFI AMPOULE	01/07/2007

740	NDA/MAL/HD P/1516	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL P	TRAMADOL/ PARACETAMO L	37.5MG/ 325MG	WIN MEDICARE PVT LIMITED- MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
741	NDA/MAL/HD P/1517	NEM LABORATORIES PRIVATE LIMITED	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	01/07/1998
742	NDA/MAL/HD P/1519	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 400	BUDESONIDE + FORMOTEROL FUMARATE	120 METERED DOSES (400MCG/6M CG)	CADILA HEALTHCARE LTD--- SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/2007

743	NDA/MAL/HD P/1522	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENAMOX	AMOXYCILLIN	250MG	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997
744	NDA/MAL/HD P/1523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
745	NDA/MAL/HD P/1524	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	125 MG / 5 ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008
746	NDA/MAL/HD P/1525	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	BENDEX	ALBENDAZOLE	20MG/5ML	CIPLA LTD ,,-PLOT NO. 9,10,15 INDORE SPECIAL ECONOMIC ZONE PHASE II PITHAMPUR DISTRICT DHAR MADHYA PRADESH PIN. 454775	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2007

747	NDA/MAL/HD P/1526	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMI DE + AMINOBUTYRI C ACID + AMINO HYDROXYBUT YRIC ACID + VITAMIN B6	75MG + 75MG + 37MG + 37MG	FERRER INTERNACIONAL S.A - -FOR LABORATORIOS NOVAG S.A GRAN VIA CARLOS III 94 08028 BARCELONA	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2015
748	NDA/MAL/HD P/1527	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV	AMOXICILLIN + CLAVULANATE POTASSIUM	200MG + 28.5MG/ 5ML	MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2012
749	NDA/MAL/HD P/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,1.0X2.0X 10.0 TABLET BLISTER	01/07/2007
750	NDA/MAL/HD P/1529	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PROVIRON	MESTEROLON E	25MG	BAYER WEIMAR GMBH & CO. KG- DOBEREINERSTRASSE 20 D- 99427 WEIMAR, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997

751	NDA/MAL/HD P/1531	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NOVATAX	CEFOTAXIME	1GM	MEDISPRAY LABORATORIES PVT LTD --L-1/1, L-1/2/2, ADDITIONAL MIDC SATARA 415004	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
752	NDA/MAL/HD P/1533	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	5D	GLUCOSE	50G/L	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2007
753	NDA/MAL/HD P/1535	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FORTIWIN-4	FORTIFIED PROCAINE PENICILLIN SODIUM	4 M.U	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X4.0 MU VIAL	01/07/2011
754	NDA/MAL/HD P/1537	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYZOLE	ALBENDAZOLE	200MG	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X2.0 TABLET BLISTER	01/07/2005

755	NDA/MAL/HD P/1543	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PROMAZINE ELIXIR	PROMETHAZI NE HYDROCHLORI DE	5MG/ML	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/1997
756	NDA/MAL/HD P/1544	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZI NE HYDROCHLORI DE B.P	PROMETHAZI NE 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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2004
757	NDA/MAL/HD P/1546	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LANPRO	LANSOPRAZOL E	30MG	UNICHEM LABORATORIES LTD--PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X2.0X10. 0 CAPSULE BLISTER	01/07/1999

758	NDA/MAL/HD P/1547	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	LUSIA-F	NORGESTREL/ ETHINYL ESTRADIOL + FERROUS FUMARATE	0.3MG/ 0.03MG + 75MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007
759	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999

760	NDA/MAL/HD P/1550	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	RUBIGEL	MULTI- INGREDIENT	MULTI- INGREDIENT	GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2007
761	NDA/MAL/HD P/1551	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CALOSHELL- 500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTD- LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
762	NDA/MAL/HD P/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	01/07/2004

763	NDA/MAL/HD P/1554	KOTRA PHARMA (M) SDN BHD	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 MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2010
764	NDA/MAL/HD P/1555	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES 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	01/07/2008
765	NDA/MAL/HD P/1556	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	DOMI UP	ONDASENTRO N	2MG/ML	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2014

766	NDA/MAL/HD P/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+DIPT HERIA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+ 13MCG+8MCG +5MCG+0.5M G	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE), 1.0X100.0 X0.5 ML VIAL (1 DOSE)	01/07/2010
767	NDA/MAL/HD P/1558	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	GABBRORAL	AMINOSIDINE SULPHATE	250MG	PHARMACIA AND UPJOHN S.P.A-RIJKSWEWEG 12, B-2870 PUURS	BELGIUM	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET STRIP	01/07/1998
768	NDA/MAL/HD P/1563	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL	AMOXYCILLIN	125MG/5ML	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

769	NDA/MAL/HD P/1566	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	VITAVIT	MULTI- INGREDIENT	MULTI- INGREDIENT	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2009
770	NDA/MAL/HD P/1569	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	KALETRA	LOPINAVIR+RI TONAVIR	80MG + 20MG	AESICA PHARMACEUTICALS SRL-QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X5.0X1.0X60. 0 ML BOTTLE	01/07/2007
771	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL (1 DOSE VIAL)	01/07/2013

772	NDA/MAL/HD P/1574	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AMTAS-5	AMLODIPINE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X2.0X7.0 TABLET BLISTER,10.0X10. 0 TABLET BLISTER	01/07/2003
773	NDA/MAL/HD P/1575	ASTRAZENECA	MACNAUGHTON LIMITED	ZESTRIL	LISINOPRIL	20MG	ASTRAZENECA PHARMACEUTICALS LP - HUANGSHAN ROAD, WUXI 214028, JIANGSU, CHINA. ASTRAZENECA MACCLESFIELD-CHESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997
774	NDA/MAL/HD P/1576	ASTRAZENECA	MACNAUGHTON LIMITED	ZESTRIL	LISINOPRIL	10MG	ASTRAZENECA PHARMACEUTICALS LP - HUANGSHAN ROAD, WUXI 214028, JIANGSU, CHINA. ASTRAZENECA MACCLESFIELD-UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/1997

775	NDA/MAL/HD P/1577	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	SPIROMIDE	SPIRONOLACT ONE + FRUSEMIDE	50MG+20MG	THE SEARLE COMPANY-32- KM MULTAN ROAD, LAHORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2005
776	NDA/MAL/HD P/1579	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PLASMINEX	TRANEXAMIC ACID	100MG/ML	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2011
777	NDA/MAL/HD P/1584	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UCLOX	CLOXACILLIN SODIUM	500MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2015
778	NDA/MAL/HD P/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	01/07/2010

779	NDA/MAL/HD P/1588	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	TORRENT PHARMACEUTICALS LIMITED -AHMEDABAD-MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X4.0X7. 0 TABLET BLISTER	01/07/2005
780	NDA/MAL/HD P/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 SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE,1.0X170. 0 ML BOTTLE	01/07/1997
781	NDA/MAL/HD P/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	01/07/1997
782	NDA/MAL/HD P/1598	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCIM 400	CIMETIDINE	400MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

783	NDA/MAL/HD P/1605	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ASPIRIN TABLETS	ACETYL SALICYLIC ACID	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2001
784	NDA/MAL/HD P/1614	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTAGRA-50	SILDENAFIL	50MG	ASTRA LIFE CARE (INDIA) PVT LIMITED-57/P RAJODA 382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4. 0 TABLET BLISTER	01/07/2011
785	NDA/MAL/HD P/1615	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APCALIS SX	TADALAFIL	20MG	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER	01/07/2005

786	NDA/MAL/HD P/1616	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEZIN	CETIRIZINE	5MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X30.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2011
787	NDA/MAL/HD P/1618	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMOXYDAR	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009
788	NDA/MAL/HD P/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	01/07/2004
789	NDA/MAL/HD P/1629	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 12.5	CARVEDILOL	12.5MG	INTAS PHARMACEUTICALS LTD-SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
790	NDA/MAL/HD P/1631	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE ORAL SUSPENSION	NEVIRAPINE	50MG/5ML	LABCOLD-UNIT III SURVEY NO 313& 314, BACHUPALLY (V),QUTHUBULLAPUR (M), RANGA REDDY (DIST) TELANGANA STATE,INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X240.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2007

791	NDA/MAL/HD P/1635	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ORITAXIM 1000MG INJECTION	CEFOTAXIME SODIUM	1GM	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/1997
792	NDA/MAL/HD P/1638	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLADAZOLE	SECNIDAZOLE	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005
793	NDA/MAL/HD P/1639	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL EXTRA WITH OPTIZORB	PARACETAMO L + CAFFEINE	500MG + 65MG	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X100. 0 TABLET CARTON	01/07/2003
794	NDA/MAL/HD P/1641	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	UNIENZYME C MPS	NICOTINAMID E+SIMETHICO NE+PAPAIN+F UNGAL DIASTASE+CH ARCOAL	25MG+50MG+ 30MG+20MG+ 75MG	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004

795	NDA/MAL/HD P/1642	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	EUCHLOR- 1000	CHLORAMPHE NICOL SODIUM SUCCINNATE B.P	1G	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2004
796	NDA/MAL/HD P/1645	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTAZOLE	MEBENDAZOL E	100MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT 57/P, RAJODA- 382220, BAVLA AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
797	NDA/MAL/HD P/1646	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZ OLE+DILOXANI DE	200MG+250M G	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2002

798	NDA/MAL/HD P/1650	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL CR 200	CARBAMAZEPI NE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID RETARD TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2006
799	NDA/MAL/HD P/1652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2009
800	NDA/MAL/HD P/1655	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	UNIGENTYL	SECNIDAZOLE	500MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2010
801	NDA/MAL/HD P/1656	ANHIU	MAISHA MEDICAL SUPPLIES LIMITED	AZIGYL-500	AZITHROMYCI N	500MG	MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/2015

802	NDA/MAL/HD P/1660	AGOG PHARMA 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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET STRIP	01/07/2005
803	NDA/MAL/HD P/1661	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA 100/25	LOPINAVIR/ RITONAVIR	100MG/25MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007
804	NDA/MAL/HD P/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 SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160. 0 ML BOTTLE	01/07/2003
805	NDA/MAL/HD P/1665	AGOG PHARMA LTD	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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/1998

806	NDA/MAL/HD P/1666	SANOFI AVENTIS	LABOREX UGANDA LIMITED	AMARYL 1	GLIMEPIRIDE	1MG	SANOFI AVENTIS-2 BOND STREET MIDRAND 1685 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
807	NDA/MAL/HD P/1669	SANOFI AVENTIS	LABOREX UGANDA 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	01/07/2005
808	NDA/MAL/HD P/1670	SANOFI AVENTIS	LABOREX UGANDA LIMITED	AMARYL 4	GLIMEPIRIDE	4MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005
809	NDA/MAL/HD P/1673	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL	AMOXYCILLIN	250MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2005

810	NDA/MAL/HD P/1675	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) 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),1.0X10.0X 0.5 ML VIAL (1 DOSE)	01/07/2007
811	NDA/MAL/HD P/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,1.0X 1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/1997
812	NDA/MAL/HD P/1679	LEBEN LABORATORIES PVT. LTD	ANDYCO PHARMACY (UGANDA) LTD	CIPROLEB	CIPROFLOXACIN	500MG	LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
813	NDA/MAL/HD P/1680	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	H-CORT	HYDROCORTISONE	0.1%W/W	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

814	NDA/MAL/HD P/1681	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR 25	LOSARTAN POTASSIUM	25MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X7.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2003
815	NDA/MAL/HD P/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	01/07/2004
816	NDA/MAL/HD P/1692	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX 50MG/5ML SUSPENSION	CEFPODOXIME PROXETIL	50MG/5ML	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2007
817	NDA/MAL/HD P/1693	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	OPTIMAL (0.05%) CREAM	TRETINOIN USP	0.5MG/1G	PHARMA INTERNATIONAL COMPANY .-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE	01/07/2005

818	NDA/MAL/HD P/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	01/07/2005
819	NDA/MAL/HD P/1698	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	AZEE-500	AZITHROMYCI N	500MG	CIPLA LTD.-VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3. 0 TABLET BLISTER	01/07/2009
820	NDA/MAL/HD P/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	01/07/2014
821	NDA/MAL/HD P/1702	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.05%W/W	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/2005

822	NDA/MAL/HD P/1704	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	500MG + 125MG	BILIM PHARMACEUTICALS-- CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2011
823	NDA/MAL/HD P/1708	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	DENTAMOL	ACETAMINOP HEN	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	01/07/1997
824	NDA/MAL/HD P/1709	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	LUCIN CREAM	HYDROCORTIS ONE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X15.0 G TUBE,1.0X5.0 G TUBE	01/07/1997
825	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997

826	NDA/MAL/HD P/1713	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LUMITER	ARTEMETHER + LUMEFANTRIN E	20 MG + 120 MG	MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101 OXALIS LABS -VILLAGE THEDA P.O LODHIMAJRA, THESIL BADDI DISTRICT SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER,1.0X1.0X 24.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET BLISTER,1.0X1.0X 18.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER	01/07/2007
827	NDA/MAL/HD P/1714	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	REMICOL EAR DROPS	CHLORAMPHE NICOL	1%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OTIC DROPS	1.0X10.0 ML BOTTLE	01/07/1999

828	NDA/MAL/HD P/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CH LORPHENIRA MINE+DEXTRO METHORPHAN +BROMHEXIN E	50MG+2MG+5 MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA SHELYS PHARMACEUTICALS LTD,- NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32, P.O.BOX 3016, DAR ES SALAAM	TANZANIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/1997

829	NDA/MAL/HD P/1716	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA 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	01/07/2010
830	NDA/MAL/HD P/1719	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA 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	01/07/2010
831	NDA/MAL/HD P/1723	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT MULTIVITAMI N DROPS	MULTI- INGREDIENT	MULTI- INGREDIENT	SAKAR HEALTHCARE PVT LTD- SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/2000

832	NDA/MAL/HD P/1724	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACT UATION	GLAXO OPERATIONS UK LTD-- -HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X120.0 METERED DOSE CANNISTER	01/07/2009
833	NDA/MAL/HD P/1725	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL CREAM 1%	CLOTRIMAZOL E	1%W/W	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000
834	NDA/MAL/HD P/1726	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	HAVRIX 720	INACTIVATED HEPATITIS A VIRUS ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED	720 ELISA UNITS ADSORBED ON 0.25MG ALUMINIUM HYDROXIDE	SMITHKLINE BEECHAM BIOLOGICALS , BELGIUM- BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/1997
835	NDA/MAL/HD P/1727	MISSION PHARMA	JOINT MEDICAL STORE (UPMB - UCMB)	TETRACYCLINE HYDROCLORID E	TETRACYCLINE HYDROCHLORI DE	3%W/W	NANJING BAIJINGYN PHARMACEUTICALS CO.LTD NO-1 HUIZHONG ROAD NANJING ECONOMIC AND TECHNICAL DEVELOPMENT ZONE	CHINA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2014

836	NDA/MAL/HD P/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,1.0X10.0X 14.0 TABLET STRIP	01/07/2007
837	NDA/MAL/HD P/1730	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCI N	500MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2008
838	NDA/MAL/HD P/1731	REGAL PHARMACEUTICALS LTD	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,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
839	NDA/MAL/HD P/1732	MICRO LABS LTD	LABOREX UGANDA LIMITED	CEFEX-250	CEPHALEXIN	250MG	MICROLABS LIMITED-PLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1999

840	NDA/MAL/HD P/1734	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMOMINT	COMPOUND MAGNESIUM TRISILICATE	500MG	TIL HEALTH CARE-PLOT 100,WEST,R- 5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSO T,SATYAVEDU MANDAL,CHITTOOR DISTRICT- ANDRA PRADESH-517588, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0 TABLET CONTAINER,250. 0 TABLET CONTAINER,500. 0 TABLET CONTAINER,100. 0 TABLET CONTAINER,100 0.0 TABLET CONTAINER	01/07/1997
841	NDA/MAL/HD P/1738	ALCON PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TEARS NATURELE II	NATURAL TEARS	15ML	ALCON COUVREUR NV- RIJKSWEIG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X15.0 ML BOTTLE	01/07/1997
842	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005

843	NDA/MAL/HD P/1745	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIGEN	GENTAMYCIN SULPHATE	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
844	NDA/MAL/HD P/1747	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN H 50	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2008
845	NDA/MAL/HD P/1748	AGOG PHARMA 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	01/07/2011

846	NDA/MAL/HD P/1750	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIFLOX	NORFLOXACIN	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
847	NDA/MAL/HD P/1751	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIFUCIN	FUSIDIC ACID	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X5.0 ML AMPOULE	01/07/2005
848	NDA/MAL/HD P/1754	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIMOL	TIMOLOL MALEATE	0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	01/07/2005
849	NDA/MAL/HD P/1755	MEMPHIS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOPAGON TABLETS	BROMOCRIPTI NE	2.5MG	MEMPHIS COMPANY--8 EL SAWAH STREET, CAIRO. EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1999

850	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
851	NDA/MAL/HD P/1759	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	AMLOPIN	AMLODIPINE	5MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
852	NDA/MAL/HD P/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	01/07/2005

853	NDA/MAL/HD P/1761	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ATAZOR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	EMCURE PHARMACEUTICALS LTD .- PLOT NO. P-2 IT-BT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2014
854	NDA/MAL/HD P/1762	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APITROPIN	ATROPINE	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2005
855	NDA/MAL/HD P/1763	LABORATORY&ALLIE D LTD	HARLEYS UGANDA LIMITED	ASPIRIN TABLETS BP	ACETYL SALICYLIC ACID	300MG	LABORATORY & ALLIED LTD.- PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997
856	NDA/MAL/HD P/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,1.0X 500.0 ML CONTAINER	01/07/2006

857	NDA/MAL/HD P/1765	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	RILIF PLUS	ACECLOFENAC + PARACETAMO L	100MG + 500MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
858	NDA/MAL/HD P/1766	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COLDEASE CAPSULES	PARACETAMO L+CAFFEINE CITRATE+CHL ORPHENIRAMI NE MALEATE+PSE UDOEPHEDRI NE HYDROCHLORI DE	400MG+30MG +4MG+30MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2005
859	NDA/MAL/HD P/1767	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PROSTEROL	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	01/07/2013

860	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/1999
861	NDA/MAL/HD P/1769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X10.0X0.5 ML VIAL (1 DOSE),1.0X25.0X 0.5 ML VIAL (1 DOSE)	01/07/1997
862	NDA/MAL/HD P/1771	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	ORAL REHYDRATION SALTS BP	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X100.0X20.5 G SACHET	01/07/2010
863	NDA/MAL/HD P/1773	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT 500	LEVOFLOXACI N 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,1.0X1.0X 10.0 TABLET BLISTER	01/07/2005
864	NDA/MAL/HD P/1777	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NUZAC 20	FLUOXETINE	20MG	CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003

865	NDA/MAL/HD P/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	01/07/1998
866	NDA/MAL/HD P/1779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SOLUTION	POVIDONE IODINE	10.0G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI- PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450. 0 ML BOTTLE,1.0X500. 0 ML BOTTLE	01/07/2006
867	NDA/MAL/HD P/1780	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM SUSPENSION	CO- TRIMOXAZOLE	240MG/5ML	RENE INDUSTRIES LIMITED- PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2000
868	NDA/MAL/HD P/1781	ASTRAZENECA	MACNAUGHTON LIMITED	ARIMIDEX	ANASTROZOLE	1MG	ASTRAZENECA PHARMACEUTICALS LP- NEWARK, DELAWARE	UNITED STATES	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2000

869	NDA/MAL/HD P/1782	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRIN E	PER 5ML: 15MG + 90MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
870	NDA/MAL/HD P/1783	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE OINTMENT	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 OINTMENTS	1.0X1.0X15.0 G TUBE	01/07/1997
871	NDA/MAL/HD P/1784	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AZICURE-500	AZITHROMYCI N	500MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2005

872	NDA/MAL/HD P/1785	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ACTION TABLETS	ACETYL SALICYLATE + CAFFEINE + PARACETAMO L	600MG+50MG +300MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X200.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 110.0 TABLET STRIP,1.0X12.0 TABLET BLISTER	01/07/1997
873	NDA/MAL/HD P/1786	AGOG PHARMA LTD	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	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2001
874	NDA/MAL/HD P/1790	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNITRIM TABLET	CO- TRIMOXAZOLE	480MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X250. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997
875	NDA/MAL/HD P/1792	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LIPODAR	ATORVASTATI N	20MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

876	NDA/MAL/HD P/1793	MACNAUGHTON LIMITED	MACNAUGHTON LIMITED	SYMBICORT TURBUHALER	BUDESONIDE+ FORMOTEROL	80MCG+4.5M CG/DOSE	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X60.0 DOSE CANNISTER	01/07/2001
877	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997
878	NDA/MAL/HD P/1796	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA 250	AZITHROMYCI N	250 MG	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARAstra STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X1.0X6.0 TABLET BLISTER	01/07/2006
879	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2010

880	NDA/MAL/HD P/1798	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	CARDITAS RETARD	NIFEDIPINE	20MG	INTAS PHARMACEUTICALS LTD, VATVA-7/3 G.I.D.C. ESTATE, PHASE-1, B/H DENA BANK VATVA, AHMEDABAD- 382 445 GUJARAT, INDIA INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
881	NDA/MAL/HD P/1799	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	SECZOL DS	SECNIDAZOLE	1GM	INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2001

882	NDA/MAL/HD P/1800	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLONG-10	AMLODIPINE	5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2009
883	NDA/MAL/HD P/1801	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN PESSARIES	CLOTRIMAZOLE	100MG	LABORATORY & ALLIED LTD.- -PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X1.0X6.0 PESSARY STRIP	01/07/1997
884	NDA/MAL/HD P/1803	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG	ESOMEPRAZOLE	40MG	ASTRAZENECA AB.- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON,1.0X28. 0 TABLET CARTON	01/07/2001
885	NDA/MAL/HD P/1804	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL	LISINOPRIL	5MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2001

886	NDA/MAL/HD P/1805	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORI DE	50MG + 1000MG	AESICA QUEESNBOROUGH LTD .-NORTH ROAD, QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2014
887	NDA/MAL/HD P/1807	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMPICLOX NEONATAL DROPS	AMPICILLIN + CLOXACILLIN	60 MG / 0.6 ML + 30 MG / 0.6 ML	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X8.0 ML BOTTLE	01/07/1997
888	NDA/MAL/HD P/1808	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTACID	MAGNESIUM TRISILICATE	370MG	ASTRA LIFE CARE (INDIA) PVT LIMITED-57/P RAJODA 382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
889	NDA/MAL/HD P/1809	AGOG PHARMA 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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2004

890	NDA/MAL/HD P/1810	AGOG PHARMA 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,1.0X100 0.0 TABLET CONTAINER	01/07/2010
891	NDA/MAL/HD P/1811	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	DUOVIR TABLETS	ZIDOVUDINE+ LAMIVUDINE	300MG + 150MG	CIPLA LTD---PLOT NO. 143 AND L-144A VERNA IND. ESTATE SALCETTE GOA 403 722 CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X60.0 TABLET BOTTLE	01/07/2001
892	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2001
893	NDA/MAL/HD P/1813	DAWA LIMITED	SUPER MEDIC LTD	MOXAFORTE	AMOXICILLIN + FLUCLOXACILL IN	125 MG + 125MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2014

894	NDA/MAL/HD P/1815	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	SUPIROCIN OINTMENT	MUIROCIN	2%W/W	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X15.0 G TUBE	01/07/2003
895	NDA/MAL/HD P/1816	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	DRESS UP CREAM	NEOMYCIN SULPHATE	0.5%W/W	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1998
896	NDA/MAL/HD P/1821	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL 500 TABLETS	MEFENAMIC ACID	500MG	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/1997
897	NDA/MAL/HD P/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	01/07/2005
898	NDA/MAL/HD P/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	01/07/2005
899	NDA/MAL/HD P/1827	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ALBASOL SUSPENSION	ALBENDAZOLE	200MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2006

900	NDA/MAL/HD P/1828	ASTRAZENECA	MACNAUGHTON LIMITED	TENORET	ATENOLOL + CHLORTHALID ONE	50 MG + 12.5 MG	ASTRA ZENECA UK LIMITED- SILK ROAD BUSINESS PARK,MACCLESFIELD,CHESHI RE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997
901	NDA/MAL/HD P/1833	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASMOX	AMOXICILLIN	500MG	ASTRA LIFE CARE (INDIA) PVT- SURVEY NO.57/P, SARKHEJ- BAVLA HIGHWAY, POST- RAJOD-382220, TALUKA- BAVLA, DIST-AHMEDABAD.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
902	NDA/MAL/HD P/1840	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	OVA-MIT	CLOMIPHENE	50MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2011
903	NDA/MAL/HD P/1841	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL CREAM	CLOTRIMAZOL E	1%W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2000

904	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2002
905	NDA/MAL/HD P/1843	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ECORIN-75	ASPIRIN	75MG	REMEDEX PHARMA-B- 249/250 PEENYA INDUSTRIAL ESTATE BANGALORE 560 058	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
906	NDA/MAL/HD P/1844	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
907	NDA/MAL/HD P/1846	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ANTAGIT DS GEL ORANGE FLAVOUR	ALUMINIUM HYDROXIDE + MAGNESIUM + SIMETHICONE	400MG + 400MG + 50MG	LEBEN LABORATORIES PVT. LTD.-PLOT NO. L-4, PHASE -III, M.I.D.C, AKOLA, 444104, MAHARASHTRA, INDIA.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X170.0 ML BOTTLE	01/07/2013

908	NDA/MAL/HD P/1847	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X 10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2007
909	NDA/MAL/HD P/1848	LABORATORY&ALLIE D LTD	HARLEYS UGANDA LIMITED	PARATAL	PARACETAMO L	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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
910	NDA/MAL/HD P/1849	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	CIFIN	CIPROFLOXACI N	0.2%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011

911	NDA/MAL/HD P/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	01/07/2010
912	NDA/MAL/HD P/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, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE,1.0X1.0X10 .0 G TUBE	01/07/2011
913	NDA/MAL/HD P/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,1.0X1 00.0X2.0 ML AMPOULE	01/07/2004

914	NDA/MAL/HD P/1856	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROPRANOLO L TABLETS B.P. 40MG	PROPRANOLO L HYDROCHLORI DE	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/1998
915	NDA/MAL/HD P/1861	GUILIN PHARMACEUTICALS CO LTD	STAR PHARMACEUTICALS LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
916	NDA/MAL/HD P/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-OBOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2004
917	NDA/MAL/HD P/1865	FDC LTD	AIVEEN (U) LIMITED	MYCODERM-C POWDER	CLOTRIMAZOL E	1%W/W	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	TOPICAL EXTERNAL POWDERS	1.0X75.0 G CONTAINER	01/07/2014

918	NDA/MAL/HD P/1866	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	NIZORAL	KETOCONAZO LE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
919	NDA/MAL/HD P/1873	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORI DE	50MG + 850MG	AESICA QUEESNBOROUGH LTD .-NORTH ROAD, QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2014
920	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/2007
921	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2004

922	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/2004
923	NDA/MAL/HD P/1881	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1.0X 1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2004
924	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2004

925	NDA/MAL/HD P/1887	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL	PARACETAMO L	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,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
926	NDA/MAL/HD P/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,1.0X 500.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 100.0 TABLET CARTON,1.0X10. 0 TABLET CARTON	01/07/1997

927	NDA/MAL/HD P/1891	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES 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	01/07/2005
928	NDA/MAL/HD P/1894	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-480	CO- TRIMOXAZOLE	480MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
929	NDA/MAL/HD P/1895	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2007

930	NDA/MAL/HD P/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	01/07/2001
931	NDA/MAL/HD P/1900	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOM 20	OMEPRAZOLE	20MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE STRIP	01/07/2007
932	NDA/MAL/HD P/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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2013

933	NDA/MAL/HD P/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	01/07/1997
934	NDA/MAL/HD P/1903	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	ARTESIANE 100	ARTEMETHER	100MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2007
935	NDA/MAL/HD P/1906	ACG PHARMAPACK PVT. LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ TABLETS 600MG	EFAVIRENZ	600MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1- 7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
936	NDA/MAL/HD P/1907	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR	ABACAVIR	300MG	CIPLA LTD-UNIT I & II A-32 & A-42 MIDC PATALGANGA 410220, DIST- RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2004
937	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1998

938	NDA/MAL/HD P/1912	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM	ALBENDAZOLE	200MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2008
939	NDA/MAL/HD P/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	01/07/2003
940	NDA/MAL/HD P/1915	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ATAZANAVIR SULPHATE + RITONAVIR	ATAZANAVIR SULPHATE + RITONAVIR	300 MG + 100 MG	HETERO LABS LTD UNIT III-22- 110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH , HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013

941	NDA/MAL/HD P/1918	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	UNIVIR	ACYCLOVIR	200MG	UNIVERSAL CORPORATION LTD-KIKUYU NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET STRIP	01/07/2010
942	NDA/MAL/HD P/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	01/07/1999
943	NDA/MAL/HD P/1921	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	ANTIMIN	LORATIDINE	10MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005
944	NDA/MAL/HD P/1922	IPCA LABORATORIES LIMITED	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCI N	500MG	IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER	01/07/2007
945	NDA/MAL/HD P/1923	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	BETAMETHAS ONE	BETAMETHAS ONE	0.1%W/W	GALENTIC PHARMA(INDIA) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005

946	NDA/MAL/HD P/1924	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2013
947	NDA/MAL/HD P/1925	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G - ALFENAC- P	ACECLOFENAC + PARACETAMO L	100MG + 500MG	BLISS GVS PHARMA LTD- PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
948	NDA/MAL/HD P/1927	REGAL PHARMACEUTICALS LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997

949	NDA/MAL/HD P/1929	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 40	ATORVASTATI N	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	01/07/2012
950	NDA/MAL/HD P/1931	ASTRAZENECA	MACNAUGHTON LIMITED	ZOLADEX LA	GOSERELIN ACETATE	10.8MG	ASTRA ZENECA UK LIMITED- ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL RETARD PRE- FILLED SYRINGES	1.0X10.8 MG IMPLANT	01/07/2010
951	NDA/MAL/HD P/1932	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	CANDISTAT CREAM	CLOTRIMAZOL E	1%W/W	ELYS CHEMICAL INDUSTRIES LIMITED-ROAD B', OFF ENTERPRISE ROAD PLOT NO. 209/8927 INDUSTRIAL AREA	KENYA	ORAL TOPICAL CREAMS	1.0X20.0 G TUBE	01/07/2001
952	NDA/MAL/HD P/1934	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHE NICOL	125MG/5ML	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

953	NDA/MAL/HD P/1935	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	SULPHA KREAM-N	SULPHANILAM IDE	15%W/W	NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X80.0 G TUBE	01/07/2006
954	NDA/MAL/HD P/1936	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON EXPECTORANT	CHLORPHENIR AMINE MALEATE + AMMONIUM CHLORIDE	MULTINGREDI ENT	GLAXO WELLCOME (KENYA) LTD-KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
955	NDA/MAL/HD P/1937	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	AUROBINDO PHARMA LIMITED (UNIT III) -AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD- 500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005
956	NDA/MAL/HD P/1940	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLOXACILLIN CAPSULES	CLOXACILLIN SODIUM	250MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2001

957	NDA/MAL/HD P/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOC IV	RABEPRAZOLE	20MG/VIAL	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	01/07/2005
958	NDA/MAL/HD P/1942	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMCLOREN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER	01/07/2009
959	NDA/MAL/HD P/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	01/07/2009
960	NDA/MAL/HD P/1946	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	SOLUDOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED- MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	10.0X10.0 TABLET STRIP	01/07/1998

961	NDA/MAL/HD P/1948	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCI N DIHYDRATE	500MG	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE PFIZER LABORATORIES (PTY) LTD;-- SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER	01/07/1998
962	NDA/MAL/HD P/1949	MACLEODS PHARMACEUTICALS LTDS LTD	NORVIK ENTERPRISES LIMITED	TRENAXA 500	TRANEXAMIC ACID	500MG	MACLEODS PHARMACEUTICALS -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X6.0 TABLET BLISTER	01/07/2011
963	NDA/MAL/HD P/1951	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	01/07/2006
964	NDA/MAL/HD P/1952	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NIZORAL	KETOCONAZO LE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X80.0 ML BOTTLE	01/07/1997

965	NDA/MAL/HD P/1956	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	MILOXY	AMOXYCILLIN	250MG	MILAN LABORATORIES -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,1.0X100 0.0 CAPSULE CONTAINER	01/07/2006
966	NDA/MAL/HD P/1958	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	MILOXY	AMOXYCILLIN	125MG/5ML	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005

967	NDA/MAL/HD P/1959	MILAN LABERATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	BETRIM 480	CO- TRIMOXAZOLE	480MG	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2005
968	NDA/MAL/HD P/1960	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC	DICLOFENAC SODIUM	50MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2003
969	NDA/MAL/HD P/1962	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	NIMBEX	CISATRACURIU M BESYLATE	2MG/ML	GLAXOSMITHKLINE S.P.A - STRADA PROVINCIALE ASOLANA 9	ITALY	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL,1.0X2.5 ML VIAL	01/07/1997

970	NDA/MAL/HD P/1964	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CLONEX	CLOTRIMAZOL E	1%W/W	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL STATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2007
971	NDA/MAL/HD P/1966	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	PARACIN	PARACETAMO L	500MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2005
972	NDA/MAL/HD P/1969	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SR 75MG	DICLOFENAC SODIUM	75MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY- NA	ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
973	NDA/MAL/HD P/1970	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	CETRAMAC	CETIRIZINE	10MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

974	NDA/MAL/HD P/1971	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMPICLOX ORAL SUSPENSION	AMPICILLIN + CLOXACILLIN	125 MG/5ML + 125 MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA- 410209,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
975	NDA/MAL/HD P/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	01/07/2013

976	NDA/MAL/HD P/1977	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LOSA-H	LOSARTAN + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
977	NDA/MAL/HD P/1984	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	CIALIS	TADALAFIL	20MG	LILLY SA, AVDA DE LA INDUSTRIA-LILLY SA, AVDA DE LA INDUSTRIA, 30 28108 ALCOBENDAS - MADRID	SPAIN	ORAL SOLID ORDINARY TABLETS	2.0X2.0 TABLET BLISTER	01/07/2004
978	NDA/MAL/HD P/1988	KUNMING PHARMACEUTICALS CORP	SINO AFRICA MEDICINES & HEALTH LTD	ARTEMEDINE INJECTION	ARTEMETHER	80MG/ML	KUNMING PHARMACEUTICAL CORP.- QIGONGLI, WEST SURBURB, KUNMING 650106 - YUNNAM PROVINCE, P.R. CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X0.5 ML AMPOULE	01/07/1999

979	NDA/MAL/HD P/1989	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	DERMOFIX	SERTACONAZ OLE NITRATE	2%W/W	FERRER INTERNACIONAL,S.A.- GRAN VIA CARLOS III 94 BARCELONA (ESPANA /SPAIN)	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2014
980	NDA/MAL/HD P/1990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X2. 0 TABLET BLISTER	01/07/2005
981	NDA/MAL/HD P/1997	AGOG PHARMA LTD	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,1.0X3.0X 10.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/2011
982	NDA/MAL/HD P/1998	M.J.BIOPHARM PVT LTD	TATA UGANDA LIMITED	TEICO 500	CEFEPIME	500MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013

983	NDA/MAL/HD P/1999	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPINE	200MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,2.0X 5.0X10.0 TABLET BLISTER	01/07/2000
984	NDA/MAL/HD P/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	10.0X10.0 TABLET BLISTER	01/07/2000
985	NDA/MAL/HD P/2004	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	R.B.TONE	FERROUS GLUCONATE + VITAMIN C + VITAMIN B12 + VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + CALCIUM PANTOTHENA TE + VITAMIN B3 + FOLIC ACID + DIBASIC CA PO4 + ZINC SULPHATE	200MG + 38MG + 4MCG + 3MG + 2.5MG + 1MG + 2.5MG + 1MG + 2.5MG + 23MG + 0.5MG + 100MG + 33MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X15.0 CAPSULE BLISTER	01/07/2008

986	NDA/MAL/HD P/2005	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA- 100	SILDENAFIL CITRATE	100MG	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
987	NDA/MAL/HD P/2007	AGOG PHARMA 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	01/07/2001
988	NDA/MAL/HD P/2008	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- CREAM	CLOTRIMAZOL E + BECLOMETAS ONE DIPROPIONA 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	01/07/2004
989	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010

990	NDA/MAL/HD P/2011	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	SIFE 50	SILDENAFIL CITRATE	50MG	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	1.0X4.0 TABLET BLISTER	01/07/2013
991	NDA/MAL/HD P/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	01/07/2004
992	NDA/MAL/HD P/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	01/07/2009
993	NDA/MAL/HD P/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	01/07/2000
994	NDA/MAL/HD P/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,1.0X100. 0 ML BOTTLE	01/07/1997

995	NDA/MAL/HD P/2019	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOHAL	HALOPERIDOL	10MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
996	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER	01/07/1997
997	NDA/MAL/HD P/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	01/07/2000

998	NDA/MAL/HD P/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,1.0X60.0 ML BOTTLE	01/07/1997
999	NDA/MAL/HD P/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZO LE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VIL L.MANAKPUR,TEH.NALAGAR H,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2004
1000	NDA/MAL/HD P/2025	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	FERRO-B COMPLEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
1001	NDA/MAL/HD P/2026	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 10MG	AMLODIPINE BESYLATE	10MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2009

1002	NDA/MAL/HD P/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	01/07/2013
1003	NDA/MAL/HD P/2028	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	SELANZ - SR	LANSOPRAZOL E	30MG	SEARLE PAKISTAN LIMITED- PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER	01/07/2005
1004	NDA/MAL/HD P/2029	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CHLORAMPHE NICOL PALMITATE	CHLORAMPHE NICOL PALMITATE	125MG/5ML	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014

1005	NDA/MAL/HD P/2031	AGOG PHARMA LTD.	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2004
1006	NDA/MAL/HD P/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	01/07/2009
1007	NDA/MAL/HD P/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,1.0X50.0 X3.0 TABLET BLISTER	01/07/2004
1008	NDA/MAL/HD P/2036	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN REGULAR	HUMAN INSULIN	100IU	ELI LILLY & COMPANY-LILLY TECHNOLOGY CENTER, 1555 S HARDING, INDIANAPOLIS, INDIANA, 46221 LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/1998

1009	NDA/MAL/HD P/2040	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 20/120	ARTEMETHER + LUMEFANTRIN E	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,1.0X3.0X 8.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER,1.0X1.0X 24.0 TABLET BLISTER,1.0X1.0X 18.0 TABLET BLISTER,1.0X1.0X 24.0 TABLET BLISTER	01/07/2006
1010	NDA/MAL/HD P/2041	IDA	KIMSY MEDS LTD	OXYTOCIN	OXYTOCIN	10IU	GLAND PHARMA LIMITED 143-148-D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2005

1011	NDA/MAL/HD P/2042	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	BURNCURE	SILVER SULFADIAZINE	1%W/W	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X200.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
1012	NDA/MAL/HD P/2043	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DIASTOP TABLETS	ATTAPULGITE/ ALUMINIUM HYDROXIDE	N/A	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/1998
1013	NDA/MAL/HD P/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	01/07/2006
1014	NDA/MAL/HD P/2046	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA	LORATADINE	10MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005

1015	NDA/MAL/HD P/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,1.0X 30.0 TABLET BOTTLE	01/07/2011
1016	NDA/MAL/HD P/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,1.0X1.0X1 0.0 TABLET BLISTER	01/07/2005
1017	NDA/MAL/HD P/2051	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON TABLETS	CHLORPHENIR AMINE MALEATE	4MG	GLAXO WELLCOME (KENYA) LTD-KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
1018	NDA/MAL/HD P/2053	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-5	AMLODIPINE BESILATE	5MG	EMCURE PHARMACEUTICALS LTD - LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI- BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005

1019	NDA/MAL/HD P/2055	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ARTESUN	ARTESUNATE	120MG	GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1 *2 ML AMPOULE OF 5% SODIUM BICARBONATE SOLUTION + 1*10 ML AMPOULE OF 0.9% SODIUM CHLORIDE	01/07/2011
1020	NDA/MAL/HD P/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	01/07/1997
1021	NDA/MAL/HD P/2058	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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,1.0X100 0.0 TABLET CONTAINER	01/07/2006

1022	NDA/MAL/HD P/2063	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROGYNON FE	LEVONORGEST REL / ETHINYLESTRA DIOL.	0.15MG / 0.03MG	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BLISTER	01/07/1997
1023	NDA/MAL/HD P/2066	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	METHOTREXA TE	METHOTREXA TE	2.5MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1024	NDA/MAL/HD P/2067	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET	CETIRIZINE DIHYDROCHLO RIDE	10MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10. 0 TABLET BLISTER	01/07/1999
1025	NDA/MAL/HD P/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	01/07/1999

1026	NDA/MAL/HD P/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	01/07/2010
1027	NDA/MAL/HD P/2070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGEST REL	52MG	BAYER OY-PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON	01/07/2009
1028	NDA/MAL/HD P/2071	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR DRY SYRUP	CEFALEXIN	125MG/5ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2000
1029	NDA/MAL/HD P/2073	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES VACCINE LIVE ATTENUATED(FREEZE-DRIED)	MEASLES VIRUS	NOT LESS THAN 1000CCID50/ DOSE	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML AMPOULE OF STERILE WATER FOR INJECTION,1.0X1 0.0 DOSE VIAL + 5ML AMPOULE OF STERILE WATER FOR INJECTION	01/07/1997

1030	NDA/MAL/HD P/2074	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN ORAL SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1031	NDA/MAL/HD P/2075	AGOG PHARMA LTD	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,10.0 X10.0 TABLET BLISTER	01/07/2006
1032	NDA/MAL/HD P/2076	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2006
1033	NDA/MAL/HD P/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	01/07/2007

1034	NDA/MAL/HD P/2078	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ALCLOX SYRUP	CLOXACILLIN SODIUM	125MG/5ML	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1035	NDA/MAL/HD P/2079	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	NETRAVIR	ACICLOVIR	5%W/W	GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/2005
1036	NDA/MAL/HD P/2080	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	BETAMETHAS ONE VALERATE	BETAMETHAS ONE VALERATE	0.1%W/V	GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE BELAPURNAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE	01/07/2009

1037	NDA/MAL/HD P/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 KOLHER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 DOSE VIAL),1.0X24.0X1 0.0 ML VIAL (10 DOSE VIAL)	01/07/2015
1038	NDA/MAL/HD P/2087	ABBVIE LOGISTICS BV	MEDICAL ACCESS (UGANDA) LIMITED	NORVIR	RITONAVIR	100MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2013
1039	NDA/MAL/HD P/2089	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN XR 500MG	METFORMIN HCL EXTENDED RELEASE	500MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
1040	NDA/MAL/HD P/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	01/07/2005

1041	NDA/MAL/HD P/2091	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CAMSTON	CLOTTRIMAZOL E	1%W/W	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES LTD-PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2001
1042	NDA/MAL/HD P/2092	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	DUOVIR-N	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	150MG + 300MG + 200MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X60.0 TABLET BOTTLE	01/07/2004
1043	NDA/MAL/HD P/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	01/07/2010
1044	NDA/MAL/HD P/2095	AGOG PHARMA 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	01/07/2010

1045	NDA/MAL/HD P/2097	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ALCLOX	CLOXACILLIN	250MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2011
1046	NDA/MAL/HD P/2098	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2006
1047	NDA/MAL/HD P/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	01/07/1998

1048	NDA/MAL/HD P/2100	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	ORALCON - F	LEVONORGEST REL & ETHINYLESTRA DIOL+ FERROUS FUMARATE	0.15MG + 0.03MG + 75MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2007

1049	NDA/MAL/HD P/2101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1050	NDA/MAL/HD P/2102	MEDREICH PLC	LABOREX UGANDA 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	01/07/2006
1051	NDA/MAL/HD P/2103	MEDREICH PLC	LABOREX UGANDA 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	01/07/2006

1052	NDA/MAL/HD P/2104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE/ NEVIRAPINE /ZIDOVUDINE DISPERSIBLE TABLETS	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2009
1053	NDA/MAL/HD P/2111	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	LOPINAVIR / RITONAVIR	LOPINAVIR / RITONAVIR	200MG /50MG	HETERO LABS LTD. UNIT (V) .- S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)- 509301 INDIA. HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2011

1054	NDA/MAL/HD P/2112	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2008
1055	NDA/MAL/HD P/2114	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXA-LEVO	LEVOFLOXACIN HEMIHYDRATE	500MG/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 VIAL	01/07/2015
1056	NDA/MAL/HD P/2116	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AMLOVAS-10	AMLODIPINE BESILATE	10MG	MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET STRIP	01/07/2005

1057	NDA/MAL/HD P/2118	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	RIFAFOURE E- 275	RIFAMPICIN+I SONIAZID+PYR AZINAMIDE+E THAMBUTOL	150MG+75MG +400MG+275 MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X20.0 TABLET BLISTER	01/07/2005
1058	NDA/MAL/HD P/2123	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	PLATFIRST	CISPLATIN	1MG/ML	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2014
1059	NDA/MAL/HD P/2125	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2009
1060	NDA/MAL/HD P/2128	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN INJECTION 500MG	TRANEXAMIC ACID	500MG/5ML	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2005

1061	NDA/MAL/HD P/2129	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/ CLAVULANIC ACID	500MG/125M G	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2011
1062	NDA/MAL/HD P/2130	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	ZERODOL-CR	ACECLOFENAC	200MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1063	NDA/MAL/HD P/2132	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LOPINAVIR/ RITONAVIR	LOPINAVIR/ RITONAVIR	200MG/ 50MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER	01/07/2010
1064	NDA/MAL/HD P/2133	NOVO NORDISK	STAR PHARMACEUTICALS LTD	ACTRAPID	HUMAN INSULIN	100 I.U/ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997

1065	NDA/MAL/HD P/2134	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR-250	CEFALEXIN	250MG	LA-MED HEALTHCARE PVT LTD-1389 TRASAD ROAD, DHOLKA, AHMEDABAD, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X20.0 CAPSULE BLISTER	01/07/1997
1066	NDA/MAL/HD P/2135	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	SOLITAX	CEFTRIAXONE	1G	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2010
1067	NDA/MAL/HD P/2136	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT SUPOSITORY	HYDROCORTIS ONE+ CINCHOCAINE + ESCULOSIDE+ FRAMYCETIN	5MG + 5MG +10MG +10MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	01/07/2003
1068	NDA/MAL/HD P/2137	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	SEPRODERM OINTMENT	SALICYLIC ACID + SULPHUR COMPOUND	3.6 + 2.4 MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/1998

1069	NDA/MAL/HD P/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	01/07/2005
1070	NDA/MAL/HD P/2144	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICOTIL	TENOXICAM	20MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE	01/07/2014
1071	NDA/MAL/HD P/2149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPRO GESTERONE HEXANOATE	250MG	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
1072	NDA/MAL/HD P/2151	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYCOMET 850	METFORMIN	850MG	FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000

1073	NDA/MAL/HD P/2154	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYNASE	GLIPIZIDE	5MG	FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000
1074	NDA/MAL/HD P/2156	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA 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	01/07/2011
1075	NDA/MAL/HD P/2158	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA 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	01/07/2010

1076	NDA/MAL/HD P/2159	SANOPI PASTEUR	LABOREX UGANDA LIMITED	VAXIGRIP	INFLUENZA VIRUS STRAINS H1N1 + H3N2 + B	15MCG + 15MCG + 15MCG	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A- 2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE)	01/07/2011
1077	NDA/MAL/HD P/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	01/07/2005
1078	NDA/MAL/HD P/2161	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX CREAM	ACICLOVIR	5%W/W	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/1997

1079	NDA/MAL/HD P/2164	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYCORT	HYDROCORTIS ONE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1080	NDA/MAL/HD P/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	01/07/2014
1081	NDA/MAL/HD P/2170	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ALSARTAN-AM	LOSARTAN + AMLODIPINE	50MG + 5MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2011
1082	NDA/MAL/HD P/2173	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEVO-500	LEVOFLOXACI N	500MG	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET BLISTER	01/07/2003

1083	NDA/MAL/HD P/2175	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PARAFIZZ	PARACETAMO L	500MG	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0X4.0 TABLET STRIP,1.0X4.0X4. 0 TABLET STRIP	01/07/2005
1084	NDA/MAL/HD P/2176	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2011
1085	NDA/MAL/HD P/2178	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEFUROXIME- 250	CEFUROXIME AXETIL	250MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2008

1086	NDA/MAL/HD P/2180	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PEN V	PHENOXYMET HYLPENICILLIN	125MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
1087	NDA/MAL/HD P/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 BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.5 ML TUBE (1 DOSE),1.0X50.0X 1.5 ML TUBE (1 DOSE)	01/07/2013
1088	NDA/MAL/HD P/2186	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL DIPHENHYDRA MINE PAEDIATRIC SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE + 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	01/07/2008

1089	NDA/MAL/HD P/2187	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VOMIZ	ONDANSETRO N	4MG/2ML	CADILA HEALTHCARE LTD--- SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE,1.0X5. 0X4.0 ML AMPOULE	01/07/2005
1090	NDA/MAL/HD P/2188	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PREDNISOLON E	PREDNISOLON E	5MG	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	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2010
1091	NDA/MAL/HD P/2189	KOTRA PHARMA (M) SDN BHD	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	01/07/2008
1092	NDA/MAL/HD P/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,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/1997

1093	NDA/MAL/HD P/2193	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	CIPLOX-500	CIPROFLOXACI N	500MG	CIPLA LIMITED.-PLOT NO. L- 139, S-103 & M-62, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE, GOA, PIN 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER	01/07/2007
1094	NDA/MAL/HD P/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	01/07/1997
1095	NDA/MAL/HD P/2196	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	MYCOBUTIN	RIFABUTIN	150MG	PHARMACIA AND UPJOHN S.P.A ITALY-VIA COMMESCION MARINO DEL TRONTO(ASCOLI PICENE)ITALY	ITALY	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BOTTLE	01/07/1998

1096	NDA/MAL/HD P/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	01/07/1997
1097	NDA/MAL/HD P/2198	TROGE MEDICAL GMBH	ECHO PHARMACY (U) LIMITED	TRO- CEFTRIAX	CEFTRIAXONE SODIUM	1G	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	DOSE AMPOULE	01/07/2014
1098	NDA/MAL/HD P/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,1.0X1.0X 30.0 TABLET BLISTER	01/07/2013
1099	NDA/MAL/HD P/2201	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	CLYCIN	CLINDAMYCIN PHOSPHATE	10MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LOTIONS	1.0X30.0 ML BOTTLE	01/07/2004

1100	NDA/MAL/HD P/2206	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	NETRA CORT	HYDROCORTIS ONE ACETATE	1%W/W	GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE BELAPURNAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005
1101	NDA/MAL/HD P/2208	KOTRA PHARMA SDN BDN	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN	CEPHALEXIN MONOHYDRA TE	500MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010
1102	NDA/MAL/HD P/2211	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES 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,1.0X100 0.0 ML BOTTLE	01/07/2005
1103	NDA/MAL/HD P/2212	DENK PHARMA	BENLE CONSULT LIMITED	CIPRO-DENK 500	CIPROFLOXACI N	500MG	ALLPHARMED PHARBIL ARZNEIMITTEL GMBH-12 D377081	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005

1104	NDA/MAL/HD P/2214	SINO AFRICA MEDICINES AND HEALTH LTD	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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/1997
1105	NDA/MAL/HD P/2216	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOCLOPRA MIDE	METOCLOPRA MIDE	5MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD- NO. 396 MINGZHU ROAD, HI- TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2005
1106	NDA/MAL/HD P/2217	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMINOPHYLIN E	AMINOPHYLLI NE	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	01/07/2005

1107	NDA/MAL/HD P/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,1.0X30.0 TABLET CONTAINER	01/07/1997
1108	NDA/MAL/HD P/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,1.0X3.0X1 0.0 TABLET BLISTER	01/07/2003
1109	NDA/MAL/HD P/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/GRAN ULES	1.0X10.0X5.0 G SACHET	01/07/2004
1110	NDA/MAL/HD P/2231	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX WITH CODEINE	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997

1111	NDA/MAL/HD P/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	01/07/2011
1112	NDA/MAL/HD P/2233	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE- 151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2005
1113	NDA/MAL/HD P/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	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006

1114	NDA/MAL/HD P/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	01/07/1997
1115	NDA/MAL/HD P/2237	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN- 30/70	INSULIN HUMAN(RECO MBINANT DNA ORIGIN)	100I.U/ML	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X3.0 ML VIAL	01/07/2006
1116	NDA/MAL/HD P/2238	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOCLOX	AMPICILLIN + CLOXACILLIN	125MG +125MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
1117	NDA/MAL/HD P/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	01/07/2006
1118	NDA/MAL/HD P/2242	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX 200 TABLETS	ACYCLOVIR	200MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997

1119	NDA/MAL/HD P/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	01/07/2008
1120	NDA/MAL/HD P/2248	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	TETRACYCLINE OPHTHALMIC	TETRACYCLINE	1%W/W	GALENTIC PHARMA PVT. LIMITED-R-673, TTC MIDC, RUBALE, THANE, INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE,1.0X5.0 G TUBE	01/07/2004
1121	NDA/MAL/HD P/2249	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	WOSULIN-R	INSULIN	100ML	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL	01/07/2006
1122	NDA/MAL/HD P/2250	GALENTIC PHARMA LTD	NORVIK ENTERPRISES LIMITED	CANDIGEN	CLOTRIMAZOL E	1%W/W	GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2004

1123	NDA/MAL/HD P/2252	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOL E	500MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2000
1124	NDA/MAL/HD P/2253	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	INDOMETHACI N	INDOMETHACI N	25MG	NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2005
1125	NDA/MAL/HD P/2254	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	BURN CUR CREAM	ACRIFLAVINE/ THYMOL	N/A	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998
1126	NDA/MAL/HD P/2256	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 457MG/5ML	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG / 5 ML	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X70.0 ML BOTTLE	01/07/2010

1127	NDA/MAL/HD P/2258	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300M G/600MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - - PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA GREEN STONE LIMITED-PLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X1.0X 30.0 TABLET BOTTLE	01/07/2009

1128	NDA/MAL/HD P/2262	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	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	01/07/2010
1129	NDA/MAL/HD P/2263	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 10 PLUS	AMINO ACIDS/ELECTR OLYTES	10%W/V+10% W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE - VASANA - CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001

1130	NDA/MAL/HD P/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 HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010

1131	NDA/MAL/HD P/2267	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG+300M G	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - - PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1132	NDA/MAL/HD P/2269	DAWA LIMITED	SUPER MEDIC LTD	DAWAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

1133	NDA/MAL/HD P/2270	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZITHROCIN 500	AZITHROMYCI N	500MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .- 128/1, G.I.D.C. INDUSTRIAL AREA, ANKLESHWAR, GUJARAT 393002 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2006

1134	NDA/MAL/HD P/2271	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	ARTEMETHER 20MG/LUMEF ANTRINE 120MG	ARTEMETHER + LUMEFANTRIN E	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,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X10.0 X1.0X6.0 TABLET BLISTER,1.0X10.0 X2.0X6.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X4.0X6.0 TABLET BLISTER,1.0X30.0 X3.0X6.0 TABLET BLISTER,1.0X30.0 X2.0X6.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X10.0 X4.0X6.0 TABLET BLISTER	01/07/2010

1135	NDA/MAL/HD P/2272	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA - 500	CLARITHROMY CIN	500MG	AJANTA PHARMA LTD .-B- 4//5/6, MIDC INDUSTRIALAREA, PAITHAN- 431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10 .0 TABLET BLISTER	01/07/2005
1136	NDA/MAL/HD P/2278	AVENTIS INTERCONTINENTAL	LABOREX UGANDA LIMITED	ORELOX	CEFPODOXIME PROXETIL	100MG	SANOFI WINTHROP INDUSTRIE-SANOFI WINTHROP INDUSTRIE 56, RUE DE CHOISY AU BAC 60205 COMPIÈGNE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
1137	NDA/MAL/HD P/2280	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	BETADROP-N	BETAMETHAS ONE + NEOMYCIN	0.1 %W/V + 0.5 %W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1999
1138	NDA/MAL/HD P/2281	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	LUMFORT	LORATADINE	10MG	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

1139	NDA/MAL/HD P/2282	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROPAN	PROPRANOLO L	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
1140	NDA/MAL/HD P/2283	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHThERIA TETANUS PERTUSIS	DIPHThERIA TOXOID+TETA NUS TOXOID+B.PER TUSIS ADSORBED ON ALUMINIUM PHOSPATE	>25LF(>30IU)+ >5LF(>40IU)+< 16OU(>4PU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE)	01/07/1997
1141	NDA/MAL/HD P/2284	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	LUMFORT SYRUP	LORATADINE	5MG/5ML	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2007
1142	NDA/MAL/HD P/2287	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON	01/07/1997

1143	NDA/MAL/HD P/2289	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORAMPHE NICOL	CHLORAMPHE NICOL	250MG	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD- NO. 396 MINGZHU ROAD, HI- TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2005
1144	NDA/MAL/HD P/2290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - -H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008

1145	NDA/MAL/HD P/2291	HETERO DRUGS LTD	AIVEEN (U) LIMITED	VALOVIR	VALACYCLOVIR	500MG	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 HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1146	NDA/MAL/HD P/2292	MEDREICH PLC	LABOREX UGANDA 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	01/07/2007

1147	NDA/MAL/HD P/2293	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIOCON	TIOCONAZOLE	1%W/W	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2005
1148	NDA/MAL/HD P/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,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
1149	NDA/MAL/HD P/2297	DAWA LIMITED	SUPER MEDIC LTD	SABULIN SYRUP	SALBUTAMOL SULPHATE	2MG/5ML	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2008
1150	NDA/MAL/HD P/2298	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	SAFELEVO 500	LEVOFLOXACI N	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	01/07/2013
1151	NDA/MAL/HD P/2299	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ROZITTA 20	ROSUVASTATI N CALCIUM	20MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013

1152	NDA/MAL/HD P/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	01/07/2014
1153	NDA/MAL/HD P/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	01/07/2014
1154	NDA/MAL/HD P/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	01/07/2014
1155	NDA/MAL/HD P/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	01/07/2010
1156	NDA/MAL/HD P/2312	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006

1157	NDA/MAL/HD P/2313	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X10.0 TABLET BLISTER	01/07/2006
1158	NDA/MAL/HD P/2314	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RABEMAC-20	RABEPRAZOLE SODIUM	20MG	MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2005
1159	NDA/MAL/HD P/2315	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O- 50	CEFIXIME	50MG/5ML	MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2006

1160	NDA/MAL/HD P/2318	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE-4	GLIMEPIRIDE	4MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2006
1161	NDA/MAL/HD P/2319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMO L	120MG/5ML	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
1162	NDA/MAL/HD P/2320	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ERO-125	ERYTHROMYCI N ESTOLATE	125MG/5ML	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2006
1163	NDA/MAL/HD P/2321	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN CHESTY	ORCIPRENALI NE+BROMHEX INE	5MG/5ML+ 4MG/5ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2001

1164	NDA/MAL/HD P/2322	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TREFLUCAN	FLUCONAZOLE	150MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X1.0 CAPSULE STRIP	01/07/2007
1165	NDA/MAL/HD P/2324	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	SWISSCLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X7.5 ML VIAL	01/07/2011
1166	NDA/MAL/HD P/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	01/07/2004

1167	NDA/MAL/HD P/2327	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ABACAVIR SULPHATE	ABACAVIR SULPHATE	300MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007
1168	NDA/MAL/HD P/2330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRIN E	20MG + 120MG	NOVARTIS PHARMA AG- SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND BEIJING NOVARTIS PHARMA LTD-31ST YONG'AN ROAD, CHANGPING DISTRICT, BEIJING P.R NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC- YENISEHIR MAHALLESİ İHLA VADISI SOKAK, NO.2, 34912 KURTKOY, İNSTANBUL - TURKEY	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X24.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X36.0 X6.0 TABLET BLISTER,1.0X3.0X 8.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET BLISTER	01/07/2005

1169	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE)	01/07/1997
1170	NDA/MAL/HD P/2334	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES MUMPS & RUBELLA	MEASLES VIRUS+MUMP S VIRUS+RUBELL A VIRUS	NLT 1000 CCID50+NLT 5000 CCID50 +NLT1000 CCID50	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF THE DILUENT	01/07/1997
1171	NDA/MAL/HD P/2335	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	AGOBEN TABLETS(THA NE)	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	10.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/2001
1172	NDA/MAL/HD P/2337	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROXETIL- 500	CEFUROXIME AXETIL	500MG	API AMMAN PHARMACEUTICAL INDUSTRIES-UNIT VI, SY. NO 329/39, 329/	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007

1173	NDA/MAL/HD P/2338	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE	01/07/2010
1174	NDA/MAL/HD P/2346	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ABACAVIR SULFATE ORAL SOLUTION	ABACAVIR SULPHATE	20MG/ML	LABCOLD-UNIT III SURVEY NO 313& 314, BACHUPALLY (V),QUTHUBULLAPUR (M), RANGA REDDY (DIST) TELANGANA STATE,INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2008
1175	NDA/MAL/HD P/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),1.0X50.0X1 .0 ML VIAL (1 DOSE VIAL)	01/07/2005
1176	NDA/MAL/HD P/2350	ASTRA ZENECA AB	MACNAUGHTON LIMITED	PULMICORT TURBUHALER	BUDESONIDE	200MCG	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X100.0 DOSE CANNISTER	01/07/2001

1177	NDA/MAL/HD P/2352	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAY TIME	PARACETAMO L/PSEUDOEPH EDRINE HCL/CAFFEINE	500MG+30MG +30MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X12.0 CAPSULE BLISTER	01/07/2007
1178	NDA/MAL/HD P/2353	ASTRA ZENECA	MACNAUGHTON LIMITED	NEXIUM	ESOMEPRAZO LE (AS MAGNESIUM TRIHYDRATE)	10MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON	01/07/2013
1179	NDA/MAL/HD P/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	01/07/2006

1180	NDA/MAL/HD P/2356	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE	QUININE DIHYDROCHLO RIDE	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	01/07/2005
1181	NDA/MAL/HD P/2359	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ASPIREM 75	ASPIRIN	75MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER	01/07/2007
1182	NDA/MAL/HD P/2361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMY CIN	500MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2007
1183	NDA/MAL/HD P/2362	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	CANDISTATIN OINTMENT	NYSTATIN	100,000I.U	GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	01/07/2009

1184	NDA/MAL/HD P/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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE	01/07/2005
1185	NDA/MAL/HD P/2364	MEDICO REMEDIES PVT LTD	MAISHA MEDICAL SUPPLIES LIMITED	VOXEL-500	LEVOFLOXACIN	500MG	MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2015
1186	NDA/MAL/HD P/2366	UNIQUE PHARMACEUTICALS LTD	TATA UGANDA LIMITED	IFICIPRO INJECTION	CIPROFLOXACIN	200MG/100ML	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304- 308 ,GIDC , PANOLI 394116	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005

1187	NDA/MAL/HD P/2367	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN 125	CEPHALEXIN MONOHYDRA TE	125MG/5ML	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
1188	NDA/MAL/HD P/2368	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DERMIDEX CREAM	MICONAZOLE NITRATE	2%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1189	NDA/MAL/HD P/2369	ARISTO PHARMACEUTICALS	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG INJECTION	TRANEXAMIC ACID	500MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2010
1190	NDA/MAL/HD P/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	01/07/2007

1191	NDA/MAL/HD P/2373	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	CLOBEN SKIN CREAM	CLOTRIMAZOL E/ BECLOMETAS ONE	1%W/W/ 0.025%W/W	INDOCO REMEDIES LIMITED- L-14 VERNA INDUSTRIAL AREA VERNA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2007
1192	NDA/MAL/HD P/2374	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PYRAZINAMID E TABLETS	PYRAZINAMID E	500MG	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,1.0X 10.0X10.0 TABLET STRIP	01/07/1997
1193	NDA/MAL/HD P/2375	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN 1G	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
1194	NDA/MAL/HD P/2378	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	01/07/1997

1195	NDA/MAL/HD P/2379	PT SANBE FARMA	MEDVIN PHARMA LIMITED	PUMPITOR	OMEPRAZOLE	40MG	PT SANBE FARMA JI INDUSTRI-NO.8 KOMPLEKS INDUSTRI CIMAREME PADALARANG BANDUNG	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + 1 AMPOULE OF SOLVENT	01/07/2014
1196	NDA/MAL/HD P/2383	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN	AMOXICILLIN + CLAVULANIC ACID	500 MG + 100 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X25.0 ML VIAL	01/07/1997
1197	NDA/MAL/HD P/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	01/07/2007
1198	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2000

1199	NDA/MAL/HD P/2386	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	NEOGAB	GABAPENTIN	100MG	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2005
1200	NDA/MAL/HD P/2387	DAWA LIMITED	SUPER MEDIC LTD	VERMOUT	MEBENDAZOL E	100MG/5ML	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2010
1201	NDA/MAL/HD P/2388	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	400MG + 57MG	BILIM PHARMACEUTICALS-- CERKEZKOY PLANT, 59500 CERKEZKOY, TEKIRDAG	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
1202	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X80.0 ML BOTTLE	01/07/2008

1203	NDA/MAL/HD P/2391	BIOMATRIX HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	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	01/07/1997
1204	NDA/MAL/HD P/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	01/07/2005
1205	NDA/MAL/HD P/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	01/07/2007

1206	NDA/MAL/HD P/2401	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ENAT	NATURAL VITAMIN E	400IU	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2005
1207	NDA/MAL/HD P/2404	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	LOSAR 50	LOSARTAN POTASSIUM	50MG	UNICHEM LABORATORIES LTD---VILLAGE BHATAULI KALA, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1208	NDA/MAL/HD P/2408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2001
1209	NDA/MAL/HD P/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	01/07/2004
1210	NDA/MAL/HD P/2410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007

1211	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/1997
1212	NDA/MAL/HD P/2420	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	LIDOCAINE INJ.BP	LIDOCAINE	2% W/V	INDOCO REMEDIES LTD-L- 32,33 AND VERNA INDUSTRIAL ESTATE VERNA - SALCATTIE GOA, 403722 INDIA	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X20.0 ML VIAL	01/07/2006
1213	NDA/MAL/HD P/2421	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	TAMIGEN EYE/EAR DROPS	GENTAMICIN SULPHATE	0.3%W/V	INDOCO REMEDIES LTD---L- 32, 33 & 34, VERNA IND. AREA, VERNA GOA-403722	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE,1.0X10.0 ML BOTTLE	01/07/2006
1214	NDA/MAL/HD P/2422	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	TAMIGEN-S EYE/EAR DROPS	GENTAMICIN SULPHATE+DE XAMETHASON E	0.3%W/V+0.1 %W/V	INDOCO REMEDIES LTD---L- 32, 33 & 34, VERNA IND. AREA, VERNA GOA-403722	INDIA	OTHER SYSTEMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2006

1215	NDA/MAL/HD P/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	01/07/2011
1216	NDA/MAL/HD P/2426	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PROBEX SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X225.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2000
1217	NDA/MAL/HD P/2427	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	CLONEM	CLOTRIMAZOL E	1%W/W	NEM LABORATORIES PVT LTD---133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
1218	NDA/MAL/HD P/2428	ERIS LTD	BENLE CONSULT LIMITED	CLOTRI-DENK 1% CREAM	CLOTRIMAZOL E	1%W/W	RUBIEPHARM ARZNEIMITTEL GMHH--BRUDER-GRIMU, STRABE 62, GERMANY	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1998

1219	NDA/MAL/HD P/2429	ERIS LTD	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOL E	100MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 PESSARY CARTON	01/07/1998
1220	NDA/MAL/HD P/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	01/07/2007

1221	NDA/MAL/HD P/2432	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 100	BUDESONIDE + FORMOTEROL FUMARATE	100MCG+6MC G	CADILA HEALTHCARE LTD--- SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2007
1222	NDA/MAL/HD P/2434	STRIDES SHASUN LIMITED .	DELMAN ENTERPRISES LIMITED	SOLCER	OMEPRAZOLE	40MG	STRIDES ARCOLAB LTD - BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2009
1223	NDA/MAL/HD P/2437	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	RISDONE	RISPERIDONE	1MG/ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2012
1224	NDA/MAL/HD P/2438	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC	ACECLOFENAC	100MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006

1225	NDA/MAL/HD P/2450	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	TODAY PESSARY	NONOXYNOL- 9	5%W/V	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	1.0X5.0 PESSARY BLISTER	01/07/2011
1226	NDA/MAL/HD P/2451	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN 75 SR	DICLOFENAC SODIUM	75 MG	ACINO PHARMA AG- DORNACHERSTRASSE 114, CH-4147 AESCH	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004
1227	NDA/MAL/HD P/2452	REGAL PHARMACEUTICALS LTD	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	01/07/2007
1228	NDA/MAL/HD P/2455	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	ARTEQUIN 600/750 LACTAB	ARTESUNATE + MEFLOQUINE	200 MG + 250 MG	ACINO PHARMA AG- DORNACHERSTRASSE 114, CH-4147 AESCH	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2004

1229	NDA/MAL/HD P/2458	XEPA SOUL PATTISON (M) SDN BHD	DELMAW 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	01/07/2006

1230	NDA/MAL/HD P/2459	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	P2	LEVONORGEST REL	0.75MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER	01/07/2007

1231	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/2000
1232	NDA/MAL/HD P/2461	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	UMERAN SR - 100	DICLOFENAC	100MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1233	NDA/MAL/HD P/2462	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	HISTALIN SYRUP	CHLORPHENIR AMINE MALEATE/PRO METHAZINE/D IPHENHYDRA MINE/EPHEDR INE/AMMONI UM CHLORIDE/SO DIUM CITRATE	1.0MG+ 2.5MG+5.0MG +7.5MG+90.0 MG+48.0MG/ 5ML.	REGAL PHARMACEUTICALS LTD.-PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997
1234	NDA/MAL/HD P/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	01/07/2003

1235	NDA/MAL/HD P/2470	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EURAX	CROTAMITON	10%W/W	NOVATIS CONSUMER HEALTH INC -ZYMA SA-CH- 1260 NYON SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2004
1236	NDA/MAL/HD P/2471	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.1% NASAL DROPS	XYLOMETAZOL INE	0.1%W/V	NOVARTIS CONSUMER HEALTH SA-CH-1260 NYON SWTZERLAND	SWITZERLAND	NASAL SYSTEMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2003
1237	NDA/MAL/HD P/2472	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TRAN-GEL	DICLOFENAC DIETHYLAMM ONIUM	1%W/W	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X20.0 G TUBE	01/07/2011
1238	NDA/MAL/HD P/2473	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUGREL	CLOPIDOGREL	75MG	MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010

1239	NDA/MAL/HD P/2474	SANOPI PASTEUR	LABOREX UGANDA LIMITED	TYPHIM VI	POLYSACCHAR IDES OF SALMONELLA TYPHI(TY2 STRAIN)	25MCG	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A- 2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE)	01/07/1997
1240	NDA/MAL/HD P/2475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORI DE	50MG/ML	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0X2. 0 ML AMPOULE	01/07/2001
1241	NDA/MAL/HD P/2476	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	DERIVA AQUEOUS GEL	ADAPALENE	0.1%W/W	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE	01/07/2003
1242	NDA/MAL/HD P/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	01/07/2005

1243	NDA/MAL/HD P/2480	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	ARTESIANE 40	ARTEMETHER	40MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
1244	NDA/MAL/HD P/2481	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	NETRACORT	HYDROCORTIS ONE	1%W/W	GALENTIC PHARMA PVT LIMITED-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X20.0 G TUBE	01/07/2005
1245	NDA/MAL/HD P/2496	MACLEODS PDHARMACEUTICALS LT	NORVIK ENTERPRISES LIMITED	ZETIVAS 20	ATORVASTATI N/EZETIMIBE	20MG/10MG	MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

1246	NDA/MAL/HD P/2497	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NEVIMUNE	NEVIRAPINE	50MG/5ML	CIPLA LTD --PLOT NO 9, 10 & 15, PHARMA ZONE, PHASE II, SECTOR III, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
1247	NDA/MAL/HD P/2498	MACLEODS PDHARMACEUTICALS LT	NORVIK ENTERPRISES LIMITED	ZETIVAS 10	ATORVASTATI N/EZETIMIBE	10MG/10MG	MACLEODS PHARMACEUTICALS LTD - PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
1248	NDA/MAL/HD P/2500	MACLEODS PHARMACEUTICALS LTD	ROYAL PHARMA 2011 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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2007

1249	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X7.5 ML VIAL	01/07/1997
1250	NDA/MAL/HD P/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	01/07/2011
1251	NDA/MAL/HD P/2507	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	EXERMET 1000	METFORMIN HCL	1000MG	CIPLA LTD ----D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007
1252	NDA/MAL/HD P/2508	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	HYOSCINE	HYOSCINE	20MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD- NO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2011

1253	NDA/MAL/HD P/2509	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	OPELE LOTION	BENZYL BENZOATE	25%W/V	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LOTIONS	1.0X50.0 ML BOTTLE	01/07/1997
1254	NDA/MAL/HD P/2510	PANACEA BIOTEC LTD	VITACARE LIMITED	GIRO	ORDNIDAZOLE	500MG	PANACEA BIOTEC LTD-- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN HIMACHAL PRADESH – 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X2.0X10. 0 TABLET BLISTER	01/07/2013
1255	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/1999

1256	NDA/MAL/HD P/2513	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMET HYLPENICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1257	NDA/MAL/HD P/2519	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	VITA CAP	MULTI- INGREDIENT	MULTI- INGREDIENT	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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2009
1258	NDA/MAL/HD P/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	01/07/2005

1259	NDA/MAL/HD P/2522	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PANTAZ TABLETS	PANTOPRAZO LE	40MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI 8AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
1260	NDA/MAL/HD P/2523	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	NEM LABORATORIES PVT LTD---133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/1997
1261	NDA/MAL/HD P/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 8AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

1262	NDA/MAL/HD P/2525	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER	01/07/1998
1263	NDA/MAL/HD P/2526	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOL E	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	VAGINAL COMBINATION PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE	01/07/2009
1264	NDA/MAL/HD P/2527	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ACIVIR CREAM	ACICLOVIR	5%W/W	CIPLA LTD-VERNA INDUSTRIAL ESTATE, GOA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X5.0 G TUBE	01/07/1998
1265	NDA/MAL/HD P/2528	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN	CLOTRIMAZOL E	1%W/W	LABORATORY & ALLIED LTD.-- -PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X1.0X20 .0 G TUBE	01/07/1997
1266	NDA/MAL/HD P/2529	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	G-CEFTRIA	CEFTRIAXONE	1G	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI,1.0X1.0X50. 0 G VIAL,1.0X1.0 VIAL CARTON	01/07/2012

1267	NDA/MAL/HD P/2549	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AZY-250	AZITHROMYCI N	250MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011
1268	NDA/MAL/HD P/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	01/07/2005
1269	NDA/MAL/HD P/2553	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ESOZ-20	ESOMEPRAZO LE	20MG	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0 TABLET STRIP	01/07/2003
1270	NDA/MAL/HD P/2554	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ESOZ	ESOMEPRAZO LE	40MG	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP,1.0X10.0X 10.0 TABLET STRIP	01/07/2005

1271	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER	01/07/1998
1272	NDA/MAL/HD P/2556	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	TRUVADA	EMTRICITABIN E/TENOFOVIR	200MG/300M G	PATHEON INC-ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA TAKEDA GMBH-16515 ORANIENBURG GERMANY ASPEN PHARMACARE-7 FAIRCLOUGH ROAD KORSTEN PORT ELIZABETH, 6020 SOUTH AFRICA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2005
1273	NDA/MAL/HD P/2557	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	EPSITRON 25 TABLETS	CAPTOPRIL	25MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1999

1274	NDA/MAL/HD P/2558	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U/ML	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007
1275	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2007
1276	NDA/MAL/HD P/2561	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	LANOMYCIN	AMIKACIN SULPHATE	500MG	PHARMATHEN S.A- 6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/1997
1277	NDA/MAL/HD P/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	01/07/2001

1278	NDA/MAL/HD P/2567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACI N	500MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA- 403 115, INDIA S.KANT HEALTHCARE LIMITED--PLOT NO. 1802-1805,GIDC PHASE II- 396195,DIST.VALSAD,GUJAR AT,INDIA PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328 - 1330, VILLAGE MANPURA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH - 174101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
1279	NDA/MAL/HD P/2568	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON	01/07/1997

1280	NDA/MAL/HD P/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,100.0X1 0.0 CAPSULE BLISTER	01/07/1997
1281	NDA/MAL/HD P/2571	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRIN E	180 MG + 1080 MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2010
1282	NDA/MAL/HD P/2575	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	MYTEKA	MONTELUKAS T SODIUM	10MG	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005
1283	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/2000

1284	NDA/MAL/HD P/2577	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOPCEF 200	CEFIXIME	200MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VIL L.MANAKPUR,TEH.NALAGAR H,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
1285	NDA/MAL/HD P/2578	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT TABLETS	MAGNESIUM TRISILICATE+A LUMINIUM HYDROXIDE	250MG+120M G	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER,1.0X50.0 X2.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997
1286	NDA/MAL/HD P/2579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	ARTEQUIN 300/375 LACTAB	ARTESUNATE + MEFLOQUINE	300 MG + 375 MG	ACINO PHARMA AG- DORNACHERSTRASSE 114, CH-4147 AESCH	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2005
1287	NDA/MAL/HD P/2593	E DENK OHG	BENLE CONSULT LIMITED	ATENOLOL DENK 50	ATENOLOL	50MG	ARTESAN PHARMA GMBH & CO. KG -WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

1288	NDA/MAL/HD P/2594	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2009
1289	NDA/MAL/HD P/2597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMO L	250MG	RUBIEPHARM ARZNEIMITTEL GMHH -GERMANY BENE- ARZNEIMITTEL GMBH- HERTERICHSTR. 1,81479 MUENCHEN, GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5. 0 SUPPOSITORY STRIP	01/07/2005
1290	NDA/MAL/HD P/2600	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	CLARIE-OD	CLARITHROMY CIN(EXTENTED RELEASE)	500MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X1.0X7. 0 TABLET BLISTER	01/07/2008
1291	NDA/MAL/HD P/2603	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2011

1292	NDA/MAL/HD P/2604	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	SAKAR HEALTHCARE PVT LTD- SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2000
1293	NDA/MAL/HD P/2610	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ATROPINE	ATROPINE	1MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2009
1294	NDA/MAL/HD P/2612	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER	01/07/2005
1295	NDA/MAL/HD P/2615	ASTRA ZENECA AB	MACNAUGHTON LIMITED	SYMBICORT TURBUHALER	BUDESONIDE+ FORMOTEROL	160MCG+4.5 MCG/DOSE	ASTRAZENECA AB,- GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 DOSE CANNISTER	01/07/2001
1296	NDA/MAL/HD P/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	01/07/2004

1297	NDA/MAL/HD P/2647	DENK PHARMA	BENLE CONSULT LIMITED	IBUPROFEN DENK 400MG	IBUPROFEN	400MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X1.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
1298	NDA/MAL/HD P/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 SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5. 0 SUPPOSITORY STRIP	01/07/2005
1299	NDA/MAL/HD P/2650	DENK PHARMA	BENLE CONSULT LIMITED	VIT-B-DENK	THIAMINE HCL + PYRIDOXINE HCL	100MG + 200MG	DENK PHARMA GMBH & CO.- PRINZREGENTENSTR. 79, 81675 MÜNCHEN, GÖLLSTR. 1, 84529 TITTMONING, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CARTON,1.0X10. 0X10.0 TABLET BLISTER	01/07/2005
1300	NDA/MAL/HD P/2651	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINAVIT SYRUP	MULTIVITAMI N	MULTI- INGREDIENT	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997

1301	NDA/MAL/HD P/2652	SANOFI - AVENTIS	LABOREX UGANDA LIMITED	FLAGENTYL TABLETS	SECNIDAZOLE	500MG	FAMAR LYON-29 AVENUE CHARLES DE GAULLE SAINT	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/1997
1302	NDA/MAL/HD P/2653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	SONADERM- GM	CLOBETASOL + MICONAZOLE + GENTAMICIN	0.05%W/W + 2% W/W+ 0.1%W/W	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2007
1303	NDA/MAL/HD P/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 PHARMACEUTICALS -HEAD OFFICE 36 6TH DISTRICT NASR CITY CAIRO EGYPT PLANT ABUSULTAN ISMAILIA	EGYPT	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	01/07/2006
1304	NDA/MAL/HD P/2657	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	XEPIL	CARBAMAZEP INE	200MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X5.0 TABLET BLISTER	01/07/1997
1305	NDA/MAL/HD P/2670	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	SENSINIL	LIDOCAINE	2%W/V	CLARIS INJECTABLE LIMITED-- CHACHARWADI VASANA AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL,1.0X20.0 ML VIAL,1.0X30.0 ML VIAL	01/07/2005

1306	NDA/MAL/HD P/2671	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	DUOLIN RESPULES	IPRATROPIUM BROMIDE & SALBUTAMOL	500MG + 2.5 MG /2.5ML	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION LIQUID FOR INHALATION	4.0X5.0X2.5 ML VIAL	01/07/2005
1307	NDA/MAL/HD P/2673	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	STRADUMEL	ALLOPURINOL	300MG	PHARMATHEN S.A- 6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BOTTLE,1.0X25.0 TABLET BOTTLE	01/07/1997
1308	NDA/MAL/HD P/2675	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	LIBITUS PLUS SYRUP	TERBUTALINE/ BROMHEXINE/ GUAIPHENESI N	1.25MG/ 4MG/ 50 MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011
1309	NDA/MAL/HD P/2678	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FORCAN-150	FLUCONAZOLE	150MG	CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE BLISTER	01/07/2004

1310	NDA/MAL/HD P/2679	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2006
1311	NDA/MAL/HD P/2680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007
1312	NDA/MAL/HD P/2681	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2007
1313	NDA/MAL/HD P/2683	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN C	ASCORBIC ACID	100MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005

1314	NDA/MAL/HD P/2685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUS PENSION)	PARACETAMO L	120MG/5ML	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X 60.0 ML BOTTLE	01/07/2007
1315	NDA/MAL/HD P/2686	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMOXYDAR FORTE	AMOXICILLIN TRIHYDRATE	250MG/5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009
1316	NDA/MAL/HD P/2687	M.J BIOPHARM PVT LTD	TATA UGANDA LIMITED	TEICO 1000	CEFEPIME	1000MG	M.J BIOPHARM PVT LTD- TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2013
1317	NDA/MAL/HD P/2688	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMOXYN-250	AMOXICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2011
1318	NDA/MAL/HD P/2690	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-250	AMPICILLIN	250MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2011

1319	NDA/MAL/HD P/2691	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AMPIMAX-500	AMPICILLIN	500MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL	01/07/2011
1320	NDA/MAL/HD P/2696	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	AMPHOTRET	AMPHOTERICI N B	50MG	BHARAT SERUMS AND VACCINES LTD- PLOT NO. K- 27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON	01/07/2012
1321	NDA/MAL/HD P/2697	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTIS ONE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1322	NDA/MAL/HD P/2698	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-500	AZITHROMYCI N	500MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	01/07/2009

1323	NDA/MAL/HD P/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	01/07/2005
1324	NDA/MAL/HD P/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	01/07/2004
1325	NDA/MAL/HD P/2704	MACLEODS PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	PRIMACORT- 100	HYDROCORTIS ONE 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	01/07/2005
1326	NDA/MAL/HD P/2705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE- 151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL	01/07/2011

1327	NDA/MAL/HD P/2706	SOLVAY PHARMACEUTICALS BV	HARLEYS UGANDA LIMITED	DUSPATALIN	MEBEVERINE HCL	135MG	SOLVAY PHARMACEUTICALS PV-VEERVEG 12 8121 AA 0187 NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X5.0 TABLET BLISTER	01/07/2008
1328	NDA/MAL/HD P/2707	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMCLOXA	CLOXACILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,250. 0 CAPSULE CONTAINER,500. 0 CAPSULE CONTAINER,100 0.0 CAPSULE CONTAINER,10.0 CAPSULE CONTAINER	01/07/1997
1329	NDA/MAL/HD P/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,1.0X 2.0X50.0 TABLET BLISTER	01/07/2000
1330	NDA/MAL/HD P/2710	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/1997

1331	NDA/MAL/HD P/2712	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	ANAWIN	BUPIVACAINE	0.025%W/V	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2014
1332	NDA/MAL/HD P/2714	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	ANAFRANIL	CLOMIPRAMI NE	25MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY- NA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
1333	NDA/MAL/HD P/2715	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE	LAMIVUDINE	150MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X60.0 TABLET CONTAINER	01/07/2008
1334	NDA/MAL/HD P/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	01/07/2000

1335	NDA/MAL/HD P/2718	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	GYNOMIN	Z	Z	SHAIGAN PHARMACEUTICALS (PVT) LIMITED-14 KM ADYALA RD, RAWALPINDI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/1997
1336	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X80.0 ML BOTTLE	01/07/2007
1337	NDA/MAL/HD P/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	01/07/2007
1338	NDA/MAL/HD P/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	01/07/2007
1339	NDA/MAL/HD P/2723	TABROS PHARMA	HEALTHCARE LTD.	DURAGESIC TABLET	PARACETAMO L + ORPHENADRI NE	450MG+35MG	TABROS PHARMA-L-20/B SECTOR 22 FB INDUSTRIAL AREA KARACHI PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

1340	NDA/MAL/HD P/2730	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	TRICLOVERA	MEDROXYPRO GESTERONE ACETATE	150MG/ML	PT TUNGGAI IDAMAN ABDI,- J1.JEND.YANI NO.7 JAKARTA TIMUR	INDONESIA	PARENTERAL ORDINARY I M VIALS	1.0X20.0X1.0 ML VIAL	01/07/2010
1341	NDA/MAL/HD P/2734	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMLODAR-10	AMLODIPINE BESILATE	10MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2009
1342	NDA/MAL/HD P/2737	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	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	01/07/2004
1343	NDA/MAL/HD P/2738	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ INFUSION	L-ORNITHINE- L-ASPARTATE	5MG/ML	WIN-MEDICARE PRIVATE LIMITED-MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X5.0X10.0 ML VIAL	01/07/2001
1344	NDA/MAL/HD P/2739	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	BISPANOL TABLET	HYOSCINE BUTYLBROMID E	10MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2001

1345	NDA/MAL/HD P/2745	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENFORMIN	METFORMIN HYDROCHLORI DE	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2015
1346	NDA/MAL/HD P/2746	ERIS LTD	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER	01/07/2000
1347	NDA/MAL/HD P/2751	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	FLUDAC CAPSULES	FLUOXETINE HCL	20MG	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRCT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER	01/07/1997
1348	NDA/MAL/HD P/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	01/07/2009

1349	NDA/MAL/HD P/2754	FDC LTD	AIVEEN (U) LIMITED	ZATHRIN 500	AZITHROMYCIN DIHYDRATE	500MG	FDC LIMITED -PLOT NO. L121 B VERNA INDUSTRIAL ESTATE VERNA SALCETE GOA 403 722	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER, 1.0X50.0 X1.0X1.0X3.0 TABLET BLISTER	01/07/2016
1350	NDA/MAL/HD P/2756	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	CYTOTEC	MISOPROSTOL	200MCG	PIRAMAL HEALTHCARE LIMITED-WALTON ROAD MORPETH NORTHUMBERLAND NE 613YA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
1351	NDA/MAL/HD P/2760	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELATED DRY COUGH SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE+DEXTROM ETHORPHAN+ SODIUM CITRATE+MEN THOL	14MG+6.5MG +57MG+2MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
1352	NDA/MAL/HD P/2765	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HAEM F	FOLICACID+ VITAMIN B12+IRON AMMONIUM CITRATE	1MG+5MCG+2 00MG/15ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2004

1353	NDA/MAL/HD P/2767	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	PHENOXYMET HYLPENICILLIN TABLETS BP	PHENOXYMET HYLPENICILLIN	250MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010
1354	NDA/MAL/HD P/2773	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	BISPANOL ELIXIR	HYOSCINE-N- BUTYLBROMID E	5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2004
1355	NDA/MAL/HD P/2774	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	BACTIFLOX NEO 500	CIPROFLOXACI N	500MG	ACINO PHARMA AG.- DORNACHERSTRASSE 114, CH-4147 AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2005

1356	NDA/MAL/HD P/2776	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	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,1.0X100 0.0 TABLET CONTAINER,14.0 X10.0 TABLET BLISTER	01/07/1997
1357	NDA/MAL/HD P/2779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SURGICAL SCRUB	POVIDONE IODINE	7.5%W/V	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI- PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450. 0 ML BOTTLE,1.0X500. 0 ML BOTTLE	01/07/2006
1358	NDA/MAL/HD P/2781	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 6.25	CARVEDILOL	6.25MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

1359	NDA/MAL/HD P/2783	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIE S 25MG	DICLOFENAC SODIUM	25MG	DELPHARM HUNINGUE S.A.S- -SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006
1360	NDA/MAL/HD P/2784	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	AMOXICILLIN ORAL SUSPENSION	AMOXICILLIN	125MG/5ML	MEDICAMEN BIOTECH LTD- SP-1192, A & B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009
1361	NDA/MAL/HD P/2788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIVITAMI N TABLETS	MULTIINGRED IENT	N/A	RENE INDUSTRIES LIMITED- PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010
1362	NDA/MAL/HD P/2790	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	TG-TOR 20	ATORVASTATI N	20MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003

1363	NDA/MAL/HD P/2792	UNICHEM LABORATORIES LIMITEDv	EUROPA HEALTHCARE (U) LTD	TG-TOR 10	ATORVASTATI N	10MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2003
1364	NDA/MAL/HD P/2793	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	VIREAD	TENOFOVIR DISOPROXIL FUMARATE	300MG	PATHEON YM INC. TORONTO TORONTO, CANADA ASPEN PHARMACARE-7 FAIRCLOUGH ROAD KORSTEN PORT ELIZABETH, 6020 SOUTH AFRICA TAKEDA GMBH,PLANT ORANIENBURG- LEHNITZSTRASSE 70- 98,16515,ORANIENBURG- GERMANY	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE	01/07/2004

1365	NDA/MAL/HD P/2796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICIL LIN INJECTION	BENZYL PENICIL LIN SODIUM	1,000,000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE (WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON, 1.0X50. 0 VIAL CARTON	01/07/2001
1366	NDA/MAL/HD P/2797	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	LUMAREN	ARTEMETHER + LUMEFANTRIN E	20 MG + 120 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER	01/07/2010
1367	NDA/MAL/HD P/2800	NOVO NORDISK	STAR PHARMACEUTICALS LTD	ACTRAPID HM PENFILL	HUMAN INSULIN	100 I.U/ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.5 ML PREFILLED PEN, 1.0X3.0 ML PREFILLED PEN	01/07/1997
1368	NDA/MAL/HD P/2802	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	TASOL	CLOBETASOL	0.05%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005

1369	NDA/MAL/HD P/2805	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 20R TABLETS	NIFEDIPINE	20MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
1370	NDA/MAL/HD P/2807	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ASAQ GPSC	ARTESUNATE + AMODIAQUIN E	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,1.0X20.0 X6.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2011
1371	NDA/MAL/HD P/2809	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	MAITRI	PEG 150OBP/ PEG 100OBP	1280MG/ 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	VAGINAL TABLETS	1.0X5.0 PESSARY STRIP	01/07/2008

1372	NDA/MAL/HD P/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	01/07/2001
1373	NDA/MAL/HD P/2812	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	CO-ARTESIANE	BETA ARTEMETHER + LUMEFANTRIN E	180 MG/60ML + 1080 MG/60ML	MANUFACTURING PACKAGING FARMACIA APPELHOF OUDEHASK- NETHERLANDS	NETHERLANDS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2005
1374	NDA/MAL/HD P/2813	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	INTACYCLINE SKIN OINTMENT	TETRACYCLINE HYDROCHLORI DE	3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1375	NDA/MAL/HD P/2814	THE ARAB DRUG COMPANY	GOODMAN INTERNATIONAL LTD	VENTAL PLUS	SALBUTAMOL + BECLOMETHA SONE DIPROPIONAT E	0.1MG + 0.05MG/ PUFF	THE ARAB DRUG COMPANY- 5-EL MASSANEI ST AL AMEREYA CAIRO	EGYPT	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 DOSE CANNISTER	01/07/2014
1376	NDA/MAL/HD P/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	01/07/1997

1377	NDA/MAL/HD P/2821	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DIOLIN-M	GLIBENCLAMI DE+METFORM IN HYDROCHLORI DE TABLETS	5MG+500MG	LINCOLN PHARMACEUTICAL LIMITED..-LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2011
1378	NDA/MAL/HD P/2826	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON SYRUP	CHLORPHENIR AMINE MALEATE	4MG/10ML	GLAXOSMITHKLINE-LIKONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L BOTTLE	01/07/1997
1379	NDA/MAL/HD P/2830	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX MIXTURE	QUININE HYDROCHLORI DE	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD (BWEYOGERERE)	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2003
1380	NDA/MAL/HD P/2838	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 120	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORI DE	120MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2010

1381	NDA/MAL/HD P/2848	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROGENTA OINTMENT	BETAMETHAS ONE /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	01/07/2001
1382	NDA/MAL/HD P/2850	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DISPERCAM	PIROXICAM	20MG	MEDICAL UNION PHARMACEUTICALS-36 DR MOHAMED HASSAN EL- GAMAL ST.6TH DISTRICT NASR CITY EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE	01/07/2007
1383	NDA/MAL/HD P/2867	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII RABIVAX	RABIES VACCINE	2.5I.U/ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2005
1384	NDA/MAL/HD P/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,1.0X10.0 X7.0 TABLET BLISTER	01/07/2003

1385	NDA/MAL/HD P/2869	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PRIORIX VACCINE	MEASLES + MUMPS + RUBELLA	103.0CCID50 + 103.7CCID50 + 103.0CCID50	GLAXO SMITHKLINE BIOLOGICALS S.A-RUE DE L'INSTITUT, 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2010
1386	NDA/MAL/HD P/2873	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HELIGO KIT	TINIDAZOLE/C LARITHROMYC IN/LANSOPRA ZOLE	500MG+ 250MG+30MG	INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET BLISTER	01/07/2001
1387	NDA/MAL/HD P/2875	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.05% NASAL DROPS	XYLOMETAZOL INE	0.05%W/V	NOVARTIS CONSUMER HEALTH SA-CH-1260 NYON SWTZERLAND	SWITZERLAND	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2003
1388	NDA/MAL/HD P/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	01/07/2000

1389	NDA/MAL/HD P/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,1.0X2.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,10.0X1.0 X10.0 TABLET BLISTER	01/07/2004
1390	NDA/MAL/HD P/2880	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CARBIMAZOLE 5	CARBIMAZOLE	5MG	REMEDICA LIMITED,- LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1391	NDA/MAL/HD P/2885	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FORECOX- TRAC	RIFAMPICIN + ISONIAZID + PYRAZINAMID E + ETHAMBUTOL	150MG + 75MG+ 400MG + 275MG	MACLEODS PHARMACEUTICALS LTD .- PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA OXALIS LABS LIMITED-VILLAGE THEDA, P.O LODHIMAJRA, TEHSIL,BADDI, DIST.SOLAN, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X6.0 TABLET BLISTER,1.0X24.0 X28.0 TABLET BLISTER	01/07/2005

1392	NDA/MAL/HD P/2887	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	QUININE SULPHATE	QUININE SULPHATE	300MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2009
1393	NDA/MAL/HD P/2888	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	SUCCICORT	HYDROCORTIS ONE SODIUM SUCCINATE	100MG/VIAL	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL	01/07/2013
1394	NDA/MAL/HD P/2890	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL N	BETAMETHAS ONE+NEOMYC IN	1MG/G+5MG/ G	KPI INDUSTRIES (1996) LTD- PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2005

1395	NDA/MAL/HD P/2891	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	01/07/2006
1396	NDA/MAL/HD P/2892	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	NICARDIA-20 TABLETS	NIFEDIPINE	20MG	UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
1397	NDA/MAL/HD P/2893	DAWA LIMITED	SUPER MEDIC LTD	STOPACID SUSPENSION	MAGNESIUM TRISILICATE + ALUMINIUM HYDROXIDE	250MG/5ML + 120MG/5ML	DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009

1398	NDA/MAL/HD P/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 SUSPENSIONS	1.0X125.0 ML BOTTLE	01/07/2005
1399	NDA/MAL/HD P/2896	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	MCG CREAM	MICONAZOLE NITRATE BP + CLOBETASOL PROPIONATE BP + GENTAMYCIN SULPHATE	2.0%W/W + 0.05%W/W + 0.1 %W/W	KPI INDUSTRIES (1996) LTD- PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X25.0 G TUBE	01/07/2005
1400	NDA/MAL/HD P/2898	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	01/07/2006

1401	NDA/MAL/HD P/2900	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O- 200	CEFIXIME	200MG	MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2005
1402	NDA/MAL/HD P/2902	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MEGALIS-20	TADALAFIL	20MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X15.0X1.0X4. 0 TABLET STRIP	01/07/2005
1403	NDA/MAL/HD P/2903	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	ABACAVIR SULPHATE TABLETS	ABACAVIR SULFATE	300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2009

1404	NDA/MAL/HD P/2905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHA NE SYRUP	GUAIPHENESI N+EPHEDRINE HYDROCHLORI DE+DIPHENHY DRAMINE HYDROCHLORI DE+DEXTROM ETHORPHAN	50MG+7.5MG +5MG+4.58M G	EGYPT INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. EIPICO- 10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE	01/07/2007
1405	NDA/MAL/HD P/2907	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART DS	ARTEMETHER + LUMEFANTRIN E	80 MG + 480 MG	BLISS GVS PHARMA LIMITED- NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2013
1406	NDA/MAL/HD P/2908	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	PAINGO MEDICATED CREAM	METHYLSALIC YLATE+CAPSIC UM OLEORESIN+T URPENTINE OIL	15%W/W + 1%W/W + 1.47%W/W	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X2.0X15.0 G TUBE	01/07/2010

1407	NDA/MAL/HD P/2910	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	TENVIR EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABIN E	300MG+200M G	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2009
1408	NDA/MAL/HD P/2911	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL LORATADINE	LORATADINE	10MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1409	NDA/MAL/HD P/2912	FDC LTD	AIVEEN (U) LIMITED	MYCODERM	SALICYLIC ACID + BENZOIC ACID	3%W/W + 6%W/W	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G CONTAINER	01/07/2004
1410	NDA/MAL/HD P/2914	REGAL PHARMACEUTICALS LTD	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	01/07/1997

1411	NDA/MAL/HD P/2917	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CETAMOL TABLETS	PARACETAMO L	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,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET STRIP	01/07/1997
1412	NDA/MAL/HD P/2919	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 5	MONTELUKAS T	5MG	CADILA HEALTHCARE LTD--- SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1413	NDA/MAL/HD P/2920	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	TRANSLIPO -C CREAM	CLOTRIMAZOL E	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2001

1414	NDA/MAL/HD P/2923	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	COLD PLUS SYRUP	PARACETAMO L + PHENYLEPHRI NE HYDROCHLORI DE + CHLORPHENIR AMINE MALEATE	125MG + 2.5MG + 2.5MG/ 5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- -N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2014
1415	NDA/MAL/HD P/2934	ASTRA LIFE CARE PVT LTD	ASTRA PHARMA (U) LIMITED	ASTOLON	PREDNISOLON E	5MG	ASTRA LIFE CARE PVT LTD- 57/P RAJODA-382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2007
1416	NDA/MAL/HD P/2936	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	FEMIN-P	NYSTATIN	100,000IU	ASTRA LIFE CARE (INDIA) PVT LTD-57/P,RAJODA 382220, BAVLA AHMEDABAD INDIA	INDIA	VAGINAL TABLETS	1.0X15.0 PESSARY BLISTER	01/07/2007
1417	NDA/MAL/HD P/2939	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTODIUM	LOPERAMIDE HYDROCHLORI DE	2MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
1418	NDA/MAL/HD P/2940	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	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	1.0X2.0 G TUBE	01/07/2005

1419	NDA/MAL/HD P/2941	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 20	ATORVASTATI N	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,1.0X5.0X 7.0 TABLET BLISTER	01/07/2005
1420	NDA/MAL/HD P/2942	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARGISSEPT CREAM	CHOLRHEXIDI NE GLUCONATE/S ILVER SULPHADIAZIN E	0.2%W/W / 1%W/W	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X10.0 G TUBE	01/07/2005
1421	NDA/MAL/HD P/2945	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ONCET	CETIRIZINE DIHYDROCHLO RIDE	10MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

1422	NDA/MAL/HD P/2946	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO ORAL SUSPENSION(T HANE)	CO- TRIMOXAZOLE	240MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1998
1423	NDA/MAL/HD P/2947	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO TABLETS	CO- TRIMOXAZOLE	480MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 250.0 BLISTER CARTON	01/07/1998
1424	NDA/MAL/HD P/2948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORI DE	850MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X 15.0 TABLET BLISTER	01/07/2007

1425	NDA/MAL/HD P/2950	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	XALATAN	LATANOPROST	0.005%W/V	PFIZER MANUFACTURING - NV/NA, RIJKSWEIG 12 2870, PUURS	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/1998
1426	NDA/MAL/HD P/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	1.0X10.0X2.0X6. 0 TABLET BLISTER	01/07/2007
1427	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2007

1428	NDA/MAL/HD P/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,1.0X3.0X 10.0 CAPSULE BLISTER	01/07/2009
1429	NDA/MAL/HD P/2959	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CETAMOL SYRUP	PARACETAMO L	120MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
1430	NDA/MAL/HD P/2960	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN/ CLAVULANIC ACID	400MG/57MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GRANULES	1.0X70.0 ML BOTTLE	01/07/2010
1431	NDA/MAL/HD P/2966	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	TENVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	CIPLA LTD.-VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1432	NDA/MAL/HD P/2967	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	HAEM-F	FERROUS FUMARATE	200MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BOTTLE	01/07/2003

1433	NDA/MAL/HD P/2969	UNIQUE PHARMACEUTICALS LTD	TATA UGANDA LIMITED	TENSIMIN-50	ATENOLOL	50MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)- 216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,14.0X10. 0 TABLET BLISTER	01/07/1997
1434	NDA/MAL/HD P/2970	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYCOMET 500	METFORMIN	500MG	FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000
1435	NDA/MAL/HD P/2971	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VIL L.MANAKPUR,TEH.NALAGAR H,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2004

1436	NDA/MAL/HD P/2978	SANOPI PASTEUR	LABOREX UGANDA LIMITED	TETAVAX	TETANUS VACCINE	40 I.U	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A- 2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE)	01/07/1997
1437	NDA/MAL/HD P/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	01/07/1997
1438	NDA/MAL/HD P/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	1.0X10.0X3.0X8. 0 TABLET BLISTER	01/07/2007

1439	NDA/MAL/HD P/2982	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	NEURO-FORTE TABLETS	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	200MG + 50MG + 1MG	CENTAUR PHARMACEUTICALS LTD- PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
1440	NDA/MAL/HD P/2983	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FUCOL 200	FLUCONAZOLE	200MG	CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA CIPLA LTD KURKUMBH-D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TALUKA- DAUND, PUNE, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X4.0 CAPSULE BLISTER	01/07/2004
1441	NDA/MAL/HD P/2985	SANOFI WINTHROP LTD	LABOREX UGANDA LIMITED	EPILIM CHRONO	SODIUM VALPROATE PH. EUR	500MG	SANOFI WINTHROP INDUSTRIE-1,RUE DE LA VIERGE ,AMBARES ET LAGRAVE 33565,CARBON BLANC CEDEX FRANCE	FRANCE	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004

1442	NDA/MAL/HD P/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,1.0X3.0X 4.0 TABLET BLISTER	01/07/2004
1443	NDA/MAL/HD P/2992	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	HAVRIX1440	HEPATITIS A ANTIGEN(HM 175 STRAIN)	NLT 1440 ELISA UNITS OF VIRAL ANTIGENS(HM 175 STRAIN)	SMITHKLINE BEECHAM BIOLOGICALS , BELGIUM- BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL (1 DOSE)	01/07/1997
1444	NDA/MAL/HD P/2995	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	GALLOP	LOPERAMIDE HYDROCHLORI DE USP	2MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0 CAPSULE CONTAINER	01/07/2007
1445	NDA/MAL/HD P/2997	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	ACENAC TABLETS	ACECLOFENAC	100 MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

1446	NDA/MAL/HD P/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 0AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1447	NDA/MAL/HD P/3002	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	KELVIN	PARACETAMO L	500MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2011
1448	NDA/MAL/HD P/3003	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2007

1449	NDA/MAL/HD P/3004	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AUROPODOX 100	CEFPODOXIME PROXETIL	100MG	AUROBINDO PHARMA LTD (UNIT VI) ,,,,-SURVEY NOS. 329/39 & 329/47, CHITKUL VILLAGE, PATANCHERU MANDAL, MEDAK DISTRICT PIN CODE 502307, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	07/01/2007
1450	NDA/MAL/HD P/3005	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN-100 SR DEPOCAPS	DICLOFENAC SODIUM	100MG	ACINO PHARMA AG (FORMER MEPHA LLC)- DORNACHERSTRASSE 114 P.O BOX 445 CH4147, AESCH/BL	SWITZERLAND	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/1997
1451	NDA/MAL/HD P/3007	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	TORTAS 5	TORSEMIDE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

1452	NDA/MAL/HD P/3008	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	BLEOSOL	BLEOMYCIN	15 UNITS	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 ML VIAL	01/07/2014
1453	NDA/MAL/HD P/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOMA X 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	01/07/2009
1454	NDA/MAL/HD P/3011	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	GYNEST	CLOTRIMAZOL E	100MG	ASTRA LIFE CARE (INDIA) PVT-PLOT 57 ROJADA382220, BAVLA AHMEDABAD INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET BLISTER	01/07/2008

1455	NDA/MAL/HD P/3012	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED- MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998
1456	NDA/MAL/HD P/3013	AGOG PHARMA LTD	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	01/07/2007
1457	NDA/MAL/HD P/3015	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA-50 TABLETS	SILDENAFIL	50MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0 X4.0 TABLET BLISTER	01/07/2001

1458	NDA/MAL/HD P/3019	MJ BIOPHARM PRT LTD	TATA UGANDA LIMITED	BIOSULIN 30/70	INSULIN SOLUBLE + INSULIN ISOPHANE	30 I.U + 70 I.U	MJ BIOPHARM PRT LTD-L-7 MIDC INDUSTRIAL AREA, TALOJA, NARI MUMBAI MAHARASHTRA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2008
1459	NDA/MAL/HD P/3020	M.J BIOPHARM PVT LTD	TATA UGANDA LIMITED	BIOSULIN N	INSULIN ISOPHANE	100 I.U/ML	M.J .BIOPHARM-L7, M.I.D.C INDUSTRIAL AREA TALOJA, NAVI MUMBAI MAHARAHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008
1460	NDA/MAL/HD P/3021	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2012
1461	NDA/MAL/HD P/3022	M.J BIOPHARM PVT LTD	TATA UGANDA LIMITED	BIOSULIN L	INSULIN ZINC SUSPENSION	100 I.U/ML	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008

1462	NDA/MAL/HD P/3023	AGOG PHARMA LTD	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,1.0X10.0X 1.0X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER	01/07/2007
1463	NDA/MAL/HD P/3024	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	150MG + 200MG + 300MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - -H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA QUESTA CARE LIMITED-PLOT NO 209/7184 HOMABAY RD TERMINUS GATE NO-19, INDUSTRIAL AREA NAIROBI, KENYA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008

1464	NDA/MAL/HD P/3029	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOZOLE SUSPENSION	ALBENDAZOLE USP	200 MG/ 5 ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/2007
1465	NDA/MAL/HD P/3030	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	BIOSULIN R	INSULIN SOLUBLE	100 IU/ML	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2008
1466	NDA/MAL/HD P/3031	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2007
1467	NDA/MAL/HD P/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	01/07/2007

1468	NDA/MAL/HD P/3033	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENAMOX	AMOXICILLIN	125MG/5ML	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1469	NDA/MAL/HD P/3035	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOFORTE TONIC	FERRIC AMMONIUM + FOLIC ACID + PYRIDOXINE + THIAMINE	50 MG + 0.55 MG + 2.4 MG + 1.2 MG	AGOG PHARMA LIMITED- PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2007
1470	NDA/MAL/HD P/3037	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOVIT SYRUP	MULTI- INGREDIENT	N/A	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,1.0X1.0X 100.0 ML BOTTLE	01/07/2007

1471	NDA/MAL/HD P/3040	AGOG PHARMA LTD	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,1.0X100 0.0 CAPSULE CONTAINER,1.0X 100.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2007
1472	NDA/MAL/HD P/3041	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LEVOFLOXACIN	LEVOFLOXACIN	250MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1473	NDA/MAL/HD P/3044	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PIRICAM-20 CAPSULES	PIROXICAM	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA- 403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,2.0X10.0 CAPSULE BLISTER	01/07/1997

1474	NDA/MAL/HD P/3046	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	400 MG + 57 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2009
1475	NDA/MAL/HD P/3047	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAM IVUDINE+ZIDO VUDINE	ABACAVIR SULFATE + LAMIVUDINE + ZIDOVUDINE	300 MG + 150 MG + 300 MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H- 13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2008
1476	NDA/MAL/HD P/3048	AGOG PHARMA 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,1.0X2.0X 14.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET CONTAINER,1.0X 3.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2007

1477	NDA/MAL/HD P/3049	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ	EFAVIRENZ	600MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007
1478	NDA/MAL/HD P/3050	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	PEFLOX	PEFLOXACIN	400MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	
1479	NDA/MAL/HD P/3051	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE	DILOXANIDE FUROATE/ME TRONIDAZOLE	25MG/ML + 20MG/ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2005

1480	NDA/MAL/HD P/3052	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	IBUPROFEN TABLETS	IBUPROFEN	200MG	GUILIN PHARMACEUTICAL CO. LTD-NO. 17 SHANGHAI ROAD, GUILIN 541002, GUANXI CHINA	CHINA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010
1481	NDA/MAL/HD P/3054	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	NOSIC	DOXYLAMINE SUCCINATE + PYRIDOXINE HYDROCHLORI DE	10MG+10MG	INDOCO REMEDIES LTD - O-.L- 14 Verna INDUSTRIAL AREA, VERNA, GOA-403722	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
1482	NDA/MAL/HD P/3055	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR SULFATE	ABACAVIR SULPHATE	300MG	CIPLA LTD-MIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2007
1483	NDA/MAL/HD P/3057	AGOG PHARMA 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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2007

1484	NDA/MAL/HD P/3058	SANOFI-AVENTIS	LABOREX UGANDA 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	01/07/2008
1485	NDA/MAL/HD P/3060	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	KETOS TABLET	KETOCONAZO LE 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,1.0X10.0 X10.0 TABLET BLISTER	07/07/2007

1486	NDA/MAL/HD P/3062	MULTISORB	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE,Z IDOVUDINE, NEVIRAPINE	LAMIVUDINE/ ZIDOVUDINE/ NEVIRAPINE	150MG + 300MG + 200MG	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH 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	1.0X60.0 TABLET BOTTLE	01/07/2007
1487	NDA/MAL/HD P/3063	AGOG PHARMA 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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2007

1488	NDA/MAL/HD P/3064	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TIN-TIN TABLETS	TINIDAZOLE	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2007
1489	NDA/MAL/HD P/3067	AGOG PHARMA 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,1.0X1.0X 60.0 ML BOTTLE	01/07/2007
1490	NDA/MAL/HD P/3068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHE NICOL	0.5%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/1999

1491	NDA/MAL/HD P/3069	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMOVE CAPSULES	PIROXICAM	20MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100. 0 CAPSULE CONTAINER	01/07/2007
1492	NDA/MAL/HD P/3072	AGOG PHARMA 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,1.0X 1000.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/1998
1493	NDA/MAL/HD P/3073	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	50MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X14.0 TABLET STRIP	01/07/1997

1494	NDA/MAL/HD P/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	01/07/2007
1495	NDA/MAL/HD P/3077	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOL E + HYDROCORTIS ONE	1%W/W + 1%W/W	REGAL PHARMACUTICALS - PLOT 7879/18 OFF BABA RWARAKA NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2008
1496	NDA/MAL/HD P/3078	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB ALLERGY CONGESTION	PARACETAMO L/ CHLORPHENIR AMINE/ EPHEDRINE	500MG/ 2MG/ 30MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
1497	NDA/MAL/HD P/3079	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	CO-AMOX ACINO 457	CO- AMOXICLAV	400MG+47MG / 5ML	LEK D.D PREVALJE SDOVENIA- DORNACHERSTASSE 144 P.O.BOX 445,CH 4147 AESCH (BASEL) SWITZERLAND	SWITZERLAND	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2008

1498	NDA/MAL/HD P/3080	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	CO-AMOX ACINO 156.25	CO- AMOXICLAV	125MG+31.25 MG/ 5ML	LEK PHARMACEUTICALS- PREVALJE SITE, PERZONALI 47, S1-2391, PREVALJE	SWITZERLAND	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008
1499	NDA/MAL/HD P/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	01/07/2007
1500	NDA/MAL/HD P/3084	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	NEVIRAPINE	NEVIRAPINE	200MG	CIPLA LTD--PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA-403 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007
1501	NDA/MAL/HD P/3085	AGOG PHARMA 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,1.0X10.0 X10.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER,1.0X50.0 X4.0 TABLET BLISTER	01/07/2007

1502	NDA/MAL/HD P/3088	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PILL 72	LEVONORGEST REL	0.75MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2014
1503	NDA/MAL/HD P/3090	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	100MG/5ML	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X50.0 ML BOTTLE	01/07/2004
1504	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013

1505	NDA/MAL/HD P/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-SCHAFFHARVSTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E- 08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2015
1506	NDA/MAL/HD P/3095	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007
1507	NDA/MAL/HD P/3097	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DEBACRON	GLICLAZIDE	80MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER	01/07/2008

1508	NDA/MAL/HD P/3098	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOSEDIN	LORATADINE	5MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2004
1509	NDA/MAL/HD P/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	01/07/2007
1510	NDA/MAL/HD P/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	01/07/2010
1511	NDA/MAL/HD P/3102	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	EPANUTIN READY MIXED	PHENYTOIN SODIUM	50MG/ML	ACTAVIS ITALY S.P.A-VIALE PASTEUR, 10 20014 NERVIANO(MILAN) - ITALY	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/1997
1512	NDA/MAL/HD P/3104	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NYSTALEB ORAL SUSPENSION	NYSTATIN	100000IU/ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2007

1513	NDA/MAL/HD P/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	01/07/1997
1514	NDA/MAL/HD P/3108	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ZERODOL	ACECLOFENAC	100MG	IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2005
1515	NDA/MAL/HD P/3110	VENUS REMEDIES LIMITED	AARON PHARMACEUTICALS LTD	ZYDOTUM	CEFTAZIDIME + SULBACTAM	1000 MG + 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	01/07/2011
1516	NDA/MAL/HD P/3111	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CALPOL	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997

1517	NDA/MAL/HD P/3113	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	PANCURONIUM	PANCURONIUM BROMIDE	4MG/2ML	ROTEX MEDICA GMBH- BUNSENSTRASSE 4 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE	01/07/2004
1518	NDA/MAL/HD P/3116	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	125MG/5ML	LABORATORY & ALLIED LTD.-- -PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE, 1.0X100.0 ML BOTTLE	01/07/1997
1519	NDA/MAL/HD P/3117	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE SODIUM SUCCINATE	100MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL, 1.0X50.0X100.0 MG VIAL	01/07/2010

1520	NDA/MAL/HD P/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,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X 18.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER	01/07/2011
1521	NDA/MAL/HD P/3122	USV PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT CHEWABLE TABLETS	MULTI- INGREDIENT	MULTI- INGREDIENT	REMIDEX PHARMA PVT LTD- B-249+ 250 II STAGE PEENYA INDUSTRIAL ESTATE BANGLORE 560058.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2002

1522	NDA/MAL/HD P/3123	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	RECTOL 250 SUPPOSITORY	PARACETAMO L BP	250 MG	BLISS GVS PHARMA LIMITED- PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
1523	NDA/MAL/HD P/3125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMLODAR 5	AMLODIPINE BESILATE	5MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2009
1524	NDA/MAL/HD P/3127	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DIDANOSINE DELAYED - RELEAS	DIDANOSINE DELAYED RELEASE	250MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2009

1525	NDA/MAL/HD P/3130	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE 200 SUPPOSITORY	ARTESUNATE	200MG	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 SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP	01/07/2009
1526	NDA/MAL/HD P/3134	PANACEA BIOTEC LTD	VITACARE LIMITED	TOFF PLUS	PARACETAMO L+CHLORPHEN IRAMINE MALEATE+ DEXTROMETH ORPHAN + PHENYLEPHRI NE	500 MG + 2 MG + 15 MG + 10 MG	PANACEA BIOTEC LTD- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2004
1527	NDA/MAL/HD P/3136	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2007

1528	NDA/MAL/HD P/3138	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANUSOL SUPPOSITORY	BISMUTH SUBGALLATE + BISMUTH OXIDE + ZINC OXIDE	59 MG + 24 MG + 296 MG	PERFORMANCE HEALTH LTD- 241 NAIN ROAD RETREAT SOUTH AFRICA 7945	SOUTH AFRICA	TOPICAL EXTERNAL SUPPOSITORIES	1.0X10.0 SUPPOSITORY BLISTER	01/07/1997
1529	NDA/MAL/HD P/3139	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	OMEDAR	OMEPRAZOLE	20MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/2009
1530	NDA/MAL/HD P/3140	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	ULTIVA INJECTION 1MG	REMIFENTANI L	1ML	GLAXOSMITHKLINE MANUFACTURING SPA ,,- STRADA PROVINCIALE ASOLANA, 90-43056, S.POLO DI TORRILE (PARMA)	ITALY	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON	01/07/1999
1531	NDA/MAL/HD P/3141	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	AMLOPRESS-5	AMLODIPINE BESYLATE	5MG	CIPLA LTD-CIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	01/07/2007
1532	NDA/MAL/HD P/3143	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	OMIPIX 20	OMEPRAZOLE	20 MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2009

1533	NDA/MAL/HD P/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	01/07/2007
1534	NDA/MAL/HD P/3145	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXICAP	AMOXYCILLIN	500MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2010
1535	NDA/MAL/HD P/3146	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZOKAST	MONTELUKAS T SODIUM	10MG	UNICHEM LABORATORIES LTD ,,-PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA- 403511	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
1536	NDA/MAL/HD P/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	01/07/2009

1537	NDA/MAL/HD P/3150	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	MTX-VHB	METHOTREX A TE	50MG/2ML	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL	01/07/2010
1538	NDA/MAL/HD P/3153	M.J BIOPHARM PVT LTD	TATA UGANDA LIMITED	CEFUROXIME- MJ	CEFUROXIME	750MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2011

1539	NDA/MAL/HD P/3155	MEDREICH PLC	LABOREX UGANDA LIMITED	BIOFERON	FERRIC AMMONIUM CITRATE + CYANOCOBAL AMIN + FOLIC ACID	200MG/5ML + 10MG/5ML + 750MCG/5ML	MEDREICH LTD (UNIT III) - SURVEY 4/3 AVALAHALI ANJANAPURA POST OFF KARNAKATA BANGALORE 560 062 TEJKAMAL PHARMACEUTICALSPVT. LTD- -SURVEY NO. 6/2, ALADAHALLI VILLAGE, SOMAPURA HOBCI NELAMANGALA TALUKI BANGALORE RURAL	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2007
1540	NDA/MAL/HD P/3156	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN FOR COLDS	PSEUDOEPHE 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	01/07/2008
1541	NDA/MAL/HD P/3158	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	GLIBEX-5	GLIBENCLAMI DE	5MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2012

1542	NDA/MAL/HD P/3161	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASCILLIN	AMPICILLIN	250MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/1997
1543	NDA/MAL/HD P/3162	M.J BIOPHARM PST LTD	TATA UGANDA LIMITED	KLAROL	LORATADINE	10MG	M.J BIOPHARM PVT LTD --L-7 MIDC TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2012
1544	NDA/MAL/HD P/3163	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIE S 50MG	DICLOFENAC SODIUM	50MG	DELPHARM HUNINGUE S.A.S- -SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP	01/07/2006
1545	NDA/MAL/HD P/3166	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	TRIMETHOPRI M + SULPHAMETH OXAZOLE	40MG/5ML + 200MG/5ML	GLAXO WELLCOME EGYPT CO. S.A.E-CAIRO	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X50.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997

1546	NDA/MAL/HD P/3167	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	MONAN-0.5G	MEROPENEM	0.5G	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2010
1547	NDA/MAL/HD P/3175	M.J.BIOPHARM PVT LTD	TATA UGANDA LIMITED	SPACOVIN	DROTAVERINE	40MG	M.J. BIOPHARM PVT. LTD-L- 7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
1548	NDA/MAL/HD P/3176	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	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,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2005
1549	NDA/MAL/HD P/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	01/07/1997

1550	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2005
1551	NDA/MAL/HD P/3179	GOOD DAY PHARMACY LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	KREMOINT PHARMA PVT LTD---B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE	01/07/2013
1552	NDA/MAL/HD P/3180	MJ BIOPHARM PVT LTD	TATA UGANDA 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	01/07/2008
1553	NDA/MAL/HD P/3182	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	TADACIP 20	TADALAFIL	20MG	CIPLA LTD-CIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2005

1554	NDA/MAL/HD P/3184	M.J BOPHARM PUT LTD	TATA UGANDA LIMITED	MONAN	MEROPENEM	1G	M.J BIOPHARM PUT LTD -L-7 MIDC INDUSTRIAL DIST GAIDED TOLOJA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2008
1555	NDA/MAL/HD P/3191	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ERECTO -100	SILDENAFIL CITRATE	100 MG	CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2007
1556	NDA/MAL/HD P/3192	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ANZAVIR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
1557	NDA/MAL/HD P/3193	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ERECTO- 50	SILDENAFIL CITRATE	50MG	CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER	01/07/2005

1558	NDA/MAL/HD P/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	01/07/2000
1559	NDA/MAL/HD P/3197	ERIS LTD	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOL ONE ACETONIDE	40 MG/ML	DENK PHARMA, GOLLSTR.,-1- D-845 529 TITTMONING GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2004
1560	NDA/MAL/HD P/3198	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-125	PHENOXYMET HYL PENICILLIN SODIUM	125MG/ML	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA- 410209,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/2011

1561	NDA/MAL/HD P/3199	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ISENTRESS	RALTEGRAVIR	400MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD - ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD XUNQIAE LINHAI ZHUJIANG	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2011
1562	NDA/MAL/HD P/3200	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LETRAX	LEVAMISOLE HYDROCHLORI DE	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,1.0X 200.0 TABLET CONTAINER,1.0X 25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER	01/07/1997
1563	NDA/MAL/HD P/3202	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN- 50	LOSARTAN	50MG	IPCA LABORATORIES LTD- PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2008

1564	NDA/MAL/HD P/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)	01/07/2013
1565	NDA/MAL/HD P/3204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	RELKER GEL	ALUMINIUM HYDROXIDE/M AGNESIUM HYDROXIDE/DI METHICONE/L QUORICE	6G+80MG+10 0MG+400MG/ 5ML	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X180.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2000
1566	NDA/MAL/HD P/3205	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	AZIFAST-250	AZITHROMYCI N	250MG	IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER	01/07/2007
1567	NDA/MAL/HD P/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	01/07/2010

1568	NDA/MAL/HD P/3208	NIRMA LIMITED.	LIFE PHARMA AFRICA LIMITED	NIRFOL 1%	PROPOFOL	1%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0X20 .0 ML VIAL,1.0X10.0X5 0.0 ML VIAL	01/07/2010
1569	NDA/MAL/HD P/3212	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	CLOPIVAS 75MG	CLOPIDOGREL BISULPHATE	75MG	CIPLA LTD--PLOT NO L- 139,VERNA IND ESTATE, VERNA GOA-403 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
1570	NDA/MAL/HD P/3214	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	INDICONTIN	INDAPAMIDE	1.5MG	MODI MUNDIPHARMA PVT. LTD-MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1571	NDA/MAL/HD P/3215	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	SEROFLO- 125MG	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG + 125MCG	CIPLA LTD-CIPLA LTD PLOT NO L-139,VERNA IND ESTATE, VERNA GOA INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009

1572	NDA/MAL/HD P/3219	AGOG PHARMA 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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1998
1573	NDA/MAL/HD P/3220	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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)	01/07/2005
1574	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X5.0 ML VIAL	01/07/1999
1575	NDA/MAL/HD P/3224	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM FLUFED ELIXIR	MULTI- INGREDIENT	MULTI- INGREDIENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE	01/07/1997
1576	NDA/MAL/HD P/3226	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	PEDITRAL	ORAL REHYDRATION SALT	N/A	THE SEARLE COMPANY-32- KM MULTAN ROAD, LAHORE	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X29.5 G SACHET	01/07/1997

1577	NDA/MAL/HD P/3232	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM	SULFAMETHO XAZOLE + TRIMETHOPRI M	400MG + 80MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2016
1578	NDA/MAL/HD P/3233	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	WHITFIELD'S OINTMENT BP	BENZOIC ACID + SALICYLIC ACID	0.06G+0.03G	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	01/07/1997
1579	NDA/MAL/HD P/3236	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM COTRI	CO- TRIMOXAZOLE	480MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/1997

1580	NDA/MAL/HD P/3243	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ALIVA	LEVODROPRO PIZINE	30MG/5ML	MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 ML BOTTLE	01/07/2011
1581	NDA/MAL/HD P/3244	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMICILLIN	AMPICILLIN	250MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
1582	NDA/MAL/HD P/3245	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NYSTATIN ORAL DROPS	NYSTATIN	100,000 I.U/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL TOPICAL DROPS	1.0X30.0 ML BOTTLE	01/07/2013

1583	NDA/MAL/HD P/3246	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2000
1584	NDA/MAL/HD P/3249	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR-H	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2004
1585	NDA/MAL/HD P/3251	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	UROGRAFIN	DIATRIZOIC ACID	76%W/V	SCHERING N.V, SA-SPAIN	SPAIN	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X20.0 ML VIAL	01/07/1997
1586	NDA/MAL/HD P/3252	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	PYLOOCAIN	BETAMETHAS ONE + PHENYLEPHRI NE + 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	01/07/2005

1587	NDA/MAL/HD P/3254	VENUS REMEDIES LIMITED	AARON PHARMACEUTICALS LTD	ROBOL	DOXORUBICIN HCL	50MG/25ML	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X30.0 ML VIAL	01/07/2009
1588	NDA/MAL/HD P/3255	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	SATISFIL-50	SILDENAFIL CITRATE	50MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2011
1589	NDA/MAL/HD P/3259	NEM LABORATORIES PRIVATE LIMITED	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-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X3.0 G TUBE,1.0X15.0 G TUBE	01/07/1997

1590	NDA/MAL/HD P/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 431136 MAHARASTRA MYLAN LABORATORIES LIMITED - PLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2008
1591	NDA/MAL/HD P/3262	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	250MG + 250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

1592	NDA/MAL/HD P/3263	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	TRIMEX MUCOLYTIC SYRUP	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORI DE + GUAIFENESIN	2MG/5ML + 4MG/5ML + 100MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2009
1593	NDA/MAL/HD P/3266	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	SALIMIA LINIMENT	METHYL SALICYLATE+T URPENTINE OIL	5ML+25ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
1594	NDA/MAL/HD P/3270	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4000000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50. 0 VIAL CARTON	01/07/2001

1595	NDA/MAL/HD P/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	01/07/1997
1596	NDA/MAL/HD P/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	01/07/2001
1597	NDA/MAL/HD P/3278	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	TOPIDIC 2% OINTMENT	SODIUM FUSIDATE	20MG/G	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2007

1598	NDA/MAL/HD P/3279	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	HAEMOFORTE SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA BAROQUE PHARMACEUTICALS PVT LTD --S.NO.192/2 & S.NO.192/2 &3 SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250. 0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/1997
1599	NDA/MAL/HD P/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	01/07/2009

1600	NDA/MAL/HD P/3284	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	CHALEATE	CHLORPHENIRAMINE MALEATE	4MG	LABORATORY & ALLIED LTD-- PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
1601	NDA/MAL/HD P/3285	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXIL FORTE 250MG/5ML	AMOXYCILLIN	250MG/5ML	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
1602	NDA/MAL/HD P/3286	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	LOMAC-20	OMEPRAZOLE	20 MG	CIPLA LTD --PLOT NO 9, 10 & 15, PHARMA ZONE, PHASE II, SECTOR III, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2009

1603	NDA/MAL/HD P/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,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
1604	NDA/MAL/HD P/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,1.0X100. 0 G BOTTLE	01/07/1999
1605	NDA/MAL/HD P/3291	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FINTOP	BUTENAFINE HCL	1%W/W	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2003
1606	NDA/MAL/HD P/3292	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED PAEDIATRIC SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE+SODIUM CITRATE+MEN THOL	7MG+28.5MG +0.55MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
1607	NDA/MAL/HD P/3293	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	AZITHROMYCI N SANDOZ	AZITHROMYCI N MONOHYDRA TE	200MG/5ML	SC SANDOZ SRL-LIVEZENI 7A STR. TARGU MURES 540472	ROMANIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	01/07/2003
1608	NDA/MAL/HD P/3294	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORI DE	50 MG	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2004

1609	NDA/MAL/HD P/3295	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEVATE	CLOBETASOL	0.05%W/W	GLENMARK PHARMACEUTICALS LTD- PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
1610	NDA/MAL/HD P/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,1.0X 60.0 TABLET CONTAINER	01/07/2011
1611	NDA/MAL/HD P/3299	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	METODINE-DF SUSPENSION	METRONIDAZ OLE/DILOXANI DE FUROATE	200MG/250M G	SEARLE PAKISTAN LIMITED- PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2004
1612	NDA/MAL/HD P/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	01/07/2003
1613	NDA/MAL/HD P/3302	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	AMOXICILLIN ORAL SUSPENSION	AMOXICILLIN	125MG/5ML	OKASA PVT LTD-346 KUNDAIM INDUSTRIAL ESTATE GOA, 403115	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009

1614	NDA/MAL/HD P/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	01/07/2007
1615	NDA/MAL/HD P/3309	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS 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	01/07/2002
1616	NDA/MAL/HD P/3312	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TIDOMET FORTE	CO- CARELDOPA	25MG/250MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1617	NDA/MAL/HD P/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	01/07/2004

1618	NDA/MAL/HD P/3315	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ERO-250 TABLETS	ERYTHROMYCIN STEARATE	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2003
1619	NDA/MAL/HD P/3316	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR- 361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1620	NDA/MAL/HD P/3318	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM TABLETS	CO- TRIMOXAZOLE	480MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2000
1621	NDA/MAL/HD P/3319	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	FERROTONE CAPSULES	FERROUS FUMERATE+F OLIC ACID+VITAMI N B12	162MG +0.75MG +7.5MCG	MEGA LIFESCIENCES LTD.- 384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2005

1622	NDA/MAL/HD P/3322	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE	NEVIRAPINE	50MG	LABCOLD-UNIT III SURVEY NO 313& 314, BACHUPALLY (V),QUTHUBULLAPUR (M), RANGA REDDY (DIST) TELANGANA STATE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2012
1623	NDA/MAL/HD P/3328	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZYL PENICIL LIN INJECTION	BENZYL PENICIL LIN	1 MU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL,1.0X10.0X1. 0 MU VIAL	01/07/2001
1624	NDA/MAL/HD P/3333	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	NOVACLAV- 625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MEDISPRAY LABORATORIES PVT LTD,UNIT II-368-348 KUNDAIM INDUSTRIAL ESTATE,KUNDAIM GOA - 403115,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0 TABLET BLISTER	01/07/2009

1625	NDA/MAL/HD P/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,1.0X10.0X 6.0 TABLET STRIP	01/07/2005
1626	NDA/MAL/HD P/3340	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	POVED	POVIDONE IODINE	200MG	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	1.0X2.0X7.0 PESSARY STRIP	01/07/2008
1627	NDA/MAL/HD P/3342	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	METODINE DF TABLETS	METRONIDAZ OLE+DILOXANI DE	400MG+500M G	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X5.0 TABLET BLISTER	01/07/2004
1628	NDA/MAL/HD P/3343	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDIVEN- CREAM	BETAMETHAS ONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

1629	NDA/MAL/HD P/3345	ASTRA PHARMACY (U) PVT LTD	ASTRA PHARMA (U) LIMITED	PAINOL-P	PARACETAMO L + CAFFEINE	650MG + 50MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2010
1630	NDA/MAL/HD P/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	01/07/1997
1631	NDA/MAL/HD P/3347	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMET HYLPENICILLIN	250MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997

1632	NDA/MAL/HD P/3348	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PIMCEF	CEFEPIME USP	1G	VENUS REMEDIES LTD.-UNIT 11 HOLL TOP INDUSTRIAL ESTATE JHARMAJRI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2007
1633	NDA/MAL/HD P/3354	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDIVEN OINTMENT	BETAMETHAS ONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1634	NDA/MAL/HD P/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	01/07/2001
1635	NDA/MAL/HD P/3357	CENTAUR PHARMACEUTICALS LTD	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	01/07/2008
1636	NDA/MAL/HD P/3359	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	ARTI	ARTEMETHER	80MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2011

1637	NDA/MAL/HD P/3364	CENTAUR PHARMACEUTICALS LTD	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	01/07/2008
1638	NDA/MAL/HD P/3366	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	DIAS	GLIBENCLAMI DE	5MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011
1639	NDA/MAL/HD P/3367	AGOG PHARMA 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 SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2000
1640	NDA/MAL/HD P/3368	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	VIAGRA 50MG	SILDENAFIL	50MG	PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER	01/07/1998
1641	NDA/MAL/HD P/3370	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DERMOREN 500	GRISEOFULVIN	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

1642	NDA/MAL/HD P/3372	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	MUCOLEX	AMBROXOL HYDROCHLORI DE + SALBUTAMOL SULPHATE + GUAIFENESIN + MENTHOL	30 MG/5ML + 1 MG/5ML + 50 MG/5ML + 0.5 MG/5ML	S KANT HEALTHCARE LTD- 1802-1805 GIDC PHASE III VAPI 396 195	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
1643	NDA/MAL/HD P/3373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 625	AMOXILLICIN/ CLAVULANATE	500MG/125M G	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,1.0X10.0X 6.0 TABLET STRIP	01/07/2005
1644	NDA/MAL/HD P/3374	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	ZITHROX 250MG	AZITHROMYCI N	250MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2008
1645	NDA/MAL/HD P/3377	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AMILINE	AMITRIPTYLIN E	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,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2011

1646	NDA/MAL/HD P/3378	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CHLOZINE TABLETS	CHLORPROMA ZINE	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
1647	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON	01/07/2011
1648	NDA/MAL/HD P/3382	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOFEN SUSPENSION	IBUPROFEN	100MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2010
1649	NDA/MAL/HD P/3383	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ZEPIN	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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2010

1650	NDA/MAL/HD P/3384	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 250MG	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
1651	NDA/MAL/HD P/3385	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL-P- SUSPENSION	MEFENAMIC ACID	100MG/5ML	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2007
1652	NDA/MAL/HD P/3387	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA 500MG	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
1653	NDA/MAL/HD P/3389	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARINASE REPE TABS	LORATADINE + PSEUDOEPHE DRINE	5MG + 120MG	SCHERING PLOUGH LABO N.V.-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	BELGIUM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2009
1654	NDA/MAL/HD P/3390	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ALUGEL	ALUMINIUM HYDROXIDEL / MAGNESIUM TRISCLICATE	120MG/250M G	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X5.0 ML JERRYCAN	01/07/1997

1655	NDA/MAL/HD P/3391	AGOG PHARMA LTD	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 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER,100.0X1 0.0 TABLET BLISTER	01/07/2017
1656	NDA/MAL/HD P/3393	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN 375MG	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X10.0 TABLET BLISTER	01/07/1997
1657	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X25.0X4.0 ML AMPOULE	01/07/2007
1658	NDA/MAL/HD P/3397	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	LABCOLD-UNIT III SURVEY NO 313& 314, BACHUPALLY (V),QUTHUBULLAPUR (M), RANGA REDDY (DIST) TELANGANA STATE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2011

1659	NDA/MAL/HD P/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	01/07/2013
1660	NDA/MAL/HD P/3400	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN GEL	DICLOFENAC SODIUM	1%W/W	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997
1661	NDA/MAL/HD P/3401	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASCODYL	BISACODYL	5MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

1662	NDA/MAL/HD P/3404	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN	AMOXICILLIN + CLAVULANIC ACID	500 MG + 100 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X600.0 MG VIAL	01/07/2009
1663	NDA/MAL/HD P/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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2008
1664	NDA/MAL/HD P/3411	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABNAL NASAL DROPS	SODIUM CHLORIDE	0.9%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	NASAL SYSTEMIC DROPS	1.0X10.0 ML VIAL	01/07/2011
1665	NDA/MAL/HD P/3412	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TETRACYCLINE	TETRACYCLINE HYDROCHLORI DE	250 MG	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/2005

1666	NDA/MAL/HD P/3413	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	COMBANTRIN	PYRANTEL PAMOATE	125MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER	01/07/1997
1667	NDA/MAL/HD P/3414	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 10MG/160MG	AMLODIPINE + VALSARTAN	10 MG + 160 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERTRASSE NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2007
1668	NDA/MAL/HD P/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	01/07/2004
1669	NDA/MAL/HD P/3416	USAID	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	INJECTAPLAN	MEDROXYPRO GESTERONE	150MG	KAMPALA PHARMACEUTICAL INDUSTRIES LTD-P.O.BOX 7551 KAMPALA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2001

1670	NDA/MAL/HD P/3419	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX BABY COUGH LINCTUS	COUGH LINCTUS WITH DILUTE ACETIC ACID	0.42ML/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2006
1671	NDA/MAL/HD P/3421	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	COMBINOL E			ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1999
1672	NDA/MAL/HD P/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,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/1997
1673	NDA/MAL/HD P/3428	MEDI PHARMA IDUSTRIES E.A LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO- PACK	MULTI INGREDIENT	MULTI INGREDIENT	MEDI PHARMA INDUSTRIES E.A LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE	UGANDA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X2.0X20.5 G SACHET + 1*60.0 ML BOTTLE	01/07/2013
1674	NDA/MAL/HD P/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	01/07/2006

1675	NDA/MAL/HD P/3431	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NAZOL-200	KETOCONAZO LE	200MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1676	NDA/MAL/HD P/3433	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOR OTHIAZIDE	80 MG +12.5 MG	NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016
1677	NDA/MAL/HD P/3434	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	CO- TRIMOXAZOLE	480MG	GLAXO WELLCOME EGYPT CO. S.A.E-CAIRO	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0 TABLET CARTON,1.0X50. 0 TABLET CARTON	01/07/1997
1678	NDA/MAL/HD P/3435	UNIVERSAL CORPORATION LTD	ROYAL PHARMA 2011 LIMITED	CLOTRINE	CLOTRIMAZOL E	1%W/W	UNIVERSAL CORPORATION LTD-KIKUYU NAIROBI KENYA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE	01/07/2007

1679	NDA/MAL/HD P/3437	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	REMYCIN 100 CAPSULES	DOXYCYCLINE HYDROCHLORI DE	100MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
1680	NDA/MAL/HD P/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,10.0 X10.0 CAPSULE BLISTER	01/07/2001
1681	NDA/MAL/HD P/3440	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG	INSULIN LISPRO	100IU	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2000
1682	NDA/MAL/HD P/3441	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LEVOFLOXACI N	LEVOFLOXACI N	500MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

1683	NDA/MAL/HD P/3443	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL OINTMENT	BETAMETHAS ONE VALERATE	0.1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
1684	NDA/MAL/HD P/3444	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 10	AMLODIPINE BESILATE	10MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2010
1685	NDA/MAL/HD P/3446	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CORDARONE	AMIODARONE HYDROCHLORI DE	50MG/ML	SANOFI WINTHROP INDUSTRIE-LAGRAGE 33565 CARBON BLANC CEDEX FRANCE	FRANCE	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1998

1686	NDA/MAL/HD P/3449	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAXONE SODIUM	1000MG	VENUS REMEDIES LIMITED ,,- HILL TOP,INDUSTRIAL ESTATE,JHARMAJRI, EPIP,PHASE 1,(EXTN.) ,BHATOLI KALAN,BADDI - H.P.INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL,1.0X10.0X1. 0X10.0 ML VIAL	01/07/2008
1687	NDA/MAL/HD P/3451	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL CAPSULES (THANEO	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,1.0X100. 0 CAPSULE CONTAINER,1.0X 1000.0 CAPSULE CONTAINER,1.0X 500.0 CAPSULE CONTAINER	01/07/1998
1688	NDA/MAL/HD P/3452	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PAXOL	PACLITAXEL USP	30MG/5ML	VENUS REMEDIES LTD-VNIT- 11 HILL TOP INDUSTRIAL ESTATE JHARRUJIRI EPIP INDIA	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X5.0 ML VIAL	01/07/2008
1689	NDA/MAL/HD P/3453	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	AMINOPHYLLI NE	AMINOPHYLLI NE	25MG/ML	M.J BIOPHARM PVT LTD- TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1 0.0 ML AMPOULE	01/07/2014

1690	NDA/MAL/HD P/3455	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	30MG + 60MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2009
1691	NDA/MAL/HD P/3457	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANUSOL OINTMENT	BISMUTH SUBGALLATE + BISMUTH OXIDE + ZINC OXIDE	22.5 MG + 8.75 MG + 107.5 MG	PERFORMANCE HEALTH LTD- 241 NAIN ROAD RETREAT SOUTH AFRICA 7945	SOUTH AFRICA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE	01/07/1997
1692	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997
1693	NDA/MAL/HD P/3459	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ENEMAX	HYPERTONIC SOLUTION OF SODIUM PHOSPHATES	6GM AND 16GM/100ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997

1694	NDA/MAL/HD P/3460	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL ADULT TABLETS	ATOVAQUONE + PROGUANIL HCL	250MG + 100MG	GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007
1695	NDA/MAL/HD P/3461	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZIDOVUDINE	ZIDOVUDINE	300MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H- 13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2008
1696	NDA/MAL/HD P/3462	VENUS REMIDIES LTD	AARON PHARMACEUTICALS LTD	PLATOL	CISPLATIN	500MG/100M L	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2014

1697	NDA/MAL/HD P/3464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TARTAR CONTROL LISTERINE ANTISEPTIC	ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL	18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML	JOHNSON&JOHNSON PTY LTD.-241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2007
1698	NDA/MAL/HD P/3465	MONDI-MUNDI PHARMA PVT LIMITED	SURGIPHARM (U) LIMITED	FECONTIN-Z	FERROUS GLYCINE SULPHATE+ZI NC SULPHATE+FO LIC 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	01/07/2008
1699	NDA/MAL/HD P/3466	DAWA LIMITED	SUPER MEDIC LTD	DAWASEC	SECNIDAZOLE	1G	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	01/07/2015
1700	NDA/MAL/HD P/3467	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM TRIHYDRATE	1000MG	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL	01/07/2008

1701	NDA/MAL/HD P/3471	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PAXOL	PACLITAXEL	100MG/16.7M L	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2008
1702	NDA/MAL/HD P/3473	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE	CEFTRIAXONE	1G	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100 SHANDONG P.R & INJECT CARE PARENTERALS PVT LTD- PLOT 130, SILVASSA ROAD,G.I.D.C,VAPI- 396195,GUJARAT,INDIA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL,1.0X10.0X1. 0 G VIAL	01/07/2011
1703	NDA/MAL/HD P/3474	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125M G/5ML	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2008

1704	NDA/MAL/HD P/3475	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM	500MG	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2010
1705	NDA/MAL/HD P/3478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1706	NDA/MAL/HD P/3480	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	HYOSPAN	HYOSCINE BUTYL BROMIDE	10MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2009
1707	NDA/MAL/HD P/3482	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLOX-250	CLOXACILLIN	250MG	MILAN LABORATORIES -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	01/07/2011

1708	NDA/MAL/HD P/3483	JOHNSON&JOHNSON PTY LTD. 241	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB 3- WAY	IBUPROFEN + PSEUDOEPHE DRINE HCL	200MG + 30MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2007
1709	NDA/MAL/HD P/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	01/07/2007
1710	NDA/MAL/HD P/3489	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	NEO MEDROL	METHYLPRED NISOLONE ACETATE+ NEOMYCIN SULFATE	2.5MG+2.5MG	PATHEON YM INC. TORONTO TORONTO, CANADA	CANADA	TOPICAL EXTERNAL LOTIONS	1.0X25.0 ML BOTTLE	01/07/1997
1711	NDA/MAL/HD P/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	01/07/2003
1712	NDA/MAL/HD P/3492	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN-50	DICLOFENAC SODIUM	50MG	ACINO PHARMA AG - DORNACHERSTRASSE, 114, 4147, AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/1997

1713	NDA/MAL/HD P/3493	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASVIR	ACICLOVIR	200MG	ASTRA LIFE CARE (INDIA) PVT LTD-57/P,RAJODA 382220, BAVLA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1714	NDA/MAL/HD P/3494	LABORATORIOS NOVAG SA	LABOREX UGANDA LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMI DE + AMINOBUTYRI C ACID + AMINO HYDROXYBUT YRIC ACID + VITAMIN B6	2G + 2G + 1G +1G	FERRER INTERNACIONAL S.A - -FOR LABORATORIOS NOVAG S.A GRAN VIA CARLOS III 94 08028 BARCELONA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X80.0 ML BOTTLE	01/07/2015
1715	NDA/MAL/HD P/3497	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIVOLIN FORTE	MULTI- INGREDIENT	MULTI- INGREDIENT	MEGA LIFE SCIENCES LIMITED-: PLANT I : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009
1716	NDA/MAL/HD P/3500	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 300	IRBESARTAN	300MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014

1717	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI	01/07/2010
1718	NDA/MAL/HD P/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	01/07/2015
1719	NDA/MAL/HD P/3505	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASF LIC	FOLIC ACID	5MG	ASTRA LIFE CARE (INDIA) PVT LTD-57/P,RAJODA 382220, BAVLA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2007
1720	NDA/MAL/HD P/3506	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ULTANE	SEVOFLURANE	100%W/W	AESICA QUEESNBOROUGH LTD- NORTH RD. QUEENSBOROUGH KENT	UNITED KINGDOM	NASAL SYSTEMIC UNIT DOSE LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2011

1721	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/2015
1722	NDA/MAL/HD P/3515	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 40/240	ARTEMETHER + LUMEFANTRIN E	40 MG + 40 MG	AJANTA PHARMA LTD .-B- 4//5/6, MIDC INDUSTRIALAREA, PAITHAN- 431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	01/07/2007
1723	NDA/MAL/HD P/3516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHEXYPHENI DYL HYDROCHLORI DE	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,1.0X 100.0 TABLET BLISTER	01/07/1998

1724	NDA/MAL/HD P/3517	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TOTO ZINC	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTD- SP-1192, A & B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013
1725	NDA/MAL/HD P/3519	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	STRIDES ARCOLAB LIMITED - 36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2010
1726	NDA/MAL/HD P/3522	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2011

1727	NDA/MAL/HD P/3523	PT NOVELL PHARMACEUTICAL LABORATORIES	MEDIPHARM SALES LIMITED	NOTRIXUM	ATRACURIUM	10MG/ML	PT NOVELL PHARMACEUTICALS LABORATORIES-JL WANAHERANG NO. 35 NAJUNG UDIK, GUNUNG PUTRI BOGOR 16962 INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2011
1728	NDA/MAL/HD P/3525	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLLIN	AMPICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARAstra- 410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/1998

1729	NDA/MAL/HD P/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	01/07/2009
1730	NDA/MAL/HD P/3533	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZIN E	5MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
1731	NDA/MAL/HD P/3535	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ADIFLAM-50	DICLOFENAC SODIUM TABLETS BP	50MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007

1732	NDA/MAL/HD P/3536	SANOPI PASTEUR	LABOREX UGANDA LIMITED	TETRAXIM	DIPHTHERIA/ TETANUS/ PERTUSSIS (ACELLULAR, COMPONENT) POLIOMYELITIS (INACTIVATED) VACCINE (ADSORBED)	301IU/ 401IU/ 25MCG/ POLIOMYELITIS - 40DU (TYPE 1)/ 8DU TYPE 2/ 32DU TYPE 3	SANOPI PASTEUR CAMPUS MERIEUX--1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOPI PASTEUR S.A-2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2011
1733	NDA/MAL/HD P/3540	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	CLOPACT-75	CLOPIDOGREL	75 MG	IPCA LABORATORIESLIMITED- IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
1734	NDA/MAL/HD P/3541	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	CARBOL	CARBOPLATIN	450MG/45ML	VENUS REMEDIES LTD, UNIT II, -HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X45.0 VIAL CARTON	01/07/2008

1735	NDA/MAL/HD P/3542	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	MARA MOJA	ASPIRIN + PARACETAMO L + CAFFEINE	400MG + 200MG + 50MG	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X110.0 X2.0 TABLET STRIP	01/07/2005
1736	NDA/MAL/HD P/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	01/07/2000
1737	NDA/MAL/HD P/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,1.0X500. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/2013

1738	NDA/MAL/HD P/3547	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-10	BISOPROLOL	10 MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008
1739	NDA/MAL/HD P/3548	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BECLATE 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 ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2009
1740	NDA/MAL/HD P/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	01/07/2007

1741	NDA/MAL/HD P/3550	VENUS REMEDIES LIMITED	AARON PHARMACEUTICALS LTD	DOXOL	DOCETAXEL	20MG/0.5ML	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X7.5 ML VIAL	01/07/2008
1742	NDA/MAL/HD P/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	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X10.0 X1.0X3.0 TABLET BLISTER	01/07/2009
1743	NDA/MAL/HD P/3552	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	CARBOL	CARBOPLATIN	150MG/15ML	VENUS REMEDIES LTD-VNIT- 11 HILL TOP INDUSTRIAL ESTATE JHARRUJIRI EPIP INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2008

1744	NDA/MAL/HD P/3553	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 25/67.5 B/L	ARTESUNATE+ AMODIAQUIN E	25MG+67.5M G	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2014
1745	NDA/MAL/HD P/3556	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	GRISACTIN- 500 TABLETS	GRISEOFULVIN TABLETS	500MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
1746	NDA/MAL/HD P/3558	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	SEROFLO-250	SALMETEROL+ FLUTICASONE PROPIONATE	25MCG + 250MCG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2009

1747	NDA/MAL/HD P/3560	ASTRA PHARMA UGANDA LIMITED	ASTRA PHARMA (U) LIMITED	DERMIZOL	KETOCONAZO LE	200MG	ASTRA LIFE CARE(INDIA) PVT LTD-PLOT NO. 57/P, SARKHEJ – BAVLA HIGHWAY, POST. RAJODA – 382220, TALUKA: BAVLA, DIST. AHMEDABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2009
1748	NDA/MAL/HD P/3561	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCILLIN ORAL SUSPENSION	AMPICILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
1749	NDA/MAL/HD P/3562	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	ORAL REHYDRATION SALTS	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + SODIINCITRAT E + POTASSIUM CHLORIDE	13.5G + 2.6G + 2.9G + 1.5G	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X20.0X20.8 G SACHET	01/07/2013

1750	NDA/MAL/HD P/3563	EUROLIFE HEALTHCARE PVT LIMITED	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	01/07/2010
1751	NDA/MAL/HD P/3566	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ARTESUN	ARTESUNATE	60 MG	GUILIN PHARMACEUTICAL CO LTD--NO. 43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5% NAHCO3 + 5 ML NACL INJECTION	01/07/2008
1752	NDA/MAL/HD P/3569	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CARBADAC- 200	CARBAMAZEPINE	200MG	CADILA HEALTH CARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
1753	NDA/MAL/HD P/3570	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTRIM-960	TRIMETHOPRIM/ SULFAMETHOXAZOLE	160MG/800MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2008

1754	NDA/MAL/HD P/3571	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	CADIPHEN EXPECTORANT	CHLORPHENIR AMINE/GUAIF ENESIN/AMM ONIUM CHLORIDE	2MG//80MG/ 100MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
1755	NDA/MAL/HD P/3573	VENUS REMEDIES LIMITED	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	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	01/07/2008
1756	NDA/MAL/HD P/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,KARASWADA,MAPU SA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2007
1757	NDA/MAL/HD P/3575	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 400 CAPSULES	CEFIXIME	400MG	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER	01/07/2007

1758	NDA/MAL/HD P/3578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2005
1759	NDA/MAL/HD P/3580	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADIN E HYDROCHLORI DE	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	01/07/2008
1760	NDA/MAL/HD P/3581	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOOZ 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD- PLANT I-PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAPU SA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2007
1761	NDA/MAL/HD P/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	01/07/2009
1762	NDA/MAL/HD P/3583	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	SIMVA-DENK 40	SIMVASTATIN	40MG	DENK PHARMA GMBH & CO- GO 11 STR.1 84529 T,HMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

1763	NDA/MAL/HD P/3584	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORAMPHE NICOL EYE DROPS	CHLORAMPHE NICOL	0.5%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2007
1764	NDA/MAL/HD P/3585	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	AMPILIN	AMPICILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997
1765	NDA/MAL/HD P/3586	VENUS REMEDIES LIMITED	AARON PHARMACEUTICALS LTD	DOXOL	DOCETAXEL	80MG/2ML	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2008
1766	NDA/MAL/HD P/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	01/07/2008

1767	NDA/MAL/HD P/3589	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	SIMVA-DENK 20	SIMVASTATIN	20MG	DENK PHARMA GMBH & CO- .GK GOII STR.1 84529 TIHMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1768	NDA/MAL/HD P/3590	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ALFOXAN 500 FC TABLETS	MEFENAMIC ACID	500MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2004
1769	NDA/MAL/HD P/3591	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	ARTESIANE 80MG/ML	ARTEMETHER	80MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/1998
1770	NDA/MAL/HD P/3595	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOXIL 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
1771	NDA/MAL/HD P/3597	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	ARTESIANE 20 PAEDIATRIC	ARTEMETHER	20MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2001
1772	NDA/MAL/HD P/3598	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	MYOSPAZ	PARACETAMO L + CHLORZOXAZ ONE	500MG + 250MG	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

1773	NDA/MAL/HD P/3600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTE 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	01/07/2008
1774	NDA/MAL/HD P/3601	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYDROKANT	HYDROCORTIS ONE ACETATE	1%W/W	SKANT HEALTH CARE LTD - 1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
1775	NDA/MAL/HD P/3603	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	VUMTREX SYRUP	LEVAMISOLE	40MG/5ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/2003

1776	NDA/MAL/HD P/3604	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AC-FENAC	ACECLOFENAC	100MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
1777	NDA/MAL/HD P/3607	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	LINOPRIL	LISINOPRIL DIHYDRATE	20MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X14.0X2.0 TABLET BLISTER	01/07/2004
1778	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER	01/07/1998

1779	NDA/MAL/HD P/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL SYRUP	PARACETAMO L + CHLORPHENIR AMINE + PSEUDOPHE DRINE	120MG+1MG+ 10MG	SHELYS PHARMACEUTICALS LTD,-NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32, P.O.BOX 3016, DAR ES SALAAM BETA HEALTHCARE INTERNATIONAL LIMITED- PLOT NUMBER LR 209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA ROAD INDUSTRIAL AREA, P.O.BOX 42569-00100 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010

1780	NDA/MAL/HD P/3612	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-HT	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
1781	NDA/MAL/HD P/3613	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ZIDOVUDINE ORAL SOLUTION	ZIDOVUDINE	50MG/5ML	HETERO LABS LTD UNIT III-22- 110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE	01/07/2013
1782	NDA/MAL/HD P/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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2008

1783	NDA/MAL/HD P/3618	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG)CO. LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE(WORKSHOP 406 AND 407)	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2011
1784	NDA/MAL/HD P/3619	ERIS LTD	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	01/07/2000
1785	NDA/MAL/HD P/3620	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN 10 TABLETS	HALOPERIDOL BP	10MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2004
1786	NDA/MAL/HD P/3621	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	AMPILIN	AMPICILLIN	125MG/5ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

1787	NDA/MAL/HD P/3622	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PROXIMEXA	CEFUROXIME AXETIL	125MG/5ML	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X50.0 ML BOTTLE	01/07/2007
1788	NDA/MAL/HD P/3624	AVENTIS INTERCONTINENTAL	LABOREX UGANDA LIMITED	ORELOX	CEFPODOXIME	40MG/5ML	SANOFI WINTHROP INDUSTRIE-SANOFI WINTHROP INDUSTRIE 56, RUE DE CHOISY AU BAC 60205 COMPIÈGNE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/2011

1789	NDA/MAL/HD P/3626	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX CAPSULES	CEPHALEXIN	250MG	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA. SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1997
1790	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE	01/07/2001

1791	NDA/MAL/HD P/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	01/07/2009
1792	NDA/MAL/HD P/3631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
1793	NDA/MAL/HD P/3634	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOPLUS	PARACETAMO L/ DEXTROMETH ORPHAN HCL/ CHLORPHENIR AMINE	500MG/ 15MG/ 2MG /10MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2008
1794	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2011

1795	NDA/MAL/HD P/3637	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TINODERM	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X18.0 G TUBE	01/07/1997
1796	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER,1.0X2.0X 10.0 TABLET BLISTER	01/07/2010
1797	NDA/MAL/HD P/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	01/07/2009
1798	NDA/MAL/HD P/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	1.0X10.0X2.0X7. 0 TABLET BLISTER	01/07/2007

1799	NDA/MAL/HD P/3643	GLAXOSMITHKLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	LAMISIL CREAM	TERBINAFINE	1%W/W	NOVARTIS CONSUMER HEALTH-SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
1800	NDA/MAL/HD P/3645	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	NEUROBEX	THIAMINE + RIBOFLAVIN + PYRIDOXINE + CYANOCOBAL AMIN+ FOLIC ACID	250MG + 15MG + 200MG + 250MG + 500MCG	TRIVENI FORMULATIONS LTD .-PLOT NO. 52, 53,54 ALEAP INDUSTRIAL ESTATE SURAMPALLI VILLAGE GANNAVARAM MANDAL KRISHNA (DT) A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2014
1801	NDA/MAL/HD P/3647	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NYSTAGO ORAL SUSPENSION	NYSTATIN	100000 IU	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2008
1802	NDA/MAL/HD P/3648	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 400	THEOPHYLLIN E	400MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009

1803	NDA/MAL/HD P/3650	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	ANTINAL	NIFUROXAZID E	220MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2011
1804	NDA/MAL/HD P/3651	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX SYRUP	CEPHALEXIN	125MG/5ML	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA. SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

1805	NDA/MAL/HD P/3653	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN	ARTEMETHER + LUMEFANTRIN E	80 MG + 480 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	1.0X6.0 TABLET BLISTER (WITH AMFM LOGO),1.0X6.0 TABLET BLISTER (WITHOUT AMFM LOGO),30.0X1.0X 6.0 TABLET BLISTER (WITH AMFM LOGO),30.0X1.0X 6.0 TABLET BLISTER (WITHOUT AMFM LOGO)	01/07/2008
1806	NDA/MAL/HD P/3656	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LUMERAX	ARTEMETHER / LUMEFANTRIN E	80MG/480MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X6. 0 TABLET BLISTER	01/07/2011
1807	NDA/MAL/HD P/3657	DAWA LIMITED	SUPER MEDIC LTD	DAWASTIN	NYSTATIN	100000IU/ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2009

1808	NDA/MAL/HD P/3660	ASTRA PHARMA (U) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTAGRA	SILDENAFIL CITRATE	100MG	ASTRA LIFE CARE (INDIA) PVT LTD-57/P,RAJODA 382220, BAVLA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2010
1809	NDA/MAL/HD P/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,1.0X3.0X1 0.0 TABLET BLISTER	01/07/2003
1810	NDA/MAL/HD P/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	01/07/2011
1811	NDA/MAL/HD P/3668	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN BD	AMOXICILLIN + CLAVULANIC ACID	200 MG/ 5 ML + 28.5 MG/ 5 ML	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE,1.0X140. 0 ML BOTTLE	01/07/1998

1812	NDA/MAL/HD P/3669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO- TRIMOXAZOLE	SULFAMETHO XAZOLE/TRIM ETHOPRIM	200MG/40MG	MEDICAMEN BIOTECH LTD -- SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2014
1813	NDA/MAL/HD P/3670	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TETRAREN CAPSULES	TETRACYCLINE HYDROCHLORI DE	250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2000
1814	NDA/MAL/HD P/3671	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLAVULIN TABLETS	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET STRIP,10.0X10.0 TABLET STRIP,1.0X20.0 TABLET STRIP	01/07/2003
1815	NDA/MAL/HD P/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	01/07/2008

1816	NDA/MAL/HD P/3674	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZI NE HYDROCHLORI DE	5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN	01/07/1997
1817	NDA/MAL/HD P/3675	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASCOPAN - SC	HYOSCINE BUTYLBROMID E	10MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2008
1818	NDA/MAL/HD P/3677	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	IBUREN	IBUPROFEN	200MG	RENE INDUSTRIES LTD- 680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
1819	NDA/MAL/HD P/3680	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	SUXAMETHON IUM CHLORIDE INJECTION B.P	SUXAMETHON IUM CHLORIDE	50MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2011

1820	NDA/MAL/HD P/3681	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL	PARACETAMO L	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2000
1821	NDA/MAL/HD P/3684	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	I-PILL	LEVONORGEST REL	1.5MG	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	1.0X1.0X1.0 TABLET BLISTER	01/07/2009
1822	NDA/MAL/HD P/3686	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBIN E	MULTIVITAMI N	MULTINGREDI ENT	ACINO PHARMA AG (FORMER MEPHA LLC)- DORNACHERSTRASSE 114 P.O BOX 445 CH4147, AESCH/BL	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/1997
1823	NDA/MAL/HD P/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 SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2010
1824	NDA/MAL/HD P/3693	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	IMODIUM	LOPERAMIDE HCL	2MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0 CAPSULE BLISTER	01/07/1997

1825	NDA/MAL/HD P/3694	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LORIDIN RAPITAB	LORATADINE	10MG	CADILANHEALTH CARE LTD ,,,-KUNDAIN INDUSTRIAL ESTATE PONDA GOA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2002
1826	NDA/MAL/HD P/3698	CADILA HEALTHCARE PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPHEN SYRUP	AMOXICILLIN	125MG/5ML	SPARSH BIO-TECH LTD -PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
1827	NDA/MAL/HD P/3699	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2005
1828	NDA/MAL/HD P/3702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATI N	20MG	AJANTA PHARMA LTD--B- 4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2005

1829	NDA/MAL/HD P/3703	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPYRIDINI UM CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2014
1830	NDA/MAL/HD P/3704	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA 100	SILDENAFIL	100MG	CADILA HEALTHCARE LTD- KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER,1.0X20.0 X4.0 TABLET BLISTER	01/07/2002
1831	NDA/MAL/HD P/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,1.0X2.0X 10.0 CAPSULE BLISTER	01/07/2005
1832	NDA/MAL/HD P/3707	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	OBETAS-120	ORLISTAT	120MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2010

1833	NDA/MAL/HD P/3708	SANOFI AVENTIS	LABOREX UGANDA LIMITED	AMARYL M	GLIMEPIRIDE+ METFORMIN HYDROCHLORI DE	2MG+500MG	HANDOK INC-78, DAEPUNGSANDAN-RO, DAESO-MYEON, EUMSEONG- GUN, CHUNGCHEONGBUK- DO, KOREA	NORTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
1834	NDA/MAL/HD P/3709	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	NIGHT & DAY - N	PARACETAMO L/ DIPHENHYDRA MINE CHLORIDE + PARACETAMO L/ PSEUDOPHE DRINE	500MG/ 25MG +600MG/ 90MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2010
1835	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/1997

1836	NDA/MAL/HD P/3711	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	POLY-MXB	POLYMYXIN B	500,000 UNITS	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0 ML VIAL	01/07/2013
1837	NDA/MAL/HD P/3712	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLOZAAR	LOSARTAN POTASSIUM / AMLODIPINE	50MG + 5MG	MICRO LABS LTD-92,SIPCOT INDUSTRIAL COMPLEX,HOSUR-635- 126(T.N)INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
1838	NDA/MAL/HD P/3717	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEFTRIAZONE SODIUM	CEFTRIAZONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICALS LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL,1.0X10.0X1. 0 G VIAL	01/07/1999

1839	NDA/MAL/HD P/3723	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	125MG/5ML	LABORATORY & ALLIED LTD-- PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	07/07/1997
1840	NDA/MAL/HD P/3724	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	EPIGAB	PREGABALIN	150MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	01/07/2015
1841	NDA/MAL/HD P/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	01/07/2007

1842	NDA/MAL/HD P/3728	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER + 1 * 10 SAMPLE	01/07/1998
1843	NDA/MAL/HD P/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	01/07/2008
1844	NDA/MAL/HD P/3730	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX	MOXIFLOXACI N HYDROCHLORI DE	400MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	2.0X5.0 TABLET BLISTER,1.0X5.0 TABLET BLISTER	01/07/2001

1845	NDA/MAL/HD P/3731	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ 50MG	EFAVIRENZ	50MG	AUROBINDO PHARMA LIMITED (UNIT III) -AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD- 500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2007
1846	NDA/MAL/HD P/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	01/07/2003
1847	NDA/MAL/HD P/3734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTIS ONE	2%W/W + 1%W/W	XEPA SAUL PATTINSON MALAYSIA-1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998

1848	NDA/MAL/HD P/3736	PHARMAVET LTD	DELMAW ENTERPRISES LIMITED	RECTOL 125 SUPPOSITORY	PARACETAMO L	125MG	BLISS GVS PHARMA LIMITED- PLOT NO. 10/11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
1849	NDA/MAL/HD P/3737	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ECOFLOX 500 TABLETS	CIPROFLOXACI N HYDROCHLORI DE	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	01/07/2009
1850	NDA/MAL/HD P/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,1.0X50.0X5 00.0 MG VIAL	01/07/2010

1851	NDA/MAL/HD P/3739	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ALDREN	ALENDRONAT E	70MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2011
1852	NDA/MAL/HD P/3741	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ACTIZINE	CETIRIZINE HYDROCHLORI DE	10MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X10.0 TABLET BLISTER	01/07/2006
1853	NDA/MAL/HD P/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	01/07/2006
1854	NDA/MAL/HD P/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,1.0X10.0 X15.0 ML BOTTLE	01/07/2001

1855	NDA/MAL/HD P/3745	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	WINDERM CREAM	BECLOMETHA SONE+MICON AZOLE+NEOM YCIN	0.025%W/W + 2%W/W + 0.5%W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2008
1856	NDA/MAL/HD P/3746	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENDRO	BENDROFLUM ETHIAZIDE	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
1857	NDA/MAL/HD P/3747	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	30.0X2.0 TABLET BLISTER	01/07/2002
1858	NDA/MAL/HD P/3748	AGOG PHARMA 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	01/07/2010

1859	NDA/MAL/HD P/3752	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PAINOTAB 200	PARACETAMO L/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	01/07/2003
1860	NDA/MAL/HD P/3753	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 180	MYCOPHENOL ATE SODIUM	180MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-OEFLINGER STR. 4479664 WEHR GERMANY	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006
1861	NDA/MAL/HD P/3754	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	SINAREST PD NASAL DROPS	OXYMETAZOLI NE HYDROCHLORI DE	0.025%W/V	CENTAUR PHARMACEUTICALS LTD- PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	01/07/2006

1862	NDA/MAL/HD P/3757	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNITRIM SUSPENSION	CO- TRIMOXAZOLE	240MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
1863	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/1998
1864	NDA/MAL/HD P/3762	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LAMICTAL 2MG	LAMOTRIGINE	2MG	GLAXO WELLCOME INC-ZI DE LA PEYENNIERE, 53100, MAYENNE	UNITED STATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2001
1865	NDA/MAL/HD P/3766	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	BUKOL TABLETS	HYOSCINE N- BUTYLBROMID E	10MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997

1866	NDA/MAL/HD P/3767	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/1999
1867	NDA/MAL/HD P/3768	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP 30MG	NIMODIPINE	30MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1868	NDA/MAL/HD P/3770	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCI N	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER	01/07/2005
1869	NDA/MAL/HD P/3773	AGOG PHARMA LTD	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,1.0X 100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005

1870	NDA/MAL/HD P/3777	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	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/1999
1871	NDA/MAL/HD P/3778	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCI N	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE	01/07/2004
1872	NDA/MAL/HD P/3779	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LOSIUM 50	LOSARTAN POTASSIUM	50MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X1.0X14. 0 TABLET BLISTER	01/07/2011
1873	NDA/MAL/HD P/3780	THE ARAB DRUG COMPANY	GOODMAN INTERNATIONAL LTD	VENTAL INHALER	SALBUTAMOL	200MCG	THE ARAB DRUG COMPANY- 5-EL MASSANEI ST AL AMEREYA CAIRO	EGYPT	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	01/07/1997

1874	NDA/MAL/HD P/3781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTEL	ALBENDAZOLE	20MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/2014
1875	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
1876	NDA/MAL/HD P/3783	PT NOVELL PHARMACEUTICAL LABORATORIES	ECHO PHARMACY (U) LIMITED	NOPRENIA	RISPERIDONE	2MG	PT NOVELL PHARMACEUTICALS LABORATORIES-JL WANAHERANG NO. 35 NAJUNG UDIK, GUNUNG PUTRI BOGOR 16962 INDONESIA	INDONESIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

1877	NDA/MAL/HD P/3784	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X60.0 ML BOTTLE	01/07/2011
1878	NDA/MAL/HD P/3787	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMET HYLPENICILLIN	125MG/5ML	SPARSH BIO-TECH PVT. LTD .- PLOT NO. 1, SURVEY NO. 42/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
1879	NDA/MAL/HD P/3789	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	5MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005
1880	NDA/MAL/HD P/3790	AGOG PHARMA	GITTOES PHARMACEUTICALS LIMITED	AGOFLOX-P	PEFLOXACIN	400MG	AGOG PHARMA-PLOT 33 SECTOR THE VASAI-TULUKA CO-OP ESTATE LTD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

1881	NDA/MAL/HD P/3792	MEDREICH PLC	LABOREX UGANDA LIMITED	FLEMING 228.5	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	200MG+28.5 MG	MEDREICH LIMITED UNIT 1- 12TH MILE, OLD MADRAS ROAD, VIRGONAGAR, BANGLORE-560049	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2007
1882	NDA/MAL/HD P/3794	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMET-200 (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	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2005
1883	NDA/MAL/HD P/3797	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	PROVIVE 1%	PROPOFOL	10MG/ML	CLARIS LIFE SCIENCES LIMITED-CHACHOSWADIII VASNA.AHMEDABAD- 382213,INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL	01/07/2002
1884	NDA/MAL/HD P/3798	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROTON TABLET	MULTI- INGREDIENT	N/A	AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004

1885	NDA/MAL/HD P/3801	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	FUNGISTIN ORAL SUSPENSION	NYSTATIN	100000 IU/ML	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2002
1886	NDA/MAL/HD P/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	01/07/2005
1887	NDA/MAL/HD P/3803	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	DICLODYNE SUPPOSITORY	DICLOFENAC SODIUM	100MG	BLISS GVS PHARMA LTD- PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER	01/07/2007
1888	NDA/MAL/HD P/3804	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBIN E IM	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100M G+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	01/07/1997

1889	NDA/MAL/HD P/3807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	NINGBO DAHONGYING PHARMACEUTICALS-N0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2008
1890	NDA/MAL/HD P/3808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 12.5MG	DICLOFENAC SODIUM	12.5MG	DELPHARM HUNINGUE S.A.S- SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY BLISTER	01/07/2006
1891	NDA/MAL/HD P/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	01/07/2006
1892	NDA/MAL/HD P/3810	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	TRIOSPORINE OINTMENT	NEOMYCIN+ POLYMYXIN B +BACITRACIN	3.4%W/W + 5%W/W + 0.4%W/W	GALENTIC PHARMA(INDIA) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2006

1893	NDA/MAL/HD P/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,1.0X 10.0 TABLET BLISTER	01/07/1997
1894	NDA/MAL/HD P/3813	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ACTIPAR	PIPERAZINE CITRATE	500MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	01/07/1997
1895	NDA/MAL/HD P/3814	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	50MG/1ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
1896	NDA/MAL/HD P/3818	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN	RECOMBINAN T HUMAN ERYTHROPOIE TIN	2000 I.U/0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML VIAL,1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2012
1897	NDA/MAL/HD P/3819	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	STRADUMEL	ALLOPURINOL	100MG	PHARMATHEN S.A-- 6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER,1.0X28.0 TABLET BLISTER	01/07/1997

1898	NDA/MAL/HD P/3825	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOXIL 250	AMOXICILLIN	250MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015
1899	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2005
1900	NDA/MAL/HD P/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,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET STRIP	01/07/2006

1901	NDA/MAL/HD P/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	01/07/2007
1902	NDA/MAL/HD P/3833	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	LABSTATIN VAGINAL TABLETS	NYSTATIN	100.000 I.U	LABORATORY & ALLIED LTD.- PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	VAGINAL TABLETS	1.0X15.0 PESSARY STRIP	01/07/2000
1903	NDA/MAL/HD P/3835	GLAXOSMITHKLINE LTD	BETA HEALTHCARE UGANDA LIMITED	HEDEX CAPLETS	PARACETAMO L+ASPIRIN+CA FFEINE ANHYDROUS	200MG+400M G+50MG	SMITHKLINE BEECHAM (NAIROBI)-NAIROBI, KENYA BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK	01/07/1997

1904	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/1998
1905	NDA/MAL/HD P/3839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOP HEN + PHENIRAMINE MALEATE	500 MG + 10.5 MG	KAMPALA PHARMACEUTICALS INDUSTIES-PLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER	01/07/2006
1906	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2000
1907	NDA/MAL/HD P/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	01/07/1998

1908	NDA/MAL/HD P/3844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSETRASSE CH-4332 STEIN SWITZERLAND. NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1- 80052, TORRE ANNUNCIATA (NA) ITALY	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER	01/07/1997
1909	NDA/MAL/HD P/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	01/07/2011
1910	NDA/MAL/HD P/3846	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	20 MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2005

1911	NDA/MAL/HD P/3848	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	AZIWOK	AZITHROMYCIN	200MG/5ML	WOCKHARDT LIMITED -- PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	01/07/1998
1912	NDA/MAL/HD P/3850	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
1913	NDA/MAL/HD P/3853	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	ZINC SULPHATE TABLET USP	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
1914	NDA/MAL/HD P/3854	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS 50 TABLETS	LOSARTAN POTASSIUM	50MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2003

1915	NDA/MAL/HD P/3859	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	IFIMOL	PARACETAMO L	10MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES--PLOT NO. 4 PASE IV, GIDC PANOLI -394 116 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
1916	NDA/MAL/HD P/3860	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOLAC	LACTULOSE	3.35MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/2009
1917	NDA/MAL/HD P/3862	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LAMITOR 100	LAMOTRIGINE	100MG	TORRENT PHAMACEUTICALS LTD-TORRENT PHAMACEUTICALS LTD INDRAD 382721 DIST MEHSANA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

1918	NDA/MAL/HD P/3866	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	RL	COMPOUND SODIUM LACTATE INFUSION BP	0.6/ 0.25 /0.04 / 0.027 % W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500. 0 ML BOTTLE	01/07/2010
1919	NDA/MAL/HD P/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	01/07/1997
1920	NDA/MAL/HD P/3871	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	DOVERIN 40	DROTAVERINE HYDROCHLORI DE	40MG	INTAS PHARMACEUTICALS LIMITED-PLOT NO. 457 / 458 SARKHEJ-BAVLA HIGHWAY, MATODA - 382 210, TALUKA - SANAND, DISTRICT - AHMEDABAD, STATE -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

1921	NDA/MAL/HD P/3872	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET SYRUP	CETIRIZINE HYDROCHLORI DE	5MG/5ML	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA THE MADRAS PHARMACEUTICALS-137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE	01/07/2006
1922	NDA/MAL/HD P/3873	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORPROMA ZINE INJECTION B.P	CHLORPROMA ZINE	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2011
1923	NDA/MAL/HD P/3874	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	RIDMAL 40/320	DIHYDROARTE MISININ + 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,1.0X1.0X 3.0 TABLET BLISTER,1.0X1.0X 8.0 TABLET BLISTER,1.0X1.0X 9.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER	01/07/2010

1924	NDA/MAL/HD P/3875	PHAMA INTERNATIONAL CO	OMAB UGANDA LIMITED	OPTIMAL(0.05 % GEL	TRETINOIN USP	0.25MG/1G	PHARMA INTERNATIONAL COMPANY .-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN	JORDAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X1.0X30.0 G TUBE	01/07/2005
1925	NDA/MAL/HD P/3879	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	METRIM SUSPENSION	CO- TRIMOXAZOLE	240MG/5ML	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
1926	NDA/MAL/HD P/3880	SOLVAY PHARMACEUTICALS BV	HARLEYS UGANDA LIMITED	FAVERIN	FLUVOXAMIN E MALEATE	100MG	SOLVAY PHARMACEUTICALS BV--SOLVAY PHARMACEUTICALS BV VEERWEG 12 8121 AA, THE NETHERLANDS	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2008
1927	NDA/MAL/HD P/3881	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MOXACIL	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2009

1928	NDA/MAL/HD P/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	01/07/1997
1929	NDA/MAL/HD P/3883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOL ATE SODIUM	360MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS PHARMA PRODUKTIONS GMBH-OEFLINGER STR.4479664 WEHR GERMANY	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER	01/07/2006
1930	NDA/MAL/HD P/3886	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	DELOR	CLOBETASOL PROPIONATE	0.5 MG/G	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE	01/07/2004

1931	NDA/MAL/HD P/3887	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 150MG	PREGABALIN	150 MG	PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007
1932	NDA/MAL/HD P/3888	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PYRIREN	PYRIDOXINE HYDROCHLORI DE	25MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2014
1933	NDA/MAL/HD P/3889	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 75MG	PREGABALIN	75 MG	PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007
1934	NDA/MAL/HD P/3891	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	LADININ	CIPROFLOXACI N	500MG	PHARMATHEN S.A-- 6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1997
1935	NDA/MAL/HD P/3892	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TETRAX	LEVAMISOLE HYDROCHLORI DE	40MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE	01/07/1997

1936	NDA/MAL/HD P/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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2008
1937	NDA/MAL/HD P/3896	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	MODI MUNDIPHARMA PVT. LTD-MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
1938	NDA/MAL/HD P/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	01/07/2010
1939	NDA/MAL/HD P/3899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDATE + PYRIDOXINE + CYANOCOBAL AMIN + FOLIC ACID	216.87MG + 1.5MG + 7.5MCG + 1.5MG	AJANTA PHARMA LIMITED- 31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2013

1940	NDA/MAL/HD P/3900	ASTRA PHARMA UGANDA LTD	ASTRA PHARMA (U) LIMITED	ASTIBA-500	TINIDAZOLE	500MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET BLISTER	01/07/2009
1941	NDA/MAL/HD P/3901	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	MICROGYNON ED FE	LEVONORGEST REL + ETHINYLESTRA DIOL	0.15MG + 0.03MG	BAYER WEIMER GMBH- DOBEREINERSTRASSE 20, D- 99427 WEIMER 2.BAYER PHARMA AG 13342, BERLIN BAYER PHARMA AG - 51368 LEVERKUSEN GERMANY	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER	01/07/2011
1942	NDA/MAL/HD P/3903	PFIZER LABS LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CESENTRI 300MG	MARAVIROC	300MG	GODECKE GMBH - MOOSWALDALLEE 179090, FREIBERG GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0X6 .0 TABLET BLISTER	01/07/2008
1943	NDA/MAL/HD P/3906	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	LEROLE	PANTOPRAZO LE	40MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL 1*10ML 0.9%NACL AMPOULE	01/07/2011

1944	NDA/MAL/HD P/3913	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN	SODIUM VALPROATE	200 MG	MODI MUNDIPHARMA PVT. LTD-MEERUT- MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
1945	NDA/MAL/HD P/3914	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN	AMOXICILLIN + CLAVULANATE POTASSIUM	875 MG + 125 MG	SMITHKLINE BEECHAM PHARMACEUTICALS,- CLARENDON ROAD, WORTHING, WEST SUSSEX, BN148QH	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X1.0X7.0 TABLET BLISTER	01/07/2010
1946	NDA/MAL/HD P/3916	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	METOCLOPRA MIDE HYDROCHLORI DE INJECTION	METOCLOPRA MIDE HYDROCHLORI DE	5MG/ML	KIVIPHARM CO. LTD-NO.5 HANGTIAN STREET DONGSHAN HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, SHALINGZI TOWN ZHANGJIAKOU CITY, HEBEI PROVINCE	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008

1947	NDA/MAL/HD P/3919	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HALOPERIDOL	HALOPERIDOL	10MG	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 BLISTER	01/07/2005
1948	NDA/MAL/HD P/3920	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PHOTERICIN B	AMPHOTERICI N B	50MG	CIPLA LTD-M-61, M-62 & M- 63, VERNA INDUSTRIAL ESTATE VERNA GOA,INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 MG VIAL	01/07/2011
1949	NDA/MAL/HD P/3922	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	DIAZI	DIAZEPAM	5MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011

1950	NDA/MAL/HD P/3923	ASTRA PHARMA UGANDA LIMITED	ASTRA PHARMA (U) LIMITED	AXASONE	DEXAMETHAS ONE	0.5MG	ASTRA LIFE CARE(INDIA) PVT LTD-PLOT NO. 57/P, SARKHEJ – BAVLA HIGHWAY, POST. RAJODA – 382220, TALUKA: BAVLA, DIST. AHMEDABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2008
1951	NDA/MAL/HD P/3924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMO L+PSEUDOEPH 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,1.0X 100.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 10.0 TABLET BLISTER	01/07/1997
1952	NDA/MAL/HD P/3925	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CALCIUM GLUCONATE INJECTION	CALCIUM GLUCONATE	10 %W/V	NINGBO DAHONGYING PHARMACEUTICALS-N0.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE	01/07/2009

1953	NDA/MAL/HD P/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	01/07/1997
1954	NDA/MAL/HD P/3927	KOTRA PHARMA (M) SDN BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL CEPHALEXIN 125	CEPHALEXIN MONOHYDRA TE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2008
1955	NDA/MAL/HD P/3928	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MALAREN	SULPHADOXIN E + PYRIMETHAMI NE	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,1.0X10.0 X10.0 TABLET BLISTER,1.0X50.0 X3.0 TABLET BLISTER	01/07/2004

1956	NDA/MAL/HD P/3931	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM 80/480	ARTEMETHER + LUMEFANTRIN E	80MG +480MG	NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ İHLA VADISI SOKAK, NO.2, 34912 KURTKOY, İNSTANBUL - TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER	01/07/2014
1957	NDA/MAL/HD P/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	01/07/2008
1958	NDA/MAL/HD P/3933	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER	01/07/2001

1959	NDA/MAL/HD P/3938	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ADRENALINE INJECTION	ADRENALINE	1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE	01/07/2013
1960	NDA/MAL/HD P/3945	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	CEFONE	CEFTRIAXONE	1G	SWISS PARENTERALS LTD, UNIT- II-PLOT NO. 402,412- 414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011

1961	NDA/MAL/HD P/3947	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	RABTAS-20	RABEPRAZOLE SODIUM	20 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2008
1962	NDA/MAL/HD P/3949	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION	MAGNESIUM TRISILICATE+A LUMINIUM HYDROXIDE	500MG/5ML+ 250MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997

1963	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2014
1964	NDA/MAL/HD P/3951	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	125MG/5ML + 125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR- 361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2004
1965	NDA/MAL/HD P/3960	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMO L/IBUPROFEN	325/400MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	01/07/2008

1966	NDA/MAL/HD P/3961	MEDREICH PLC	LABOREX UGANDA LIMITED	BIOFERON	MULTI INGREDIENT	N/A	MEDREICH STERILAB LIMITED-NO. 4/3, AVALAHALI ANJANAPURA POST,OFF KANAKAPWA ROAD, BANGALORE 560062 INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2007
1967	NDA/MAL/HD P/3963	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM DISPERSIBLE TABLETS	ARTEMETHER + LUMEFANTRIN E	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,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER,2.0X1.0X 24.0 TABLET BLISTER,2.0X1.0X 18.0 TABLET BLISTER,1.0X36.0 X6.0 TABLET BLISTER	01/07/2009
1968	NDA/MAL/HD P/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	01/07/2004

1969	NDA/MAL/HD P/3966	DAWA LIMITED	SUPER MEDIC LTD	ASCORBIC ACID TABLETS	ASCORBIC ACID	100 MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER	01/07/2008
1970	NDA/MAL/HD P/3967	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCLOX-125	CLOXACILLIN	125MG/5ML	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2011
1971	NDA/MAL/HD P/3969	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRAN ULES	1.0X6.5 G SACHET	01/07/2002

1972	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
1973	NDA/MAL/HD P/3971	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE-SL	CEFTRIAXONE + SULBACTAM	1G+500MG	VIRCHOW HEALTHCARE PVT LTD,-PLOT NO.130, SILVASSA ROAD, GGID VAPI-396 195, GUJURAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 10 ML AMPOULE WFI	01/07/2013
1974	NDA/MAL/HD P/3972	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FERTOMID-50	CLOMIPHENE	50MG	CIPLA LTD-VERNA INDIA ESTATES 403722 GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2007
1975	NDA/MAL/HD P/3973	IPCA LABORATORIES LIMITED	MEDVIN PHARMA LIMITED	LARITHER	ARTEMETHER	80MG/ML	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE,1.0X8. 0X1.0 ML AMPOULE	01/07/1999

1976	NDA/MAL/HD P/3977	CHINOIN PHARMACEUTICALS AND CHEMICAL WORKS, CO. LTD	LABOREX UGANDA 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,1.0X2.0X 10.0 TABLET BLISTER	01/07/1998
1977	NDA/MAL/HD P/3980	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AB-TONE TONIC	VITAMIN B1 + VITAMIN B2 + VITMAIN B6 + VITAMIN B12 + FOLIC ACID + VITAMIN B5 + CALCIUM GLUCONATE + VITAMIN B3 + IRON + ZINC SULPHATE + COPPER SULPHATE + MANGANESE CHLORIDE + LYSINE HCL + HONEY + MALT	MG PER 5ML: 5 + 1 + 1 + 5 + 50 + 2 + 20 + 10 + 10 + 3 + 0.2 + 0.25 + 20 + 100 + 100	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X200.0 ML BOTTLE,1.0X90.0 ML BOTTLE	01/07/2008
1978	NDA/MAL/HD P/3981	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENAMOX	AMOXYCILLIN	500MG	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	25.0X20.0 CAPSULE BLISTER,10.0X10. 0 CAPSULE BLISTER,1.0X500. 0 CAPSULE CONTAINER	01/07/1997

1979	NDA/MAL/HD P/3983	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMO L/CAFFEINE TABLETS	500MG/65MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0 X2.0 TABLET BLISTER	01/07/2008
1980	NDA/MAL/HD P/3985	AGOG PHARMA LTD	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 SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2008
1981	NDA/MAL/HD P/3987	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ROHISOL SYRUP	LEVAMISOLE HYDROCHLORI DE	40MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997

1982	NDA/MAL/HD P/3989	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	UNICELIB 200	CELECOXIB	200MG	UNICHEM LABORATORIES LTD UNIT II ,,-VILLAGE, BHATAULI KALAN BADDI DIST. SOLAN (H.P) 173 205 UNICHEM LABORATORIES LTD--PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
1983	NDA/MAL/HD P/3990	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL SYRUP	AMOXYCILLIN TRIHYDRATE	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X100.0 ML BOTTLE	01/07/1997
1984	NDA/MAL/HD P/3991	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOFULVIN	GRISEOFULVIN TABLETS	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

1985	NDA/MAL/HD P/3993	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	NEM SCAB	MULTI- INGREDIENT	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
1986	NDA/MAL/HD P/3996	AGOG PHARMA 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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2007
1987	NDA/MAL/HD P/3998	AGOG PHARMA 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,1.0X1.0X 60.0 ML BOTTLE	01/07/2008

1988	NDA/MAL/HD P/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	01/07/2008
1989	NDA/MAL/HD P/4001	AGOG PHARMA 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,1.0X1.0X 60.0 ML BOTTLE	01/07/2008
1990	NDA/MAL/HD P/4002	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCID	ALUMINIUM HYDROXIDE+ MAGNESIUM HYDROXIDE	250MG/5ML+ 250MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X170. 0 ML BOTTLE	01/07/2007

1991	NDA/MAL/HD P/4003	TATA UGANDA LIMITED	TATA UGANDA LIMITED	OXYTOCIN INJ	OXYTOCIN	10IU/ML	GLAND PHARMA LIMITED 143-148-D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/2008
1992	NDA/MAL/HD P/4006	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	RHINATHIOL 5% FOR ADULTS SUGARFREE	CARBOCISTEIN E	5G/100ML	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2004
1993	NDA/MAL/HD P/4007	SANOFI PASTEUR	LABOREX UGANDA LIMITED	SHANCHOL CHOLERA VACCINE	V.CHOLERA STRAINS- 01 INABA FORMALDEHY DE KILLED +01 OGAWA HEAT KILLED + 01 OGAWA FORMALDEHY DE KILLED + 01 INABA HEAT KILLED + 0139 FORMALDEHY DE KILLED	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACC HARIDE (LPS)	SHANTHA BIOTECHNICS LTD - SURVEY NO. 274, ATHVELLI VILLAGE, MEDCHAL MANDAL - 501401, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X1.5 ML VIAL (1 DOSE)	01/07/2016

1994	NDA/MAL/HD P/4010	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	PYRI	PYRIDOXINE HYDROCHLORI DE	25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 10.0 TABLET BLISTER	01/07/1997
1995	NDA/MAL/HD P/4012	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 2000	CEFTRIAZONE	2000MG	LABESFAL LABORATORIOS ALMIRO, S.A ,.-ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X50.0 ML VIAL	01/07/2004
1996	NDA/MAL/HD P/4014	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	FUSIGEN	SODIUM FUSIDATE	20MG/G	GENO PHARMACEUTICALS LIMITED- KARASWADA,MAPUSA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	01/07/2011

1997	NDA/MAL/HD P/4015	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TAMBAC 50	CEFPODOXIME PROXETIL	50MG/5ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2005
1998	NDA/MAL/HD P/4016	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	COMPOUND SODIUM LACATE INTRAVENOUS INFUSION	MULTI- INGREDIENT	MULTI- INGREDIENT	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2007

1999	NDA/MAL/HD P/4018	MEDREICH PLC	LABOREX UGANDA LIMITED	ZEBEN	ALBENDAZOLE	100MG/5ML	MEDREICH LTD-4/3 OFF KANAPURA ROAD, AVALAHALLI, A, TEJKAMAL PHARMACEUTICAL PVT, SURVEY NO.6/2 ALADAHALLI,SOMAPURAO BIL,NELAMANGALA TALUK,BANGALORE RURAL- 562111,INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE	01/07/2007
2000	NDA/MAL/HD P/4019	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 1G	AMOXICILLIN + FLUCLOXACILLIN	500 MG + 500 MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2007
2001	NDA/MAL/HD P/4021	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AZY-500	AZITHROMYCIN	500MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2011

2002	NDA/MAL/HD P/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	01/07/1997
2003	NDA/MAL/HD P/4024	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAC SYRUP	LACTULOSE	3.350G/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2007
2004	NDA/MAL/HD P/4030	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	XBETA- N	BETAMETHAS ONE + NEOMYCIN	0.1%W/V +0.5%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	01/07/2011
2005	NDA/MAL/HD P/4031	SEDICO PHARMACEUTICAL CO	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SALBUTAMOL SYRUP	SALBUTAMOL	2MG/5ML	SIDECO PHARMACEUTICAL CO LTD- EGYPT-1ST INDUSTRIAL ZONE, 6 OCTOBER CITY- EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X120.0 ML BOTTLE	01/07/2007

2006	NDA/MAL/HD P/4033	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN PAEDIATRIC SYRUP	DIPHENHYDRA MINE HYDROCHLORI DE	7MG/5ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	01/07/2007
2007	NDA/MAL/HD P/4035	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	YASMIN	DROSPIRENON E + ETHINYLESTRA DIOL	3MG+0.3MG	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X21.0 TABLET BLISTER	01/07/2010
2008	NDA/MAL/HD P/4038	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	PREDSONE-5	PREDNISOLON E	5MG	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2012
2009	NDA/MAL/HD P/4047	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	NEOGAB	GABAPENTIN	300MG	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER	01/07/2007

2010	NDA/MAL/HD P/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,1.0X2.0X 5.0 TABLET BLISTER,1.0X20.0 X5.0 TABLET BLISTER,1.0X6.0X 2.0X5.0 TABLET BLISTER	01/07/2004
2011	NDA/MAL/HD P/4052	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	HETERO DRUGS LTD-UNIT- 111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055 HETERO LABS LTD. UNIT (V) .-S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2010
2012	NDA/MAL/HD P/4055	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	BAYER ASPIRIN CARDIO	ACETYLSALICYLIC ACID	100MG	BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2006

2013	NDA/MAL/HD P/4057	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X10.0 X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2011
2014	NDA/MAL/HD P/4062	GLAXO SMITH KLEINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	KIVEXA	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	GLAXO WELLCOME S.A.- AVENIDA DE EXTREMADURA 3 09400 ARANDA DE DUERO BURGOS SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET CONTAINER,1.0X 3.0X10.0 TABLET BLISTER	01/07/2006
2015	NDA/MAL/HD P/4064	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	TERAFINE	TERBINAFINE	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2010

2016	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/1997
2017	NDA/MAL/HD P/4068	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE/ ZIDOVUDINE/ EFAVIRENZ	LAMIVUDINE+ ZIDOVUDINE + EFAVIRENZ	150MG + 300MG + 600MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X15.0 TABLET BLISTER	01/07/2007
2018	NDA/MAL/HD P/4074	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	UMICORT-100	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL	01/07/2001
2019	NDA/MAL/HD P/4078	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	EPIGAB	PREGABALIN	75MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER	01/07/2013

2020	NDA/MAL/HD P/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	01/07/2009
2021	NDA/MAL/HD P/4082	SANOFI AVENTIS	LABOREX UGANDA LIMITED	NO-SPA FORTE	DROTAVERINE HCL	80MG	CHINOIN PHARMACEITCAULS AND CHEMICAL WORKS CO. LTD- H10-45 BUDAPEST TOU HUNGARY.	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
2022	NDA/MAL/HD P/4085	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINACEF	CEFUROXIME SODIUM	750MG	GLAXO WELLCOME -VERONA ITALY	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL	01/07/1997
2023	NDA/MAL/HD P/4086	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	KELVIN SUSPENSION	PARACETAMO L	120MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2008

2024	NDA/MAL/HD P/4091	HILTON PHARMA PVT LTD	HEALTHCARE LTD.	MYTEKA TABLETS	MONTELUKAS T SODIUM	5MG	HILTON PHARMA PVT,LTD- 13 SECTOR 15,KORANG,IND.AREA,8TH FLOOR PROGRESSIVE PLAZA,BEAMONT RD,KARACHI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2005
2025	NDA/MAL/HD P/4092	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLORANORM	SACCHAROMY CES BOULARDII	250MG	BHARAT BIOTECH INTERNATIONAL LTD- TURKPALLY SHAMEX 500 078 MYDERAHAD INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X2.0X250.0 MG SACHET,1.0X10.0 X250.0 MG SACHET	01/07/2010
2026	NDA/MAL/HD P/4093	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	BECLOMIN OINTMENT	BECLOMETHA SONE+MICON AZOLE+NEOM YCIN	0.025%W/W + 2%W/W + 0.5%W/W	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/2007
2027	NDA/MAL/HD P/4095	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2007

2028	NDA/MAL/HD P/4097	GLAXOSMITHKLINE LTD UK	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE - GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X30.0 G TUBE	01/07/1997
2029	NDA/MAL/HD P/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	01/07/2007
2030	NDA/MAL/HD P/4100	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NORETHISTER ONE	NORETHISTER ONE	5MG	REMEDICA LIMITED - AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007
2031	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER	01/07/2015

2032	NDA/MAL/HD P/4102	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	AZULIX-2	GLIMEPIRIDE	2MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2007
2033	NDA/MAL/HD P/4103	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	POLIO SABIN - ONE AND THREE [ORAL]	LIVE ATTENUATED POLIOMYELITIS VIRUS VACCINE OF THE SABIN STRAINS TYPE 1 +TYPE 2	10^6 CCID ₅₀ + 10^5 . ^{8} CCID ₅₀	GLAXO SMITHKLINE BIOLOGICALS S.A-RUE DE L'INSTITUT, 89 B-1330 RIXENSART	BELGIUM	ORAL LIQUID ORDINARY DROPS	1.0X100.0X2.0 ML VIAL (20 DOSES)	01/07/2016
2034	NDA/MAL/HD P/4104	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	25MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2009
2035	NDA/MAL/HD P/4107	ABBOTT HEALTHCARE , SAS	HARLEYS UGANDA LIMITED	DUSPATALIN 200 MG	MEBEVERINE	200MG	SOLVY PHARMACEUTICALS LTD-VEERWEG 12 NL 8121 NETHERLANDS	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008
2036	NDA/MAL/HD P/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	01/07/2005

2037	NDA/MAL/HD P/4114	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RINALIN SYRUP	CHLORPHENIR AMINE MALEATE	2MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2038	NDA/MAL/HD P/4115	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	PREDILONE	PREDNISOLON E	5.0 MG	REGAL PHARMACEUICALS LTD-PLOT NO 7879 OFF BABA DOGO ROAD KUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2007
2039	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2005
2040	NDA/MAL/HD P/4121	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	RIFINAH 300	RIFAMPICIN + ISONIAZID	300MG + 150MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	01/07/2005

2041	NDA/MAL/HD P/4125	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PARACETAMO L SUSPENSION	PARACETAMO L	120MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997
2042	NDA/MAL/HD P/4126	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	UNICELIB 100	CELECOXIB	100MG	UNICHEM LABORATORIES LTD-UNIT II, VILLAGE BHATAULI KALAN, BADDI SOLAN (HP) 173205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2003
2043	NDA/MAL/HD P/4127	SANOFI AVENTS FRANCE	LABOREX UGANDA LIMITED	EPILIM	SODIUM VALPROATE	200MG/5ML	UNITHER LIQUID MANUFACTURING INDUSTRIE -COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X300. 0 ML BOTTLE	01/07/1998
2044	NDA/MAL/HD P/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,1.0X1.0X 100.0 ML BOTTLE	01/07/2008

2045	NDA/MAL/HD P/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	01/07/2005
2046	NDA/MAL/HD P/4131	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	NEVIRAPINE	NEVIRAPINE	200MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD - H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2008

2047	NDA/MAL/HD P/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	01/07/2001
2048	NDA/MAL/HD P/4140	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	DIAZEPAM INJECTION	DIAZEPAM	10MG/2ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2004
2049	NDA/MAL/HD P/4141	SANOFI WINTHROP A.M.O	LABOREX UGANDA LIMITED	EPILIM 200	SODIUM VALPROATE	200MG	FISONS LTD (ALSO KNOWN AS SANOFI-AVENTIS)-RIELL, SPAIN	SPAIN	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2001
2050	NDA/MAL/HD P/4142	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	CO-ARTESAIN	ARTEMETHER + LUMEFANTRIN E	360MG + 2160MG	MPF BV-APPLEHOF 13; NI 8465 RX OUDEHASKE NETHERLANDS	NETHERLANDS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X120.0 ML BOTTLE	01/07/2010
2051	NDA/MAL/HD P/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	01/07/2013

2052	NDA/MAL/HD P/4146	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA- 410209,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
2053	NDA/MAL/HD P/4147	ERIS LTD	BENLE CONSULT LIMITED	NIFEDI-DENK 20 RETARD	NIFEDIPINE	20MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529	GERMANY	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2000
2054	NDA/MAL/HD P/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,1.0X100. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1998

2055	NDA/MAL/HD P/4149	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	TRACRIUM INJECTION	ATRACURIUM BESYLATE	10MG/ML	GLAXO SMITHKLINE MANUFACTURING S.P.A .- STARDA PROVINCIALE ASOLANA 90, 43056 SAN POLO DI TORRILE (PARMA) GLAXOSMITHKLINE SPA FLEMING -2, 37135 PARMA	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X2.5 ML AMPOULE,1.0X5. 0 ML AMPOULE,1.0X1 0.0 ML AMPOULE	01/07/2010
2056	NDA/MAL/HD P/4150	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VIL L.MANAKPUR,TEH.NALAGAR H,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER	01/07/1997
2057	NDA/MAL/HD P/4153	TATA UGANDA LIMITED	TATA UGANDA LIMITED	DIAZEPAM INJECTION	DIAZEPAM	5MG/ML	GLAND PHARMA LTD.- GLAND PHARMA LTD, D.P. PALLY, SURVEY NO. 143,150 &	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2009

2058	NDA/MAL/HD P/4165	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ZEFONE INJECTION	CEFTRIAXONE SODIUM	1G	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100 INJECTCARE PARENTERALS PVT. LTD.-PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT ZEISS PHARMACEUTICALS PVT LTD- 72 EXPORT PROMOTION INDUSTRIAL PARK ,PHASE- 1,JHARMAJRI, BADDI DIST:SOLAN H.P INDIA ZYDUS HEALTHCARE LIMITED-SURVEY NO. 49/3, 51/1, 51/2 RINGANWADA VILLAGE, DAMAN (U.T)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2001

2059	NDA/MAL/HD P/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,1.0X5.0X 4.0 CAPSULE BLISTER	01/07/2008
2060	NDA/MAL/HD P/4170	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC	TRAMADOL HYDROCHLORI DE	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	01/07/2000
2061	NDA/MAL/HD P/4171	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TOREX	MULTIINGRED IENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2062	NDA/MAL/HD P/4172	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	KOF OFF EXPECTORANT	MULTI- INGREDIENT	MULTI- INGREDIENT	RENE INDUSTRIES-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X110.0 ML BOTTLE	01/07/2005

2063	NDA/MAL/HD P/4175	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT 156.25	AMOXYCILLIN TRIHYDRATE+ POTASSIUM CLAVUNALATE	156.25MG/5M L	AUROBINDO PHARMA LTD, UNIT XII,--SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2007
2064	NDA/MAL/HD P/4180	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	OSMOWIN	LACTULOSE	10G/15ML	G.S PHAMBUTOR PVT LTD- G.S PHAMBUTOR PVT LTD B- 172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/2015
2065	NDA/MAL/HD P/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,1.0X50.0 X4.0 TABLET STRIP	01/07/2007
2066	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011

2067	NDA/MAL/HD P/4187	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORIGYNON	ESTRADIOL VALERATE +NORETHINDR ONE ENANTHATE	5 MG+50 MG / ML	BAYER PHARMA A.G- MULLERSTRASSE 178, 13353 BERLIN, GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997
2068	NDA/MAL/HD P/4188	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRAZ	PRAZIQUANTE L	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,1.0X2.0X 4.0 TABLET BLISTER,1.0X1.0X 4.0 TABLET BLISTER	01/07/2013
2069	NDA/MAL/HD P/4209	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	POZINEG 1000	CEFEPIME	1000MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 1*1AMP WATER FOR INJECTION	01/07/2008

2070	NDA/MAL/HD P/4241	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMPICILLIN SODIUM FOR INJECTION BP	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2011
2071	NDA/MAL/HD P/4276	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	FALCI CARE	ARTESUNATE	60MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 5 ML NACL + 1 ML SODIUM BICARBONATE	01/07/2013
2072	NDA/MAL/HD P/4277	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	VIVIRON PLUS SYRUP	FERRIC AMMONIUM CITRATE +FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMID E	50MG + 0.5MG + 2.2MG + 1.3MG +11MG	NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2014

2073	NDA/MAL/HD P/4279	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROTIM	TIMOLOL MALEATE	0.5% W/V	AUROLAB-NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
2074	NDA/MAL/HD P/4280	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAM IVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	MYLAN LABORATORIES LTD , - PLOT NO. 11, 12, & 13 INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III PITHAMPUR 454775, DIST DHAR – MADHYA PRADESH MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013
2075	NDA/MAL/HD P/4289	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TWINRIX ADULT	INACTIVATED HEPATITIS A ANTIGEN + HEPATITIS B SURFACE ANTIGEN	720 ELISA UNITS + 20MCG	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL (1 DOSE)	01/07/2013

2076	NDA/MAL/HD P/4291	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
2077	NDA/MAL/HD P/4292	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	HERCEPTIN 150MG	TRASTUZUMA B	150MG	ROCHE DIAGNOSTICS GMBH MANNHEIM--SANDHOFER STRASSE 116 -68305 MANNHEIM GERMANY.	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
2078	NDA/MAL/HD P/4295	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTRAFLAM TABLETS	PARACETAMO L + IBUPROFEN	500MG + 400MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2079	NDA/MAL/HD P/4297	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CLOBEN-G	CLOTRIMAZOL E/BECLOMETH ASONE/GENTA MYCIN	1%W/W+0.02 5%W/W+0.1% W/W	INDOCO REMEDIES LIMITED- L-14 VERNA INDUSTRIAL AREA VERNA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
2080	NDA/MAL/HD P/4303	PFIZER LABORATORIES (PTY)	LABOREX UGANDA LIMITED	SAYANA PRESS	MEDROXYPRO GESTERONE ACETATE	104MG/0.65M L	PFIZER MANUFACTURING - NV/NA, RIJKSWEIG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY I M PRE-FILLED SYRINGES	1.0X200.0X0.65 ML PRE- FILLED SYRINGE	01/07/2010

2081	NDA/MAL/HD P/4307	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	MIKACIN	AMIKACIN SULPHATE	500MG/2ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X8.0X2.0 ML VIAL,1.0X1.0X2.0 ML VIAL	01/07/2009
2082	NDA/MAL/HD P/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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA HETERO LABS LTD- 22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2010

2083	NDA/MAL/HD P/4312	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F	FOLLITROPIN ALFA	75IU/IE	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY MERCK SERONO S.A. (MSA) - 1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI	01/07/2016
2084	NDA/MAL/HD P/4315	DENK PHARMA GMBH &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	01/07/2016
2085	NDA/MAL/HD P/4317	DENK PHARMA GMBH &CO. KG	BENLE CONSULT LIMITED	COLOSAR- DENK 50/12.5	LOSARTAN + HYDROCHLOR OTHIAZIDE	50MG + 12.5MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/2011

2086	NDA/MAL/HD P/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	07/01/2016
2087	NDA/MAL/HD P/4323	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ANDARAN	IRBESARTAN	300 MG	LEK PHARMACEUTICALS LTD- LEK PHARMACEUTICALS VEROVSKOVA 57 SI 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2088	NDA/MAL/HD P/4324	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PRASUSAFE 5	PRASUGREL	5MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2089	NDA/MAL/HD P/4325	AJANTA PHARMA LTD 31-0	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC 100	ACECLOFENAC	100MG	AJANTA PHARMA LIMITED-B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X2.0X10 .0 TABLET BLISTER	01/07/2009

2090	NDA/MAL/HD P/4329	AGOG PHARMA 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,1.0X1.0X 60.0 ML BOTTLE	01/07/2010
2091	NDA/MAL/HD P/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	01/07/2016
2092	NDA/MAL/HD P/4333	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	CARVIBERG	CARVEDILOL USP	6.25MG	THE MADRAS PHARMACEUTICALS-137- B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENN AL INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

2093	NDA/MAL/HD P/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	01/07/2011
2094	NDA/MAL/HD P/4335	DAWA LIMITED	SUPER MEDIC LTD	CURAMOL SUSPENSION	PARACETAMO L	120MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009
2095	NDA/MAL/HD P/4338	MISSION PHARMA	JOINT MEDICAL STORE (UPMB - UCMB)	ALBENDAZOLE	ALBENDAZOLE	400MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER	01/07/2008
2096	NDA/MAL/HD P/4339	GLAXOSMITHKLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	SERETIDE 125 EVOHALER	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG/125M CG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER	01/07/2007

2097	NDA/MAL/HD P/4343	PASTEUR MERIEUX CONNANGHT	LABOREX UGANDA LIMITED	EUVAX B (PAEDIATRIC)	HEPATITIS B VACCINE, RECOMBINAN T	20MCG/ML	LG LIFE SCIENCES LTD- 601, YONGJEI-DONG, IKSAN, JE	SOUTH KOREA	PARENTERAL ORDINARY I M VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2007
2098	NDA/MAL/HD P/4344	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LISTRIL-10	LISINOPRIL	10MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2000
2099	NDA/MAL/HD P/4347	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	VERTIGON	CINNARIZINE	25MG	GENO PHARMACEUTICALS LTD. -TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA, GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10. 0 TABLET BLISTER	01/07/2010
2100	NDA/MAL/HD P/4348	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDICLOAMP SYRUP	CLOXACILLIN+ AMPICILLIN	250MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997

2101	NDA/MAL/HD P/4350	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN-75	DICLOFENAC SODIUM	75MG/2ML	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN HAUPT PHARMA WULFING GMBH.- BETHELNER LANDSTR. 18, 31028 GRONAU/LEINE	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/1997
2102	NDA/MAL/HD P/4351	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR SULFATE	ABACAVIR SULPHATE	60MG	CIPLA LTD-PATALGANGA UNIT II PLOT MO A-33 A42 MIDC RAIGAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2010
2103	NDA/MAL/HD P/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	01/07/2001

2104	NDA/MAL/HD P/4354	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RUXID 300	ROXITHROMY CIN	300MG	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	1.0X7.0 TABLET BLISTER	01/07/2011
2105	NDA/MAL/HD P/4355	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ANDARAN	IRBESARTAN	150MG	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2106	NDA/MAL/HD P/4356	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	FRESHEN	BISACODYL	5 MG	ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X12.0 TABLET BLISTER	01/07/2005

2107	NDA/MAL/HD P/4358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES- VIA 3 SETTE SANTI FLORENCE 50131 ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE	01/07/2016
2108	NDA/MAL/HD P/4360	ASTRAZENECA	MACNAUGHTON LIMITED	ZESTRIL	LISINOPRIL	5MG	ASTRAZENECA PHARMACEUTICALS LP - HUANGSHAN ROAD, WUXI 214028, JIANGSU, CHINA. ASTRAZENECA MACCLESFIELD-UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X 14.0 TABLET BLISTER	01/07/1997
2109	NDA/MAL/HD P/4362	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	LEVOMAC 750	LEVOFLOXACIN HEMIHYDRATE	750MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016

2110	NDA/MAL/HD P/4363	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEPTRIN	CO- TRIMOXAZOLE	480MG	THE MADRAS PHARMACEUTICALS-137- B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENN AL INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2111	NDA/MAL/HD P/4364	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VOMIZ OD 8	ONDANSETRO N HYDROCHLORI DE DIHYDRATE	8MG	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	01/07/2016
2112	NDA/MAL/HD P/4365	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC PLUS	ACECLOFENAC + PARACETAMO L	100 MG + 500 MG	AJANTA PHARMA LIMITED-B- 4/5/6,MIDC AREA, PAITHAN,431 148 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2009
2113	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER	01/07/2004

2114	NDA/MAL/HD P/4367	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 8MG	CANDESARTAN	8MG	ASTRA ZENECA AB, SODERTALJE- GARTUNAYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2115	NDA/MAL/HD P/4368	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	150MG + 300MG + 200MG	CIPLA LTD-VERNA INDIA ESTATES 403722 GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2007
2116	NDA/MAL/HD P/4369	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE+PARACETAMOL	1.25MG+10MG+120MG	TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSO T,SATYAVEDU MANDAL,CHITTOOR DISTRICT- ANDRA PRADESH-517588, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2117	NDA/MAL/HD P/4373	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	AZIBERG	AZITHROMYCIN DIHYDRATE	500MG	THE MADRAS PHARMACEUTICALS-137- B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2016

2118	NDA/MAL/HD P/4375	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCI N DIHYDRATE	200MG/5ML	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORG SAN,MICHELE PFIZER LABORATORIES (PTY) LTD;-- SOUTH AFRICA	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	01/07/1997
2119	NDA/MAL/HD P/4376	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ+LA MIVUDINE & TENOFVIR TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFVIR	600MG +300MG + 300MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2016
2120	NDA/MAL/HD P/4377	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE	13.5MG + 2.6MG + 2.9MG + 1.5MG	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET,1.0X10.2 5 G SACHET	01/07/2008
2121	NDA/MAL/HD P/4379	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	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,1.0X1.0X 6.0X20.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER	01/07/2010

2122	NDA/MAL/HD P/4380	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZINNAT SUSPENSION	CEFUROXIME AXETIL-	125MG/5ML	GLAXOSMITHKLINE UK LTD- HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1998
2123	NDA/MAL/HD P/4388	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS 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	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL	01/07/2016
2124	NDA/MAL/HD P/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	01/07/2011
2125	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016

2126	NDA/MAL/HD P/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	01/07/2003
2127	NDA/MAL/HD P/4394	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NS	SODIUM CHLORIDE	0.9% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2010

2128	NDA/MAL/HD P/4396	MYLAN LABORATORIES LIMITED (OTL)	KIMSY MEDS LTD	ABACAVIR SULPHATE	ABACAVIR SULFATE	300MG	MYLAN LABORATORIES LTD-- F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE MYLAN LABORATORIES LTD-- PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2007
2129	NDA/MAL/HD P/4398	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA 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	01/07/1997

2130	NDA/MAL/HD P/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	01/07/1997
2131	NDA/MAL/HD P/4401	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE DISODIUM	2G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL + 2*5 ML OF WFI GLASS AMPOULES	01/07/2014
2132	NDA/MAL/HD P/4404	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	FOLIGRAF	RECOMBINAN T HUMAN FOLLICLE STIMULATING HORMONE	75I.U/ VIAL	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL RETARD OTHER VIALS	1.0X1.0 VIAL CARTON	01/07/2016

2133	NDA/MAL/HD P/4406	AGOG PHARMA	GITTOES PHARMACEUTICALS LIMITED	SATISFIL -100	SILDENAFIL	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2011
2134	NDA/MAL/HD P/4408	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOL E	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2135	NDA/MAL/HD P/4410	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 4	MONTELUKAS T CHEWABLE TABLETS 4 MG	4MG	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 CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

2136	NDA/MAL/HD P/4411	ASTRA ZENECA	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	01/07/2010
2137	NDA/MAL/HD P/4412	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 5	MONTELUKAS T SODIUM	5MG	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 CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2138	NDA/MAL/HD P/4413	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE	1G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 2 PLASTIC AMPOULES OF WFI	01/07/2011

2139	NDA/MAL/HD P/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,1.0X2.0X 10.0 TABLET BLISTER	01/07/1997
2140	NDA/MAL/HD P/4417	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE SODIUM	500MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES	01/07/1999
2141	NDA/MAL/HD P/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	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NACL	01/07/2010

2142	NDA/MAL/HD P/4420	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HALOPERIDOL	HALOPERIDOL	5MG	MACLEODS PHARMACEUTICALS LTD. ...- UNIT I/UNIT II, PLOT 25-27, SR. NO. 366, PREMIER IND. ESTATE, KACHIGAM, DAMAN (U.T)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2005
2143	NDA/MAL/HD P/4425	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN FC	QUININE	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2011

2144	NDA/MAL/HD P/4468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZO LE SODIUM SESQUIHYDRA TE	40MG	AUROBINDOPHARMA LIMITED,-UNIT VII, SEZ APIIC, PLOT NO.SI SURVEY NO'S 425, 434,435 & 458 GREEN INDUSTRIAL PARK, POLEPALLY VILLAGEJEDCHERTA MANDAL, MAHABOBNAGAR DISTRICT, ANDRA PRADESH, INDIA. AUROBINDO UNIT XV-PLOT NO. 17 A, E. BONANGI (VILLAGE), JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM DIST, ANDHRA PRADESH -531021 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

2145	NDA/MAL/HD P/4480	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 5	MONTELUKAS T	5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2146	NDA/MAL/HD P/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	01/07/2007
2147	NDA/MAL/HD P/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	01/07/2007

2148	NDA/MAL/HD P/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	01/07/2008
2149	NDA/MAL/HD P/4526	AGOG PHARMA 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	01/07/2011
2150	NDA/MAL/HD P/4528	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE MF 15/500	PIOGLITAZONE + METFORMIN	15 MG + 500 MG	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2008

2151	NDA/MAL/HD P/4534	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	LORYTEC 10	LORATADINE	10MG	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2007
2152	NDA/MAL/HD P/4536	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX	FLUCLOXACILL IN + AMOXICILLIN	250MG+250M G	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X4.0 CAPSULE STRIP	01/07/2004
2153	NDA/MAL/HD P/4539	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	CRISTOL	VINCRIStINE SULPHATE	1MG	VENUS REMIDIES LTD-UNIT- 11 HILL TOP INDUSTRIAL ESTATE JHARMATI	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	01/07/2009
2154	NDA/MAL/HD P/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	01/07/2008

2155	NDA/MAL/HD P/4543	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	RHINATHIOL 5%	CARBOCISTEIN E	5%W/V	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE	01/07/2015
2156	NDA/MAL/HD P/4544	COSMOS LTD	ASTRA PHARMA (U) LIMITED	SALBUT TABLET 4MG	SALBUTAMOL	4MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER	01/07/2000
2157	NDA/MAL/HD P/4545	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-ART 20/120	ARTEMETHER + LUMEFANTRIN E	20 MG + 120 MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X8.0 TABLET BLISTER	01/07/2010
2158	NDA/MAL/HD P/4546	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CHLORAMPHE NICOL INJECTION IG	CHLORAMPHE NICOL SODIUM SUCCINATE	1G	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0X1.0 G VIAL,1.0X50.0X1. 0 G VIAL	01/07/1998

2159	NDA/MAL/HD P/4550	SANOVI AVENTS FRANCE	LABOREX UGANDA LIMITED	RHINATHIOL 2%	CARBOCISTEIN E	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	01/07/2001
2160	NDA/MAL/HD P/4553	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ARTESUN	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO. LTD.-NO. 43 QILIDIAN ROAD, GUILIN 541004	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE	01/07/2011
2161	NDA/MAL/HD P/4558	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	IFICIPRO 500	CIPROFLOXACI N	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	01/07/2003

2162	NDA/MAL/HD P/4559	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	PREGASAFE 75	PREGABALIN	75MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2014
2163	NDA/MAL/HD P/4561	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LORVAS SR	INDAPAMIDE	1.5MG	TORRENT PHARMACEUTICALS LTD- VILLAGE. BHUD-MAKHNU MAJRA, TEHSIL: BADDI 173205 DIST SOLAN (H.P)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET CONTAINER	01/07/2009
2164	NDA/MAL/HD P/4570	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE	NEVIRAPINE	200MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2005

2165	NDA/MAL/HD P/4571	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE STRIP,1.0X1000. 0 CAPSULE CONTAINER	01/07/1997
2166	NDA/MAL/HD P/4575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHAS ONE+GENTAM ICIN	0.1%+0.3%W/ V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2010
2167	NDA/MAL/HD P/4579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 500 IV VIALS	CEFTRIAXONE	500MG	LABESFAL LABORATORIOS ALMIRO, S.A ,.-ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*5 ML WFI AMPOULE	01/07/2005

2168	NDA/MAL/HD P/4586	PT NOVELL PHARMACEUTICAL LABORATORIES	MEDIPHARM SALES LIMITED	NOTRIXUM	ATRACURIUM	10MG/ML	PT NOVELL PHARMACEUTICALS LABORATORIES-JL WANAHERANG NO. 35 NAJUNG UDIK, GUNUNG PUTRI BOGOR 16962 INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.5 ML AMPOULE	01/07/2011
2169	NDA/MAL/HD P/4587	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIRATRO	ATROPINE	1MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1 .0 ML AMPOULE	01/07/2008
2170	NDA/MAL/HD P/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	01/07/2009
2171	NDA/MAL/HD P/4593	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKAN T-250	ERYTHROMYCI N STEARATE	250MG	S.KANT HEALTHCARE LTD- PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2011

2172	NDA/MAL/HD P/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,1.0X25.0 X4.0 TABLET BLISTER	01/07/1997
2173	NDA/MAL/HD P/4598	AGOG PHARMA LTD	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 TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011
2174	NDA/MAL/HD P/4601	SANOFI PASTEUR	LABOREX UGANDA LIMITED	PENTAXIM VACCINE	MULTI- INGREDIENT	MULTI- INGREDIENT	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE SANOFI PASTEUR S.A- 2,AVENUE PONT PASTEUR 69007 LYON- FRANCE(BUSINESS ADDRESS)	FRANCE	PARENTERAL ORDINARY I M PRE-FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE,1.0X0.5 ML VIAL	01/07/2010

2175	NDA/MAL/HD P/4602	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMALOG MIX 50	INSULIN LISPRO	100 .IU(50 I.U+50 I.U)	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X5.0 ML VIAL	01/07/2000
2176	NDA/MAL/HD P/4603	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN - 5	HALOPERIDOL	5MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005
2177	NDA/MAL/HD P/4605	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTRO METHORPHAN HBR+AMMONI UM CHLORIDE+ME NTHOL	4MG/5ML+5M G/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,1.0X1.0X 60.0 ML BOTTLE	01/07/2009
2178	NDA/MAL/HD P/4606	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATI N	10MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2179	NDA/MAL/HD P/4609	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYCORT	HYDROCORTIS ONE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

2180	NDA/MAL/HD P/4611	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	DAFRACLAV	AMOXYCILLIN + POTASSIUM CLAVULANATE	200MG + 28MG	BILIM PHARMACEUTICALS- ISLETMESI 59501 CERKEZKOY TEKIRDAG	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2011
2181	NDA/MAL/HD P/4614	GALENTIC PHARMA LTD	NORVIK ENTERPRISES LIMITED	COMPOUND BENZOIC ACID OINTMENT	BENZOIC ACID + SALICYLIC ACID	6 %W/W + 3 %W/W	GALENTIC PHARMA(INDIA) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE,1.0X500.0 G TUBE	01/07/2006
2182	NDA/MAL/HD P/4615	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 150	NILOTONIB HYDROCHLORI DE MONOHYDRA TE	150MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER	01/07/2014
2183	NDA/MAL/HD P/4617	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATI N	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	01/07/2010

2184	NDA/MAL/HD P/4620	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	MALANIL PAEDIATRIC TABLET	ATOVAQUONE + PROGUANIL	62.5 MG + 25.0 MG	GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER	01/07/2007
2185	NDA/MAL/HD P/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	01/07/2006
2186	NDA/MAL/HD P/4622	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	CLOXAREN	CLOXACILLIN	250MG	RENE INDUSTRIES-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER	01/07/2007
2187	NDA/MAL/HD P/4623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORI DE	2MG	RENE INDUSTRIAL LTD-RENE INDUSTRIES LTD, PLOT 680, KAMULI-KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2007
2188	NDA/MAL/HD P/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	01/07/2005

2189	NDA/MAL/HD P/4627	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM CREAM	HYDROCORTIS ONE	1%W/W	LABORATORY AND ALLIED LTD-PLOT 209/10349- MOMBASA ROAD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2190	NDA/MAL/HD P/4629	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN MONOHYDRA TE	125MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015
2191	NDA/MAL/HD P/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	01/07/2011
2192	NDA/MAL/HD P/4636	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLARAM 0.5	ALPRAZOLAM	0.5MG	DELORBIS PHARMACEUTICALS LTD-17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES P.O. BOX 28629, 2081 LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009

2193	NDA/MAL/HD P/4637	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PARACETAMO L	PARACETAMO L	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD- 368 JIANSHE ST HENGSHUI CITY HEBEI 053000	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2194	NDA/MAL/HD P/4645	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATI N 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	01/07/2010
2195	NDA/MAL/HD P/4647	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	LEVOLIN	LEVOSALBUTA MOL	50MCG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X200.0 METERED DOSE CANNISTER	01/07/2013
2196	NDA/MAL/HD P/4652	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII TETANUS TOXOID VACCINE	TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	≥ 5 LF (≥ 40 IU) ON ≤ 1.25 MG OF ALUMINIUM PHOSPHATE	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE (1 DOSE AMPOULE),1.0X1 0.0 ML VIAL (20 DOSE VIAL)	01/07/1997

2197	NDA/MAL/HD P/4657	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	VOLAR 300MG	GABAPENTIN	300MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2013
2198	NDA/MAL/HD P/4658	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN 0.5	MEROPENEM	0.5G	PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL	01/07/2014
2199	NDA/MAL/HD P/4660	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	RISDONE 2MG	RISPERIDONE	2MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2013

2200	NDA/MAL/HD P/4662	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASDOL	TRAMADOL	50MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2011
2201	NDA/MAL/HD P/4663	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	LORATAN	LORATIDINE	5MG/5ML	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2013
2202	NDA/MAL/HD P/4666	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	ANTIPLEX	CLOPIDOGREL BISULFATE	30MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013

2203	NDA/MAL/HD P/4669	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC 100MG SUPPOSITORIE S	DICLOFENAC SODIUM.	100MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	TOPICAL EXTERNAL ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2013
2204	NDA/MAL/HD P/4675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC RETARD 100	DICLOFENAC SODIUM	100MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER	01/07/2013

2205	NDA/MAL/HD P/4682	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE	LAMIVUDINE	10MG/ML	AUROBINDO PHARMA LIMITED-UNIT – III-SURVEY NO.:313 & 314,BACHUPALLY (VILLAGE)QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, TELANGANA STATE.INDIA.	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X240.0 ML BOTTLE	01/07/2006
2206	NDA/MAL/HD P/4686	AUROBINDOM PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	ZIDOVUDINE ORAL SOLUTION USP	ZIDOVUDINE	50MG/5ML	AUROBINDO PHARMA LTD .- UNIT III SURVEY NO.313 BACHU	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X240.0 ML BOTTLE	01/07/2007
2207	NDA/MAL/HD P/4690	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYPEN	PHENOXYMET HYL PENICILLIN	250MG	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997

2208	NDA/MAL/HD P/4693	ELYS CHEMICAL INDUSTRIES LTD	VELVET PHARMA LIMITED	ELYVATE	BETAMETHAS ONE VALERATE	1%W/W	ELYS CHEMICAL INDUSTRIES LTD-ROAD 'B' OFF ENTERPRISE ROAD, INDUSTRIAL AREA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	01/07/1997
2209	NDA/MAL/HD P/4694	MERCK SHARP & DOHME INTAPHARMA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ROTATEQ	ROTAVIRUS LIVE REASSORTANT VIRUS G1+G2+G3+G4 &P1	2.2M IU+2.8M IU+2.2M IU+2.0M IU	MERK & CO. INC- SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	ORAL LIQUID ORDINARY EMULSIONS	1.0X10.0 ML BOTTLE	01/07/2011
2210	NDA/MAL/HD P/4697	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	SANBE CLANEKSI	AMOXICILLIN + CLAVULANIC ACID	1000 MG + 200 MG	PT SANBE FARMA-JI LEUIGAJAH NO. 162 CIMINDI, INDONESIA	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X6.0 VIAL CARTON	01/07/2011
2211	NDA/MAL/HD P/4700	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIZOLE	METRONIDAZ OLE	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2006

2212	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/1997
2213	NDA/MAL/HD P/4702	PHARMACIE BETHEL	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	01/07/2011
2214	NDA/MAL/HD P/4703	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZ OLE	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	01/07/2011

2215	NDA/MAL/HD P/4704	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC 12.5	DICLOFENAC SODIUM	12.5MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2012
2216	NDA/MAL/HD P/4705	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DICLOGESIC- 50	DICLOFENAC	50MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2012
2217	NDA/MAL/HD P/4707	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL INJECTION	DICLOFENAC SODIUM	25MG/ML	WIN MEDICARE PVT LIMITED- MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE	01/07/1998

2218	NDA/MAL/HD P/4708	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIFEN	IBUPROFEN	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2006
2219	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/1998
2220	NDA/MAL/HD P/4712	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFINAL-500	MEFENAMIC ACID	500MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2009
2221	NDA/MAL/HD P/4713	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEFLAM	MEFENAMIC ACID	50MG/5ML	AJANTA PHARMA LIMITED- 31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	01/07/2011

2222	NDA/MAL/HD P/4714	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEPHOXIN 250MG/5ML	CEPHALEXIN	250MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1998
2223	NDA/MAL/HD P/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	1.0X5.0X2.0X10. 0 TABLET BLISTER	01/07/2008
2224	NDA/MAL/HD P/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	01/07/2008
2225	NDA/MAL/HD P/4718	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ACNOTIN 20	ISOTRETINOIN	20MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011

2226	NDA/MAL/HD P/4719	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	ACNOTIN 10	ISOTRETINOIN	10MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011
2227	NDA/MAL/HD P/4721	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	MEGABAL	MECOBALAMI N	5000MCG	PT SANBE FARMA,UNIT 1-JI INDUSTRI NO.9 LEUWIGAJAH CIMINDI CIMAHI WEST JAVA,INDONESIA	INDONESIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2011
2228	NDA/MAL/HD P/4723	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	MEGYL SUSPENSION	METRONIDAZ OLE BENZOATE	200MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/1997
2229	NDA/MAL/HD P/4724	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED DRY COUGH & COLD	TRIPROLIDINE HYDROCHLORI DE+PSEUDOEP HEDRINE HYDROCHLORI DE+DXTROM ETHORPHAN	1.25MG+30M G+10MG	GLAXOSMITHKLINE SAE ,.-EL SALAM CITY-11491, CAIRO	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X2.0 L BOTTLE	01/07/1997

2230	NDA/MAL/HD P/4725	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEGYL TABLET	METRONIDAZ OLE	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,1.0X 1000.0 TABLET CONTAINER	01/07/1997
2231	NDA/MAL/HD P/4726	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	ADB MIN MULTIPOWER	MULTI- INGREDIENT	MULTI- INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X300. 0 ML BOTTLE	01/07/1997
2232	NDA/MAL/HD P/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	01/07/2007
2233	NDA/MAL/HD P/4728	M.J.BIOPHARM PVT LTD	TATA UGANDA LIMITED	ADRENALINE	ADRENALINE	IMG/ML	M.J BIOPHARM PVT LTD- TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE	01/07/2014

2234	NDA/MAL/HD P/4730	SANOFI PASTEUR	LABOREX UGANDA LIMITED	MENACTRA	MENINGOCOCCAL GROUPS (A + C +Y + W-135) + POLYSACCHARIDE DIPHTEIRIA TOXOID CONJUGATE VACCINE	4MCG + 4MCG + 4MCG + 4MCG + 48MCG	SANOFI PASTEUR-INC DISCOVERY DRIVE SWIFTWATER PENNSYLVANIA 183370- 0187	UNITED STATES	PARENTERAL ORDINARY I M VIALS	1.0X5.0 ML VIAL (10 DOSE VIAL)	01/07/2011
2235	NDA/MAL/HD P/4731	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	MENAFRIVAC	MENINGOCOCCAL A CONJUGATE VACCINE	10MCG/ 0.5ML + 10- 33MCG/0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 DOSE VIAL + 1*5ML AMPOULE OF DILUENT	01/07/2011
2236	NDA/MAL/HD P/4735	MENTHOLATUM	HARLEYS UGANDA LIMITED	MENTHOLATUM BALM	MULTI- INGREDIENT	MULTI- INGREDIENT	THE MENTHOLATUM COMPANY LTD- TWYFORD, BENKSHIRE, E	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X4.0 G TUBE	01/07/1997
2237	NDA/MAL/HD P/4737	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CICOL DROPS	DICYCLOMINE HYDROCHLORIDE + SIMETICONE	10MG + 40MG/ 5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X10.0 ML BOTTLE	01/07/2014

2238	NDA/MAL/HD P/4739	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	MERO	MEROPENEM	1G	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011
2239	NDA/MAL/HD P/4743	DAFRA PHARMA N.V/S.A	LABOREX UGANDA LIMITED	MERONIA 1000	MEROPENEM	1000MG	DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY VIALS	1.0X1000.0 MG VIAL	01/07/2013
2240	NDA/MAL/HD P/4744	DAFRA PHARMA N.V/S.A	LABOREX UGANDA LIMITED	MERONIA 500	MEROPENEM	500MG	DEMO SA-21ST KM NATIONAL ROAD, ATHENS, LAMIA 14568 KRYONERI, ATHENS	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013
2241	NDA/MAL/HD P/4748	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE +SIMETHICON E	720MG+25MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER	01/07/2006
2242	NDA/MAL/HD P/4749	PT SANBE FARMA	MEDVIN PHARMA LIMITED	MEROSAN	MEROPENEM	1G	PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAH I WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2012

2243	NDA/MAL/HD P/4751	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2009
2244	NDA/MAL/HD P/4757	ERIS LTD	BENLE CONSULT LIMITED	METFORMIN- DENK 500	METFORMIN	500MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X 10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/1998
2245	NDA/MAL/HD P/4758	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	METFORMIN DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2011

2246	NDA/MAL/HD P/4759	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CIPRODAR	CIPROFLOXACIN	500MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2009
2247	NDA/MAL/HD P/4760	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	FEROSOFT	IRON (III) HYDROXIDE POLYMALTOSE COMPLEX	50MG/5ML	HILTON PHARMA (PVT) LTD- PLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/2005
2248	NDA/MAL/HD P/4765	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	FEROSOFT-FA	IRON(III)HYDR OXIDE POLYMALTOSE COMPLEX/FOL IC ACID	100MG/0.35M G	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2005

2249	NDA/MAL/HD P/4766	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEN SUSPENSION	MEBENDAZOL E	100MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2001
2250	NDA/MAL/HD P/4768	REMYNTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	METHACHLOR EYE DROPS	DEXAMETHAS ONE/CHLORA MPHENICOL	1MG/2MG	REMYNTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/1999
2251	NDA/MAL/HD P/4769	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER	01/07/2009
2252	NDA/MAL/HD P/4771	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	METHYLERGO METRINE	METHYLERGO METRINE MALEATE	20MCG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE	01/07/1997

2253	NDA/MAL/HD P/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	01/07/2014
2254	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2000
2255	NDA/MAL/HD P/4782	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	CYBIN PF	CYTARABINE	100MG/ML	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/2013

2256	NDA/MAL/HD P/4784	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	D50	GLUCOSE INTRAVENOUS INFUSION	50%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2257	NDA/MAL/HD P/4785	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	DAKTACORT	MICONAZOLE NITRATE+HYD ROCORTISONE	2%W/W+1%W /W	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997
2258	NDA/MAL/HD P/4786	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	COTRIMOXAZ OLE 960MG	SULPHAMETH OXAZOLE + TRIMETHOPRI M	800MG + 160MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2009
2259	NDA/MAL/HD P/4787	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	DAKTARIN	MICONAZOLE NITRATE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2260	NDA/MAL/HD P/4788	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	DAKTARIN ORAL GEL	MICONAZOLE NITRATE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL TOPICAL GELS AND SOLS	1.0X40.0 G TUBE	01/07/1997

2261	NDA/MAL/HD P/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,1.0X2.0 X8.0 CAPSULE STRIP	01/07/1997
2262	NDA/MAL/HD P/4790	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORI DE	150MG	FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	BELGIUM	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE STRIP,1.0X100.0 CAPSULE CARTON	01/07/1997
2263	NDA/MAL/HD P/4791	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PALMITATE	75MG/5ML	PHARMACIA AND UPJOHN S.P.A-RIJKSWEG 12, B-2870 PUURS	BELGIUM	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X80.0 ML BOTTLE	01/07/1997
2264	NDA/MAL/HD P/4792	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PHOSPHATE	150MG/ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL,1.0X2.0 ML VIAL	01/07/1997
2265	NDA/MAL/HD P/4793	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN T	CLINDAMYCIN PHOSPHATE	1%W/V	PHARMACIA AND UPJOHN S.P.A-RIJKSWEG 12, B-2870 PUURS	BELGIUM	TOPICAL EXTERNAL LIQUIDS	1.0X30.0 ML BOTTLE	01/07/1997

2266	NDA/MAL/HD P/4794	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	DALADOL	DICLOFENAC SODIUM + PARACETAMO L	50MG+500MG	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2012
2267	NDA/MAL/HD P/4795	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	DAROXIME	CEFUROXIME	500MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2010
2268	NDA/MAL/HD P/4796	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	DARROWS SOLUTION (HALF STRENGTH)	POTASSIUM CHLORIDE+SO DIUM CHLORIDE+SO DIUM LACTATE	0.13%+0.20%+ 0.30%	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2011

2269	NDA/MAL/HD P/4798	VENUS REMIDIES LTD	AARON PHARMACEUTICALS LTD	CITABOL	GEMCITABINE	2MG/ML	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2009
2270	NDA/MAL/HD P/4799	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITROLIN SOLUTION	CETRIMIDE+LI DOCAINE	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	01/07/1998
2271	NDA/MAL/HD P/4800	DAWA LIMITED	SUPER MEDIC LTD	DAWAVITE SYRUP	MULTI- INGREDIENT	MULTI- INGREDIENT	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2009

2272	NDA/MAL/HD P/4801	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DAZEL KIT	FLUCONAZOLE + AZITHROMYCI N + SECNIDAZOLE	150MG + 1G + 1G	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	01/07/2009
2273	NDA/MAL/HD P/4804	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLAVODAR	AMOXICILLIN + CLAVULANIC	200MG + 28MG /5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2012
2274	NDA/MAL/HD P/4805	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2000

2275	NDA/MAL/HD P/4806	AGOG PHARMA LTD	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,1.0X 100.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2009
2276	NDA/MAL/HD P/4807	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
2277	NDA/MAL/HD P/4809	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCORT	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	01/07/2013

2278	NDA/MAL/HD P/4811	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2009
2279	NDA/MAL/HD P/4812	AGOG PHARMA LTD	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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001
2280	NDA/MAL/HD P/4813	AGOG PHARMA LTD	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,1.0X 100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER	01/07/1998

2281	NDA/MAL/HD P/4814	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	METLIFE	METRONIDAZ OLE	500MG/100M L	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010
2282	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2014
2283	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997

2284	NDA/MAL/HD P/4821	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	METPURE-XL 50	METOPROLOL	50MG	EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI- BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2009
2285	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997
2286	NDA/MAL/HD P/4824	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	FERROUS SULPHATE+FO LIC ACID	FERROUS SULPHATE+FO LIC ACID	200MG+0.25 MG	BIO NOVA PHARM LTD.-C- 66/1 OKHLA INDUSTIAL AREA PHASE II NEW DEHLI	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2008

2287	NDA/MAL/HD P/4826	UNIQUE PHARMACEUTICALS LTD	TATA UGANDA LIMITED	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	01/07/2004
2288	NDA/MAL/HD P/4828	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	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	01/07/2001

2289	NDA/MAL/HD P/4830	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	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 DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-- 304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/1997

2290	NDA/MAL/HD P/4834	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	FINAGEN	FINASTERIDE	5MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2004
2291	NDA/MAL/HD P/4836	AGOG PHARMA 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,1.0X100. 0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2009
2292	NDA/MAL/HD P/4838	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	METRONIDAZ OLE	METRONIDAZ OLE	200MG/5ML	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2014

2293	NDA/MAL/HD P/4839	PHARMAVET LTD	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 SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER,1.0X2.0X 5.0 SUPPOSITORY BLISTER	01/07/2007
2294	NDA/MAL/HD P/4845	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ANTIDEP	IMIPRAMINE	25MG	TORRENT PHARMACEUTICALS LTD- INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VIL L.MANAKPUR,TEH.NALAGAR H,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/1997
2295	NDA/MAL/HD P/4851	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	CLOZOX V	CLOTRIMAZOL E	100MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	VAGINAL TABLETS	1.0X1.0X6.0 TABLET BLISTER	01/07/2004

2296	NDA/MAL/HD P/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	01/07/2014
2297	NDA/MAL/HD P/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,1.0X100. 0 ML BOTTLE	01/07/2000
2298	NDA/MAL/HD P/4856	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN	METRONIDAZ OLE	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,1.0X20.0 X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2001
2299	NDA/MAL/HD P/4858	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	METROREN SUSPENSION	METRONIDAZ OLE BENZOATE	200MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

2300	NDA/MAL/HD P/4859	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FLOXAPEN	FLUCLOXACILL IN	250MG	SMITHLINE BEECHAM CLARENDON RD WORTHIN- CLARENDON RD WORTHING WEST SUSSEX	UNITED KINGDOM	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CARTON	01/07/1997
2301	NDA/MAL/HD P/4863	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICALS LTD.	MICONAZ ORAL GEL	MICONAZOLE	2%W/W	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2003
2302	NDA/MAL/HD P/4865	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICALS LTD.	MICONAZ CREAM	MICONAZOLE NITRATE	2%W/W	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X20.0 G TUBE	01/07/2003
2303	NDA/MAL/HD P/4867	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	MICONA ORAL GEL	MICONAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT LTD --PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X40.0 G TUBE,1.0X20.0 G TUBE	01/07/2003

2304	NDA/MAL/HD P/4868	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA LIMITED	FLUCANIR	FLUCONAZOLE	2MG/ML	NIRMA LIMITED (HEALTHCARE DIVISION)- VILLAGE-SACHANA, TALUKA- VIRAMGAM DISTRICT- AHMEDABAD 382 150, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2305	NDA/MAL/HD P/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	01/07/2013
2306	NDA/MAL/HD P/4873	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCAS	FLUCONAZOLE	200MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2011
2307	NDA/MAL/HD P/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	01/07/2009

2308	NDA/MAL/HD P/4875	PHARM ACCESS AFRICA LTD	MARIE STOPES UGANDA LIMITED	MISOCLEAR	MISOPROSTOL	200MCG	ACME FORMULATION PVT LTD,-ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011
2309	NDA/MAL/HD P/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	01/07/2009
2310	NDA/MAL/HD P/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	01/07/2009
2311	NDA/MAL/HD P/4878	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	FLUCOLIFE	FLUCONAZOLE	200MG/100M L	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010

2312	NDA/MAL/HD P/4879	SANOFI-AVENTIS	LABOREX UGANDA 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	01/07/2009
2313	NDA/MAL/HD P/4880	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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,1.0X7.0X 4.0 TABLET BLISTER,1.0X15.0 X4.0 TABLET BLISTER	01/07/2014
2314	NDA/MAL/HD P/4884	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASFULVIN-500	GRISEOFULVIN	500MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT NO. 57/P, SARKHEJ-BAVLA HIGHWAY, POST RAJODA-382220, TALUKA BAVLA, AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

2315	NDA/MAL/HD P/4895	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLOMIFERT	CLOMIPHENE	50MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010
2316	NDA/MAL/HD P/4901	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX IV	MOXIFLOXACI N HCL	400MG/250M L	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE	01/07/2004
2317	NDA/MAL/HD P/4903	AGOG PHARMA LTD.	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,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2008
2318	NDA/MAL/HD P/4904	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30	INSULIN HUMAN	100 I.U/ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997

2319	NDA/MAL/HD P/4905	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX CREAM	ACYCLOVIR	5%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/1997
2320	NDA/MAL/HD P/4906	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	200MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP	01/07/1997
2321	NDA/MAL/HD P/4908	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD	DENMARK	PARENTERAL ORDINARY CARTRIDGES	1.0X3.0 ML CARTRIDGE,1.0X 1.5 ML CARTRIDGE	01/07/1997
2322	NDA/MAL/HD P/4909	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXAGYL	METRONIDAZ OLE	0.5%W/V	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2015

2323	NDA/MAL/HD P/4910	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	FLUZOL	FLUCONAZOLE	200MG	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2324	NDA/MAL/HD P/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	01/07/2008
2325	NDA/MAL/HD P/4917	KOTRA PHARMA (M) SDN BHD	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 SUSPENSIONS	1.0X120.0 ML BOTTLE	01/07/2010

2326	NDA/MAL/HD P/4919	KOTRA PHARMA (M) SDN BHD	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 MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2008
2327	NDA/MAL/HD P/4920	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	FOLIBEN	FOLIC ACID	5MG	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2011
2328	NDA/MAL/HD P/4922	KOPRAN LIMITED	TATA UGANDA LIMITED	CIPROQUIN- 500	CIPROFLOXACI N	500MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER	01/07/1999
2329	NDA/MAL/HD P/4924	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	MULTIVIT TABLET	MULTIVITAMI N	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	01/07/2001

2330	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
2331	NDA/MAL/HD P/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	1.0X1.0 ML AMPOULE	01/07/1997
2332	NDA/MAL/HD P/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	1.0X1.0 ML AMPOULE	01/07/1997

2333	NDA/MAL/HD P/4933	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUDOX	DOXYCYCLINE HYDROCHLORI DE	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD - PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X 10.0 CAPSULE BLISTER,1.0X500. 0 CAPSULE CONTAINER,1.0X 250.0 CAPSULE CONTAINER,1.0X 1000.0 CAPSULE CONTAINER	01/07/1997
2334	NDA/MAL/HD P/4935	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	BACTROBAN OINTMENT	MUPIROCIN	2%W/W	GLAXO OPERATIONS UK LTD - PRIORY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X3.0 G TUBE,1.0X15.0 G TUBE	01/07/1997
2335	NDA/MAL/HD P/4936	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COMBIFEN	IBUPROFEN + PARACETAMO L	400MG + 500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2011
2336	NDA/MAL/HD P/4937	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	MOTILIUM	DOMPERIDON E	10MG	SPECPHARM HOLDINGS (PTY) LTD. -15TH ROAD, HALFWAY HOUSE, 1685	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0 TABLET CARTON,1.0X30. 0 TABLET CARTON	01/07/1997

2337	NDA/MAL/HD P/4938	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	BACTROBAN CREAM	MUPIROCIN	2%W/W	GLAXO OPERATIONS UK LTD - PRIORY STREET, WARE HERTFORDSHIRE SG12 0DJ, UK	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	01/07/2012
2338	NDA/MAL/HD P/4939	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FOLIREN	FOLIC ACID	5MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2005
2339	NDA/MAL/HD P/4940	AGOG PHARMA LTD	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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2006

2340	NDA/MAL/HD P/4943	ASTRAZENECA	MACNAUGHTON LIMITED	NOLVADEX	TAMOXIFEN	20MG	ASTRAZENECA UK LIMITED - ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/1997
2341	NDA/MAL/HD P/4944	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	BENA EXPECTORANT	DIPHENHYDRA MINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE	14MG + 135MG + 57.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE	01/07/1997
2342	NDA/MAL/HD P/4945	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	FORMIT	METFORMIN	850MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2343	NDA/MAL/HD P/4946	ESAPHARMA S.R.L..	BYAMAKA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/1999

2344	NDA/MAL/HD P/4948	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	FORMIT 1000	METFORMIN HYDROCHLORI DE	1000MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2345	NDA/MAL/HD P/4949	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETH ORPHAN HYDROBROMI DE	15MG/ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2346	NDA/MAL/HD P/4950	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	FORMIT 500	METFORMIN	500MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL- HUSSEIN STREET. AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2009

2347	NDA/MAL/HD P/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&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE,1.0X2.5 L BOTTLE	01/07/1997
2348	NDA/MAL/HD P/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&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200. 0 ML BOTTLE	01/07/1997
2349	NDA/MAL/HD P/4953	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	NAT-B	MULTI- INGREDIENT	MULTI- INGREDIENT	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED-384 SOIB PATTANA 3 RD BANGPOO INDUSTRIAL ESTATE SAMUTPRAKARN 10280	THAILAND	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2009

2350	NDA/MAL/HD P/4955	NIRMA LIMITED.	LIFE PHARMA AFRICA 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	01/07/1997
2351	NDA/MAL/HD P/4956	UNIQUE PHARMACEUTICALS LABORATORIES	PLANET PHARMACEUTICALS UGANDA LTD	CONTRAPAQU E 350	IOHEXOL	350MG	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD- PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2010
2352	NDA/MAL/HD P/4957	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	MUMFER	IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID	100MG + 500MCG	GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004

2353	NDA/MAL/HD P/4958	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BENZOSED	MIDAZOLAM	1MG/ML	TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	01/07/2011
2354	NDA/MAL/HD P/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,1.0X1.0X15 .0 G TUBE	01/07/2010
2355	NDA/MAL/HD P/4965	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETAFEN SYRUP	IBUPROFEN	100MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2001

2356	NDA/MAL/HD P/4967	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX JUNIOR	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1998
2357	NDA/MAL/HD P/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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2008
2358	NDA/MAL/HD P/4969	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X2.4 MU VIAL	01/07/2001

2359	NDA/MAL/HD P/4970	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX DRY COUGH SYRUP	DIPHENHYDRA MINE HCL/ DEXTROMETH ORPHAN HBR/ PSEUDOPHE DRINE HCL	14MG+15MG+ 30MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2006
2360	NDA/MAL/HD P/4972	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	COOLMINT LISTERINE	MENTHOL + ALCOHOL 95%	0.02% + 4.58ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X 500.0 ML CONTAINER	01/07/2001
2361	NDA/MAL/HD P/4973	MERCK (PTY) LTD	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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI	01/07/2014
2362	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/1998

2363	NDA/MAL/HD P/4976	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PERGLIM 2	GLIMEPIRIDE	2MG	INVENTIA HEALTHCARE PVT. LTD .-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2015
2364	NDA/MAL/HD P/4979	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	FUROSEMIDE	FUROSEMIDE	10MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2010
2365	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER	01/07/1998
2366	NDA/MAL/HD P/4983	PT SAMBE FARMA	MEDVIN PHARMA LIMITED	PELASTIN	IMIPENEM + CILASTATIN	500MG + 500MG	PT SANBE FARMA-JI LEUWIGAJAH I62 CIMINDI CIMAHI WEST JAVA INDONESIA	INDONESIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2011

2367	NDA/MAL/HD P/4987	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	PYRAZINAMID E	PYRAZINAMID E	400 MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X24.0X28.0 TABLET BLISTER	01/07/2009

2368	NDA/MAL/HD P/4998	MYLAN LABS LTD	NORVIK ENTERPRISES LIMITED	HYAN	LEVONORGEST REL	0.03MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606- 1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL- UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA. MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER	01/07/2006

2369	NDA/MAL/HD P/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,1.0X1.0X10 0.0 ML VIAL	01/07/2010
2370	NDA/MAL/HD P/5002	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG MIX 25	INSULIN LISPRO + INSULIN LISPRO PROTAMINE®	25I.U+75I.U	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	01/07/2000

2371	NDA/MAL/HD P/5004	GLAXOSMITHKLINE LIMITED LIKONI	BETA HEALTHCARE UGANDA LIMITED	COFTA TABLETS	MULTI- INGREDIENT	N/A	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0 TABLET CARTON,1.0X50. 0 TABLET CARTON,1.0X150 .0 TABLET CARTON	01/07/1997
2372	NDA/MAL/HD P/5005	MACK BROWN PHARMECEUTICALS PVT 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	1.0X50.0X1.0X4. 0 TABLET BLISTER	01/07/2010

2373	NDA/MAL/HD P/5008	UNIMED	METAPLUS (U) LIMITED	COLDAFEX	MULTI- INGREDIENT	MULTI- INGREDIENT	UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
2374	NDA/MAL/HD P/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	01/07/1997
2375	NDA/MAL/HD P/5013	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	GENTAMYCIN EYE/EAR DROPS	GENTAMYCIN	0.3%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL	01/07/2009

2376	NDA/MAL/HD P/5015	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	COLD CAP CAPSULES	PHENYLEPHRI NE HYDROCHLORI DE+CHLORPHE NIRAMINE	5MG+4MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X500.0 CAPSULE CONTAINER, 1.0X 1000.0 CAPSULE CONTAINER, 1.0X 8.0X12.0 CAPSULE BLISTER, 1.0X10.0 X10.0 CAPSULE BLISTER, 1.0X12.0 CAPSULE BLISTER, 1.0X10.0 CAPSULE BLISTER	01/07/1997
2377	NDA/MAL/HD P/5017	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	COLD CAP SYRUP	PARACETAMO L+PROMETHA ZINE HYDROCHLORI DE+CODEINE PHOSPATE+PS EUDOEPHEDRI NE HYDROCHLORI DE	120MG+6.5M G+5MG+25M G	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2378	NDA/MAL/HD P/5018	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	VENTOLIN	SALBUTAMOL	100MCG	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE NO.2 23, RUE LAVOISIER 27000 EVREUX, FRANCE.	FRANCE	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/1997

2379	NDA/MAL/HD P/5019	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	COLOSPASMIN FORTE	MEBEVERINE	135MG	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)- EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER	01/07/2011
2380	NDA/MAL/HD P/5020	GLAXO WELLCOME (KENYA) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	VENTOLIN	SALBUTAMOL	2MG/ML	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/1997

2381	NDA/MAL/HD P/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATIO N 3	ETHINYL ESTRADIOL+ LEVONORGEST REL+FERROUS FUMARATE	0.03MG+0.15 MG+75MG	DELPHARMA SAS ZONE INDUSTRIELLE -DELPHARMA SAS ZONE INDUSTRIELLE DE ROUBAIX EST RUE DE TOUFFLERS BP 50070 59452 LYS LEZLANNOY CEDEX / BAYER PHARMA AG BERLIN BAYER PHARMA AG -13353 BERLIN GERMANY BAYER WEIMAR GMBH UND CO. KG,-WEIMAR DEBEREINERSTRASSE 20, 99427 WEIMAR GERMANY	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X100.0X28.0 TABLET BLISTER	01/07/2011
2382	NDA/MAL/HD P/5027	PFIZER LAB LTD	LABOREX UGANDA LIMITED	TERRA- CORTIL	MULTI- INGREDIENT	MULTI- INGREDIENT	PFIZER PGM ORLEANS FRANCE-AVENUE DE CONCYR, F-450	FRANCE	OPHTHALMIC LIQUIDS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE,1.0X4.0 ML BOTTLE	01/07/1997

2383	NDA/MAL/HD P/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	01/07/1997
2384	NDA/MAL/HD P/5030	PFIZER LAB LTD	LABOREX UGANDA LIMITED	SOLU-MEDROL	METHYLPRED NISOLONE HEMISUCCINA TE	125MG/2ML	PFIZER GLOBAL MANUFACTURING BELGIUM NV-RIJKSWEWEG 12, 2870 PUURS - BELGIUM	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL,1.0X8.0 ML VIAL	01/07/1997
2385	NDA/MAL/HD P/5031	THE MENTHOLATUM COMPANY LTD	HARLEYS UGANDA LIMITED	DEEP HEAT RUB	MULTI- INGREDIENT	MULTI- INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,-1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X35.0 G TUBE,1.0X67.0 G TUBE,1.0X100.0 G TUBE	01/07/1997

2386	NDA/MAL/HD P/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	01/07/2004
2387	NDA/MAL/HD P/5035	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEBENDAZOL E	MEBENDAZOL E	100MG/5ML	MEDICAMEN BIOTECH LTD - - SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2014
2388	NDA/MAL/HD P/5036	MYLAN LABORATORIES LIMITED	NORVIK ENTERPRISES LIMITED	DEPO PROGESTIN	MEDROXYPRO GESTERONE ACETATE	150MG	PT HARSEN LABORATORIES, JL RAYA - JL RAYA BOGOR, KM 24.6, JAKARTA TIMUR 13750	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X20.0 VIAL CARTON,1.0X25. 0X1.0 ML VIAL	01/07/2010

2389	NDA/MAL/HD P/5038	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-CAM TABLETS	MELOXICAM	15MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10. 0 TABLET BLISTER	01/07/2002
2390	NDA/MAL/HD P/5039	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	GILOBA	GINKO BILOBA EXTRACT	40MG	MEGA LIFE SCIENCES LIMITED-: PLANT I : 384 SOI 6, PATTANA 3 ROAD, BANGPOO INDUSTRIAL ESTATE, SAMUTPRAKAN 10280, THAILAND	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2010
2391	NDA/MAL/HD P/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	01/07/1997

2392	NDA/MAL/HD P/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,1.0X 500.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER	01/07/1998
2393	NDA/MAL/HD P/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	PARENTERAL ORDINARY I M VIALS	1.0X3.5 ML VIAL,1.0X1.0 ML VIAL	01/07/1997
2394	NDA/MAL/HD P/5046	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN PLUS 150/12.5	IRBESARTAN+ HYDROCHLOR OTHIAZIDE	150MG+12.5 MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
2395	NDA/MAL/HD P/5047	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	MAXINEM 500MG	MEROPENEM	500MG	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2013

2396	NDA/MAL/HD P/5048	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	MAXINEM 1G	MEROPENEM	1G	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
2397	NDA/MAL/HD P/5049	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN PLUS 300/12.5	IRBESARTAN/ HYDROCHLOR OTHIAZIDE	300MG/12.5M G	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2013
2398	NDA/MAL/HD P/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	01/07/2005
2399	NDA/MAL/HD P/5052	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	GLAMIDE TABLETS	GLIBENCLAMI DE	5 MG	LA-MED HEALTHCARE PVT LTD-1389 TRASAD ROAD, DHOLKA, AHMEDABAD, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997

2400	NDA/MAL/HD P/5054	SANOFI AVENTIS KENYA LTD	LABOREX UGANDA LIMITED	MAALOX	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	200MG + 200MG	WINTHROP PHARMACEUTICALS (PTY) LTD.-PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETO RIA-PRIVATE BAG X516,SILVERTON,0127,SOUT H AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0 TABLET BLISTER,1.0X5.0X 10.0 TABLET BLISTER	01/07/2011
2401	NDA/MAL/HD P/5055	GLAXOSMITHKLINE LTD UK	UNITED HEALTHCARE DISTRIBUTORS LTD	DERMOVATE	CLOBETASOL PROPIONATE	0.05%W/W	GLAXOSMITHKLINE HARMIRE - GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X25.0 G TUBE	01/07/1997
2402	NDA/MAL/HD P/5056	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	MAALOX SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	665MG/5ML + 200MG/5ML	WINTHROP PHARMACEUTICALS (PTY) LTD.-PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETO RIA-PRIVATE BAG X516,SILVERTON,0127,SOUT H 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	01/07/1997

2403	NDA/MAL/HD P/5057	SANOFI AVENTIS KENYA LTD	LABOREX UGANDA LIMITED	MAALOX PLUS	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE + SIMETHICONE	200MG + 200MG + 25MG	WINTHROP PHARMACEUTICALS (PTY) LTD.-PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETO RIA-PRIVATE BAG X516,SILVERTON,0127,SOUT H AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0X10.0 TABLET BLISTER	01/07/2011
2404	NDA/MAL/HD P/5059	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	MAALOX PLUS SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SI METHICONE	200MG+175M G+25MG/5ML	WINTHROP PHARMACEUTICALS (PTY) LTD.-PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETO RIA-PRIVATE BAG X516,SILVERTON,0127,SOUT H 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	01/07/1997
2405	NDA/MAL/HD P/5062	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	MANNILIFE	MANNITOL	20MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010

2406	NDA/MAL/HD P/5064	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	LIFE PHARMA AFRICA LIMITED	MANNITOL INFUSION	MANNITOL	20%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2011
2407	NDA/MAL/HD P/5066	M.J.BIOPHARM PVT LTD	TATA UGANDA 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	01/07/2015
2408	NDA/MAL/HD P/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	01/07/2010
2409	NDA/MAL/HD P/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	01/07/2009

2410	NDA/MAL/HD P/5071	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-40	ENOXAPARIN SODIUM	40MG/0.4ML	EMCURE PHARMACEUTICALS LTD - PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X1.0 ML PRE- FILLED SYRINGE	01/07/2009
2411	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE,1.0X2.5 ML BOTTLE	01/07/1997
2412	NDA/MAL/HD P/5074	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHAS ONE DISODIUM PHOSPHATE	4MG/ML	SAKAR HEALTH CARE PVT LTD-10/13 CHONGODAR SARKHEJ BAVLA ROAD DIST AHMEDABAD 382213 GUJARATI CADILA HEALTH CARE LTD-SARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDAD 382210, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X6.0X2.0 ML VIAL,16.0X6.0X2. 0 ML VIAL	01/07/1997

2413	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET STRIP	01/07/1997
2414	NDA/MAL/HD P/5078	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	GLANDIN E2 VAGINAL	DINOPROSTO NE	3MG	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	VAGINAL TABLETS	1.0X1.0 TABLET STRIP	01/07/2006
2415	NDA/MAL/HD P/5080	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	LOBAK	DICLOFENAC/ PARACETAMO L/CHLORZOXA ZONE	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	01/07/2011

2416	NDA/MAL/HD P/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	01/07/1998
2417	NDA/MAL/HD P/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	01/07/2011
2418	NDA/MAL/HD P/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,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2419	NDA/MAL/HD P/5095	MICRO LABS LTD	LABOREX UGANDA LIMITED	DIAPRIDE PLUS	GLIMEPIRIDE + METFORMIN	1MG + 500MG	MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2420	NDA/MAL/HD P/5097	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	GLUCOLIFE	GLUCOSE	5%W/V	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010

2421	NDA/MAL/HD P/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,1.0X2.0X 14.0 TABLET BLISTER,1.0X4.0X 14.0 TABLET BLISTER	01/07/2005
2422	NDA/MAL/HD P/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,1.0X 6.0X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER	01/07/2010
2423	NDA/MAL/HD P/5103	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 1000MG	METFORMIN	1000MG	NKUNZI PHARMACEUTICALS (PTY) LTD --259 DAVIDSON ROAD, WADEVILLE, EXT 1, GERMINSTON, SOUTH AFRICA	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	01/07/2010

2424	NDA/MAL/HD P/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	DENMARK	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN	01/07/2014
2425	NDA/MAL/HD P/5106	ESAPHARM SRL	BYAMAKA PHARMACEUTICAL COMPANY LTD	LEMONVATE CREAM	CLOBETASOL PROPIONATE	0.05%W/W	ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2003
2426	NDA/MAL/HD P/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,1.0X100 0.0 CAPSULE CONTAINER	01/07/2000
2427	NDA/MAL/HD P/5109	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	LEBASMA ORAL SOLUTION	SALBUTAMOL	2MG/5ML	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2011
2428	NDA/MAL/HD P/5110	NIRMA LIMITED.	LIFE PHARMA AFRICA 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	01/07/1997

2429	NDA/MAL/HD P/5112	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL SR TABLETS	DICLOFENAC SODIUM	100MG	WIN MEDICARE PVT LIMITED- MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1998
2430	NDA/MAL/HD P/5114	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	LATONE MULTIVITAMI N	MULTIVITAMI N	MULTI- INGREDIENT	NEM LABORATORIES PVT LTD-NEM LABORATORIES PVT LTD, 133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2009
2431	NDA/MAL/HD P/5115	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	INDOS- 25(THANE)	INDOMETHACI N	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,20.0 X5.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2000

2432	NDA/MAL/HD P/5117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMMEDIES-UNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	01/07/2011
2433	NDA/MAL/HD P/5120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER	01/07/1999
2434	NDA/MAL/HD P/5121	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	DICLORAN GEL	DICLOFENAC DIETHYLAMM ONIUM	1%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304- 308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE	01/07/1997
2435	NDA/MAL/HD P/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,1.0X60.0 ML BOTTLE	01/07/2007

2436	NDA/MAL/HD P/5124	GLAXOSMITHKLINE LTD BELGIUM	UNITED HEALTHCARE DISTRIBUTORS LTD	INFANRIX- HEXA	DIPHTHERIA + PERTUSSIS + BORDETELLA/ PERTUSSIS + PERTUSSIS + HAEMAGGLUT ININ + PERTACTIN + (HEPATITIS B/POLIOVIRUS TYPE 1 +2 +3)	NLT 30 IU + NLT 40IU + 25MCG + 25MCG + 8MCG + 10MCG + (TYPE I 40D +TYPE 2 + TYPE 3)	GLAXOSMITHKLINE BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X0.5 ML VIAL (1 DOSE)	01/07/2013
2437	NDA/MAL/HD P/5125	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	GLYGESIC FORTE RHUMETIC CREAM	MULTI INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1998
2438	NDA/MAL/HD P/5126	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	KNAC-75	DICLOFENAC	75MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011
2439	NDA/MAL/HD P/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,1.0X5. 0X3.0 ML AMPOULE	01/07/1997

2440	NDA/MAL/HD P/5128	MEDIPHARM SALES LTD	ABACUS PHARMA (AFRICA) LIMITED	GOFEN 400 CLEARCAP	IBUPROFEN	400MG	MEGA LIFESCIENCES LTD.- 384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	6.0X1.0X10.0 CAPSULE BLISTER	01/07/2009
2441	NDA/MAL/HD P/5129	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	KLEEN ENEMA	DISODIUM BISPHOSPHAT E/ SODIUM PHOSPHATE	19.2G+7.2G/ 120ML	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X135.0 ML BOTTLE	01/07/2006
2442	NDA/MAL/HD P/5130	UNIQUE PHARMACEUTICALS LTD	TATA UGANDA LIMITED	DICLORAN MS GEL	DICLOFENAC+ METHYL SALICYLATE+ MENTHOL	1%W/W+10% W/W+5%W/ W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304- 308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2005
2443	NDA/MAL/HD P/5131	NOVO NORDISK	STAR PHARMACEUTICALS LTD	INSULATARD HM	ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/1997

2444	NDA/MAL/HD P/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	01/07/1997
2445	NDA/MAL/HD P/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	SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 20 NEEDLES FOR INJECTION,1.0X1 .0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION.	01/07/2015
2446	NDA/MAL/HD P/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,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON	01/07/1997

2447	NDA/MAL/HD P/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	01/07/2010
2448	NDA/MAL/HD P/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,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/1997
2449	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2010
2450	NDA/MAL/HD P/5139	NOVO NORDISK	STAR PHARMACEUTICALS LTD	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PHARMA- NOVO ALLE	DENMARK	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.5 ML CARTRIDGE,1.0X 3.0 ML CARTRIDGE	01/07/1997

2451	NDA/MAL/HD P/5140	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	200MG	FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X7.0 CAPSULE BLISTER	01/07/1997
2452	NDA/MAL/HD P/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/WASHES	75.0 ML BOTTLE	01/07/2003
2453	NDA/MAL/HD P/5142	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	INTAMINE CREAM	MEPYRAMINE MALEATE	2%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400.0 G TUBE	01/07/1997
2454	NDA/MAL/HD P/5143	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 25MG	METOPROLOL	25MG	ASTRA ZENECA AB- GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER	01/07/2011
2455	NDA/MAL/HD P/5144	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOCONAZO LE 200MG	KETOCONAZO LE	200MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008

2456	NDA/MAL/HD P/5146	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 100MG	METOPROLOL	100MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011
2457	NDA/MAL/HD P/5147	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 50MG	METOPROLOL	50MG	ASTRA ZENECA AB- GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2011
2458	NDA/MAL/HD P/5148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	BETANASE TABLETS	GLIBENCLAMI DE	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,1.0X5.0X 3.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 2.0X50.0 TABLET BLISTER	01/07/1997
2459	NDA/MAL/HD P/5149	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE SYRUP	DIMENHYDRIN ATE	12.5MG/4ML	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/1997
2460	NDA/MAL/HD P/5150	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	KETO PLUS SHAMPOO	KETOCONAZO LE/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	01/07/2003

2461	NDA/MAL/HD P/5151	SOLVAY PHARMACEUTICALS BV	HARLEYS UGANDA LIMITED	BETASERC	BETAHISTINE	8MG	SOLVAY PHARMACEUTICALS - VEERWENG 12,8121AA,DIST. THE NETHERLANDS	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	4.0X25.0 TABLET BLISTER	01/07/2001
2462	NDA/MAL/HD P/5153	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE TABLETS	DIMENHYDRIN ATE	50MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2463	NDA/MAL/HD P/5154	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	BETASIL PAEDIATRIC SYRUP	IPECACUANHA TINCTURE	0.5ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X50.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/1997
2464	NDA/MAL/HD P/5155	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	BETAVEL	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/1997

2465	NDA/MAL/HD P/5157	NEM LABORATORIES PRIVATE LIMITED	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	01/07/1997
2466	NDA/MAL/HD P/5158	NIRMA LIMITED.	LIFE PHARMA AFRICA LIMITED	KETANIR	KETAMINE	50MG/ML	NIRMA LIMITED (HEALTHCARE DIVISION)- VILLAGE-SACHANA, TALUKA- VIRAMGAM DISTRICT- AHMEDABAD 382 150, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X10.0 ML VIAL	01/07/2012
2467	NDA/MAL/HD P/5161	AFRICURE PHARMACEUTICALS (INDIA) PRIVATELIMITED	ROYAL PHARMA 2011 LIMITED	GRISEOSIM- 500	GRISEOFULVIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

2468	NDA/MAL/HD P/5162	VENUS REMIDIES LTD	AARON PHARMACEUTICALS LTD	IRINOL	IRINOTECAN HYDROCHLORI DE TRIHYDRATE	20MG/ML	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X2.0 ML VIAL	01/07/2009
2469	NDA/MAL/HD P/5163	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	KETAMINE HYDROCHLORI DE INJECTION	KETAMINE HYDROCHLORI DE	50MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY VIALS	10.0 ML VIAL	01/07/1998
2470	NDA/MAL/HD P/5164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BR OMHEXINE HYDROCHLORI DE+GUAIFENE SIN+MENTHOL	1MG+2MG+50 MG+0.5MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
2471	NDA/MAL/HD P/5165	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GRISEOFULVIN 500 TABLETS	GRISEOFULVIN	500MG	REMEDICA LIMITED- LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER	01/07/2003

2472	NDA/MAL/HD P/5166	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	KETAMINE HYDROCHLORI DE	KETAMINE HYDROCHLORI DE	50MG/ML	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2004
2473	NDA/MAL/HD P/5167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMO L	400MG + 300MG	SUN PHARMACEUTICALS IND. LTD-B-2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA-403404, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1998
2474	NDA/MAL/HD P/5169	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GVGYL SUPPOSITORY	METRONIDAZ OLE BP	500MG	BLISS GVS PHARMA LTD- PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER	01/07/2007
2475	NDA/MAL/HD P/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	01/07/2000

2476	NDA/MAL/HD P/5171	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KETAMAX-50	KETAMINE	50MG/ML	TROIKAA PHARMACUETICALS LIMITED- C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2011
2477	NDA/MAL/HD P/5174	BAYER AG	SURGIPHARM (U) LIMITED	CANESTEN CREAM	CLOTRIMAZOL E	1%W/V	BAYER AG-D-51368 LEVERKUSEN GERMANY	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2478	NDA/MAL/HD P/5175	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	GYNO- DAKTARIN	MICONAZOLE NITRATE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/1997
2479	NDA/MAL/HD P/5176	BAYER AG	SURGIPHARM (U) LIMITED	CANESTEN	CLOTRIMAZOL E	100MG	BAYER AG -D-51368 LEVERKUSEN GERMANY	GERMANY	VAGINAL TABLETS	1.0X6.0 TABLET STRIP	01/07/1997
2480	NDA/MAL/HD P/5178	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	CARBOTEEN	CARBOPLATIN	450 MG / 45 ML	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL	01/07/2014

2481	NDA/MAL/HD P/5179	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 200MG CAPSULES	CEFIXIME TRIHYDRATE	200MG	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X8.0 CAPSULE BLISTER	01/07/2007
2482	NDA/MAL/HD P/5180	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (PAEDRIATIC)	EPHEDRINE HYDROCHLORI DE	5MG/ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2483	NDA/MAL/HD P/5182	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (ADULT)	EPHEDRINE HYDROCHLORI DE	10MG/ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2484	NDA/MAL/HD P/5183	PHARCO B PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CAPSULES	MICONAZOLE NITRATE	400MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL SUPPOSITORIES	1.0X3.0 CAPSULE BLISTER	01/07/2000

2485	NDA/MAL/HD P/5184	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X40.0 G TUBE	01/07/2000
2486	NDA/MAL/HD P/5186	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ISOTROY 250	ISOFLURANE	250ML	TROIKAA PHARMACEUTICALS LTD- THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2014
2487	NDA/MAL/HD P/5188	AGOG PHARMA LTD.	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,1.0X6.0X 10.0 CAPSULE BLISTER	01/07/2009

2488	NDA/MAL/HD P/5189	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	HEMOZEBEX	FERROUS SULPHATE+FO LIC ACID+PYRIDO XINE HCL+CYANOC OBALAMIN+ZI NC SULPHATE	300MG+1000 MCG+1.5MG+ 7.5MG+61.8M G	TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62- 64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2014
2489	NDA/MAL/HD P/5199	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM OINTMENT	HYDROCORTIS ONE	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	1.0X15.0 G TUBE	01/07/1997
2490	NDA/MAL/HD P/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,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1998

2491	NDA/MAL/HD P/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,1.0X250. 0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997
2492	NDA/MAL/HD P/5202	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	HYDROCORT INJECTION	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL	01/07/2010

2493	NDA/MAL/HD P/5203	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM METRO	METRONIDAZ OLE	200MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER,1.0X250. 0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER	01/07/1997
2494	NDA/MAL/HD P/5205	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-VENT	SALBUTAMOL	4MG	KAMPALA PHARMACEUTICALS INDUSTRIES-PLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CARTON,1.0X250 .0 TABLET JAR,1.0X500.0 TABLET JAR,1.0X1000.0 TABLET CONTAINER	01/07/1997
2495	NDA/MAL/HD P/5207	NEM LABORATORIES PRIVATE LIMITED	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,1.0X100 0.0 TABLET CONTAINER	01/07/2013

2496	NDA/MAL/HD P/5211	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DINAC GEL	DICLOFENAC	1%W/W	S KANT HEALTHCARE LTD- 1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2009
2497	NDA/MAL/HD P/5214	NIRMA LIMITED.	LIFE PHARMA AFRICA LIMITED	NIRMET	METRONIDAZ OLE	500MG/100M L	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010
2498	NDA/MAL/HD P/5215	J.B CHEMICALS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	METROGYL TABLETS	METRONIDAZ OLE	200MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .- 128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0 X5.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 5.0X2.0X10.0 TABLET BLISTER	01/07/2001

2499	NDA/MAL/HD P/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	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3 .0 ML AMPOULE	01/07/2006

2500	NDA/MAL/HD P/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. H-12 & H- 13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA. 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 CONTAINER	07/07/2008

2501	NDA/MAL/HD P/5224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EMTRICITABIN E+TENOFIVIR DISOPROXIL FUMERATE	EMTRICITABIN E/TENOFIVIR 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	01/07/2009
2502	NDA/MAL/HD P/5226	HETERO DRUGS LTD	AIVEEN (U) LIMITED	EMTRICITABIN E+TENOFIVIR DISOPROXIL FUMERATE	EMTRICITABIN E+TENOFIVIR 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) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2013

2503	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2009
2504	NDA/MAL/HD P/5231	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL 10	ENALAPRIL MALEATE	10MG	INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

2505	NDA/MAL/HD P/5232	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2006
2506	NDA/MAL/HD P/5233	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ENVAS 10 MG TABLETS	ENALAPRIL	10MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
2507	NDA/MAL/HD P/5234	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ENVAS 5MG TABLETS	ENALAPRIL MALEATE	5MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997

2508	NDA/MAL/HD P/5235	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	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	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,5.0X 2.0X10.0 TABLET BLISTER	01/07/1997
2509	NDA/MAL/HD P/5237	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	EUROCIP	CIPROFLOXACI N	200MG/100M L	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2010
2510	NDA/MAL/HD P/5243	IND SWIFT LTD	PLANET PHARMACEUTICALS UGANDA LTD	EZO 20	ESOMEPRAZO LE MAGNESIUM	20MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2013

2511	NDA/MAL/HD P/5245	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FABUTAS-40	FEBUXOSTAT	40MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2512	NDA/MAL/HD P/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,1.0X 100.0 CAPSULE CONTAINER,1.0X 1000.0 CAPSULE CONTAINER,1.0X 500.0 CAPSULE CONTAINER,1.0X 250.0 CAPSULE CONTAINER	01/07/1997
2513	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	01/07/2013

2514	NDA/MAL/HD P/5250	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1998
2515	NDA/MAL/HD P/5251	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	150MG	PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X1.0 CAPSULE BLISTER	01/07/1997
2516	NDA/MAL/HD P/5253	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOZOL SUSPENSION	BENZOYL METRONIDAZ OLE	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	01/07/1998
2517	NDA/MAL/HD P/5254	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	FARMORUBIC IN RD	EPIRUBICIN HYDROCHLORI DE	10MG	PHARMACIA AND UPJOHN S.P.A.-EUROPE	EUROPE	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X10.0 ML VIAL	01/07/1998

2518	NDA/MAL/HD P/5255	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO LEMONFRUIT SALT	MULTI- INGREDIENT	MULTI- INGREDIENT	GLAXO SMITH KLINE LTD- LIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA GLAXOSMITHLINE-CAPE TOWN, S.A	SOUTH AFRICA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRAN ULES	1.0X8.0X4.5 G SACHET,1.0X10.0 X4.5 G SACHET,1.0X48.0 X4.5 G SACHET,1.0X4.0X 4.5 G SACHET,1.0X24.0 X4.5 G SACHET	01/07/1997
2519	NDA/MAL/HD P/5258	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ERYMED ORAL SUSPENSION	ERYTHROMYCIN	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD (BWEYOGERERE)	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2007
2520	NDA/MAL/HD P/5259	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	100MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	2.0X14.0 TABLET STRIP	01/07/1997
2521	NDA/MAL/HD P/5261	ABBOTT LABORATORIES S.A (PTY) LIMITED	HARLEYS UGANDA LIMITED	ENTAMIZOLE	DILOXINIDE FUROATE/ME TRONIDAZOLE	250MG/200M G	ABBOTT LABORATORIES (PAKISTAN) LTD-PLOT NO.13 SECTOR 20 KORANG INDUSTRIAL AREA, KARACHI PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2006

2522	NDA/MAL/HD P/5263	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROSALIC OINTMENT	BETAMETHAS ONE + SALICYLIC ACID	0.5 %W/W + 0.3 %W/W	SCHERING-PLOUGH LABO N.V.--INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN- BERG	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 MG TUBE	01/07/2001
2523	NDA/MAL/HD P/5265	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROSONE OINTMENT	BETAMETHAS ONE DIPROPIONAT E	0.5%W/W	SCHERING PLOUGH LABO N.V.-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIAM	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G CONTAINER,1.0X 10.0 G CONTAINER	01/07/2001
2524	NDA/MAL/HD P/5266	ABBOTT LABORATORIES S.A (PTY) LIMITED	HARLEYS UGANDA LIMITED	ENTAMIZOLE SUSPENSION	DILOXANIDE FUROATE/ METRONIDAZ OLE	250MG+200M G/10ML	ABBOTT LABORATORIES PAKSTAN LTD-PLOT 13, SECTOR 20, KORANGI INDUSTRIAL AREA, KARACHI PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2006
2525	NDA/MAL/HD P/5267	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROMYCI N STEARATE	ERYTHROMYCI N STEARATE	250MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014

2526	NDA/MAL/HD P/5268	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	ERYTHROMYCI N STEARATE TABLETS	ERYTHROMYCI N	100MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER	01/07/2010
2527	NDA/MAL/HD P/5269	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2010
2528	NDA/MAL/HD P/5270	ABBOTT LABORATORIES S.A (PTY) LIMITED	HARLEYS UGANDA LIMITED	ENTAMIZOLE DS	DILOXANIDE FUROATE/ METRONIDAZ OLE	500MG/400M G	ABBOT LABORATORIES (PAKISTAN) LTD-PLOT NO.13 SECTOR 20 KORANG INDUSTRIAL AREA, KARACHI PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER	01/07/2006

2529	NDA/MAL/HD P/5271	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ERYTHYL SYRUP	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
2530	NDA/MAL/HD P/5272	AGOG PHARMA LTD	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,1.0X100 0.0 TABLET CONTAINER	01/07/2011
2531	NDA/MAL/HD P/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	01/07/2008

2532	NDA/MAL/HD P/5275	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ	EFAVIRENZ	200MG	AUROBINDO PHARMA LIMITED (UNIT III) -AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD- 500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X90.0 CAPSULE CONTAINER,1.0X 30.0 CAPSULE CONTAINER	01/07/2007
2533	NDA/MAL/HD P/5279	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOSIN	DOXAZOCIN	2MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2011

2534	NDA/MAL/HD P/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	01/07/2015
2535	NDA/MAL/HD P/5282	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DORFEN	ACECLOFENAC	100MG	TRIVENI FORMULATIONS LIMITED --PLOT NO 52-54,62- 64 ALEAP INDUSTRIAL ESTATE SURAMPALLI (V) VIJAYAWADA A.P	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
2536	NDA/MAL/HD P/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	01/07/2001

2537	NDA/MAL/HD P/5287	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMERATE	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMERATE	600MG + 300MG + 300MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), - SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2015
2538	NDA/MAL/HD P/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	01/07/1997
2539	NDA/MAL/HD P/5290	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) 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	01/07/2000

2540	NDA/MAL/HD P/5291	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X20.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER	01/07/1997
2541	NDA/MAL/HD P/5294	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) 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	01/07/2000
2542	NDA/MAL/HD P/5295	LABORATORY&ALLIE D 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,1.0X 280.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/2000
2543	NDA/MAL/HD P/5296	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	DOMAXIN-RD	DOXORUBICIN	50MG	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 MG VIAL	01/07/2010

2544	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2015
2545	NDA/MAL/HD P/5301	SANOFI PASTEUR	LABOREX UGANDA LIMITED	DULTAVAX	DIPHTERIA/ TETANUS/ AND (INACTIVATED) POLIOMYELITI S VACCINE (ADSORBED)	2 IU/ 20IU/ POLIOMYELITI S (40DU/ 8DU/ 32DU)	SANOFI PASTEUR CAMPUS MERIEUX--1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I V PRE FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2011
2546	NDA/MAL/HD P/5302	AGOG PHARMA LTD	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,1.0X10.0 X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2014

2547	NDA/MAL/HD P/5305	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	IBUGO	IBUPROFEN	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2008
2548	NDA/MAL/HD P/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	01/07/2005
2549	NDA/MAL/HD P/5309	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	DOXYCYCLINE CAPSULES BP	DOXYCYCLINE	100MG	MEDICAMEN BIOTECH LTD- SP-1192, A &B, PHASE -IV, INDUSTRIAL AREA BHIWADI - 301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER	01/07/2010

2550	NDA/MAL/HD P/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	01/07/2001
2551	NDA/MAL/HD P/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	01/07/2009
2552	NDA/MAL/HD P/5317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FROMULA	GUAIFENESIN+ BROMHEXINE	100MG + 8MG/5ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2003
2553	NDA/MAL/HD P/5318	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR AQ (1ML)	DICLOFENAC SODIUM	75MG/ML	TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2009

2554	NDA/MAL/HD P/5320	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	INDOL	INDOMETHACIN	25MG	LEBEN LAB PVT LTD-L4 PHASE 111 MIDCS AKOLA 444104 MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER,1.0X100. 0X10.0 CAPSULE BLISTER	01/07/2010
2555	NDA/MAL/HD P/5321	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	IBUGESIC COLD & SINUS	IBUPROFEN/P SEUDOEPHEDRINE	200MG/30MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GELATIN-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2012
2556	NDA/MAL/HD P/5326	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ECODAX G CREAM	ECONAZOLE NITRATE + GENTAMYCIN + BECLAMETASONE	1%+0.1%+0.025%	UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X100.0 G TUBE	01/07/1997
2557	NDA/MAL/HD P/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,100 0.0 TABLET CONTAINER,250. 0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/1997

2558	NDA/MAL/HD P/5334	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ETHAM-400	ETHAMBUTOL	400MG	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,1.0X100 0.0 TABLET CONTAINER	01/07/1997
2559	NDA/MAL/HD P/5336	SANOPI PASTEUR	LABOREX UGANDA LIMITED	AVAXIM 160U	INACTIVATED HEPATITIS A VACCINE ADSORBED	160 ANTIGEN UNITS	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M PRE-FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2011
2560	NDA/MAL/HD P/5337	SANOPI PASTEUR	LABOREX UGANDA LIMITED	AVAXIM 80IU PAEDIATRIC	INACTIVATED HEPATITIS A VACCINE ADSORBED	80 ANTIGEN UNITS	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M PRE-FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE	01/07/2011
2561	NDA/MAL/HD P/5340	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLLIN SYRUP	DIPHENHYDRA MINE HCL/DEXTRO METHORPHAN HBR	5MG/6.25MG	THE SEARLE COMPANY-32- KM MULTAN ROAD, LAHORE	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE	01/07/1997

2562	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/1997
2563	NDA/MAL/HD P/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	01/07/2000
2564	NDA/MAL/HD P/5345	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY LIMITED	CEFTRIMAX	CEFTRIAXONE SODIUM + SULBACTAM	1G + 0.5G	VHB MEDI SCIENCES LTD- PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	01/07/2014

2565	NDA/MAL/HD P/5346	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFUTIL 500	CEFUROXIME AXETIL	500MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET CONTAINER	01/07/2014
2566	NDA/MAL/HD P/5347	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFUTIL 250	CEFUROXIME AXETIL	250MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2014
2567	NDA/MAL/HD P/5348	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEPID 20	INTRAVENOUS FAT EMULSION	20%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500. 0 ML BOTTLE	01/07/2005
2568	NDA/MAL/HD P/5350	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEPHADAR FORTE	CEPHALEXIN	250MG/5ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2010

2569	NDA/MAL/HD P/5351	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEPHADAR	CEPHALEXIN MONOHYDRA TE	125MG/5ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2009
2570	NDA/MAL/HD P/5352	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	MUMFER	IRON(111) POLYMALTOSE COMPLEX	50MG/5ML	GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2005
2571	NDA/MAL/HD P/5356	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	BURNNEM	MULTI- INGREDIENT	N/A	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/1997
2572	NDA/MAL/HD P/5357	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	CA-C 1000	CALCIUM CARBONATE+ ASCORBIC ACID	327MG+1000 MG	NOVARTIS CONSUMER HEALTH-SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET CONTAINER	01/07/2004
2573	NDA/MAL/HD P/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,1.0X60.0 ML BOTTLE	01/07/1997

2574	NDA/MAL/HD P/5361	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	CALFIC	MULTI- INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
2575	NDA/MAL/HD P/5362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMID E	150MG	ASTRAZENECA MACCLESFIELD-CESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP	01/07/2001
2576	NDA/MAL/HD P/5363	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 50MG	BICALUTAMID E	50MG	ASTRA ZENECA UK LIMITED- ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA, BULK CORDEN PHARMA GMBH-OTT HAHN STRASSE ,68723 GERMANY	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/1997
2577	NDA/MAL/HD P/5364	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 25MG TABLETS	DICLOFENAC POTASSIUM	25MG	NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY NOVARTIS--URUNLERI INSTABUL TURKEY	ITALY	ORAL SOLID ORDINARY COATED TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 20.0 TABLET CONTAINER	01/07/1997

2578	NDA/MAL/HD P/5365	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM ORAL DROPS	DICLOFENAC POTASSIUM	15MG/ML	NOVARTIS PHARMA SPA- RUE DE LA CHAPELLE, HUNIGUE	FRANCE	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/1997
2579	NDA/MAL/HD P/5366	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	400MG	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE STRIP	01/07/2005
2580	NDA/MAL/HD P/5367	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	CEFIM	CEFIXIME	100MG/5ML	HILTON PHARMA (PVT) LTD- PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2005
2581	NDA/MAL/HD P/5368	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFIX 100MG/5ML DRY SUSPENSION	CEFIXIME	100MG/5ML	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE	01/07/2007

2582	NDA/MAL/HD P/5370	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYOSCINE BUTYLBROMID E	HYOSCINE N- BUTYLBROMID E	10 MG	COSMOS LIMITED -RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0 TABLET BLISTER, 1.0X100 0.0 TABLET BLISTER	01/07/2005
2583	NDA/MAL/HD P/5371	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE	LAMIVUDINE	10MG/ML	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2007
2584	NDA/MAL/HD P/5373	MICRO LABS LTD GOA	PHARMA VILLE LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	MICRO LABS LTD GOA- MICRO LABS LTD PLOT NO. S- 155 TO S-159 VERNA INDUSTRIAL ESTATE III VERNA GOA 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2013

2585	NDA/MAL/HD P/5374	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	LAMIVIR ORAL SOLUTION	LAMIVUDINE	50MG/5ML	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE –II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE,1.0X240. 0 ML BOTTLE	01/07/2004

2586	NDA/MAL/HD P/5376	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE & ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG+300M G	AUROBINDOPHARMA LIMITED,-SURVEY NO. 313 & 314, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, HYDERABAD, RANGA REDDY (DT), ANDHRA PRADESH - 500090 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER	01/07/2005
2587	NDA/MAL/HD P/5377	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN FOUR FLU LIQUID	DIPHENHYDRA MINE + PARACETAMO L + PSEUDOEPHE DRINE	25MG/20ML + 1G/20ML + 45MG/20ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	01/07/2001

2588	NDA/MAL/HD P/5379	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLANAS-30	LANSOPRAZOL E	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,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2008
2589	NDA/MAL/HD P/5380	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIROZEP	DIAZEPAM	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	01/07/2013
2590	NDA/MAL/HD P/5381	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ADIFLAM GEL	DICLOFENAC DIETHYLAMIN E	1.16%W/W	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2008

2591	NDA/MAL/HD P/5386	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	UDIHEP TABLETS	URSODEOXYC HOLIC ACID	150MG	WIN- MEDICARE LTD- MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2001
2592	NDA/MAL/HD P/5388	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	LARINATE-60	ARTESUNATE	60MG	IPCA LABORATORIES LTD,- SEJAVTA,RATLAM 457-002 REG.OFF.48 KANDIVLI IND.ESTATE MUMBAI 400067	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML SODIUM CHLORIDE INJECTION + 1*1 ML AMPOULE OF SODIUM BICARBONATE INJECTION	01/07/2011
2593	NDA/MAL/HD P/5389	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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,1.0X1.0X 6.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER,1.0X1.0X 18.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET BLISTER,1.0X30.0 X24.0 TABLET BLISTER	01/07/2011

2594	NDA/MAL/HD P/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	01/07/2008
2595	NDA/MAL/HD P/5392	DENK PHARMA GMBH &CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRATE	10MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008
2596	NDA/MAL/HD P/5393	DENK PHARMA GMBH &CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTESTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2008
2597	NDA/MAL/HD P/5395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2005

2598	NDA/MAL/HD P/5400	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ALBEN SUSPENSION	ALBENDAZOLE	400MG/10ML	PANACEA BIOTEC LTD- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	01/07/1999
2599	NDA/MAL/HD P/5401	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	HALOTHANE	HALOTHANE	250ML	PIRAMAL ENTERPRISES LTD -- DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	01/07/2005
2600	NDA/MAL/HD P/5404	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC P	ACECLOFENAC + PARACETAMO L	100 MG + 500 MG	INTAS PHARMACEUTICALS LTD-SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2013
2601	NDA/MAL/HD P/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	01/07/2005

2602	NDA/MAL/HD P/5406	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	01/07/2007
2603	NDA/MAL/HD P/5409	LINCON PHARMCUETICALS LIMITED	METRO PHARMACEUTICALS LIMITED	MINTO GEL	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	150 MG + 150 MG + 25 MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X180.0 ML BOTTLE	01/07/2012
2604	NDA/MAL/HD P/5410	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	UNICTAM 1500	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	MEDICAL UNION PHARMACEUTICALS LTD - - ABU SULTAN, CR 13363 ISMAILLIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2009

2605	NDA/MAL/HD P/5413	PASTEUR MERIEUX CONNANGHT	LABOREX UGANDA LIMITED	EUVAX B (ADULT)	HEPATITIS B VACCINE	1ML	PASTEUR MERIEUX CONNANGHT-SOUTH KOREA LG LIFE SCIENCES LTD- 601, YONGJEI-DONG, IKSAN, JE	SOUTH KOREA	PARENTERAL ORDINARY I M VIALS	1.0X10.0 ML VIAL, 1.0X1.0 ML VIAL	01/07/2007
2606	NDA/MAL/HD P/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	01/07/2007
2607	NDA/MAL/HD P/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 VIAL	01/07/2009
2608	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2005

2609	NDA/MAL/HD P/5417	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CIPROPHARM	CIPROFLOXACI N	500MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2007
2610	NDA/MAL/HD P/5418	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	PAEDIATRIC CO- TRIMOXAZOLE	CO- TRIMOXAZOLE	240MG/5ML	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
2611	NDA/MAL/HD P/5419	AGOG PHARMA 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,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0X10.0 TABLET BLISTER	01/07/2005

2612	NDA/MAL/HD P/5420	MICRO LABS LTD	PHARMA VILLE LIMITED	EFAVIRENZ	EFAVIRENZ	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X90.0 CAPSULE CONTAINER	01/07/2014
2613	NDA/MAL/HD P/5421	MICRO LABS LTD	PHARMA VILLE LIMITED	EFAVIRENZ	EFAVIRENZ	50MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER	01/07/2014
2614	NDA/MAL/HD P/5422	KOTRAPHARMA (M) SDN.BHD	ABACUS PHARMA (AFRICA) LIMITED	VAXCEL CEFUROXIME- 750	CEFUROXIME	750MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2008

2615	NDA/MAL/HD P/5423	HETERO LABS LTD	AIVEEN (U) LIMITED	EFAVIRENZ+LA MIVUDINE+TE NOFOVIR	EFAVIRENZ+LA MIVUDINE+TE NOFOVIR	600MG/300M G/300MG	HETERO DRUGS LTD-UNIT- 111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055 HETERO LABS LTD. UNIT (V) .-S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER,1.0X 90.0 TABLET JAR,1.0X100.0 TABLET JAR	01/07/2013
2616	NDA/MAL/HD P/5425	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAMO L	PARACETAMO L	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD- INDIA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2014
2617	NDA/MAL/HD P/5426	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	CEPROLEN	CIPROFLOXACI N	0.3%W/V	INDOCO REMEDIES LTD---L- 32, 33 & 34, VERNA IND. AREA, VERNA GOA-403722	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2006

2618	NDA/MAL/HD P/5427	NIRMA LIMITED.	LIFE PHARMA AFRICA 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	01/07/2010
2619	NDA/MAL/HD P/5429	AGOG PHARMA 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,1.0X10.0 X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 100.0 TABLET CARTON	01/07/2006
2620	NDA/MAL/HD P/5431	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ZIDOVUDINE	ZIDOVUDINE	300MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2005

2621	NDA/MAL/HD P/5434	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO- PACK	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA 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 SPECIAL FORMS	1.0X2.0X20.5 G SACHET + 1.0*10.0 TABLET BLISTER	01/07/2016
2622	NDA/MAL/HD P/5435	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PIC	PARACETAMO L+IBUPROFEN +CAFFEINE	500MG+200M G+30MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP	01/07/2015

2623	NDA/MAL/HD P/5436	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFICAD 1000	CEFEPIME HCL	1000MG	CADILA PHARMACEUTICALS LTD. -1389, TRASAD ROAD, DHOLKA-387810, GUJARAT STATE	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1000.0 MG VIAL	01/07/2009
2624	NDA/MAL/HD P/5437	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE ORANGE	GLUCOSE/NAC L/TRISODIUM CITRATE/KCL	13.5G/ 2.6G/ 2.9G/ 1.5G	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL SOLID ORDINARY POWDERS	1.0X20.8 G SACHET,1.0X10.4 G SACHET	01/07/2011
2625	NDA/MAL/HD P/5438	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	TAMIN	PARACETAMO L	10MG/ML	CLARIS INJECTABLES LIMITED- --CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X1.0X 50.0 ML BOTTLE,1.0X1.0X 100.0 ML VIAL	01/07/2013
2626	NDA/MAL/HD P/5439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENIRON SYRUP	VITAMIN B6 + FERROUS GLUCONATE + VITAMIN B1 + VITAMIN C + VITAMIN B2	2MG/5ML + 200MG/5ML + 2MG/5ML + 20MG/5ML + 2MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2001

2627	NDA/MAL/HD P/5441	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL NASATAB TABLETS	PARACETAMO L+CHLORPHEN IRAMINE+PSE UDOEPHEDRI NE	500MG+4MG+ 60MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2008
2628	NDA/MAL/HD P/5442	NEM LABORATORIES PRIVATE LIMITED	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	01/07/2013
2629	NDA/MAL/HD P/5445	ESKAYEF BANGLADESH LTD	MEDVIN PHARMA LIMITED	AZITHRAX 500	AZITHROMYCI N DIHYDRATE	500 MG	ESKAYEF BANGLADESH LTD-- 400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI- GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X6.0 TABLET BLISTER,1.0X1.0X 3.0 TABLET BLISTER	01/07/2014

2630	NDA/MAL/HD P/5447	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	DICLOFENAC	DICLOFENAC SODIUM	50MG	TRIVENI FORMULATION LTD- PLOT NO.52,53,54,63,62,64, ALEAP INDUSTRIAL ESTATE SURAMPALI, AP-INDIA – 521212	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON,1.0X10. 0X10.0 TABLET BLISTER	01/07/2012
2631	NDA/MAL/HD P/5448	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	FLUNER-5	FLUNARIZINE	5MG	GENO PHARMACEUTICALS LTD--PHARMACEUTICAL COMPLEX, TIVIM INDUSTRIAL ESTATE, P.O. KARASWADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10. 0 TABLET BLISTER	01/07/2011
2632	NDA/MAL/HD P/5449	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC 50	DICLOFENAC SODIUM	50MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010

2633	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X10.0 ML BOTTLE	01/07/1998
2634	NDA/MAL/HD P/5454	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	MOXILEB	AMOXICILLIN	125MG/5ML	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE	01/07/2010
2635	NDA/MAL/HD P/5456	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 125MG/5ML	AMOXICILLIN	125MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2015

2636	NDA/MAL/HD P/5457	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 100/270 B/L	ARTESUNATE+ AMODIAQUIN E	100MG+270M G	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2014
2637	NDA/MAL/HD P/5458	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 50/135 B/L	ARTESUNATE+ AMODIAQUIN E	50MG+135MG	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER	01/07/2014
2638	NDA/MAL/HD P/5460	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ASQA GPSC	ARTESUNATE+ AMODIAQUIN E	50MG+135MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X20. 0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2011
2639	NDA/MAL/HD P/5461	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUIN E	ARTESUNATE+ AMODIAQUIN E	25MG+67.5M G	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL ZENATA AIRI SEBAA, 00212522678099 - MOROCCO	MOROCCO	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER	01/07/2008

2640	NDA/MAL/HD P/5462	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUIN E WINTHROP	ARTESUNATE+ AMODIAQUIN E	50MG+135MG	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL ZENATA AIRI SEBAA, 00212522678099 - MOROCCO	MOROCCO	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER	01/07/2010
2641	NDA/MAL/HD P/5463	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUIN E WINTHROP	ARTESUNATE+ AMODIAQUIN E	100MG+270M G	MAPHAR S.A. GROUP OF SANOFI,-KM 10, ROUTE COTIERE 111 QUARTIER, INDUSTRIEL ZENATA AIRI SEBAA, 00212522678099 - MOROCCO	MOROCCO	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER	01/07/2008

2642	NDA/MAL/HD P/5464	AGOG PHARMA 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,1.0X3.0X 8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,2.0X6.0 TABLET BLISTER,4.0X6.0 TABLET BLISTER,1.0X1.0X 24.0 TABLET BLISTER,1.0X1.0X 6.0 TABLET BLISTER,1.0X1.0X 12.0 TABLET BLISTER	01/07/2007
2643	NDA/MAL/HD P/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,1.0X100. 0 TABLET CARTON,1.0X250 .0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997

2644	NDA/MAL/HD P/5468	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIVAL TABLETS	SODIUM VALPROATE	200MG	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	1.0X50.0 TABLET BOTTLE	01/07/2013
2645	NDA/MAL/HD P/5469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY I V VIALS	1.0X50.0 ML VIAL	01/07/2009
2646	NDA/MAL/HD P/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	01/07/2013
2647	NDA/MAL/HD P/5472	CLARIS OTSUKA LIMITED	REDDYS PHARMA LIMITED	NS	SODIUM CHLORIDE	0.9%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500. 0 ML BOTTLE,1.0X100. 0 ML BAG	01/07/2007

2648	NDA/MAL/HD P/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	01/07/2012
2649	NDA/MAL/HD P/5474	PHARMA INTERNATIONAL.CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	200MG	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2005
2650	NDA/MAL/HD P/5475	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	VAXCEL CEFTAZIDIME	CEFTAZIDIME	1G	KOTRA PHARMA (M) SDN.BHD,-1,2 & 3 JALAN TTC 12 CHENG INDUSTRIAL ESTATE 75250 MELAKA	MALAYSIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2013
2651	NDA/MAL/HD P/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 BESTEIRIOS PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI	01/07/2002

2652	NDA/MAL/HD P/5478	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BECLATE-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 ADMINISTRATION METERED-DOSE INHALER	1.0X1.0X200.0 METERED DOSE CANNISTER	01/07/2010
2653	NDA/MAL/HD P/5482	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOLIN	SALBUTAMOL	2MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2010
2654	NDA/MAL/HD P/5483	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	1.0X1.0X3.0X20. 0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	01/07/2011
2655	NDA/MAL/HD P/5486	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	FOSEAL 400	SEVELAMER HCL	400MG	EMCURE PHARMACEUTICALS LTD .-C- 10(12) MIDC BHOSAN PUNE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X6.0X 10.0 TABLET BLISTER	01/07/2009

2656	NDA/MAL/HD P/5489	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-5	BISOPROLOL	5MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	01/07/2008
2657	NDA/MAL/HD P/5496	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 16MG	CANDESARTAN CILEXETIL	16MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2010
2658	NDA/MAL/HD P/5507	GALENTIC PHARMA LTD	NORVIK ENTERPRISES LIMITED	CALADIN LOTION	CALAMINE	15 %W/W	GALENTIC PHARMA(INDIA) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2001
2659	NDA/MAL/HD P/5525	UMEDICA LABS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	RILIF-SR	ACECLOFENAC	200 MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2011

2660	NDA/MAL/HD P/5591	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	SWISSCILLIN	AMPICILLIN	500MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL	01/07/2011
2661	NDA/MAL/HD P/5619	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	RABELOC 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP	01/07/2006
2662	NDA/MAL/HD P/5636	ATCO LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	BETADERM NM CREAM	MICONAZOLE+ NEOMYCIN +BETAMETHA SONE VALERATE	2MG+0.5G + 0.1G	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2004

2663	NDA/MAL/HD P/5644	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNITS	CSPC ZHONGNUO PHARMACEUTICAL (SCIJIAZHUANG) CO. LTD WORKSHOP -NO. 88 YANGZI ROAD, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA WORKSHOP 406 AND 407	CHINA	PARENTERAL ORDINARY VIALS	1.0X4.0 MU VIAL	01/07/2001
2664	NDA/MAL/HD P/5648	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL	01/07/2010
2665	NDA/MAL/HD P/5685	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOL E	20MG/5ML	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/1998

2666	NDA/MAL/HD P/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	28/03/2019
2667	NDA/MAL/HD P/6033	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	OMEZING	OMEPRAZOLE	20MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19- 20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR- 249403	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	28/03/2019
2668	NDA/MAL/HD P/6034	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN -250 DT	AMOXICILLIN TRIHYDRATE	250 MG	MILAN LABS PVT LTD-63-67 JAWAHAR CO.OP. INDUSTRIAL ESTATE KAMOTHE,NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X2.0X 10.0 TABLET BLISTER	01/07/2016
2669	NDA/MAL/HD P/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	1.0X10.0X10.0 TABLET BLISTER	28/03/2019

2670	NDA/MAL/HD P/6037	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AVIT	VITAMIN A	200,000 IU	OLIVE HEALTHCARE-197/2, ATHIYAWAD DABHEL VILLAGE DAMAN 396210 (U.T)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER,1.0X100 0.0 TABLET JAR	01/07/2017
2671	NDA/MAL/HD P/6038	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	FIXDEP-180	FEXOFENADIN E HYDROCHLORI DE	180MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
2672	NDA/MAL/HD P/6040	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	U-TRYP	ULINASTATIN	100,000 I.U	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2017

2673	NDA/MAL/HD P/6041	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CANDIZOL	CLOTRIMAZOL 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	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP	01/07/2017
2674	NDA/MAL/HD P/6043	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	ZEMILAST	IMIPENEM + CILASTATIN	500MG+500M G	ZEISS PHARMACEUTICALS PVT. LIMITED-PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML BOTTLE	01/07/2017
2675	NDA/MAL/HD P/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	01/07/2017

2676	NDA/MAL/HD P/6047	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 150	TRASTUZUMA B (R-DNA ORIGIN)	150MG	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X150.0 MG VIAL ,1X10ML VIAL OF WFI	01/07/2017
2677	NDA/MAL/HD P/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,1.0X10.0 CAPSULE BLISTER	01/07/2017
2678	NDA/MAL/HD P/6053	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	4MG	LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKOW- INDUSTRIAL ESTATES	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	01/07/2017
2679	NDA/MAL/HD P/6054	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	1MG	LEK S.S POLAND UI PODLIPIE 16 95-01O STRYKOW- INDUSTRIAL ESTATES	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2017
2680	NDA/MAL/HD P/6055	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A	LABOREX UGANDA LIMITED	EURARTESIM	PIPERAQUINE TETRAPHOSPH ATE + DIHYDROARTE MISININ	160MG + 20MG	SIGMA- TAU I.F.R . S.P.A-VIA PONTINA KM 30,400 POMEZIA ROME	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER	01/07/2017

2681	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2009
2682	NDA/MAL/HD P/6059	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS 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	01/07/2017
2683	NDA/MAL/HD P/6060	NOVARTIS ACCESS	SURGIPHARM (U) LIMITED	SALBUTAMOL	SALBUTAMOL	100MCG	AEROPHARM GMBH...- RUDOLSTADT ALLEMAGNE	GERMANY	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X200.0 METERED DOSE CONTAINER	01/07/2017
2684	NDA/MAL/HD P/6061	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2017
2685	NDA/MAL/HD P/6065	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PROXYREN	PIROXICAM	20MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2017

2686	NDA/MAL/HD P/6070	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	10MG	DEVA-CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH ATATURK CAD.,NO.: 32 KAPAKLI	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	01/07/2017
2687	NDA/MAL/HD P/6071	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	VAZKOR	AMLODIPINE BESILATE	5MG	DEVA-CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAH ATATURK CAD.,NO.: 32 KAPAKLI	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	01/07/2017
2688	NDA/MAL/HD P/6072	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	HYDRALAZINE HYDROCHLORI DE	HYDRALAZINE HYDROCHLORI DE	20MG/ML	SWISS PARENTERALS PVT LTD.-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X1 0.0X1.0 ML AMPOULE	01/07/2017
2689	NDA/MAL/HD P/6075	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OLOHISTINE	OLOPATADINE HYDROCHLORI DE	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

2690	NDA/MAL/HD P/6076	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	FALCI CARE	ARTESUNATE	30MG	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*5 ML OF 0.9%W/V NACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE	01/07/2017
2691	NDA/MAL/HD P/6077	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	GLIMIWEI M2	GLIMEPIRIDE + METFORMIN HYDROCHLORI DE	2MG + 500MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19- 20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR- 249403	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/03/2019
2692	NDA/MAL/HD P/6078	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIMOLOL MALEATE	TIMOLOL MALEATE	5MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

2693	NDA/MAL/HD P/6079	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP 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	01/07/2017
2694	NDA/MAL/HD P/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	01/07/2017
2695	NDA/MAL/HD P/6081	EXPHAR SA	SURGIPHARM (U) LIMITED	ANTALGEX T	PARACETAMO L/TRAMADOL HYDROCHLORI DE	325MG/37.5M G	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	01/07/2017

2696	NDA/MAL/HD P/6082	EXPHAR SA	SURGIPHARM (U) LIMITED	CROMSOL	SODIUM CROMOGLYCA TE	2%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017
2697	NDA/MAL/HD P/6086	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	ACEWEL-P	ACECLOFENAC +PARACETAM OL	100MG+500M G	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER, 1.0X10.0 X10.0 TABLET BLISTER	01/07/2017
2698	NDA/MAL/HD P/6090	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	PROSTAR 200	PROGESTERO NE	100MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2017

2699	NDA/MAL/HD P/6093	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
2700	NDA/MAL/HD P/6094	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250 MG + 125 MG	SPARSH BIO-TECH PVT. LTD- PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR- 361 006, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
2701	NDA/MAL/HD P/6099	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HARIPIL-60	ARTESUNATE	60MG	PSYCHOTROPICS INDIA LTD - PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE- 1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR- 249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML OF 0.9% W/V NACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE	01/07/2017

2702	NDA/MAL/HD P/6101	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-H 40/12.5	TELMISARTAN + HYDROCHLOR OTHIAZIDE	40MG + 12.5MG	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
2703	NDA/MAL/HD P/6102	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 80	TELMISARTAN	80MG	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
2704	NDA/MAL/HD P/6103	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 5	OLANZAPINE	5MG	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
2705	NDA/MAL/HD P/6105	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPIL 200	AZITHROMYCI N	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	01/07/2017

2706	NDA/MAL/HD P/6107	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SULPREX	IPRATROPIUM BROMIDE+SAL BUTAMOL SULPHATE	500MCG/2.5M L+2.5MG/2.5 ML	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X10.0 AMPOULE CARTON	01/07/2017
2707	NDA/MAL/HD P/6111	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	MOTIFAST	DOMPERIDON E	10MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	01/07/2017
2708	NDA/MAL/HD P/6114	FDC LTD	AIVEEN (U) LIMITED	ZOXAN	CIPROFLOXACI N	0.3% W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.☐	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	01/07/2005
2709	NDA/MAL/HD P/6115	WEST-COAST PHARMACEUTICAL WORKS LTD	SUPER MEDIC LTD- MBARARA	TIZOLE	TINIDAZOLE	500MG	WEST COAST PHARMACEUTICAL WORKS LTD-1143,MELDI ESTATE,NR PRASANG PARTY PLOT,GOTA, AHMEDEBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET STRIP	01/07/1997

2710	NDA/MAL/HD P/6116	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ZOLEDRO- DENK 4MG/5ML	ZOLEDRONIC ACID	4MG/5ML	HAMELN PHARMACEUTICALS GMBH- LANGES FELD 13 31789 HAMELN	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X5.0 ML VIAL	01/07/2017
2711	NDA/MAL/HD P/6117	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	GRAN-DENK	GRANISETRON HYDROCHLORI DE	1MG/ML	SIEGFRIED HAMELN GMBH- LANGES FELD 13,31789 HAMELN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE	01/07/2017
2712	NDA/MAL/HD P/6118	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM DS	SULPHAMETH OXAZOLE + TRIMETHOPRI M	800MG + 160MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
2713	NDA/MAL/HD P/6120	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	KMINE	KETAMINE HYDROCHLORI DE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIRA 3 BARA NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2017
2714	NDA/MAL/HD P/6121	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	DEXIREN	DEKXETOPROF EN TROMETAMOL	25MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017

2715	NDA/MAL/HD P/6122	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ROCUTROY	ROCURONIUM BROMIDE	10MG	TROIKAA PHARMACEUTICALS LTD- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	01/07/2017
2716	NDA/MAL/HD P/6126	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DERMOTRACI N	NEOMYCIN SULPHATE + BACITRACIN	165,000 IU + 12,500 IU	MEDICAL UNION PHARMACEUTICALS-36 DR MOHAMED HASSAN EL- GAMAL ST.6TH DISTRICT NASR CITY EGYPT	EGYPT	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER	01/07/2016
2717	NDA/MAL/HD P/6127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016

2718	NDA/MAL/HD P/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	UNITED KINGDOM	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER	01/07/2016
2719	NDA/MAL/HD P/6132	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID	KETOCONAZO LE	2%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X120.0 ML BOTTLE	01/07/2016
2720	NDA/MAL/HD P/6133	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	RILIF-100	ACECLOFENAC	100MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

2721	NDA/MAL/HD P/6134	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	01/07/2016
2722	NDA/MAL/HD P/6135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAXONE SODIUM+SULB ACTAM	1000MG+500 MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	01/07/2016
2723	NDA/MAL/HD P/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	01/07/2016

2724	NDA/MAL/HD P/6137	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	LUPRODEX	LEUPROLIDE ACETATE	3.75MG	BHARAT SERUMS AND VACCINES LIMITED,-PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X1.0 ML VIAL + 1*2ML GLASS AMPOULE OF DILUENT (EACH ML CONTAINS 50MG OF D- MANNITOL AND WFI TO Q.S) + 1 DISPOSABLE SYRINGE, 2 NEEDLES AND 2 ALCOHOL SWABS	01/07/2016
2725	NDA/MAL/HD P/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	01/07/2016
2726	NDA/MAL/HD P/6139	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SERVIN CAPSULE	FERROUS SULPHATE+FO LIC ACID+THIAMI NE MONONITRAT E+RIBOFLAVIN +PYRIDOXINE HYDROCHLORI DE+NICOTINA MIDE+ASCORB IC ACID	150MG+0.5M G+2MG+2MG +1MG+10MG+ 50MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X 10.0 CAPSULE BLISTER	01/07/2016

2727	NDA/MAL/HD P/6141	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	ACEWEL	ACECLOFENAC	100MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016
2728	NDA/MAL/HD P/6142	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCARB	ACTIVATED CHARCOAL	0.25MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016
2729	NDA/MAL/HD P/6143	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICALS LIMITED	CONTRACTUB EX	EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLA NTOIN	10G+5000 I.U+1G/100G	MARCYRL PHARMACEUTICAL INDUSTRIES.-EL OBOUR CITY CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2016
2730	NDA/MAL/HD P/6144	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NIKO	PARACETAMO L	500MG	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016

2731	NDA/MAL/HD P/6145	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ENDULIN SELECT	INSULIN GLARGINE(R- DNA ORGIN)	100I.U/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099 INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X3.0 ML PREFILLED PEN	01/07/2016
2732	NDA/MAL/HD P/6147	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ENDULIN VAIL	INSULIN GLARGINE (R- DNA ORIGIN)	100I.U/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099 INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL	01/07/2016
2733	NDA/MAL/HD P/6158	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	DESEFIN	CEFTRIAXONE SODIUM	1G	DEVA LIAC SAN. VE TIC. A.S. - ORGANISE SANAYI BOLGESI ATATURK MAH. ATATURK CAD. NO: 32 KARAAGAC CERKEZKOY	TURKEY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2016

2734	NDA/MAL/HD P/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,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016
2735	NDA/MAL/HD P/6162	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	IRBESARTAN/ HYDROCHLOR OTHIAZIDE SANDOZ	IRBESARTAN,H YDROCHLORO THIAZIDE	150MG,12.5M G	LEK PHARMACEUTICALS .D.D -VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2016
2736	NDA/MAL/HD P/6163	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ANDARAN HCT	IRBESARTAN,H YDROCHLORO THIAZIDE	300MG,12.5M G	LEK PHARMACEUTICALS .D.D -VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER	01/07/2016
2737	NDA/MAL/HD P/6165	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	CEFTRISONE - 1000	CEFTRIAZONE SODIUM	1G/VIAL	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	1.0X1.0 G VIAL	01/07/2016

2738	NDA/MAL/HD P/6166	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	GMICIN	GENTAMICIN SULPHATE	0.3%W/V	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2016
2739	NDA/MAL/HD P/6167	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUROSE	IRON SUCROSE	20MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE	07/01/2016
2740	NDA/MAL/HD P/6169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016
2741	NDA/MAL/HD P/6171	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	SUXAMETHON IUM CHLORIDE	SUXAMETHON IUM CHLORIDE	50MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY DRY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016
2742	NDA/MAL/HD P/6172	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	PHYTOMENAD IONE	PHYTOMENAD IONE	10MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK- BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2016

2743	NDA/MAL/HD P/6173	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2016
2744	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2016
2745	NDA/MAL/HD P/6176	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G-GLUTAMIN PLUS	VITAMIN B1 +B6+B12 WITH L- GLUTAMIC ACID	100MG+50MG +100MCG+50 MG	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	1.0X2.0X10.0 TABLET BLISTER	01/07/2010
2746	NDA/MAL/HD P/6179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON- DENK 4MG ODT	ONDANSETR ON	4MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016

2747	NDA/MAL/HD P/6180	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	LABOREX UGANDA LIMITED	EURARTESIM	PIPERAQUINE TETRAPHOSPH ATE + DIHYDROARTE MISININ	320MG+40MG	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A -VIALE SHAKESPEARE 47-00144 ROME ITALY	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X9.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER	01/07/2016
2748	NDA/MAL/HD P/6181	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZINOWEL- 500	AZITHROMYCI N	500MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2016
2749	NDA/MAL/HD P/6183	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	PRAZQUANTE L TABLETS	PRAZQUANTE L	600MG	CIPLA LTD .-352 KUNDAIM INDL. ESTATE KUNDAIM GOA 403 115	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X100.0 TABLET BOTTLE,1.0X500. 0 TABLET BOTTLE	01/07/2016

2750	NDA/MAL/HD P/6184	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 60MG	ETORICOXIB	60MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
2751	NDA/MAL/HD P/6185	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	DOLOFORTE DENK	TRAMADOL HYDROCHLORI DE + PARACETAMO L	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	01/07/2016
2752	NDA/MAL/HD P/6186	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 90MG F.C. TABLETS	ETORICOXIB	90MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

2753	NDA/MAL/HD P/6187	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLOXCIP	CIPROFLOXACIN HYDROCHLORIDE	500MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2754	NDA/MAL/HD P/6188	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	GAMA PHARMACEUTICALS (U) LIMITED	GIZLAN 150	IRBESARTAN	150MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
2755	NDA/MAL/HD P/6189	UNEEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	WORMEE-4	ALBENDAZOLE	400MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER	01/07/2016

2756	NDA/MAL/HD P/6190	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	D-LYTE	ANHYDROUS GLUCOSE,SOD IUM CHLORIDE,TRI SODIUM CITRATE DIHYDRATE,P OTASSIUM CHLORIDE	2.7G + 0.52G + 0.58G + 0.30G/ 200ML	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,1.0X100 0.0 ML SACHET,1.0X200. 0 ML SACHET	01/07/2015
2757	NDA/MAL/HD P/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- BOOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE	01/07/2016
2758	NDA/MAL/HD P/6197	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN	NYSTATIN	100,000 IU	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	VAGINAL TABLETS	1.0X14.0 PESSARY STRIP	01/07/2016

2759	NDA/MAL/HD P/6201	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	AMOXICILLIN AND FLUCLOXACILL IN CAPSULES 500MG	AMOXICILLIN TRIHYDRATE + FLUCLOXACILL IN SODIUM	250MG + 250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
2760	NDA/MAL/HD P/6202	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SALPRAZ 20	PANTOPRAZO LE SODIUM	20MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD .-NO. 172 & 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR - MANDAL RR DIST HYDERABAD 500100, TELANGANA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	01/07/2016
2761	NDA/MAL/HD P/6203	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-5	AMLODIPINE BESILATE	5MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	01/07/2016

2762	NDA/MAL/HD P/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	01/07/2016
2763	NDA/MAL/HD P/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	01/07/2013
2764	NDA/MAL/HD P/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,MAHARAstra- 410209,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

2765	NDA/MAL/HD P/6215	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	NEORAL 25	CYCLOSPORIN	25MG	R P SCHERER GMBH & CO. EBERBACH BALEN-R P SCHERER GMBH & CO. EBERBACH BALEN	GERMANY	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2016
2766	NDA/MAL/HD P/6216	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	NEORAL 100	CYCLOSPORIN	100MG	R P SCHERER GMBH & CO. EBERBACH BALEN-R P SCHERER GMBH & CO. EBERBACH BALEN	GERMANY	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER	01/07/2016
2767	NDA/MAL/HD P/6217	INDIAN IMMUNOLOGICALS LTD	TATA UGANDA LIMITED	ELOVAC -B	HEPATITIS B (RDNA)	20MCG/ML	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD)- RAKSHAPURAM GACHIBOWLI POST HYDERABAD 500032	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE VIAL)	01/07/2016
2768	NDA/MAL/HD P/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	01/07/2016

2769	NDA/MAL/HD P/6220	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	METHYLDOPA	METHYLDOPA	250MG	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
2770	NDA/MAL/HD P/6223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST- RT	LATANOPROST	0.005%W/V	AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE	01/07/2016
2771	NDA/MAL/HD P/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	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X5.0X2. 0 ML AMPOULE	01/07/2016

2772	NDA/MAL/HD P/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	01/07/2016
2773	NDA/MAL/HD P/6229	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CO- FLUAMPICIL CAPSULES BP 500MG	FLUCLOXACILL IN SODIUM + AMPICILLIN TRIHYDRATE	250MG +250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP	01/07/2016
2774	NDA/MAL/HD P/6230	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	EMITINO	ONDANSENTR ON	4MG	CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

2775	NDA/MAL/HD P/6231	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	01/07/2016
2776	NDA/MAL/HD P/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 LANSOPRAZOLE + 2 TABLETS OF CLARITHROMYCI N + 2 TABLETS OF TINIDAZOLE)	01/07/2016
2777	NDA/MAL/HD P/6234	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	D-ARTEPP	DIHYDROARTE MESININE/ PIPERAQUINE PHOSPHATE	40MG/320MG	GUILIN PHARMACEUTICAL CO.,LTD-NO 43 QILIDIAN ROAD GUILIN 541002, GUANGXI	CHINA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X2.0X3.0 TABLET BLISTER	01/07/2016
2778	NDA/MAL/HD P/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	1.0X40.0X2.0X10 .0 CAPSULE BLISTER	01/07/2016

2779	NDA/MAL/HD P/6237	HETERO LABS LTD	AIVEEN (U) LIMITED	LOPINAVIR/RITONAVIR	LOPINAVIR/RITONAVIR	100MG/25MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X120.0 TABLET BOTTLE	01/07/2016
2780	NDA/MAL/HD P/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	01/07/2016
2781	NDA/MAL/HD P/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)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML AMPOULE OF 0.9%W/V NACL + 1*1 ML OF 5%W/V SODIUM BICARBONATE	01/07/2016
2782	NDA/MAL/HD P/6242	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	1.0X2.0X3.0 TABLET BLISTER	01/07/2016

2783	NDA/MAL/HD P/6243	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SURVANTA	BERACTANT	100MG/4ML	ABBVIE NORTH CHICAGO FACILITY-1401 SHERDAN ROAD NORTH CHICAGO FACILITY ILLINOIS 60064 - 4000	UNITED STATES	TOPICAL EXTERNAL INSTILLATION VIALS	1.0X4.0 ML VIAL,1.0X8.0 ML VIAL	01/07/2016
2784	NDA/MAL/HD P/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	01/07/2016
2785	NDA/MAL/HD P/6245	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIR AMINE MALEATE + SODIUM CITRATE + AMMONIUM CHLORIDE	7MG+2 MG+ 3.25 MG+28 MG/5 ML.	BIOLOGICAL E. LTD -PLOT NO.31 & 32 PHARMA CITY SELAQUI INDUSTRIAL AREA SELAQUI DEHRADUN-248 197 UTTARAKHAND,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2016

2786	NDA/MAL/HD P/6246	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	LUTHER	ARTEMETHER	80MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT. LTD-N-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE	01/07/2016
2787	NDA/MAL/HD P/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	01/07/2016
2788	NDA/MAL/HD P/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	01/07/2016
2789	NDA/MAL/HD P/6249	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL METRONIDAZ OLE -200 TABLETS	METRONIDAZ OLE	200MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

2790	NDA/MAL/HD P/6250	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	ROCIP EYE DROPS	CIPROFLOXACI N HYDROCHLORI DE	3MG/ML	REMINGTON PHARMACEUTICAL INDUSTRIES (PVT) LTD-18 KM MULTAN ROAD LAHORE 53800 PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016
2791	NDA/MAL/HD P/6251	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TORGABALIN 75	PREGABALIN	75MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2016
2792	NDA/MAL/HD P/6252	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TORGABALIN 150	PREGABALIN	150MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA- KADI,DIST.MEHSANA,INDRA D-382721	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2016
2793	NDA/MAL/HD P/6256	PLOUGH	UNITED HEALTHCARE DISTRIBUTORS LTD	AZIMAX- 250	AZITHROMYCI N DIHYDRATE	250MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016

2794	NDA/MAL/HD P/6257	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	EDURANT	RILPIVIRINE	25MG	JANSSEN CILAG S.P.A-VIA C.JANSSEN, BORGO	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2016
2795	NDA/MAL/HD P/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	PARENTERAL ORDINARY I V VIALS	1.0X100.0 ML VIAL	01/07/2016
2796	NDA/MAL/HD P/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 EFFERVESCENT TABLETS	1.0X10.0 TABLET BOTTLE	01/07/2016
2797	NDA/MAL/HD P/6270	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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, 1.0X3.0X 10.0 TABLET BLISTER	01/07/2017

2798	NDA/MAL/HD P/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	07/11/2018
2799	NDA/MAL/HD P/6282	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEBUX-40	FEBUXOSTAT	40MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
2800	NDA/MAL/HD P/6283	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEBUX-80	FEBUXOSTAT	80 MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
2801	NDA/MAL/HD P/6284	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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	07/11/2018

2802	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION BAGS	1.0X493.0 ML BAG (1*[250ML AMINO ACID SOLUTION WITH ELECTROLYTES + 149ML GLUCOSE 42% SOLUTION + 94ML LIPID EMULSION], MULTI- CHAMBER PLASTIC BAGS	07/11/2018
2803	NDA/MAL/HD P/6289	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	UNOPROG GEL	PROGESTERO NE	8.0% W/W	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	VAGINAL GELS AND SOLS	1.0X1.0X1.0X1.1 25 G PREFILLED PEN	17/12/2018
2804	NDA/MAL/HD P/6293	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	17/12/2018

2805	NDA/MAL/HD P/6296	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	FLUTIFORM	FLUTICASONE PROPIONATE + FORMOTEROL FUMARATE DIHYDRATE	50MCG + 5MCG / ACTUATION	FISONS LTD (TRADING AS SANOFI)-72 LONDON ROAD, HOLMES CHAPEL CREWE, CHESHIRE, CW4 8BE, UNITED KINGDOM.	UNITED KINGDOM	LUNG ADMINISTRATION BREATH- ACTUATED METERED-DOSE INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	17/12/2018
2806	NDA/MAL/HD P/6297	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	FLUTIFORM	FLUTICASONE PROPIONATE + FORMOTEROL FUMARATE DIHYDRATE	250MCG + 10MCG / ACTUATION	FISONS LTD (TRADING AS SANOFI)-72 LONDON ROAD, HOLMES CHAPEL CREWE, CHESHIRE, CW4 8BE, UNITED KINGDOM.	UNITED KINGDOM	LUNG ADMINISTRATION BREATH- ACTUATED METERED-DOSE INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	20/12/2018
2807	NDA/MAL/HD P/6298	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	OFLOTECH-O SUSPENSION	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19- 20,21, SECTOR 6-4, SIDCUL, IIE, RANIPUR HARIDWAR- 249403	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X60.0 ML BOTTLE	28/03/2019

2808	NDA/MAL/HD P/6300	GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD	PHILLIPS PHARMACEUTICALS (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,1.0X 2.0X10.0 CAPSULE BLISTER	31/01/2018
2809	NDA/MAL/HD P/6302	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) 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	28/03/2019
2810	NDA/MAL/HD P/6303	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	OXYNORM 5MG	OXYCODONE HYDROCHLORI DE	5MG	BARD PHARMACEUTICALS LIMITED-UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, U.K	UNITED KINGDOM	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	20/12/2018

2811	NDA/MAL/HD P/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	28/03/2019
2812	NDA/MAL/HD P/6308	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D SYRUP	DES Loratadi NE	5MG/ 5ML	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT.: HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	28/03/2019
2813	NDA/MAL/HD P/6310	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	ZIMCOX 100	CELECOXIB	100MG	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	26/09/2018

2814	NDA/MAL/HD P/6311	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	OXYNORM 10MG	OXYCODONE HYDROCHLORI DE	10MG	BARD PHARMACEUTICALS LIMITED-UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, U.K	UNITED KINGDOM	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	20/12/2018
2815	NDA/MAL/HD P/6312	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	DARUNAVIR (AS ETHANOLATE) TABLETS 800 MG	DARUNAVIR ETHANOLATE	800MG	CIPLA LIMITED,-PLOT NO A-42 (UNIT-II) MIDC PATALGANGA, DISTRICT RAIGAD, 410 220 MAHARASHTRA,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	07/11/2018
2816	NDA/MAL/HD P/6315	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	ACE SYRUP, 100ML	PARACETAMO L	120MG/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)- SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	31/01/2018

2817	NDA/MAL/HD P/6320	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	PROSTAR 100	PROGESTERO NE	100MG	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/03/2019
2818	NDA/MAL/HD P/6321	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	OXYNORM 20MG	OXYCODONE HYDROCHLORI DE	20MG	BARD PHARMACEUTICALS LIMITED-UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, U.K	UNITED KINGDOM	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER	20/12/2018
2819	NDA/MAL/HD P/6324	AUROCHEM LABORATORIES(I) PVT LTD	SUPER MEDIC LTD	FUSIGO	FUSIDIC ACID	2.0%W/W	AUROCHEM LABS (I) PVT LTD- PLOT 08, PTICE LTD PALGHAR 401404	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X10.0 G TUBE	28/03/2019
2820	NDA/MAL/HD P/6325	LEBEN LABORATORIES PVT. LTD.	ANDYCO PHARMACY (UGANDA) LTD	PZQ TABLET	PRAZIQUANTE L	600MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4. 0 TABLET BLISTER	29/11/2017

2821	NDA/MAL/HD P/6326	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	ONCOGEM 1000	GEMCITABINE HYDROCHLORI DE	1000MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S- 103 TO S-105, S-107 TO S- 112, L-147/1 TO L-147/3, L- 138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA	INDIA	PARENTERAL ORDINARY I V VIALS	1.0X1000.0 MG VIAL	20/12/2018
2822	NDA/MAL/HD P/6331	BHARAT BIOTECH INTERNATIONAL LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TYPBAR	VI CAPSULAR POLYSACCHAR IDE TYPHOID VACCINE	50MGG/ML	BHARAT BIOTECH INTERNATIONAL LTD- GENOME VALLEY, SHAMEERPET MANDAL, RANGAREDDY, TELANGANA STATE-500078 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X0.5 ML VIAL,1.0X1.0X2.5 ML VIAL	28/03/2019

2823	NDA/MAL/HD P/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	28/03/2019
2824	NDA/MAL/HD P/6334	BHARAT SERUMS AND VACCINES LTD	GITTOES PHARMACEUTICALS LIMITED	ENDOPROST 250MCG/1ML	CARBOPROST TROMETHAMI NE	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	28/03/2019
2825	NDA/MAL/HD P/6335	BILTHOVEN BIOLOGICALS	NORVIK ENTERPRISES LIMITED	POLIOMYELITIS VACCINE	POLIOMYELITIS VIRUS TYPE 1, INACTIVATED + POLIOMYELITIS VIRUS TYPE 2, INACTIVATED + POLIOMYELITIS VIRUS TYPE 3, INACTIVATED	40 DU + 8 DU + 32 DU / 0.5ML	BILTHOVEN BIOLOGICALS BV- ANTONIE VAN LEEUVENHOEKLAAN, 9- 13,3721 MA BILTHOVEN	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL	28/03/2019

2826	NDA/MAL/HD P/6336	BILTHOVEN BIOLOGICALS	NORVIK ENTERPRISES LIMITED	POLIOMYELITIS VACCINE MULTIDOSE	POLIOMYELITIS VIRUS TYPE 1, INACTIVATED + POLIOMYELITIS VIRUS TYPE 2, INACTIVATED + POLIOMYELITIS VIRUS TYPE 3, INACTIVATED	40 DU + 8 DU + 32 DU / 0.5ML	BILTHOVEN BIOLOGICALS BV- ANTONIE VAN LEEUVENHOEKLAAN, 9- 13,3721 MA BILTHOVEN	NETHERLANDS	PARENTERAL ORDINARY VIALS	1.0X2.5 ML VIAL	28/03/2019
2827	NDA/MAL/HD P/6338	BIOTON S.A.	BHL HEALTHCARE LIMITED	GENSULIN M30 (30/70)	INSULIN HUMAN OF RECOMBINANT DNA ORIGIN (30% SOLUBLE INSULIN + 70% ISOPHANE INSULIN)	100 IU/ML	BIOTON S.A-MACIERZYSZ, POZNANSKA 12 STR., 05-850 OZAROW MAZOWIECKI	POLAND	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	28/03/2019
2828	NDA/MAL/HD P/6339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYC LINE HCL + POLYMYXIN B SULPHATE	5MG+10000IU /G	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O -- 10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	30/05/2018

2829	NDA/MAL/HD P/6340	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN CAPSULES	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	250MG +250 MG	LABORATORY & ALLIED LTD- PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018
2830	NDA/MAL/HD P/6341	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	31/01/2018
2831	NDA/MAL/HD P/6342	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFENAC EYE DROPS	DICLOFENAC SODIUM SALT	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE	30/05/2018

2832	NDA/MAL/HD P/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	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	28/03/2019
2833	NDA/MAL/HD P/6344	S KAGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LACTEASE	LACTULOSE SOLUTION	66.7% W/W	S KANT HEALTHCARE LTD- PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	26/09/2018
2834	NDA/MAL/HD P/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	PARENTERAL ORDINARY S C VIALS	1.0X1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE	28/03/2019
2835	NDA/MAL/HD P/6348	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP	SODIUM LACTATE SOLUTION +SODIUM CHLORIDE + CALCIUM CHLORIDE + POTASSIUM CHLORIDE	0.533 GM +0.600 GM + 0.027G+ 0.040 GM/100ML	ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	28/03/2018

2836	NDA/MAL/HD P/6349	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE -120	ARTESUNATE	120MG	BLISS INDASI LIFESCINCES PRIVATE LIMITED - -PLOT 73- 76 SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN 396 210, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*10ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*2ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE	26/09/2018
2837	NDA/MAL/HD P/6350	MEGA LIFESCINCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	INVEL	METRONIDAZ OLE + MICONAZOLE NITRATE	500MG + 100MG	M/S BLISS GVS PHARMA LIMITED -PLOT 10, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE PALGHAR, DIST. THANE - 401404	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X7.0 SUPPOSITORY STRIP	28/03/2019
2838	NDA/MAL/HD P/6352	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	28/03/2019

2839	NDA/MAL/HD P/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	01/07/2017
2840	NDA/MAL/HD P/6355	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYVIR 0.5	ENTECAVIR	0.5MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	28/03/2019
2841	NDA/MAL/HD P/6356	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ZYVIR 1	ENTECAVIR	1MG	CADILA HEALTHCARE LIMITED -KUNDAIM INDUSTRIAL ESTATE,PLOT NO.203-213, KUNDAIM GOA, 403115,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	28/03/2019

2842	NDA/MAL/HD P/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	28/03/2019
2843	NDA/MAL/HD P/6358	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 20	ROSUVASTATI N 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	28/03/2019
2844	NDA/MAL/HD P/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	28/03/2019
2845	NDA/MAL/HD P/6361	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSKA-P	NYSTATIN	1,00,000 I.U/ML	S.KANT HEALTHCARE LTD- PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2017

2846	NDA/MAL/HD P/6364	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ	EFAVIRENZ	400MG	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	28/03/2019
2847	NDA/MAL/HD P/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	28/03/2019

2848	NDA/MAL/HD P/6371	MEDISEL(K) LTD	AIVEEN (U) LIMITED	RILIF MR	ACECLOFENAC + PARACETAMO L + CHLORZOAZ ONE	100MG + 500MG + 375MG	CORONA REMEDIES PVT LTD- CORONA HOUSE, C MONDEAL BUSINESS PARK, NR. GURUDWARA GOVINDDHAM LANE, SG HIGHWAY, THALTEJ, AHMEDABAD 380059, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	28/03/2019
2849	NDA/MAL/HD P/6374	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	PREDLEB-5 DT	PREDNISOLON E	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	28/03/2018
2850	NDA/MAL/HD P/6375	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	ETHAMBUTOL HYDROCHLORI DE	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	06/02/2019

2851	NDA/MAL/HD P/6379	KWALITY AFRO-ASIA LTD	KWALITY AFRO ASIA LTD	SURGICAL SPIRIT	METHYL SALICYLATE + DIETHYL PTHALATE +CASTOR OIL + INDUSTRIAL METHYLATED SPIRIT	0.5%W/V + 2.0%W/V +2.5W/V + Q.S	KWALITY AFROASIA LTD- KAWEMPE	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE	15/03/2019
2852	NDA/MAL/HD P/6381	MANKIND PHARM LTD	TATA UGANDA LIMITED	SERTAKIND	SERTACONAZ 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	28/03/2019
2853	NDA/MAL/HD P/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	01/07/2017
2854	NDA/MAL/HD P/6384	FDC LTD	UHMG GOODLIFE PHARMACY	RESTORS	ORAL REHYDRATION SALTS + ZINC SULPHATE	20.5G + 20MG	FDC LIMITED - GOA III-PHASE III/A, PLOT NO. L-121/B, SALCETTE, VERNA INDUSTRIAL ESTATE, VERNA, GOA-403722	INDIA	ORAL SOLID ORDINARY COMBINATION PACK POWDERS/GRAN ULES	1.0X2.0X20.5 G SACHET + 1*10 ALU-PVC BLISTER ZINC SULPHATE	28/03/2019

2855	NDA/MAL/HD P/6387	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	AZIFAM DS	AZITHROMYCI N	200MG/5ML	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	28/03/2019
2856	NDA/MAL/HD P/6388	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	RAPICLAV 250 DT	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	250MG + 62.5MG	IPCA LABORATORIES LTD.,- PLOT 69 TO 72 (B), SECTOR II, KASEZ, GANDHIDHAM - 370230, GUJARAT	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X3.0 TABLET BLISTER	28/03/2018
2857	NDA/MAL/HD P/6390	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	06/02/2019

2858	NDA/MAL/HD P/6392	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MET XL 50	METOPROLOL SUCCINATE	50 MG	AJANTA PHARMA LTD .-B- 4//5/6, MIDC INDUSTRIALAREA, PAITHAN- 431 128, AURANGBAD	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018
2859	NDA/MAL/HD P/6393	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LUMARTEM HS 80	ARTEMETHER + LUMEFANTRIN E	80MG + 480MG	CIPLA LTD UNIT I-VILLAGE UPPER MALPUR, P.O. BHUD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH 173205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X6.0 TABLET BLISTER	01/07/2011
2860	NDA/MAL/HD P/6394	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DANSET	ONDANSETRO N HYDROCHLORI DE	8MG	ADWIA -1ST INDUSTRIAL ZONE, A1, 10TH OF RAMADAN CITY	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X1.0X3.0X4.0 ML AMPOULE	29/05/2019
2861	NDA/MAL/HD P/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	29/05/2019

2862	NDA/MAL/HD P/6396	NVS KENYA LTD	SURGIPHARM (U) LIMITED	LETROZOLE 2.5	LETROZOLE	2.5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
2863	NDA/MAL/HD P/6405	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS 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	01/07/2017
2864	NDA/MAL/HD P/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	PARENTERAL ORDINARY VIALS	1.0X25.0X30.0 ML VIAL	06/02/2019

2865	NDA/MAL/HD P/6407	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	ZIMCOX 200	CELECOXIB	200 MG	ZIM LABORATORIES LTD-B- 21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017
2866	NDA/MAL/HD P/6408	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECOZAL	XYLOMETAZOL INE 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	29/05/2019

2867	NDA/MAL/HD P/6409	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ROFAST 5	ROSUVASTATI N CALCIUM	5MG	AUROBINDO PHARMA LTD- UNIT VII ,/-SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019
2868	NDA/MAL/HD P/6412	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BUCCAZOLE ORAL GEL	MICONAZOLE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	01/07/2017

2869	NDA/MAL/HD P/6413	BHARAT BIOTECH INTERNATIONAL LIMITED	REDDYS PHARMA LIMITED	ROTAVAC	ROTAVIRUS 116E BULK, LIVE ATTENUATED	NLT 10^5.0 FFU / 0.5ML	BHARAT BIOTECH INTERNATIONAL LTD- GENOME VALLEY, SHAMEERPET MANDAL, RANGAREDDY, TELANGANA STATE-500078 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X1.0X0.5 ML VIAL, 1.0X1.0X2.5 ML VIAL, 1.0X1.0X5.0 ML VIAL	29/05/2019
2870	NDA/MAL/HD P/6414	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	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	29/05/2019
2871	NDA/MAL/HD P/6415	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	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	29/05/2019

2872	NDA/MAL/HD P/6416	EAST AFRICAN (INDIA) OVERSEAS	BETA HEALTHCARE UGANDA LIMITED	PENTARIV-D	PANTOPRAZO LE + DOMPERIDON E	40MG + 30MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/05/2019
2873	NDA/MAL/HD P/6417	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	TECAVIR 1	ENTECAVIR MONOHYDRA TE	1 MG	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 FILM- COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	27/03/2019

2874	NDA/MAL/HD P/6419	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	METRO PHARMACEUTICALS LIMITED	CLINICEF CV	CEFIXIME + POTASSIUM CLAVULANATE	200MG + 125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD -- UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.- HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	26/09/2018
2875	NDA/MAL/HD P/6424	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL LS	LEVOSALBUTA MOL SULPHATE + AMBROXOL HYDROCHLORI DE + GUAIFENESIN	1 MG + 30 MG + 100 MG	GLENMARK PHARMACEUTICALS LTD .- VILLAGE KISHANPURA, BADDI-NALAGARH ROAD, TEHSIL BADDI, DISTRICT SOLAN HP 173205	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE	27/03/2019

2876	NDA/MAL/HD P/6426	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017
2877	NDA/MAL/HD P/6427	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	FEBREX TM	PARACETAMO L + TRAMADOL HYDROCHLORI DE	325 MG + 37.5 MG	INDOCO REMEDIES LTD. .-L- 14 VERNA INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
2878	NDA/MAL/HD P/6428	KWALITY AFRO-ASIA LTD	KWALITY AFRO ASIA LTD	K-SCABIS	BENZYL BENZOATE	25%W/V	KWALITY AFROASIA LTD- KAWEMPE	UGANDA	TOPICAL EXTERNAL EMULSIONS	1.0X100.0 ML BOTTLE	15/03/2019
2879	NDA/MAL/HD P/6429	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	RABOTIDE FAST	RABEPRAZOLE SODIUM	20 MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

2880	NDA/MAL/HD P/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	27/03/2019
2881	NDA/MAL/HD P/6431	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	BRUMOX 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
2882	NDA/MAL/HD P/6432	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	UMBI-GEL	CHLORHEXIDINE GLUCONATE	4 % W/W	KAMPALA PHARMACEUTICALS INDUSTRIES (1996)LTD-STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X50.0X1.0X5.0 G TUBE	27/03/2019
2883	NDA/MAL/HD P/6433	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	FICYC CREAM	ACICLOVIR	5%W/W	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2017

2884	NDA/MAL/HD P/6434	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TORLEVA 1000	LEVETIRACETA M	1000MG	TORRENT PHARMACEUTICALS LTD. - AHMEDABAD-MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	06/02/2019
2885	NDA/MAL/HD P/6435	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	01/07/2017
2886	NDA/MAL/HD P/6436	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	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	01/07/2017
2887	NDA/MAL/HD P/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	27/03/2019

2888	NDA/MAL/HD P/6439	NTICALS LTD.	NORVIK ENTERPRISES 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,1.0X10.0X 10.0 TABLET STRIP	01/07/2017
2889	NDA/MAL/HD P/6440	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL 400	CEFIXIME TRIHYDRATE	400MG	AKUMS DRUGS & PHARMACEUTICALS LTD -- 19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

2890	NDA/MAL/HD P/6442	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	AZITO SUSPENSION	AZITHROMYCI N DIHYDRATE	200 MG/5ML	ZIM LABORATORIES LTD-B- 21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE	31/01/2018
2891	NDA/MAL/HD P/6443	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	SINURHON SUSPENSION	CHLORPHENIR AMINE + PHENYLEPHRI NE + PARACETAMO L	1MG + 5MG + 125MG	LEBEN LABORATORIES PVT LTD .-L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/03/2019
2892	NDA/MAL/HD P/6444	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CEFRAZ 100	CEFIXIME TRIHYDRATE	100MG	ZIM LABORATORIES LTD-B- 21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER	31/01/2018
2893	NDA/MAL/HD P/6446	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	SNIP PAIN	PARACETAMO L + CAFFEINE	500MG + 50MG	MEDOCHEMIE ACTORY).....-1- 10 CONSTANTINOUPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	06/02/2019

2894	NDA/MAL/HD P/6447	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	AZIBRU 500	AZITHROMYCI N DIHYDRATE	500MG	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2017
2895	NDA/MAL/HD P/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	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL	25/07/2018
2896	NDA/MAL/HD P/6451	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	ANDARAN®75 MG.	IRBESARTAN	75 MG	LEK PHARMACEUTICALS DD- VEROVSKOVA 57, SI-1526 LJUBLJANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
2897	NDA/MAL/HD P/6452	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	AMLIBON 5MG	AMLODIPINE	5MG	LEK PHARMACEUTICALS DD- VEROVSKOVA 57, SI-1526 LJUBLJANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

2898	NDA/MAL/HD P/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	06/02/2019
2899	NDA/MAL/HD P/6455	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	FICYC TABLETS	ACYCLOVIR	200MG	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
2900	NDA/MAL/HD P/6456	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	GLUCOSE INTRAVENOUS INFUSION BP (5% W/V)	GLUCOSE ANHYDROUS	5%W/V	ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	01/07/2017

2901	NDA/MAL/HD P/6458	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	ERIS 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	27/03/2019
2902	NDA/MAL/HD P/6459	MACLEODS PHARMACEUTICALS LTDS LTD	NORVIK ENTERPRISES LIMITED	MACSUNATE AQ FORTE	ARTESUNATE + AMODIAQUIN E	100MG + 270MG	MACLEODS PHARMACEUTICALS LTD ,,- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER,1.0X25.0 X6.0 TABLET BLISTER	27/03/2019
2903	NDA/MAL/HD P/6460	MANKIND PHARM LTD	TATA UGANDA LIMITED	NUROKIND- OD	MECOBALAMI N	1500MCG/ML	MANKIND PHARMA LTD.- VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X4.0X1.0 ML AMPOULE	27/03/2019

2904	NDA/MAL/HD P/6461	MANKIND PHARM LTD	TATA UGANDA LIMITED	NUROKIND	MECOBALAMI N	500 MCG/ML	MANKIND PHARMA LTD.- VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0X1.0 ML AMPOULE	27/03/2019
2905	NDA/MAL/HD P/6463	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	SNIP	PARACETAMO L + PSEUDOEPHE DRINE + CHLORPHENA MINE	325MG + 15MG + 1MG	MEDOCHÉMIE ACTORY).....-1- 10 CONSTANTINOUPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	27/03/2019
2906	NDA/MAL/HD P/6464	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	BROT	METFORMIN HYDROCHLORI DE	850 MG	MEDOCHÉMIE ACTORY).....-1- 10 CONSTANTINOUPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019

2907	NDA/MAL/HD P/6465	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	NEUROGAB 75	PREGABALIN	75MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2017
2908	NDA/MAL/HD P/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	04/02/2019

2909	NDA/MAL/HD P/6473	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	ALMIRAL	DICLOFENAC SODIUM	15MG/ML	MEDOCHEMIE LTD – FACTORY B-PLOT 48, IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL; AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X3.0 ML AMPOULE	27/03/2019
2910	NDA/MAL/HD P/6477	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDOFULVIN	GRISEOFULVIN	500 MG	MEDOCHEMIE ACTORY).....1- 10 CONSTANTINOUPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	27/03/2019
2911	NDA/MAL/HD P/6480	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICALS LIMITED	NEVILOB	NEBIVOLOL HYDROCHLORI DE	5 MG	MARCYRL PHARMACEUTICAL INDUSTRIES -WESTERN EXTENSION-PARTS NUMBER 5/6/7/8/9/10/11/12-BLOCK 20005, EL OBOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER	27/03/2019

2912	NDA/MAL/HD P/6482	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHROX 75MCG	LEVOTHYROXI NE SODIUM	75 MCG	MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X25.0 TABLET BLISTER	27/03/2019
2913	NDA/MAL/HD P/6486	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	ZIFAM GRIS 500	GRISEOFULVIN	500 MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	27/03/2019
2914	NDA/MAL/HD P/6487	EXPHAR SA.	SURGIPHARM (U) LIMITED	FLUCAZOL	FLUCONAZOLE	100 MG	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	27/03/2019

2915	NDA/MAL/HD P/6488	GUILIN PHARMACEUTICAL CO.LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PARACETAMO L INJECTION	PARACETAMO L	300MG/2ML	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE	30/05/2018
2916	NDA/MAL/HD P/6489	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL-SF	SALBUTAMOL +BROMHEXIN E HYDROCHLORI DE+GUAIFENE SIN	2MG+4MG+10 0MG/10ML	GLENMARK PHARMACEUTICALS LTD- VILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
2917	NDA/MAL/HD P/6490	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	SORVATE OINTMENT	CALCITRIOL	0.0003% W/W	GLENMARK PHARMACEUTICALS LIMITED, AT: (UNIT II)- VILLAGE BHATTANWALA, P.O. RAJPURA, NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH, 174 101, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X10.0 G TUBE	31/01/2018
2918	NDA/MAL/HD P/6491	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAM IN	75MG+750MC G	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	28/03/2018

2919	NDA/MAL/HD P/6492	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	LIDOCAINE INJECTION BP 2%W/V	LIDOCAINE HYDROCHLORI DE	2%W/V	UMEDICA LABORATORIES PVT, VAPI - -PLOT 221, GIDC II, VAPI-396195, VALSAD GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X20.0 ML VIAL	01/07/2006
2920	NDA/MAL/HD P/6494	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	AZIFAM 250	AZITHROMYCI N	250MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X6.0 CAPSULE BLISTER	29/05/2019
2921	NDA/MAL/HD P/6495	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	MACROLYN® 500 MG FILM COATED TABLETS	AZITHROMYCI N DIHYDRATE	500MG	DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017

2922	NDA/MAL/HD P/6497	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	SERETIDE DISKUS 50/100MCG	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	50MCG + 100MCG / DELIVERED DOSE	GLAXOSMITHKLINE, LLC- 1011 NORTH ARENDELL AVENUE ZEBULON, NORTH CAROLINA 27597	UNITED STATES	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0 METERED DOSE DEVICE (DISKUS DEVICE)	29/05/2019
2923	NDA/MAL/HD P/6498	MICRO LABS LIMITED	PHARMA VILLE LIMITED	AMOXICILLIN DISPERSIBLE TABLETS 250 MG	AMOXICILLIN TRIHYDRATE	250MG	MICRO LABS LIMITED PLOT - NO. 16, VEERASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BANGALORE – 560 100. KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	25/07/2018
2924	NDA/MAL/HD P/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	29/05/2019

2925	NDA/MAL/HD P/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	29/05/2019
2926	NDA/MAL/HD P/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	29/11/2017
2927	NDA/MAL/HD P/6502	M/S HETERO LABS LIMITED	AIVEEN (U) LIMITED	ALOVIR 400	ACYCLOVIR	400MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOONNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE,1.0X10.0 X8.0 TABLET BLISTER	01/07/2016

2928	NDA/MAL/HD P/6503	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DICHLOR-12.5	CHLORTHALID ONE	12.5MG	IPCA LABORATORIES LIMITED-P.O SEJAVTA DIST. RATLAM-457002, MADHYA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019
2929	NDA/MAL/HD P/6504	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	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	29/05/2019
2930	NDA/MAL/HD P/6506	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	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	29/05/2019
2931	NDA/MAL/HD P/6508	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	XALIPAT-100	OXALIPLATIN	100 MG/ 50ML (2MG/ML)	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	29/05/2019

2932	NDA/MAL/HD P/6509	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	ASPYROX	PIROXICAM	20MG	ASTRA LIFE CARE(INDIA) PVT LTD-PLOT NO. 57/P, SARKHEJ – BAVLA HIGHWAY, POST. RAJODA – 382220, TALUKA: BAVLA, DIST. AHMEDABAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER	01/07/2017
2933	NDA/MAL/HD P/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	29/05/2019
2934	NDA/MAL/HD P/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	29/05/2019

2935	NDA/MAL/HD P/6512	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXACIP	CIPROFLOXACI N	200MG/100M L	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	31/01/2018
2936	NDA/MAL/HD P/6513	MACARTHYS LABORATORIES	LABOREX UGANDA LIMITED	GLYCOPYRRO NIUM BROMIDE 200 MICROGRAMS PER ML SOLUTION FOR INJECTION	GLYCOPYRRO NIUM 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	29/05/2019
2937	NDA/MAL/HD P/6514	EXPHAR SA.	SURGIPHARM (U) LIMITED	FEBRILEX	PARACETAMO L + PHENYLEPHRI NE HYDROCHLORI DE + CHLORPHENA MINE 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	29/05/2019

2938	NDA/MAL/HD P/6515	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	WOMASTIN	CARBOPLATIN	150MG/15ML	KHANDELWAL LABORATORIES PVT LTD-B-1, WAGLE INDUSTRIAL ESTATE, THANE-400604	INDIA	PARENTERAL ORDINARY VIALS	1.0X15.0 ML VIAL	29/05/2019
2939	NDA/MAL/HD P/6516	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	WOMASTIN	CARBOPLATIN	450MG/45ML	KHANDELWAL LABORATORIES PVT LTD-B-1, WAGLE INDUSTRIAL ESTATE, THANE-400604	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X45.0 ML VIAL	29/05/2019
2940	NDA/MAL/HD P/6517	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	FERROTONE LIQUIZ	FERROUS FUMARATE + FOLIC ACID + CYANOCOBAL AMIN	100MG + 0.5MG + 5MCG	FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	29/05/2019

2941	NDA/MAL/HD P/6518	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CARDISAR HT	VALSARTAN + HYDROCHLOR OTHIAZIDE	80 MG + 25 MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
2942	NDA/MAL/HD P/6519	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV 750	RANOLAZINE	750MG	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	1.0X1.0X10.0 TABLET BLISTER	28/03/2019

2943	NDA/MAL/HD P/6520	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND- MD 8	ONDASENTRO N	8MG	MANKIND PHARMA LTD-- UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
2944	NDA/MAL/HD P/6521	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 4	MONTELUKAS T	4MG	MSN LABORATORIES LTD. - PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, ZIP CODE - 502 325, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019
2945	NDA/MAL/HD P/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	28/03/2019

2946	NDA/MAL/HD P/6523	EXPHAR SA.	SURGIPHARM (U) LIMITED	FLEXDOL	IBUPROFEN+ METHOCARBA MOL	200MG+500M G	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
2947	NDA/MAL/HD P/6524	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	RAMGIC	TRAMADOL HYDROCHLORI DE	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	28/03/2019
2948	NDA/MAL/HD P/6525	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	DAPOXEM 30	DAPOXETINE	30MG	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	28/03/2019

2949	NDA/MAL/HD P/6526	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	DAPOXEM 60	DAPOXETINE	60MG	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	28/03/2019
2950	NDA/MAL/HD P/6527	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 62.5	BOSENTAN MONOHYDRA TE	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	28/03/2019
2951	NDA/MAL/HD P/6528	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PULMOFIRST 125	BOSENTAN MONOHYDRA TE	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	28/03/2019

2952	NDA/MAL/HD P/6529	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	PRAZIQUANTE L TABLETS 600 MG	PRAZIQUANTE L	600MG	MACLEODS PHARMACEUTICALS LIMITED -BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH - 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0 X10.0 TABLET BLISTER	28/03/2018
2953	NDA/MAL/HD P/6530	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NECIPRO	CIPROFLOXACI N HYDROCHLORI DE	0.3%W/V	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA,	NEPAL	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	28/03/2019
2954	NDA/MAL/HD P/6531	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	DISFLAM	DICLOFENAC SODIUM	75MG/ML	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIPRA-3, BARA,	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0 ML AMPOULE	28/03/2019
2955	NDA/MAL/HD P/6532	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	BUNASE 200	BUDESONIDE	200MCG / ACTUATION	OXALIS LABS--VILLAGE THEDA, P.O. LODHIMAJRA , TEHSIL BADDI, DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON	28/03/2018

2956	NDA/MAL/HD P/6533	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NIKODIN	PARACETAMO L + CODEINE PHOSPHATE	500MG + 10MG	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIRA-3, BARA,	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	28/03/2019
2957	NDA/MAL/HD P/6535	OCTOBER PHARMA S.A.E	ABACUS PHARMA (AFRICA) LIMITED	SARCOZIDE	CANDERSATA N + HYDROCHLOR OZIDE	16MG + 12.5MG	OCTOBER PHARMA-PLOT NO. 190, 1ST INDUSTRIAL ZONE-6 OCTOBER CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	28/03/2019
2958	NDA/MAL/HD P/6536	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	OZAPEX 5MG	OLANZAPINE	5MG	PHARMATHEN S.A-6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019
2959	NDA/MAL/HD P/6537	EXPHAR SA	SURGIPHARM (U) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	31/01/2018

2960	NDA/MAL/HD P/6538	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	OZAPEX 10MG	OLANZAPINE	10MG	PHARMATHEN S.A-6, DERVENAKION STR. 15351 PALLINI ATHENS	GREECE	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/03/2019
2961	NDA/MAL/HD P/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	28/03/2019
2962	NDA/MAL/HD P/6543	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	CIFF-O	OFLOXACIN + CEFIXIME	200MG + 200MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2019
2963	NDA/MAL/HD P/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	29/03/2019
2964	NDA/MAL/HD P/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	29/03/2019

2965	NDA/MAL/HD P/6548	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	CIROPAIN GEL	DICLOFENAC DIETHYLAMIN E 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	01/07/2017
2966	NDA/MAL/HD P/6549	RAVIAN LIFE SCIENCE PVT. LTD	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	28/03/2019
2967	NDA/MAL/HD P/6550	REDDY'S PHARMA LTD -	REDDYS PHARMA LIMITED	REDCEPHIN	CEFTRIAXONE	1 G	INJECT CARE PARENTERALS PVT LTD-PLOT NO. 130 SILVASSA ROAD, GIDC VAPI 396195	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	27/03/2019
2968	NDA/MAL/HD P/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	29/03/2019
2969	NDA/MAL/HD P/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	29/03/2019

2970	NDA/MAL/HD P/6553	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSOL SOLUTION	CHLORHEXIDI NE 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	28/03/2019
2971	NDA/MAL/HD P/6554	CRATUS PHARMA PVT. LTD	METRO PHARMACEUTICALS LIMITED	RESPIQUIN- 750	LEVOFLOXACI N	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	01/04/2019
2972	NDA/MAL/HD P/6555	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	DERMIRIV OC	OFLOXACIN + ORNIDAZOLE + TERBINAFINE HYDROCHLORI DE + 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	28/08/2019

2973	NDA/MAL/HD P/6556	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BECLOGEN CREAM	CLOTRIMAZOL E USP, BECLOMETAS ONE DIPROPIONAT E BP, GENTAMICIN SULPHATE BP	1%W/W, 0.025%W/W, 0.1%W/W	SAVA HEALTHCARE LIMITED.- PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE	29/03/2019
2974	NDA/MAL/HD P/6557	STRIDES SHASUN LIMITED	DELMAW ENTERPRISES LIMITED	COMBIART-DT	ARTEMETHER + LUMEFANTRIN E	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,1.0X1.0X 12.0 TABLET BLISTER	29/03/2019
2975	NDA/MAL/HD P/6558	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZENTRISE SUSPENSION	ALBENDAZOLE	200MG	SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE- II, IDA, CHERLAPALLY INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE	28/03/2019

2976	NDA/MAL/HD P/6559	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	BIOCOBAL 500MCG	MECOBALAMI N	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	28/03/2019
2977	NDA/MAL/HD P/6562	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS 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	28/03/2019
2978	NDA/MAL/HD P/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	28/03/2019
2979	NDA/MAL/HD P/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	28/03/2019

2980	NDA/MAL/HD P/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	28/03/2019
2981	NDA/MAL/HD P/6566	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	NOSMOK	NICOTINE	4MG	UNIQUE PHARMACEUTICAL LABORATORIES ; -SURVEY NO. 101/2 & 102/1, DAMAN INDUSTRIAL ESTATE, KAPAIYA, DAMAN 396210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	28/03/2019
2982	NDA/MAL/HD P/6567	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	NOSMOK	NICOTINE	2MG	UNIQUE PHARMACEUTICAL LABORATORIES ; -SURVEY NO. 101/2 & 102/1, DAMAN INDUSTRIAL ESTATE, KAPAIYA, DAMAN 396210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER	28/03/2019

2983	NDA/MAL/HD P/6568	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNADIP 50 TABLET	DICLOFENAC	50MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
2984	NDA/MAL/HD P/6569	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	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	28/03/2019
2985	NDA/MAL/HD P/6570	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	TENAVIRON	TENOFOVIR DISOPROXIL FUMARATE	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 STRIP	29/05/2019

2986	NDA/MAL/HD P/6575	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	SENSOCAIN	BUPIVACAINE HYDROCHLORI DE	0.75% W/V	BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI- 74900	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	28/08/2019
2987	NDA/MAL/HD P/6576	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXA-ZOLE F	FLUCONAZOLE	200 MG	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	28/08/2019
2988	NDA/MAL/HD P/6579	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PLENCOXIB 200	CELECOXIB	200 MG	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT II, PLOT NO. 22, SECTOR- 6A, IIE, SIDCUL, RANIPUR, DISTT.: HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0X10.0 CAPSULE BLISTER	28/08/2019

2989	NDA/MAL/HD P/6580	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OXEPTAL 600	XCARBAZEPIN E	600 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	28/08/2019
2990	NDA/MAL/HD P/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	28/08/2019
2991	NDA/MAL/HD P/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	28/08/2019

2992	NDA/MAL/HD P/6583	ZIFAM PINNACLE LTD	BOOTS PHARMACEUTICALS LIMITED	AZIFAM 500	AZITHROMYCI N	500 MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/08/2019
2993	NDA/MAL/HD P/6584	ZIFAM PINNACLE LTD	BOOTS PHARMACEUTICALS LIMITED	ZIFLODIP 5	AMLODIPINE BESYLATE	5 MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
2994	NDA/MAL/HD P/6585	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	ZIFLODIP 10	AMLODIPINE BESYLATE	10 MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019

2995	NDA/MAL/HD P/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	29/05/2019
2996	NDA/MAL/HD P/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	29/05/2019
2997	NDA/MAL/HD P/6589	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	VANBACT	VANCOMYCIN HYDROCHLORI DE	500MG	NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	29/05/2019

2998	NDA/MAL/HD P/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	29/05/2019
2999	NDA/MAL/HD P/6591	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	TRANSIC	TRANEXAMIC ACID	250MG	NABIQASIM INDUSTRIES (PVT) LTD .-17/24 KORANGI INDUSTRIAL AREA KORANGI KARACHI	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0 ML AMPOULE	29/05/2019
3000	NDA/MAL/HD P/6592	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	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	04/02/2019
3001	NDA/MAL/HD P/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	29/05/2019

3002	NDA/MAL/HD P/6594	NABROS PHARMA PVT LTD.	SHREEJI PHARMACEUTICALS LIMITED	DOLAREN GEL	DICLOFENAC DIETHYLAMIN E	1%W/W	NABROS PHARMA PVT LTD- SURVEY NO. 110/A/2, AMIT FARM JAIN UPASRAYA, NEAR COCACOLA FACTORY, NH NO. 8, KAJIPURA, DIST. KHEDA-387411, GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/05/2019
3003	NDA/MAL/HD P/6596	NABROS PHARMA PVT LTD.	SHREEJI PHARMACEUTICALS LIMITED	ESSLIVER H	ESSENTIAL PHOSPHOLIPI DS	250MG	NABROS PHARMA PVT LTD- SURVEY NO. 110/A/2, AMIT FARM JAIN UPASRAYA, NEAR COCACOLA FACTORY, NH NO. 8, KAJIPURA, DIST. KHEDA-387411, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE	29/05/2019

3004	NDA/MAL/HD P/6597	NABROS PHARMA PVT LTD.	SHREEJI PHARMACEUTICALS LIMITED	ESMO-20	ESOMEPRAZO LE MAGNESIUM TRIHYDRATE	20MG	NABROS PHARMA PVT LTD- SURVEY NO. 110/A/2, AMIT FARM JAIN UPASRAYA, NEAR COCACOLA FACTORY, NH NO. 8, KAJIPURA, DIST. KHEDA-387411, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	29/05/2019
3005	NDA/MAL/HD P/6598	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	BREATHEZY-L (10/5)	MONTELUKAS T SODIUM + LEVOCETIRIZIN E DIHYDROCHLO RIDE	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	04/02/2019

3006	NDA/MAL/HD P/6599	NABROS PHARMA PVT LTD.	SHREEJI PHARMACEUTICALS LIMITED	ESMO-40	ESOMEPRAZO LE MAGNESIUM TRIHYDRATE	40MG	NABROS PHARMA PVT LTD- SURVEY NO. 110/A/2, AMIT FARM JAIN UPASRAYA, NEAR COCACOLA FACTORY, NH NO. 8, KAJIPURA, DIST. KHEDA-387411, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019
3007	NDA/MAL/HD P/6600	EXPHAR SA.	SURGIPHARM (U) LIMITED	PROSTALEN	ALFUZOSIN HYDROCHLORI DE	10MG	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3008	NDA/MAL/HD P/6602	EXPHAR SA.	SURGIPHARM (U) LIMITED	CARDIURINE	CAPTOPRIL + HYDROCHLOR OTHIAZIDE	50MG + 25MG	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

3009	NDA/MAL/HD P/6603	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ILIADIN 0.01% (INFANT)	OXYMETAZOLI NE HYDROCHLORI DE	0.01%W/V	NKUNZI PHARMACEUTICALS (PTY) LTD.-259 DAVIDSON ROAD, WADEVILLE, GERMINSTON, 1428	SOUTH AFRICA	NASAL TOPICAL DROPS	1.0X5.0 ML BOTTLE	29/05/2019
3010	NDA/MAL/HD P/6604	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ILIADIN 0.025% (PAEDIATRIC)	OXYMETAZOLI NE HYDROCHLORI DE	0.025%W/V	NKUNZI PHARMACEUTICALS (PTY) LTD.-259 DAVIDSON ROAD, WADEVILLE, GERMINSTON, 1428	SOUTH AFRICA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE (DROPPER BOTTLE),1.0X10. 0 ML BOTTLE (METERED- SPRAY BOTTLE)	29/05/2019
3011	NDA/MAL/HD P/6606	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ILIADIN 0.05%	OXYMETAZOLI NE HYDROCHLORI DE	0.05%W/V	NKUNZI PHARMACEUTICALS (PTY) LTD.-259 DAVIDSON ROAD, WADEVILLE, GERMINSTON, 1428	SOUTH AFRICA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE,1.0X20.0 ML BOTTLE	29/05/2019
3012	NDA/MAL/HD P/6608	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CIPROCIN 0.3%	CIPROFLOXACI N HYDROCHLORI DE	0.3%W/W	PHARCO PHARMACEUTICAL IND. LTD-KM 31, ALEX, CAIRO DESERT AMRIYA, ALEXANDRA	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	29/05/2019

3013	NDA/MAL/HD P/6609	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIZOL	FLUCONAZOLE	200MG/200M L	KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BAG	29/05/2019
3014	NDA/MAL/HD P/6610	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND	ONDANSENTR ON HYDROCHLORI DE	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	01/07/2017
3015	NDA/MAL/HD P/6611	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	MARDAGRA 100	SILDENAFIL CITRATE	100MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/05/2019

3016	NDA/MAL/HD P/6612	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE PLUS-20	OMEPRAZOLE + SODIUM BICARBONATE	20MG/6G + 1680MG/6G	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X20.0X6.0 G SACHET	01/07/2008
3017	NDA/MAL/HD P/6613	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-40	OLMESARTAN MEDOXOMIL	40MG	MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3018	NDA/MAL/HD P/6615	ALLY PHARMA OPTIONS PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	PINPAC 50	DICLOFENAC SODIUM	50MG	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR- 401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3019	NDA/MAL/HD P/6616	SHIN POONG PHARMACEUTICALS CO.LTD	ESCORTS PHARMACEUTICALS LIMITED	PYRAMAX	PYRONARIDIN E TETRAPHOSPH ATE + ARTESUNATE	180MG + 60MG	SHIN POONG PHARMA.CO.LTD-434-4 MOKNAE-DONG ANSAN- SI,KYUGGI DO KOREA	SOUTH KOREA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER	01/07/2016

3020	NDA/MAL/HD P/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	01/07/2009
3021	NDA/MAL/HD P/6619	ESAPHARMA S.R.L...	BYAMAKA PHARMACEUTICAL COMPANY LTD	ORANVATE	CLOBETASOL PROPIONATE	0.05G/100G	ESAPHARMA SRL-VIA DE GASPERI, 13-20066 MELZO (MILAN) ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	01/07/2016
3022	NDA/MAL/HD P/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,1.0X2.0X 14.0 TABLET BLISTER	01/07/2016
3023	NDA/MAL/HD P/6621	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE 20	RABEPRAZOLE	20MG	INVENTIA HEALTHCARE PVT. LTD .-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2011

3024	NDA/MAL/HD P/6622	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL-100 DT	CEFIXIME TRIHYDRATE	100MG	MALIK LIFESCIENCES PRIVATE LIMITED-PLOT NO. 16, NH 58, VARDHMAN INDUTRIAL ESTATE, VILLAGE BAHADARPUR SAINI HARIDWAR, UTTARAKHAND- 247667	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
3025	NDA/MAL/HD P/6624	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	CIPROKEN	CIPROFLOXACI N HYDROCHLORI DE	0.3%W/V	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2016

3026	NDA/MAL/HD P/6625	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/12.5	NEBIVOLOL HYDROCHLORI DE + HYDROCHLOR OTHIAZIDE	5MG + 12.5MG	BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, -) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFFER WEG 83 D-12347 BERLIN GERMANY BERLIN-CHEMIE AG/MENARINI,-GLIENICKER WEG 125, D-12489 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016

3027	NDA/MAL/HD P/6626	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	ONEGABA 300	GABAPENTIN	300MG	AUROBINDO PHARMA LIMITED, UNIT – III-SURVEY NO.:113 & 314,BACHUPALLY (VILLAGE)QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, TELANGANA STATE.INDIA.☐	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	01/07/2010
3028	NDA/MAL/HD P/6627	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS HONEY & LEMON	MULTI- INGREDIENT	MULTI- INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-65 MOO 12,LARD KRABANG- BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,50.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER	01/07/1997

3029	NDA/MAL/HD P/6628	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS ORIGINAL	MULTI- INGREDIENT	MULTI- INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED- RECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG- BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THALAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK,100.0X2.0 LOZENGE BLISTER,2.0X12.0 LOZENGE BLISTER	01/07/1997
3030	NDA/MAL/HD P/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,1.0X1.0X 4.0 TABLET BLISTER	01/07/2016

3031	NDA/MAL/HD P/6631	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOBURN	SILVER SULFADIAZINE	1%W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X500.0 G JAR	01/07/2016
3032	NDA/MAL/HD P/6632	UMEDICA LABORATORIES PVT. LTD	GITTOES PHARMACEUTICALS 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	01/07/2006

3033	NDA/MAL/HD P/6633	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	PARACETAMO L + CHLORPHENIR AMINE MALEATE + PSEUDOEPHE DRINE HCL	500MG + 30MG + 2MG	SHELYS PHARMACEUTICALS LIMITED-PLOT NO. 696, BLOCK NO. 32, MIKOCHEINI INDUSTRIAL AREA, NEW BAGAMOYO ROAD, MEWENGE, DAR ES SALAAM, TANZANIA BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	TANZANIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0 X1.0X2.0X10.0 CAPSULE BLISTER	01/07/2010
3034	NDA/MAL/HD P/6634	UMEDICA LABORATORIES PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	FIXDEP -120	FEXOFENADIN E HYDROCHLORI DE	120MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

3035	NDA/MAL/HD P/6636	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	COSAMIDE 100	LACOSAMIDE	100MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2013
3036	NDA/MAL/HD P/6637	MSN LABORATORIES PRIVATE LIMITED	METRO PHARMACEUTICALS LIMITED	COSAMIDE 200	LACOSAMIDE	200MG	MSN LABORATORIES LTD- PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016
3037	NDA/MAL/HD P/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	01/07/2016

3038	NDA/MAL/HD P/6640	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (40/ 12.5)	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	01/07/2017
3039	NDA/MAL/HD P/6641	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFTRISONE-S 1.5G	CEFTRIAXONE SODIUM + SULBACTAM SODIUM	1.0G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL + 10ML WFI AMPOULE	01/07/2016

3040	NDA/MAL/HD P/6645	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SAFETELMI H (80/ 12.5)	TELMISARTAN + HYDROCHLOR OTHIAZIDE	80MG + 12.5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3041	NDA/MAL/HD P/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	01/07/2016
3042	NDA/MAL/HD P/6652	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE +TENOFIVIR DISOPROXIL FUMARATE	LAMIVUDINE+ TENOFIVIR 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	01/07/2017

3043	NDA/MAL/HD P/6654	PANACEA BIOTEC LTD	VITACARE LIMITED	LIVOLUK FIBRE	LACTULOSE + ISPAGHULA HUSK	10G + 3.5G/ 15G	PANACEA BIOTEC LTD- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X90.0 G CONTAINER	01/07/2016
3044	NDA/MAL/HD P/6655	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ATORLIP-20	ATORVASTATI N CALCIUM	20MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2004
3045	NDA/MAL/HD P/6657	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	METFORMIN	METFORMIN HYDROCHLORI DE	500MG	CIPLA LTD-MIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2010
3046	NDA/MAL/HD P/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	01/07/2017

3047	NDA/MAL/HD P/6659	UGANDA HEALTH MARKETING GROUP LIMITED	UHMG GOODLIFE PHARMACY	RESTORS	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + SODIUM CITRATE + POTASSIUM CHLORIDE	13.5G + 2.6G + 2.9G + 1.5G	FDC LIMITED-WALUJ.-PLOT B- 8, MIDC, INDUSTRIAL AREA, WALUJ 431136 (DIST AURANGABAD)	INDIA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X20.5 G SACHET	01/07/2010
3048	NDA/MAL/HD P/6660	ELDA INTERNATIONAL DMCC	REDDYS PHARMA LIMITED	KETAJEX	KETAMINE	50MG/ML	CLARIS INJECTABLE LIMITED-- CHACHARWADI VASANA AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	01/07/2005
3049	NDA/MAL/HD P/6662	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	DIAPAM	DIAZEPAM	5MG/ML	SAKAR HEALTHCARE PVT LTD --406, SILVER OAKS COMMERCIAL COMPLEX,	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2013
3050	NDA/MAL/HD P/6663	PANACEA BIOTEC LTD	VITACARE LIMITED	SITCOM	EUPHORBIA PROSTATA DRY EXTRACT	10MG/G	PANACEA BIOTEC LTD- MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN (H.P) – 173 205	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	01/07/2013

3051	NDA/MAL/HD P/6664	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 125 KID	AMOXICILLIN TRIHYDRATE	125MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3052	NDA/MAL/HD P/6665	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/1997
3053	NDA/MAL/HD P/6666	MSN LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	NEBIEM 5	NEBIVOLOL HYDROCHLORI DE	5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

3054	NDA/MAL/HD P/6667	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 250 DT	AMOXICILLIN TRIHYDRATE	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,J AMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP	01/07/2016
3055	NDA/MAL/HD P/6669	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SUPER WELGRA -100	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORI DE	100MG + 60MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0 TABLET BLISTER	01/07/2016
3056	NDA/MAL/HD P/6670	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	METROSIM- 200	METRONIDAZ OLE	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,1.0X100 0.0 TABLET CONTAINER	01/07/1997

3057	NDA/MAL/HD P/6673	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-TZ	CEFTRIAXONE SODIUM + TAZOBACTAM	1000MG + 125MG	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	01/07/2016
3058	NDA/MAL/HD P/6675	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNOSEMIDE - 10	FUROSEMIDE	10MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2016
3059	NDA/MAL/HD P/6680	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	ATELOR TABLET	ATENOLOL	100MG	PHARMEDIC LABORATORIES (PVT) LIMITED-16KM MULTAN ROAD,LAHORE- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER,10.0X10. 0 TABLET BLISTER	01/07/1997

3060	NDA/MAL/HD P/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	01/07/2016
3061	NDA/MAL/HD P/6685	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	EVACEF	CEFOTAXIME	1 G	NEON LABORATORIES LTD- PLOT NO. 29-32, 57 & 60, PALGHAR TALUKA CO- OPERATIVE ESTATE , BOISAR ROAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2014
3062	NDA/MAL/HD P/6686	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE	5MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2010
3063	NDA/MAL/HD P/6688	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	CAREOCEF	CEFTRIAZONE SODIUM	1G	NITIN LIFESCIENCES LTD.- RAMPUR GHAT ROAD, PAOMTA SAHIB DIST. SIRMOUR H.	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 G VIAL	01/07/2016

3064	NDA/MAL/HD P/6689	DAWA LIMITED	SUPER MEDIC LTD	EFLARON	METRONIDAZ OLE	200MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	TABLET CONTAINER	01/07/1997
3065	NDA/MAL/HD P/6693	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CERTICAN1	EVEROLIMUS	1MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016
3066	NDA/MAL/HD P/6694	NOVARTIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	CERTICAN 0.5	EVEROLIMUS	0.5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2016
3067	NDA/MAL/HD P/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	29/05/2019
3068	NDA/MAL/HD P/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	28/03/2019

3069	NDA/MAL/HD P/6697	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	NOLOL-10	PROPRANLOL HYDROCHLORI DE	10MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3070	NDA/MAL/HD P/6699	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ATVIN-20	ATORVASTATI N	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	29/05/2019
3071	NDA/MAL/HD P/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	01/07/2009
3072	NDA/MAL/HD P/6701	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-ART DS	ARTEMETHER / LUMEFANTRIN E	80MG/ 480MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0 TABLET BLISTER	01/07/2011

3073	NDA/MAL/HD P/6702	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	RAVZOLE-D	RABEPRAZOLE SODIUM + DOMPERIDON E	200MG + 30MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/05/2019
3074	NDA/MAL/HD P/6703	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHCOLD PLUS	PARACETAMO L/ CAFFEINE/ PHENYLEPHRI NE/ CHLORPHENIR AMINE	500MG/ 30MG/ 5MG/ 2MG	CACHET PHARMACEUTICALS PVT LTD -THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET STRIP	01/07/2011
3075	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2010
3076	NDA/MAL/HD P/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 SUSPENSIONS	1.0X30.0 ML BOTTLE	01/07/2009

3077	NDA/MAL/HD P/6708	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	CLOMINOL TABLETS	CLOMIPHENE	50MG	PHARMEDIC LAB (PVT) LTD-# 4263, 16KM MULTAN RD, LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/1997
3078	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2012
3079	NDA/MAL/HD P/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 SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2009
3080	NDA/MAL/HD P/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	01/07/2011

3081	NDA/MAL/HD P/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	01/07/2009
3082	NDA/MAL/HD P/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	01/07/1997
3083	NDA/MAL/HD P/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 SUSPENSIONS	1.0X1.0X15.0 ML BOTTLE	01/07/2009
3084	NDA/MAL/HD P/6716	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CATAFLAM 50	DICLOFENAC POTASSIUM	50MG	CATALENT GERMANY EBERBACH GMBH..- GAMMELS BACHERSTRASSE2	GERMANY	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X20.0 CAPSULE BLISTER	01/07/2016

3085	NDA/MAL/HD P/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	01/07/2011
3086	NDA/MAL/HD P/6719	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	NAPROX-500	NAPROXEN SODIUM	500MG	PHARMEDIC LAB (PVT) LTD-# 4263, 16KM MULTAN RD, LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2003
3087	NDA/MAL/HD P/6720	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COLESTOP	ATORVASTATI N	20MG	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
3088	NDA/MAL/HD P/6722	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 40	TELMISARTAN	40MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016

3089	NDA/MAL/HD P/6724	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 80	TELMISARTAN	80MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
3090	NDA/MAL/HD P/6727	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	ZYNOL-300MG TABLET	ALLOPURINOL	300MG	PHARMEDIC LAB (PVT) LTD-# 4263, 16KM MULTAN RD, LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/1997
3091	NDA/MAL/HD P/6728	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CIPROCOS-500 TABLETS	CIPROFLOXACIN	500MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER	01/07/2000
3092	NDA/MAL/HD P/6729	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF 'C' LINCTUS	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE	01/07/2010

3093	NDA/MAL/HD P/6732	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF EXPECTORANT ORIGINAL	MULTI- INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2010
3094	NDA/MAL/HD P/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	01/07/2009
3095	NDA/MAL/HD P/6736	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SANDOSTATIN	OCTREOTIDE ACETATE	0.05MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2016
3096	NDA/MAL/HD P/6737	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	ESENVIT	GLYCERIN/ ZINC SULPHATE/ SODIUM MOLYBDATE/ MANGANESE CHLORIDE/ LYSINE HCL	5.0G/ 263.83MG/ 0.4035MG/ 57.66MG/ 612MG	CACHET PHARMACEUTICALSPVT.LTD.- -415,SHAH NAHAR,WORLI MUMBAI	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	01/07/2008

3097	NDA/MAL/HD P/6741	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ULTIBRO BREEZHALER	INDACATEROL MALEATE+GLY COPYRRONIUM BROMIDE	110MCG+50M CG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X30.0 CAPSULE BLISTER	01/07/2016
3098	NDA/MAL/HD P/6744	M.J.BIOPHARM PVT LTD	TATA UGANDA 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	01/07/2004
3099	NDA/MAL/HD P/6746	KOPRAN LTD	TATA UGANDA LIMITED	FLUPEN-250	FLUCLOXACILL IN SODIUM	250MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2016
3100	NDA/MAL/HD P/6750	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NYTIN	NYSTATIN	500,000IU	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER	01/07/2005
3101	NDA/MAL/HD P/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,1.0X 10.0X10.0 TABLET BLISTER	01/07/2000

3102	NDA/MAL/HD P/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 UDHAGAMANDALAM PIN: 643007 TAMIL NADU	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.5 I.U VIAL 1*0.5ML DILUENT(0.9%W /V SODIUM CHLORIDE INJ. B.P) - 1 DOSE VIAL	01/07/2016
3103	NDA/MAL/HD P/6755	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	FLAMAR	METHYL NICOTINATE+ MEPHENESIN+ METHYL SALICYLATE+ MENTHOL	1%W/W+5%W /W+8%W/W+ 2%W/W	INDOCO REMEDIES LTD - O.-L- 14 VERNA INDUSTRIAL AREA, VERNA, GOA-403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE	01/07/2004

3104	NDA/MAL/HD P/6756	BETA HEALTHCARE UGANDA LIMITED	BETA HEALTHCARE UGANDA LIMITED	FEVEREX TOTO SUSPENSION	PARACETAMO L	120MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	01/07/2007
3105	NDA/MAL/HD P/6758	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP 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	01/07/2016

3106	NDA/MAL/HD P/6759	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	BETAPYN	PARACETAMO L+CODEINE PHOSPHATE+ DOXYLAMINE+ CAFFEINE	450 MG+10 MG+5 MG+50 MG	ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X9.0 TABLET BLISTER,6.0X9.0 TABLET BLISTER,1.0X1.0X 9.0 TABLET BLISTER	01/07/1999
3107	NDA/MAL/HD P/6761	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	DAWANOL TABLETS	PARACETAMO L+ACETYLSALI CYLIC ACID+CAFFEIN E	200MG+300M G+30MG	ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA DAR AL DAWA-NA'UR – PRINCE HASHEM BIN AL- HUSSEIN STREET P.O. BOX 9364 AMMAN 11191 JORDAN	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON	01/07/1997

3108	NDA/MAL/HD P/6762	COSMOS LTD	ASTRA PHARMA (U) LIMITED	FLUCOLD CAPSULES	MULTIINGRED IENT	NA	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/1998
3109	NDA/MAL/HD P/6763	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	COMPRAL HEADACHE TABLETS	PARACETAMO L+ASPIRIN+CA FFEINE ANHYDROUS	100MG+400M G+130MG	ADCOCK INGRAM LIMITED - 49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X48.0X2.0 TABLET STRIP	01/07/2005
3110	NDA/MAL/HD P/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	01/07/2016

3111	NDA/MAL/HD P/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,1.0X100 0.0 TABLET CONTAINER	01/07/2010
3112	NDA/MAL/HD P/6766	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	LOCAINE A	LIDOCAINE HYDROCHLORI DE+ADRENALI NE	21.33MG/1.8 ML + 0.025MG/1.8 ML	PHARMA-Q (PTY) LTD -50 COMMANDO ROAD INDUSTRIAL WEST, JOHANNESBURG	SOUTH AFRICA	PARENTERAL ORDINARY CARTRIDGES	1.0X100.0X1.8 ML CARTRIDGE	01/07/2004
3113	NDA/MAL/HD P/6767	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP 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	01/07/2016

3114	NDA/MAL/HD P/6768	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MEDI-KEEL A BLACKCURRA NT	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	01/07/2016
3115	NDA/MAL/HD P/6769	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MEDI-KEEL A HONEY & LEMON	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	01/07/2016
3116	NDA/MAL/HD P/6771	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIFLUVID	FLUCONAZOLE	150MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE BLISTER	01/07/2016

3117	NDA/MAL/HD P/6772	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE 30	PIOGLITAZONE HCL	30MG	ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2007
3118	NDA/MAL/HD P/6774	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	AXCEL FLEMIN EXPECTORANT	DIPHENHYDRA MINE HYDROCHLORI DE +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	01/07/2008
3119	NDA/MAL/HD P/6777	KOTRA PHARMA (M) SDN,BHD	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	01/07/2016
3120	NDA/MAL/HD P/6778	KOTRA PHARMA (M) SDN,BHD	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	01/07/2016

3121	NDA/MAL/HD P/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	1.0X10.0X1.0X6. 0 TABLET BLISTER	01/07/2007
3122	NDA/MAL/HD P/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 DISINTEGRATING TABLETS	1.0X10.0X1.0X6. 0 TABLET BLISTER	01/07/2008
3123	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE	01/07/2008

3124	NDA/MAL/HD P/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	01/07/2005
3125	NDA/MAL/HD P/6790	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIMZER	OMEPRAZOLE + DOMPERIDON E	20MG + 30MG	INVENTIA HEALTHCARE PVT. LTD-FI – FI /1 ADDITIONAL AMBERNATH, M.I.D.C. AMBERNATH (EAST) – 421 506, DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP	01/07/2016
3126	NDA/MAL/HD P/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	01/07/2017

3127	NDA/MAL/HD P/6794	HETERO LABS LTD	AIVEEN (U) LIMITED	ZOLID	LINEZOLID	600MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 BOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	01/07/2017
3128	NDA/MAL/HD P/6797	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	100MG/2ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE	01/07/1997
3129	NDA/MAL/HD P/6805	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SURGIPHARM (U) LIMITED	MOBIC 7.5 TABLETS	MELOXICAM	7.5MG	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET CONTAINER	07/01/2002

3130	NDA/MAL/HD P/6806	F. HOFFMANN- LA ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	2000 IU/0.3ML	ROCHE DIAGNOSTICS GMBH MANNHEIM -SANDHOFER STRABE 116, 68305, MANNHEIM	GERMANY	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0X0.3 ML PRE- FILLED SYRINGE	01/07/2016
3131	NDA/MAL/HD P/6807	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AUGMENTIN ES	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	600MG + 42.9MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2016
3132	NDA/MAL/HD P/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 BOIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X0.5 ML VIAL,1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE) + A 25 GAUGE NEEDLE	01/07/2007
3133	NDA/MAL/HD P/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	01/07/2016
3134	NDA/MAL/HD P/6815	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ABCROM EYE DROPS	SODIUM CROMOGLYCA TE	2%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE	01/07/2016

3135	NDA/MAL/HD P/6817	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH- SCHLEEBRÜGGENKAMP 15 48159 MÜNSTER GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2016
3136	NDA/MAL/HD P/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	01/07/2016
3137	NDA/MAL/HD P/6820	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABBORI EAR DROPS	BORIC ACID	1.83%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML BOTTLE	01/07/2005
3138	NDA/MAL/HD P/6821	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	MAGNESIUM SULPHATE INJECTION	MAGNESIUM SULPHATE	50%W/V	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X10. 0 ML AMPOULE	01/07/2016

3139	NDA/MAL/HD P/6823	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	EPHEDRINE HYDROCHLORI DE	EPHEDRINE HYDROCHLORI DE	30MG/ML	MARTINDALE PHARMACEUTICALS .- ROMFORD ESSEX RM3 8UG UK	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE	01/07/2016
3140	NDA/MAL/HD P/6825	ROCHE	LABOREX UGANDA LIMITED	FANSIDAR	SULFADOXINE /PYRIMETHA MINE	525MG	ROCHE PRODUCTS PTY LTD.- 1600 ISANDO SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X3.0 TABLET STRIP,1.0X50.0X 10.0 TABLET STRIP	01/07/1997
3141	NDA/MAL/HD P/6833	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ON.SENTRON- DENK 8MG ODT	ONDANSETRO N	8MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	01/07/2016
3142	NDA/MAL/HD P/6840	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	LIPINORM	ATORVASTATI N CALCIUM TRIHYDRATE	20MG	MEDICAL UNION PHARMACEUTICALS-36 DR MOHAMED HASSAN EL- GAMAL ST.6TH DISTRICT NASR CITY EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X4.0X 7.0 TABLET BLISTER	01/07/2017

3143	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2009
3144	NDA/MAL/HD P/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	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL	01/07/2017
3145	NDA/MAL/HD P/6857	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	29/11/2017

3146	NDA/MAL/HD P/6859	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	BRUVEL-500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	BRAWN LABORATORIES LTD.-13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA -INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/09/2018
3147	NDA/MAL/HD P/6862	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	01/07/2017
3148	NDA/MAL/HD P/6865	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	DITS INJECTION	DICLOFENAC SODIUM	25MG/ML	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE	29/11/2017
3149	NDA/MAL/HD P/6868	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN	CETIRIZINE HYDROCHLORIDE	10MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019

3150	NDA/MAL/HD P/6870	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	HYDROSONE 100MG	HYDROCORTIS ONE SODIUM SUCCINATE	100MG	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON (1*100MG GLASS VIAL + 1*2ML AMP WFI)	29/11/2017
3151	NDA/MAL/HD P/6871	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	VIVAX 100	SILDENAFIL	100MG	BRAWN LABORATORIES LTD.-13,NEW INDUSTRIAL TOWNSHIP, FARIDABAD-121 001,HARYANA -INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	26/09/2018
3152	NDA/MAL/HD P/6872	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	01/07/2017
3153	NDA/MAL/HD P/6873	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	26/09/2018

3154	NDA/MAL/HD P/6874	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	CEZIN 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	01/07/2017
3155	NDA/MAL/HD P/6875	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS 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	01/07/2017
3156	NDA/MAL/HD P/6877	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	DIN-P	PANTOPRAZO LE SODIUM + DOMPERIDON E	40MG + 10MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/05/2019
3157	NDA/MAL/HD P/6878	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	AMITIVIAN	AMITRIPTYLIN E	25MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019

3158	NDA/MAL/HD P/6879	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ORAV-200	OFLOXACIN	200MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3159	NDA/MAL/HD P/6880	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	ORAV-OZ	OFLOXACIN + ORNIDAZOLE	50MG + 125MG PER 5ML	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE	29/05/2019
3160	NDA/MAL/HD P/6881	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	ASTRALEVOFL OXA	LEVOFLOXACI N	500MG	ASTRA LIFE CARE(INDIA) PVT LTD-PLOT NO. 57/P, SARKHEJ – BAVLA HIGHWAY, POST. RAJODA – 382220, TALUKA: BAVLA, DIST. AHMEDABAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	31/01/2018
3161	NDA/MAL/HD P/6882	RAVIAN LIFE SCIENCE PVT. LTD	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	29/05/2019

3162	NDA/MAL/HD P/6885	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	DIN-P 20	PANTOPRAZO LE SODIUM + DOMPERIDON E	20MG + 10MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT 34, SEC 8A, IIE, SIDCUL, HARIDWAR-269403 UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019
3163	NDA/MAL/HD P/6887	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	WELBEEN-L	LEVOCETIRIZIN E DIHYDROCHLO RIDE	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	29/05/2019
3164	NDA/MAL/HD P/6891	MUPHARMA (U) LTD	MU PHARMA CO- SMC LIMITED	FLUCARIV	FLUCONAZOLE	150MG	RIVA PHARMA-STREET NO. 6 FREE ZONE - NASR CITY - CAIRO - EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X1.0 CAPSULE BLISTER	29/05/2019
3165	NDA/MAL/HD P/6895	RIVA PHARMA FREE ZONE	MU PHARMA CO- SMC LIMITED	RIVAMOX	AMOXICILLIN TRIHYDRATE	250MG/5ML	RIVA PHARMA-STREET NO. 6 FREE ZONE - NASR CITY - CAIRO - EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	29/05/2019

3166	NDA/MAL/HD P/6897	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE GARGLE & MOUTH WASH	POVIDONE IODINE	1G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI- PAKISTAN	PAKISTAN	ORAL TOPICAL LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2006
3167	NDA/MAL/HD P/6898	F. HOFFMANN LA- ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	5000I.U/0.3M L	ROCHE DIAGNOSTICS GMBH MANNHEIM-SANDHOFER STRABE 116, 68305, MANNHEIM	GERMANY	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0X1.0X0.3 ML PRE- FILLED SYRINGE	29/05/2019
3168	NDA/MAL/HD P/6901	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ZINKORA KIT	[GLUCOSE ANHYDROUS + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE] + [ZINC SULPHATE MONOHYDRA TE]	[13.5G + 2.9G + 2.6G + 1.5G] + [20MG]	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY COMBINATION PACK POWDERS/GRAN ULES	1.0X2.0X20.5 G SACHET + 1*10 TABLET BLISTER	29/05/2019

3169	NDA/MAL/HD P/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	29/05/2019
3170	NDA/MAL/HD P/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	29/05/2019

3171	NDA/MAL/HD P/6910	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	MULTIVITAMI N TABLETS	VITAMIN A+VITAMIN D3+VITAMIN B1+VITAMIN B2+ NIACINAMIDE	1600IU+100IU +1MG+1MG+1 5MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0 TABLET BLISTER	02/09/2019
3172	NDA/MAL/HD P/6912	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 5	ROSUVASTATI N 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	28/08/2019
3173	NDA/MAL/HD P/6913	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYROVA 10	ROSUVASTATI N 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	28/08/2019

3174	NDA/MAL/HD P/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	28/08/2019
3175	NDA/MAL/HD P/6918	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICALS LIMITED	NO COLD	PARACTAMOL + PHENYL HYDROCHLORI DE + CHLORPHENA MINE MALEATE + CAFFEINE ANHYDROUS	500MG + 10MG + 2MG + 30MG	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER,1.0X25.0 X4.0 TABLET BLISTER	28/08/2019
3176	NDA/MAL/HD P/6919	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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,1.0X25.0 X3.0 TABLET BLISTER	27/03/2019

3177	NDA/MAL/HD P/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	07/11/2018
3178	NDA/MAL/HD P/6921	GUILIN PHARMACEUTICAL (SHANGHAI) CO., LTD	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	01/07/2017
3179	NDA/MAL/HD P/6923	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MACSUNATE AQ KID			MACLEODS PHARMACEUTICALS LTD ,,- PHASE I & II, PLOT NO. 25-27 SURVEY NO. 366, PREMIERE INDUSTRIAL ESTATE, KACHIGAN, DAMAN-396210	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER,1.0X25.0 X3.0 TABLET BLISTER	27/03/2019

3180	NDA/MAL/HD P/6925	NIPRO MIDDLE EAST FZE	ROYAL PHARMA 2011 LIMITED	PROKINET	DOMPERIDON E MALEATE BP	10MG	NIPRO JMI PHARMA LTD.- CHAUDDAGRAM, COMILLA BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3181	NDA/MAL/HD P/6926	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROKAN T-ES	ERYTHROMYCIN ETHYL SUCCINATE	125MG/5ML	S KANT HEALTHCARE LTD- PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	29/05/2019
3182	NDA/MAL/HD P/6927	CRATUS PHARMA PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	GOPAYN MR	ACECLOFENAC BP+TIZANIDIN E HYDROCHLORIDE USP+PARACET AMOL 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	29/05/2019
3183	NDA/MAL/HD P/6928	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MOMENAP NS 0.05	MOMETASON E FUROATE	0.05%W/V	SAVA HEALTHCARE LIMITED.- PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	GERMANY	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X12.0 ML CANNISTER	29/05/2019

3184	NDA/MAL/HD P/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	27/03/2019
3185	NDA/MAL/HD P/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	27/03/2019
3186	NDA/MAL/HD P/6931	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	AMORIV	AMBROXOL HYDROCHLORI DE	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	28/08/2019
3187	NDA/MAL/HD P/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	01/07/2017

3188	NDA/MAL/HD P/6936	SAVA HEALTHCARE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	RANKOF	PARACETAMO L+CAFFEINE, PHENYLEPHRI NE + CHLORPHENA MINE MALEATE	500MG+30MG +10MG+2MG	SAVA HEALTHCARE LIMITED.- PLOT NO 507B -512, G.I.D.C. ESTATE, WADHWANCITY-363 035 SURENDRANAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/05/2019
3189	NDA/MAL/HD P/6937	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	CEFROTIL750	CEFUROXIME SODIUM	750MG	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL 1*10ML WFI	29/05/2019
3190	NDA/MAL/HD P/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	27/03/2019

3191	NDA/MAL/HD P/6940	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	MEASLES AND RUBELLA VACCINE	MEASLES VACCINE, RUBELLA VACCINE	NOT LESS THAN 3.0 LOG10 CCID50, NOT LESS THAN 3.0 LOG10 CCID50	SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X0.5 ML VIAL,1.0X5.0 ML VIAL	29/05/2019
3192	NDA/MAL/HD P/6941	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 30	TOLVAPTAN	30MG	MSN LABORATORIES PRIVATE LIMITED - -PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT, TELANGANA 502325, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018
3193	NDA/MAL/HD P/6942	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLVAT 15	TOLVAPTAN	15MG	MSN LABORATORIES PRIVATE LIMITED - -PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT, TELANGANA 502325, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	07/11/2018

3194	NDA/MAL/HD P/6943	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ADWIFLAM	DICLOFENAC POTASSIUM	25MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)- 1ST INDUSTRIAL ZONE, 6 OCTOVER CITY, P.O. BOX 43	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	29/05/2019
3195	NDA/MAL/HD P/6944	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	NEBANOL PLUS	NEOMYCIN SULPHATE+BA CITRACIN ZINC+ POLYMYXIN B SULPHATE	3.5MG/GM+4 00I.U/GM+500 0I.U/GM	SQUARE PHARMACEUTICALS LTD.-SQUARE ROAD SALGARIA PABNA	BANGLADESH	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE	29/05/2019
3196	NDA/MAL/HD P/6945	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	TRICK-D	CHOLECALCIFE ROL	5MG/ML	SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	PAKISTAN	OTHER SYSTEMIC LIQUIDS	1.0X1.0 ML AMPOULE	29/05/2019
3197	NDA/MAL/HD P/6946	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	FEVERAL	PARACETAMO L	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	29/05/2019

3198	NDA/MAL/HD P/6947	MSN LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	RANCV 375	RANOLAZINE	375MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/03/2019
3199	NDA/MAL/HD P/6949	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	MEGAFER	IRON SUCROSE	100MG/5ML	SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X5.0 ML AMPOULE	29/05/2019
3200	NDA/MAL/HD P/6950	SWISS PARENTERALS PVT LTD	ROYAL PHARMA 2011 LIMITED	ARTESUNATE INJECTION	ARTESUNATE	30MG	SWISS PARENTERALS PVT LTD -809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD-380220 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON + (1X1ML 5% NAHCO3 AMPOULE)+(1X5 ML 0.9% NACL AMPOULE)	29/05/2019
3201	NDA/MAL/HD P/6951	SWISS PARENTERALS PVT LTD	ROYAL PHARMA 2011 LIMITED	LIDOCAINE	LIDOCAINE HYDROCHLORI DE	2%	SWISS PARENTERALS PVT LTD -809 KERALA INDUSTRIAL ESTATE GIDC NR. BAVLA DIST. AHMEDABAD-380220 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL	29/05/2019

3202	NDA/MAL/HD P/6952	SWISS PARENTERALS PVT LTD	ROYAL PHARMA 2011 LIMITED	SYN-MAL	ARTMETHER	80MG/ML	SWISS PARENTERALS PVT LTD --809, KERALA INDUSTRIAL ESTAE, GIDC NEAR BAVLA, AHMEDABAD 382220, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X6.0X1.0 ML AMPOULE	29/05/2019
3203	NDA/MAL/HD P/6953	SYNOKEM PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MISOFREE	MISOPROSTOL	200MCG	SYNOKEM PHARMACEUTICALS LIMITED -PLOT NO.- 35-36, SECTOR- 6A, IIE (SIDCUL), RANIPUR (BHEL)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER	29/05/2019
3204	NDA/MAL/HD P/6954	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMEDA)	GAMA PHARMACEUTICALS (U) LIMITED	RAMEDA	WATER FOR INJECTION	NA	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)- SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X8.0X5.0 ML AMPOULE	29/05/2019

3205	NDA/MAL/HD P/6955	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SEVOTROY 250	SEVOFLURANE	250	TROIKAA PHARMACEUTICALS LIMITED..-THOL, DIST MEHSANA PIN 382728, GUJARAT	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE	29/05/2019
3206	NDA/MAL/HD P/6956	TROIKAA PHARMACEUTICALS LIMITED	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	29/05/2019
3207	NDA/MAL/HD P/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	29/05/2019
3208	NDA/MAL/HD P/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	29/05/2019

3209	NDA/MAL/HD P/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	29/05/2019
3210	NDA/MAL/HD P/6960	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MERROBE 500	MEROPENEM USP	500MG	ZEISS PHARMACEUTICALS PVT LTD - --PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	29/05/2019
3211	NDA/MAL/HD P/6961	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MERROBE 1000	MEROPENEM	1G	ZEISS PHARMACEUTICALS PVT LTD - --PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	29/05/2019

3212	NDA/MAL/HD P/6962	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ROXONE- S	CEFTRIAZONE SODIUM + SULBACTAM SODIUM	1G+0.5G	ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL	29/05/2019
3213	NDA/MAL/HD P/6963	RAINBOW LIFE SCIENCES PVT.LTD.	ROYAL PHARMA 2011 LIMITED	LANAC	LANSOPRAZOL E	30MG	ZIM LABS LTD.-B 21/22, MIDC AREA, KALMESHWAR 441501, DIST-NAGPUR	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/05/2019
3214	NDA/MAL/HD P/6964	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	TOXXET 200	CEFPODOXIME PROXETIL	200MG	ZIM LABORATORIES LTD-B- 21/22 MIDC, KALMESHWAR 441501	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/05/2019

3215	NDA/MAL/HD P/6967	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	MICAZOLE	MICONAZOLE	2%W/W	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE	27/11/2019
3216	NDA/MAL/HD P/6971	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	MONTIRIV-10	MONTELUKAS T 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	28/08/2019
3217	NDA/MAL/HD P/6972	MANKIND PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MOXIKIND-CV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	COPMED PHARMACEUTICALS PVT LTD- UNIT II. ,-PLOT 50, GONDPUR INDUSTRIAL AREA, PAONTA, SAHIB, SIRMOUR, HIMACHAL PRADESH-173025, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER	28/03/2019

3218	NDA/MAL/HD P/6973	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED DM	TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE + DEXTROMETH ORPHAN	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	27/11/2019
3219	NDA/MAL/HD P/6974	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND- MD 4	ONDANSETRO N	4MG	MANKIND PHARMA LIMITED, UNIT-II. -VILLAGE KISHANPURA, P.O JAMNIWALA, PAONTA SAHIB IN H.P.	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3220	NDA/MAL/HD P/6975	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	CELERIV- 200	CELECOXIB	200 MG	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/08/2019
3221	NDA/MAL/HD P/6976	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	KETORIV SOAP	KETOCONAZO LE	2%W/W	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	TOPICAL EXTERNAL SOLID SOAPS/BARS	1.0X75.0 G SACHET	28/08/2019

3222	NDA/MAL/HD P/6977	EAST AFRICAN (INDIA) OVERSEAS	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	28/08/2019
3223	NDA/MAL/HD P/6978	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHAS ONE SODIUM PHOSPHATE	4 MG/ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X2.0 ML VIAL	28/08/2019
3224	NDA/MAL/HD P/6979	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	TERBIRIV	TERBINAFINE HYDROCHLORI DE	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	28/08/2019
3225	NDA/MAL/HD P/6980	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	KETORIV	KETOCONAZO LE	2.0%W/W	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	NASAL TOPICAL CREAMS	1.0X1.0X15.0 G TUBE	28/08/2019

3226	NDA/MAL/HD P/6981	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	KIT LANZ	LANSOPRAZOL E + CLARITHROMY CIN + TINIDAZOLE	30MG + 250MG + 500MG	FREDUN PHARMACEUTICALS LIMITED- 14,15,16, ZORABIAN INDUSTRIAL COMPLEX,VEOOR,PALGHAR (E), DIST: PALGHAR-401 404	INDIA	ORAL SOLID ORDINARY OTHER SPECIAL FORMS	1.0X7.0X6.0 TABLET BLISTER PACK HAS BOTH CAPSULES AND TABLETS	28/08/2019
3227	NDA/MAL/HD P/6982	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	DEXARIV	DEXAMETHAS ONE 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	28/08/2019
3228	NDA/MAL/HD P/6983	EAST AFRICAN (INDIA) OVERSEAS	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	28/08/2019
3229	NDA/MAL/HD P/6984	EAST AFRICAN (INDIA) OVERSEAS	ROYAL PHARMA 2011 LIMITED	VIREXIM-400	CEFEXIME 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,1.0X10.0 X10.0 CAPSULE BLISTER	28/08/2019

3230	NDA/MAL/HD P/6985	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID SYRUP	CETIRIZINE DIHYDROCHLO RIDE + PHENYLEPHRI NE HCL + PARACETAMO L	2.5MG + 5MG + 125MG	MEDLEY PHARMACEUTICALS, LTD- PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
3231	NDA/MAL/HD P/6986	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	REPRAZ 20 TABLETS	RABEPRAZOLE SODIUM	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3232	NDA/MAL/HD P/6987	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PORAZ CAPSULES	OMEPRAZOLE	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP	01/07/2017

3233	NDA/MAL/HD P/6988	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	ESZOLE	ESOMEPRAZO LE MAGNESIUM TRIHYDRATE	40 MG	CORONA REMEDIES PVT. LTD- VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3234	NDA/MAL/HD P/6989	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXPECTORANT	TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE + GUAIFENESIN	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	27/11/2019
3235	NDA/MAL/HD P/6990	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-40	ESOMEPRAZO LE 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	29/05/2019
3236	NDA/MAL/HD P/6991	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	ESORIV-20	ESOMEPRAZO LE 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	29/05/2019

3237	NDA/MAL/HD P/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	29/05/2019
3238	NDA/MAL/HD P/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	29/05/2019
3239	NDA/MAL/HD P/6994	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	PERLEX DRY SYRUP	CEFALEXIN MONOHYDRATE	125MG/5ML	EAST AFRICAN (INDIA) OVERSEAS-PLOT NO.1, PHARMACITY SELAQUI DEHRADUN – 248011 (U.K), INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	29/05/2019
3240	NDA/MAL/HD P/6995	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	T-MEF	TRANEXAMIC ACID + MEFENAMIC ACID	250MG + 500MG	ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019

3241	NDA/MAL/HD P/6996	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	CIROMETHER	ARTEMETHER	100MG/ML	CIRON DRUGS & PHARMACEUTICAL PVT LTD - 1, PRABHAT NAGAR, GROUND FLOOR, JOGESHWARI (W), MUMBAI - 400 102. INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X6.0X1.0 ML AMPOULE	28/03/2019
3242	NDA/MAL/HD P/6997	HETERO LABS LTD	AIVEEN (U) LIMITED	EC-PRAM 10	ESCITALOPRA M OXALATE	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 FILM- COATED TABLETS	1.0X3.0X1.0X10. 0 TABLET BLISTER	30/05/2018
3243	NDA/MAL/HD P/6998	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	L-DIPIN-55	LOSARTAN POTASSIUM + AMLODIPINE BESILATE	50MG + 5MG	ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019

3244	NDA/MAL/HD P/7000	CIRON DRUGS & PHARMACEUTICAL PVT LTD	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	28/03/2019
3245	NDA/MAL/HD P/7001	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DACIHEP 60	DACLATASVIR DIHYDROCHLO RIDE	60 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	28/08/2019
3246	NDA/MAL/HD P/7002	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	LOPINAVIR AND RITONAVIR	LOPINAVIR + RITONAVIR	40MG + 10MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S- 103 TO S-105, S-107 TO S- 112, L-147/1 TO L-147/3, L- 138, L-147/A, VERNA INDUSTRIAL ESTATE, VERNA SALCETTE-GOIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X120.0 CAPSULE BOTTLE	06/09/2019

3247	NDA/MAL/HD P/7004	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	DUOCETZ	PARACETAMO L+TRAMADOL HYDROCHLORI DE	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	31/01/2018
3248	NDA/MAL/HD P/7005	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR, DOLUTEGRAVI R AND LAMIVUDINE	ABACAVIR + DOLUTEGRAVI R + LAMIVUDINE	600MG + 50MG + 300MG	CIPLA LTD-UNIT VII PRODUCTION II, PLOT NOS. S- 103 TO S-105, S-107 TO S- 112, L-147/1 TO L-147/3, L- 138, L-147/A, VERNA INDUSTIRAL ESTATE, VERNA SALCETTE-GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	28/08/2019

3249	NDA/MAL/HD P/7006	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PREDNIMAX	PREDNISOLON E	5MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/09/2019
3250	NDA/MAL/HD P/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	25/01/2019
3251	NDA/MAL/HD P/7008	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	DARUNAVIR TABLETS	DARUNAVIR ETHANOLATE	400 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	28/08/2019

3252	NDA/MAL/HD P/7009	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	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	28/08/2019
3253	NDA/MAL/HD P/7010	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CALCAC 300	CALCIUM LACTATE	300MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/09/2019
3254	NDA/MAL/HD P/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	1.0X1.0X10.0 CAPSULE BLISTER	27/03/2019

3255	NDA/MAL/HD P/7012	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP DVIR	DACLATASVIR + SOFOSBUVIR	60MG + 400MG	MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X28.0 TABLET BOTTLE	31/01/2018
3256	NDA/MAL/HD P/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	29/11/2017
3257	NDA/MAL/HD P/7014	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	ACEAAR 100 TABLET	ACECLOFENAC	100MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET STRIP	29/11/2017
3258	NDA/MAL/HD P/7015	KOPRAN LIMITED	TATA UGANDA LIMITED	LOKIT	OMEPRAZOLE	20MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	31/01/2018

3259	NDA/MAL/HD P/7016	KPC PHARMACEUTICALS, INC	SUPER PHARMACEUTICALS LIMITED	LUOTAI	PANAX NOTOGINSEN GN SAPONINS	100MG	KPC PHARMACEUTICALS, INC.-QIGONGLI, WEST SUBURB,KUNMING, YUNNAN PROVINCE, P.R.CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BOTTLE	28/08/2019
3260	NDA/MAL/HD P/7017	KPC PHARMACEUTICALS, INC	SUPER PHARMACEUTICALS LIMITED	GENTAMEDIN E	GENTAMYCIN SULFATE	80MG/2ML	KPC PHARMACEUTICALS, INC.-QIGONGLI, WEST SUBURB,KUNMING, YUNNAN PROVINCE, P.R.CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	28/08/2019
3261	NDA/MAL/HD P/7018	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	125MG + 125MG	LABORATORY & ALLIED LTD - PLOT 209/10349 OFF MOMBASA ROAD	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	28/08/2019
3262	NDA/MAL/HD P/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	28/08/2019
3263	NDA/MAL/HD P/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	28/08/2019

3264	NDA/MAL/HD P/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	29/11/2017
3265	NDA/MAL/HD P/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	01/07/2017
3266	NDA/MAL/HD P/7023	EXPHAR SA.	SURGIPHARM (U) LIMITED	VERZOL ORAL SUSPENSION	ALBENDAZOLE	200 MG / 5 ML	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE,1.0X20.0 X10.0 ML BOTTLE	28/03/2018
3267	NDA/MAL/HD P/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	29/11/2017

3268	NDA/MAL/HD P/7026	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL OXYMETAZOLI NE NASAL SPRAY	OXYMETAZOLI NE HYDROCHLORI DE	0.05%W/V	KOTRA PHARMA (M) SDN.BHD,-1, 2 & 3, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA	MALAYSIA	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X1.0X10.0 ML BOTTLE	28/08/2019
3269	NDA/MAL/HD P/7028	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	DEXAFLOX	OFLOXACIN + DEXAMETHAS ONE	3MG + 1MG PER ML	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019
3270	NDA/MAL/HD P/7029	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	LIPIZAR 20	ATORVASTATI N 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	28/03/2018

3271	NDA/MAL/HD P/7031	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROMETHAZI NE HYDROCHLORI DE	PROMETHAZI NE HYDROCHLORI DE	25MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	02/09/2019
3272	NDA/MAL/HD P/7033	CODAL-SYNTO LTD	RENE PHARMACY LTD	CEFUROXIME- SYNTO	CEFUROXIME AXETIL	250MG	MEDOCHEMIE (FACTORY C)- 2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP	28/08/2019
3273	NDA/MAL/HD P/7037	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	O2	OFLOXACIN + ORNIDAZOLE	50MG + 125MG	MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE	28/08/2019

3274	NDA/MAL/HD P/7039	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	O2	OFLOXACIN + ORNIDAZOLE	200MG + 500MG	MEDLEY PHARMACEUTICALS LTD-LANE 03, PHASE 1, SIDCO INDUSTRIAL COMPLEX, BARI BRAHMANA JAMMU 181133	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
3275	NDA/MAL/HD P/7042	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	R.B.TONE SYRUP	FERROUS GLUCONATE + FOLIC ACID + CALCIUM LACTATE + VITAMIN B12	129.5MG + .25MG + 75MG +1.25MCG	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 LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE	28/08/2019
3276	NDA/MAL/HD P/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	28/08/2019

3277	NDA/MAL/HD P/7053	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID CREAM	KETOCONAZO LE	2%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2017
3278	NDA/MAL/HD P/7055	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST 400	ACICLOVIR	400MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	5.0X5.0 TABLET BLISTER	31/01/2018
3279	NDA/MAL/HD P/7057	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST CREAM 5%	ACICLOVIR	5%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE	01/07/2017
3280	NDA/MAL/HD P/7058	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEURAN 300 MG CAPSULE	GABAPENTIN	300MG	HOVID BERHAD,-LOT 56442, 7 1/2 MILES JALAN IPOH/CHEMOR 31200, CHEMOR PERAK HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	28/08/2019

3281	NDA/MAL/HD P/7063	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GRISEOFULVIN 500MG FILM- COATED TABLET	GRISEOFULVIN	500MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
3282	NDA/MAL/HD P/7065	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	BRIMO	BRIMONIDINE TARTRATE	2%W/V	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML BOTTLE	02/09/2019
3283	NDA/MAL/HD P/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	28/08/2019
3284	NDA/MAL/HD P/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 SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP	28/08/2019

3285	NDA/MAL/HD P/7068	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	FENSUPP-25	DICLOFENAC SODIUM	25MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY STRIP	28/08/2019
3286	NDA/MAL/HD P/7069	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	AMVASC 10	AMLODIPINE BESYLATE	10MG	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	02/09/2019
3287	NDA/MAL/HD P/7070	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 1000 MG FILM- COATED TABLET	METFORMIN HYDROCHLORI DE	1000MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

3288	NDA/MAL/HD P/7071	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FORACORT- 200	FORMOTEROL FUMARATE DIHYDRATE + BUDESONIDE	6MCG + 200MCG	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	25/07/2018
3289	NDA/MAL/HD P/7072	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	AMVASC 5	AMLODIPINE BESYLATE	5MG	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	02/09/2019
3290	NDA/MAL/HD P/7073	MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES	SWASTIK PHARMACEUTICAL LTD	NAUSILEX	ALIZAPRIDE HYDROCHLORI DE	50 MG/2ML	MINAPHARM PHARMACEUTICAL & CHEMICAL INDUSTRIES- MINA STREET PARTS NO; 15/4;16/4 INDUSTRIAL ZONE A2-10TH OF RAMADHAN CITY EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE	02/09/2019

3291	NDA/MAL/HD P/7074	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FORACORT- 100	FORMETEROL FUMARATE DIHYDRATE + BUDESONIDE	6 MCG+100 MCG	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	25/07/2018
3292	NDA/MAL/HD P/7075	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-200	QUETIAPINE FUMARATE	200MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019

3293	NDA/MAL/HD P/7076	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	DIAHEAL	LOPERAMIDE HYDROCHLORI DE	2MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	02/09/2019
3294	NDA/MAL/HD P/7077	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FORACORT- 400	FORMOTEROL FUMARATE DIHYDRATE + BUDESONIDE	6MCG + 400MCG	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	25/07/2018

3295	NDA/MAL/HD P/7080	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-100	QUETIAPINE FUMARATE	100MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOONNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3296	NDA/MAL/HD P/7082	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	VARNIL 20	VARDENAFIL HYDROCHLORI DE	20MG	MYLAN LABORATORIES LTD- S-16&S17A, SURVEY NO.408(P),410(P), 458(P). SEZ TSIIC, GREEN INDUSTRIAL PARK,POLEPALLY(V),JADCHE RLA(M),MAHABUBNAGAR- 509 302,TELANGANA-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	02/09/2019

3297	NDA/MAL/HD P/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	28/08/2019
3298	NDA/MAL/HD P/7084	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	GABA 300	GABAPENTIN	300MG	NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER	28/08/2019
3299	NDA/MAL/HD P/7085	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	DYSEN SUSPENSION	SECNIDAZOLE	750MG	NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE	28/08/2019

3300	NDA/MAL/HD P/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,1.0X3.0X 10.0 CAPSULE BLISTER	28/03/2019
3301	NDA/MAL/HD P/7087	HETERO DRUGS LTD	AIVEEN (U) LIMITED	Q-TAB-25	QUETIAPINE FUMARATE	25MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3302	NDA/MAL/HD P/7088	PINNACLE LIFE SCIENCE PVT. LTD	METRO PHARMACEUTICALS LIMITED	PINNOX 200	OFLOXACIN	200MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018

3303	NDA/MAL/HD P/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	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	28/08/2019
3304	NDA/MAL/HD P/7090	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	ENDOPROST	CARBOPROST TROMETHAMI NE	125MCG/0.5M L	BHARAT SERUMS & VACCINES LTD.-PLOT NO. K-27, JAMBIVILI VILLAGE, ANAND NAGAR, ADDITIONAL M.I.D.C., AMBERNATH (EAST)-INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON	31/01/2018
3305	NDA/MAL/HD P/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	29/11/2017
3306	NDA/MAL/HD P/7092	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	PATMAC	PANTOPRAZO LE SODIUM	40MG	NABIQASIM INDUSTRIES (PVT) LTD.-17/24, KORANGI INDUSTRIAL AREA, KORANGI,KARACHI - PAKISTAN	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL	28/08/2019

3307	NDA/MAL/HD P/7094	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	GLANDIN-E2	DINOPROSTO NE	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	28/08/2019
3308	NDA/MAL/HD P/7095	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL EXTRA	PARACETAMO L + 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	27/11/2019
3309	NDA/MAL/HD P/7097	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SOVIHEP	SOFOSBUVIR	400MG	CADILA HEALTHCARE LIMITED -PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET CONTAINER,1.0X 3.0X10.0 TABLET BLISTER	28/03/2019

3310	NDA/MAL/HD P/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	31/01/2018
3311	NDA/MAL/HD P/7099	MYLAN LABORATORIES LIMITED	NORVIK ENTERPRISES LIMITED	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	PARENTERAL ORDINARY VIALS	1.0X12.0X1.0 ML VIAL,1.0X25.0X1. 0 ML VIAL	27/11/2019
3312	NDA/MAL/HD P/7101	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ASTHAREN	SALBUTAMOL SULPHATE	4MG	RENE INDUSTRIES LIMITED- PLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016

3313	NDA/MAL/HD P/7102	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REPRAZINE	CHLORPROMA ZINE HYDROCHLORI DE	100MG	RENE INDUSTRIES LIMITED- PLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2016
3314	NDA/MAL/HD P/7103	MACARTHYS LABORATORIES LTD	LABOREX UGANDA LIMITED	CAFFEINE CITRATE 10MG/ ML SOLUTION FOR INJECTION	CAFFEINE CITRATE	10MG/ML	MACARTHYS LABORATORIES LIMITED T/A MARTINDALE PHARMA-BAMPTON ROAD, ROMFORD, ESSEX RM3 8UG,	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	27/11/2019
3315	NDA/MAL/HD P/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	01/07/2017
3316	NDA/MAL/HD P/7106	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REVIVE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE DIHYDRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	13.5G + 2.9G + 2.6G + 1.5G	RENE INDUSTRIES LIMITED- PLOT 680 KAMULI- KIREKA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0 SACHET CARTON	01/07/2016

3317	NDA/MAL/HD P/7107	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	27/03/2019
3318	NDA/MAL/HD P/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	27/11/2019
3319	NDA/MAL/HD P/7110	THE UNITED PHARMACEUTICALS MFG, CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED EXTRA	TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE + DEXTROMETH ORPHAN + 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	27/11/2019

3320	NDA/MAL/HD P/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	28/08/2019
3321	NDA/MAL/HD P/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	28/08/2019

3322	NDA/MAL/HD P/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	28/08/2019
3323	NDA/MAL/HD P/7115	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TELTAS-40 H	TELMISARTAN +HYDROCHLO ROTHIAZIDE	(40+12.5)MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI- 248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
3324	NDA/MAL/HD P/7116	THE UNITED PHARMACEUTICALS MFG. CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED	TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE	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	27/11/2019

3325	NDA/MAL/HD P/7117	THE UNITED PHARMACEUTICALS MFG. CO. LTD,	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNIFED	TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE	1.25MG + 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	27/11/2019
3326	NDA/MAL/HD P/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	27/11/2019
3327	NDA/MAL/HD P/7119	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-40 H	OLMESARTAN MEDOXOMIL + HYDROCHLOR OTHIAZIDE	40MG + 12.5MG	MICRO LABS LIMITED ,,-92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
3328	NDA/MAL/HD P/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	27/11/2019

3329	NDA/MAL/HD P/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	29/08/2019
3330	NDA/MAL/HD P/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	29/08/2019
3331	NDA/MAL/HD P/7123	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	MARTINEZ 10	MONTELUKAS T SODIUM	10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER	28/03/2018

3332	NDA/MAL/HD P/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	01/07/2017
3333	NDA/MAL/HD P/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	04/02/2019
3334	NDA/MAL/HD P/7126	PT. SYDNA FARMA	ECHO PHARMACY (U) LIMITED	BRAIN-Q 250	CITICOLINE MONOSODIU M	250MG/2ML	PT SYDNA FARMA-JL RC VETERAN NO.89- BINTARO,JARKATA, 12330, INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	29/08/2019
3335	NDA/MAL/HD P/7127	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	CASPOGIN 50	CASPOFUNGIN ACETATE	50MG	CIPLA LTD-UNIT IX, M-61, M- 62 & M-63, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	07/11/2018

3336	NDA/MAL/HD P/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	26/09/2018
3337	NDA/MAL/HD P/7129	SAKAR HEALTHCARE LIMITED	HARLEYS UGANDA LIMITED	CETICAD	CETIRIZINE DIHYDROCHLO RIDE	5MG/5ML	SAKAR HEALTHCARE PVT LTD- BLOCK NO. 10-13, NR. M.N DESAI PETRO PUMP, SARKHEJ-BAVLA ROAD, CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	29/08/2019
3338	NDA/MAL/HD P/7132	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	CASPOGIN 70	CASPOFUNGIN ACETATE	70MG	CIPLA LTD-UNIT IX, M-61, M- 62 & M-63, VERNA INDUSTRIAL ESTATE, VERNA, SALCETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	07/11/2018

3339	NDA/MAL/HD P/7133	LIPTIS EGYPT FOR PHARMACEUTICALS AND MEDICAL PRODUCTS	ERIS LTD	WELLNESS	DAY TABLET: PARACETAMO L + PSEUDOEPHE DRINE HYDROCHLORI DE + DEXTROMETH ORPHAN HYDROBROMI DE NIGHT TABLET: PARACETAMO L + PSEUDOEPHE DRINE HYDROCHLORI DE + DIPHENHYDRA MINE HYDROCHLORI DE	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	1.0X2.0X20.0 TABLET BLISTER (10 DAY TABLETS + 10 NIGHT TABLETS)	04/02/2019
3340	NDA/MAL/HD P/7135	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	CILACAR *10	CILNIDIPINE	10MG	UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

3341	NDA/MAL/HD P/7137	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	5% DEXTROSE AND 0.9% SODIUM CHLORIDE INJECTION	DEXTROSE MONOHYDRA TE + SODIUM CHLORIDE	5%W/V + 0.9%W/V	SICHUAN KELUN PHARMACEUTICAL CO., LTD- SOUTH OF NO.2, XINDU SATELLITE CITY, INDUSTRIAL DEVELOPMENT ZONE CHENGDU SICHUAN PROVINCE 610500, P .R CHINA PEOPLE'S REPULBIC OF CHINA	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	29/08/2019
3342	NDA/MAL/HD P/7138	BEIJING HOLLEY- COTEC PHARMACEUTICALS CO.,LTD	SUPER PHARMACEUTICALS LIMITED	AMOCIN-CLA TABLETS	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	REYOUNG PHARMACEUTICAL CO. LIMITED..-NO. 6, ERLANGSHAN RD, YIYUAN COUNTY, SHANDONG PROVINCE	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER,1.0X1.0X 10.0 TABLET BLISTER	29/08/2019
3343	NDA/MAL/HD P/7142	KPC PHARMACEUTICALS, INC	SUPER PHARMACEUTICALS LIMITED	EMERGINOR	LEVONORGEST REL	0.75MG	NANJING BAIJINGYU PHARMACEUTICAL CO. LTD- NO. 1 HUIZHONG ROAD, NANJING ECONOMIC AND TECHNICAL DEVELOPMENT ZONE.	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER	29/08/2019

3344	NDA/MAL/HD P/7144	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NETFORMIN- 500	METFORMIN HYDROCHLORI DE	500MG	NATIONAL HEALTHCARE PVT LTD.-VDC CHHATAPIRA-3, BARA,	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019
3345	NDA/MAL/HD P/7145	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP 0.5%	LEVOFLOXACI N	0.5%W/V	CIRON DRUGS AND PHARMACEUTICALS PVT LTD .-N-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	28/03/2019
3346	NDA/MAL/HD P/7147	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BIMAT	BIMATOPROST	0.03% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018
3347	NDA/MAL/HD P/7148	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	OMEPSUN	OMEPRAZOLE	20 MG	SUNRISE INTERNATIONAL LABS LTD.-PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 TABLET STRIP	25/07/2018

3348	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL	30/05/2018
3349	NDA/MAL/HD P/7150	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	SEFIXI - SB 1500	CEFTRIAXONE SODIUM +SULBACTAM SODIUM	1000 MG +500MG	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL + 1X10ML FFS PLASTIC BOTTLE FOR WFI	29/08/2019
3350	NDA/MAL/HD P/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	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL	30/05/2018

3351	NDA/MAL/HD P/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	04/02/2019
3352	NDA/MAL/HD P/7154	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	CIPROFLOXACI N HYDROCHLORI DE	CIPROFLOXACI N HYDROCHLORI DE	2MG/ML	ABARIS HEALTHCARE PVT LTD - -SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017
3353	NDA/MAL/HD P/7155	SANDOZ GMBH .	SURGIPHARM (U) LIMITED	NEBIVOLOL SANDOZ 5MG	NEBIVOLOL HYDROCHLORI DE	5MG	SANDOZ ILAC -SANAYI VE TICARET AS GEBZE PLASTIKCILER ORGANISE SANAYI BOLGESI ATATURK BULVARI 9, CADDE NO. 1, 41400 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	29/03/2019

3354	NDA/MAL/HD P/7156	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	METFORMIN EXTENDED RELEASE	METFORMIN HYDROCHLORI DE	500MG	S KANT HEALTHCARE LTD- PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019
3355	NDA/MAL/HD P/7157	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LINEZOLID TABLETS 600MG	LINEZOLID	600MG	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BOTTLE,1.0X20.0 TABLET CONTAINER	31/01/2018
3356	NDA/MAL/HD P/7158	ZHUHAI KINHOO PHARMACEUTICAL CO., LTD	SWASTIK PHARMACEUTICAL LTD	KIN-CEF	CEFTRIAZONE SODIUM	1G	ZHUHAI KINHOO PHARMACEUTICAL CO. LTD- BIO INDUSTRY ZONE, GOLDEN COAST, ZHUHAA, GUANGDONG	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	29/08/2019

3357	NDA/MAL/HD P/7159	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	XYLOCON 0.050%	OXYMETAZOLI NE HYDROCHLORI DE	0.050W/V%	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE	29/08/2019
3358	NDA/MAL/HD P/7160	INFUGEN PHARMA PVT. LTD.	TATA UGANDA LIMITED	PAPILON AC	ACECLOFENAC	100MG	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	04/02/2019
3359	NDA/MAL/HD P/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	29/08/2019
3360	NDA/MAL/HD P/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	01/07/2017

3361	NDA/MAL/HD P/7163	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	STODIL	LOPERAMIDE HYDROCHLORI DE	2MG	TRIVENI FORMULATIONS LTD PLOT NO. 52,53,54,63,62,64 ALEAP INDUSTRIAL ESTATE SARAMPALLI VIJAYWADA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/08/2019
3362	NDA/MAL/HD P/7164	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ARTEMETHER AND LUMEFANTRI NE TABLETS 60/360 MG	ARTEMETHER +LUMEFANTRI NE	60MG+360MG	CIPLA LTD UNIT I-VILLAGE UPPER MALPUR, P.O. BHUD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH 173205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X6.0 TABLET BLISTER	26/09/2018
3363	NDA/MAL/HD P/7165	TRIVENI FORMULATIONS LIMITED	AIVEEN (U) LIMITED	ERYMAC	ERYTHROMYCI N 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	29/08/2019

3364	NDA/MAL/HD P/7166	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ARTEMETHER /LUMEFANTRI NE 40MG/240MG	ARTEMETHER + LUMEFANTRIN E	40MG + 240MG	CIPLA LTD UNIT I-VILLAGE UPPER MALPUR, P.O. BHUD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH 173205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X6.0 TABLET BLISTER	26/09/2018
3365	NDA/MAL/HD P/7167	SPARSH BIO-TECH PVT.LTD.	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV DS	AMOXICILLIN TRIHYDRATE + CLAVULANATE	200MG + 28.5MG PER 5ML	SPARSH BIO-TECH PRIVATE LIMITED,-PLOT NO.1, SURVEY NO. 242/243/244, VILLAGE LAKHABVAD, JAMNAGAR 361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	29/08/2019

3366	NDA/MAL/HD P/7168	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	METRONIDAZ OLE	METRONIDAZ OLE	0.5% W/V	SICHUAN KELUN PHARMACEUTICAL CO., LTD- SOUTH OF NO.2, XINDU SATELLITE CITY, INDUSTRIAL DEVELOPMENT ZONE CHENGDU SICHUAN PROVINCE 610500, P .R CHINA PEOPLE'S REPULBIC OF CHINA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/08/2019
3367	NDA/MAL/HD P/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	29/08/2019

3368	NDA/MAL/HD P/7170	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	PHYTON 4.5G	PIPERACILLIN + TAZOBACTAM	4.0G + 0.5G	ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON +1X20ML WFI AMPOULE	29/08/2019
3369	NDA/MAL/HD P/7172	WOCKHARD LTD	ROYAL PHARMA 2011 LIMITED	MERIMIX	MEROPENEM TRIHYDRATE + SULBACTAM SODIUM	1G + 0.5G	ZEISS PHARMACEUTICALS PVT LTD - -PLOT 72, EPIP, PHASE 1, JHARMAJRI BADDI, 173205, DIST: SOLAN HIMACHAL PRADESH, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1X20MLWFI AMPOULE	29/08/2019
3370	NDA/MAL/HD P/7173	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	TRICLOFEM®	MEDROXYPRO GESTERONE ACETATE	150MG/ML	P.T. TUNGGAL IDAMAN ABDI- JALAN ACHMAD YANI NO. 7 JAKARTA TIMUR 13230	INDONESIA	PARENTERAL ORDINARY VIALS	1.0X4.0X5.0 ML VIAL	29/08/2019
3371	NDA/MAL/HD P/7177	PT. SYDNA FARMA	ECHO PHARMACY (U) LIMITED	SYDNATRON-4	ONDANSETRO N HYDROCHLORI DE	4MG/2ML	PT SYDNA FARMA-JL RC VETERAN NO.89- BINTARO,JARKATA, 12330, INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	29/08/2019

3372	NDA/MAL/HD P/7178	PT. SYDNA FARMA	ECHO PHARMACY (U) LIMITED	SYDNATRON-8	ONDANSETRO N HYDROCHLORI DE	8MG/4ML	PT SYDNA FARMA-JL RC VETERAN NO.89- BINTARO,JARKATA, 12330, INDONESIA	INDONESIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X4.0 ML AMPOULE	29/08/2019
3373	NDA/MAL/HD P/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	07/11/2018
3374	NDA/MAL/HD P/7180	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	IVENTI	MOXIFLOXACI N HYDROCHLORI DE	0.5%W/V	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT- KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	29/08/2019

3375	NDA/MAL/HD P/7181	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	SURGIBION	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	100MG, + 100MG + 1000MCG	SURGE LABORATORIES (PVT) LTD.,,-10TH KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA- PAKISTAN.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0X3.0 ML AMPOULE	29/08/2019
3376	NDA/MAL/HD P/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	29/08/2019
3377	NDA/MAL/HD P/7183	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LEVOSUN-500	LEVOFLOXACI N 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	29/08/2019
3378	NDA/MAL/HD P/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	29/05/2019

3379	NDA/MAL/HD P/7186	HETERO LABS LTD	AIVEEN (U) LIMITED	TELMILO 40	TELMISARTAN	40 MG	HETERO LABS LTD (UNIT-V) SY-SY. NO. 438, 439, 440 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019
3380	NDA/MAL/HD P/7187	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	ZITHROSUN- 500	AZITHROMYCI N DEHYDRATE	500MG	SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE- II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2019
3381	NDA/MAL/HD P/7188	HETERO LABS LTD	AIVEEN (U) LIMITED	TELMILO 80	TELMISARTAN	80 MG	HETERO LABS LTD (UNIT-V) SY-SY. NO. 438, 439, 440 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/05/2019

3382	NDA/MAL/HD P/7189	ACULIFE HEALTHCARE	LIFE PHARMA AFRICA LIMITED	MERONIR	MEROPENEM SODIUM	1000MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*20ML AMPOULE OF WFI	29/11/2017
3383	NDA/MAL/HD P/7190	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	TRIPSUN-25	AMITRIPTYLIN E HYDROCHLORI DE	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	29/08/2019
3384	NDA/MAL/HD P/7191	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROSOL	HYPROMELLO SE	0.7%W/V	AUROLAB .-NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJANI, MADURAI 1 - 625 020	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	06/02/2019
3385	NDA/MAL/HD P/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	29/05/2019

3386	NDA/MAL/HD P/7193	EXPHAR SA.	SURGIPHARM (U) LIMITED	FLUOXINE	CIPROFLOXACIN	500 MG	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	29/05/2019
3387	NDA/MAL/HD P/7194	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENSCRUB SOLUTION	LINEZOLID ,CHLORHEXIDINE GLUCONATE	200 MG/100 ML ,4%W/V	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE	04/02/2019

3388	NDA/MAL/HD P/7195	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 986ML - 1100KCAL	AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE + CALCIUM CHLORIDE DIHYDRATE + SODI	[7.0G + 6.0G + 5.5G + 1.5G + 2.5G + 3.7G + 3.3G + 2.2G + 2.6G + 5.6G + 3.2G + 0.50G + 2.2G + 1.0G + 0.2G + 3.1G + 0.28G + 2.1G + 0.6G + 2.2G + 1.7G + 0.0065G] + [42%] + [11.3G + 11.3G + 9.4G + 5.6G]	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X986.0 ML BAG :(1*[500ML AMINO ACID SOLUTION WITH ELECTROLYTES + 298ML GLUCOSE 42% SOLUTION + 188ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019
3389	NDA/MAL/HD P/7196	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	LORMAN	LORATADINE	10MG	SUNRISE INTERNATIONAL LABS LTD-PLOT NO. 100, LANE-5, SECTOR-II, PHASE- II, IDA, CHERLAPALLY INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/08/2019

3390	NDA/MAL/HD P/7197	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	RABIVAX-S	PURIFIED RABIES ANTIGEN (RABIES VIRUS PITMAN- MOORE STRAIN 3218)	NOT LESS THAN 2.5 I.U / DOSE	SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 DOSE VIAL + IML DILUENT AMPOULE	29/08/2019
3391	NDA/MAL/HD P/7198	UNIQUE PHARMACEUTICAL LABORATORIES. (A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD)	TATA UGANDA LIMITED	SILBECOR	SILVER SULFADIAZINE	1%W/W	UNIQUE PHARMACEUTICAL LABS LIMITED. .-215-216, 216-219, 304-308, GIDC PANOLI 394116-GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X50.0 G TUBE	29/08/2019
3392	NDA/MAL/HD P/7199	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	PREGAVALX 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	02/01/2019

3393	NDA/MAL/HD P/7200	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN,1477ML - 1600KCAL	AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE + CALCIUM CHLORIDE DIHYDRATE + SODI	"[10.5G + 9.0G + 8.2G + 2.2G + 3.8G + 5.6G + 5.0G + 3.2G + 3.8G + 8.4G + 4.9G + 0.75G + 3.3G + 1.5G + 0.30G + 4.6G + 0.42G + 3.1G + 0.90G + 3.4G + 2.6G + 0.0097G] + [42%W/V] + [16.9G + 16.9G + 14.1G + 8.4G]"	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1477.0 ML BAG :(1*[750ML AMINO ACID SOLUTION WITH ELECTROLYTES + 446ML GLUCOSE 42% SOLUTION + 281ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019
3394	NDA/MAL/HD P/7201	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	MEASLES AND RUBELLA VACCINE	LIVE, ATTENUATED MEASLES VIRUS + LIVE ATTENUATED RUBELLA VIRUS	NLT 1000 CCID50 + 1000 CCID50 / DOSE	SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X10.0 DOSE VIAL + 5ML DILUENT,1.0X50. 0X1.0 DOSE VIAL + 1ML DILUENT	29/08/2019

3395	NDA/MAL/HD P/7202	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VILDAGLIPTIN	VILDAGLIPTIN	50MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND. NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E- 08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017

3396	NDA/MAL/HD P/7203	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 2463ML- 2700KCAL	AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE + CALCIUM CHLORIDE DIHYDRATE + SODI	[17.5 G + 15.0 G + 13.8 G + 3.7 G + 6.2 G + 9.4 G + 8.4 G + 5.4 G + 6.4 G + 14.0 G + 8.1 G + 1.2 G + 5.4 G + 2.5 G + 0.49 G + 7.6 G + 0.69 G + 5.2 G + 1.5 G + 5.7 G + 4.2 G + 0.016 G] + [42 %] + 313 G + 28.1 G + 28.1 G + 23.4 G + 14.0 G]	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X2463.0 ML BAG :(1*[1250ML AMINO ACID SOLUTION WITH ELECTROLYTES + 744ML GLUCOSE 42% SOLUTION + 469ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019
3397	NDA/MAL/HD P/7204	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS LTD	ERTIVIX	ENTECAVIR MONOHYDRA TE	0.5MG	SUN PHARMACEUTICALS INDUSTRIES LTD-SEZ UNIT 1, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA, SAS NAGAR MOHALI-160071	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	29/08/2019

3398	NDA/MAL/HD P/7205	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN EMULSION FOR INFUSION INTO A CENTRAL VEIN, 1970ML - 2200KCAL	AMINO ACID SOLUTION: [ALANINE + ARGININE + GLYCINE + HISTIDINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE + CALCIUM CHLORIDE DIHYDRATE + SODI	[14G + 12.0G + 11.0G + 3.0G + 5.0G + 7.4G + 6.6G + 4.3G + 5.1G + 11.2G + 6.5G + 1.0G + 4.4G + 2.0G + 0.40G + 6.2G + 0.56G + 4.2G + 1.2G + 4.5G + 3.4G + 0.013G] + [42%] + [22.5G + 22.5G + 18.8G + 11.3G]	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1970.0 ML BAG :(1*[1000ML AMINO ACID SOLUTION WITH ELECTROLYTES + 595ML GLUCOSE 42% SOLUTION + 375ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019
3399	NDA/MAL/HD P/7206	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	LOS ANGIO	LOSARTAN POTASSIUM	50MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X1.0X10 .0 TABLET BLISTER	29/08/2019

3400	NDA/MAL/HD P/7207	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	TOXXET 50	CEFPODOXIME PROXETIL	50MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X30.0 ML BOTTLE	29/08/2019
3401	NDA/MAL/HD P/7208	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION, 1448ML- 1000KCAL	[GLUCOSE MONOHYDRA TE] + AMINO ACID SOLUTION WITH ELECTROLYTES : [ALANINE + ARGININE + GLYCINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE + C	[13%] + [6.4G + 5.5G + 5.1G + 1.3G + 2.3G + 3.3G + 2.3G + 3.3G + 3.0G + 1.9G + 2.3G + 5.1G + 3.0G + 0.46G + 2.0G + 0.91G + 0.17G + 2.9G + 0.26G + 1.9G + 0.55G + 2.0G + 1.6G + 0.006G] + [12.3G + 12.3G + 10.1G + 6.1G]	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1448.0 ML BAG :(1*[788ML GLUCOSE 13% + 456ML AMINO ACID SOLUTION WITH ELECTROLYTES + 204ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019

3402	NDA/MAL/HD P/7209	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	MINOXIN SOLUTION	MINOXIDIL	2%W/V	BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI- 74900	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X60.0 ML BOTTLE	26/09/2018
3403	NDA/MAL/HD P/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	28/03/2019
3404	NDA/MAL/HD P/7212	PHARMACO DISTRIBUTION (PTY) LTD	ECHO PHARMACY (U) LIMITED	PHARMALGAN	PARACETAMO L	10MG/ML	AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	31/01/2018

3405	NDA/MAL/HD P/7213	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	1.0X5.0X3.0 ML AMPOULE	28/08/2019
3406	NDA/MAL/HD P/7214	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	SMOFKABIVEN PERIPHERAL EMULSION FOR INFUSION, 1904ML - 1300KCAL	[GLUCOSE MONOHYDRA TE] + AMINO ACID SOLUTION WITH ELECTROLYTES : [ALANINE + ARGININE + GLYCINE + HISTIDINE + ISOLEUCINE + LEUCINE + LYSINE ACETATE + METHIONINE + PHENYLALANI NE + PROLINE + SERINE + TAURINE + THREONINE + TRYPTOPHAN + TYROSINE + VALINE +	[13%] + [8.4G + 7.2G + 6.6G + 1.8G + 3.0G + 4.4G + 4.0G + 2.6G + 3.1G + 6.7G + 3.9G + 0.60G + 2.6G + 1.2G + 0.24G + 3.7G + 0.34G + 2.5G + 0.72G + 2.7G + 2.0G + 0.008G] + [16.1G + 16.1G + 13.4G + 8.0G]	FRESENIUS KABI AB- RAPSGATAN 7, UPPSALA, SE- 751 74	SWEDEN AUSTRIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1904.0 ML BAG :(1*[1036ML GLUCOSE 13% + 600ML AMINO ACID SOLUTION WITH ELECTROLYTES + 268ML LIPID EMULSION], MULTI CHAMBER PLASTIC BAGS)	04/02/2019

3407	NDA/MAL/HD P/7216	SHIN POONG PHARMACEUTICALS CO.LTD	ESCORTS PHARMACEUTICALS LTD - WILSON ROAD	PYRAMAX	PYRONARIDIN E TETRAPHOSPH ATE + ARTESUNATE	60MG + 20MG	SHIN POONG PHARM. CO., LTD-70, SANDAN-RO, 19 BEON-GIL, DANWON-GU, ANSAN-SI, GYEONGGI-DO, REPUBLIC OF KOREA	SOUTH KOREA	ORAL LIQUID ORDINARY OTHER POWDERS/GRAN ULES	1.0X90.0 SACHET CARTON	29/08/2019
3408	NDA/MAL/HD P/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	25/07/2018
3409	NDA/MAL/HD P/7218	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARTMIN 500	METFORMIN	500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

3410	NDA/MAL/HD P/7219	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAXONE	1G	THEON PHARMACEUTICALS LTD.-VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	29/11/2017
3411	NDA/MAL/HD P/7220	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	NAPRIN	NAPROXEN	500MG	GLOBELA PHARMA PVT.LTD.- PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT- 394230,GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/08/2019
3412	NDA/MAL/HD P/7222	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	AIVEEN (U) LIMITED	SAMSUNATE	ARTESUNATE	60MG	SAMRUDH PHARMACEUTICALS PVT LTD- J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL OF ARTESUNATE +(1*1ML AMPOULE OF SODIUM BICARBONATE BP 5%W/V)+(1*5ML SODIUM CHLORIDE BP 0.9%W/V)	27/11/2019

3413	NDA/MAL/HD P/7223	LAURUS LABS LIMITED -	BEYOND LOGISTICS LTD	DOLUTEGRAVI R	DOLUTEGRAVI R	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	27/11/2019
3414	NDA/MAL/HD P/7225	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LUMITER 80/480	ARTEMETHER + LUMEFANTRIN E	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	27/11/2019
3415	NDA/MAL/HD P/7226	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	ELICA-M	MOMETASON E FUROATE + MICONAZOLE NITRATE	0.1%W/W + 2%W/W	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE	27/11/2019
3416	NDA/MAL/HD P/7227	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NEMADOL 50	TRAMADOL HYDROCHLORI DE	50MG	NATIONAL HEALTHCARE PVT. LTD.-(WORKS: STERILE BLOCK) CHHATAPIPRA-3, BARA, NEPAL	NEPAL	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	29/11/2017

3417	NDA/MAL/HD P/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	01/07/2017
3418	NDA/MAL/HD P/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	29/11/2017
3419	NDA/MAL/HD P/7231	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	LIGNAT 2%	LIDOCAINE HYDROCHLORI DE	2% W/V	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL	01/07/2017
3420	NDA/MAL/HD P/7232	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	CIFF-100 DS	CEFIXIME	100MG/5ML	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS & PHARMACEUTICALS PVT. LTD.) -B-21/22, MIDC AREA, KALMESHWAR-441 501, NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	29/08/2019

3421	NDA/MAL/HD P/7233	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	MIZOVA	MIDAZOLAM	1MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIRA 3 BARA NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL	30/05/2018
3422	NDA/MAL/HD P/7234	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	LEVOFLOXACI N INTRAVENOUS INFUSION	LEVOFLOXACI N HEMIHYDRATE + GLUCOSE ANHYDROUS	500MG + 5W/V%	ABARIS HEALTHCARE PVT. LTD-SURVEY NO. 1407/11, VILLAGE RAJPUR, TAL KADI DIST. MEHSANA, GUJARAT- 382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/08/2019
3423	NDA/MAL/HD P/7235	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	OPTIDEX-T	DEXAMETHAS ONE + TOBRAMYCIN	0.1W/V + 0.3%W/V	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019
3424	NDA/MAL/HD P/7236	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYDEKLA 30.	DACLATASVIR DIHYDROCHLO RIDE	30 MG	MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET CONTAINER	07/11/2018

3425	NDA/MAL/HD P/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	27/11/2019
3426	NDA/MAL/HD P/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	28/03/2018
3427	NDA/MAL/HD P/7239	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GITTOES PHARMACEUTICALS LIMITED	GAVISCON PEPPERMINT LIQUID	SODIUM AGINATE + SODIUM BICARBONATE + CALCIUM CARBONATE	500MG + 267MG + 160MG	RECKITT BENCKISER HEALTHCARE LTD, HULL- DAMSON LANE,HULL, HUB HU8 7DS	UNITED KINGDOM	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X12.0X10.0 ML SACHET	29/05/2019
3428	NDA/MAL/HD P/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	29/05/2019
3429	NDA/MAL/HD P/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	29/11/2017

3430	NDA/MAL/HD P/7242	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	AMINORICH	MULTIVITAMI NS, 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,1.0X1.0X 2.0 CAPSULE BLISTER	27/11/2019
3431	NDA/MAL/HD P/7243	BAL PHARMA LIMITED	SHREEJI PHARMACEUTICALS LIMITED	EMTRIM	TRIMETHOPRI M + SULPHAMETH OXAZOLE	80MG+ 400MG	BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE- PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018

3432	NDA/MAL/HD P/7245	MANKIND PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CEFAKIND-500	CEFUROXIME AXETIL	500MG	COPMED PHARMACEUTICALS PVT LTD- UNIT-II, PLOT NO. 50, GONDPUR INDUSTRIAL AREA, TEHSIL-PAONTA SAHIB, DISTT. SIRMOUR,HIMACHAI PRADESH-173025, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	04/02/2019
3433	NDA/MAL/HD P/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,1.0X30.0 ML BOTTLE	27/11/2019
3434	NDA/MAL/HD P/7250	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DOLUTEGRAVI R SODIUM, LAMIVUDINE AND TENOFVIR DISOPROXIL FUMARATE			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	29/11/2019

3435	NDA/MAL/HD P/7252	MUNDIPHARM PTY LIMITED	SURGIPHARM (U) LIMITED	ONICIT	PALONOSETR ON	0.075MG/1.5 ML	PIERRE FABRE MEDICAMENT PRODUCTION/ AQUITAINE PHARM INTERNATIONAL- AVENUE DU BEARN 64320 IDRON	FRANCE	PARENTERAL ORDINARY VIALS	1.0X3.0 ML VIAL	27/11/2019
3436	NDA/MAL/HD P/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	27/11/2019
3437	NDA/MAL/HD P/7254	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OXEPTAL 300	OXCARBAZEPI NE	300MG	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	04/02/2019
3438	NDA/MAL/HD P/7256	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG KIT	AMOXICILLIN + CLARITHROMY CIN + ESOMEPRAZO LE	1000MG + 500MG + 20MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X6.0 TABLET STRIP (2+2+2)	27/11/2019

3439	NDA/MAL/HD P/7257	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PAARPIN TABLET	PARACETAMO L	650 MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3440	NDA/MAL/HD P/7258	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMTRICITABIN E + TENOFIVIR ALAFENAMIDE	200MG/10MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61,59320 ENNIGERLOH,GERMANY	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3441	NDA/MAL/HD P/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	27/11/2019
3442	NDA/MAL/HD P/7260	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-40	ESOMEPRAZO LE MAGNESIUM TRIHYDRATE	40MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

3443	NDA/MAL/HD P/7261	NIPRO MIDDLE EAST FZE	ROYAL PHARMA 2011 LIMITED	AZALTIC	AZITHROMYCI N	200MG/5ML	NIPRO JMI PHARMA LTD.- CHAUDDAGRAM, COMILLA BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	29/05/2019
3444	NDA/MAL/HD P/7264	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE +SIMETHICON E	540MG + 40MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017
3445	NDA/MAL/HD P/7266	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ATAZANAVIR SULFATE AND RITONAVIR TABLETS	ATAZANAVIR SULFATE + RITONAVIR USP	300 MG + 100 MG	CIPLA LTD(PATALGANGA)- CIPLA LIMITED, PLOT NO. A-42 (UNIT II),MIDC,PATALGANGADISTRI CT - RAIGAD, MAHARASHTRA,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	30/05/2018
3446	NDA/MAL/HD P/7267	MICRO LABS LTD	LABOREX UGANDA LIMITED	ESOFAG-20	ESOMEPRAZO LE MAGNESIUM TRIHYDRATE	20MG	MICRO LABS LIMITED .,-92, SIPCOT, HOSUR 635126	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

3447	NDA/MAL/HD P/7268	NIPRO MIDDLE EAST FZE	ROYAL PHARMA 2011 LIMITED	ARCET	CETIRIZINE DIHYDROCHLO RIDE	5MG/5ML	NIPRO JMI PHARMA LTD.- CHAUDDAGRAM, COMILLA BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	29/05/2019
3448	NDA/MAL/HD P/7269	EXPHAR SA.	SURGIPHARM (U) LIMITED	FEBRILEX SYRUP	PARACETAMO L+DEXTROMET ORPHAN HYDROBROMI DE+CHLORPHE NAMINE MALEATE	125MG+5MG+ 1MG/5 ML	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	01/07/2017
3449	NDA/MAL/HD P/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	27/11/2019
3450	NDA/MAL/HD P/7274	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR 0.5MG	ENTECAVIR	0.5MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1- 7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3451	NDA/MAL/HD P/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	27/11/2019

3452	NDA/MAL/HD P/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 KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X20.0 TABLET BLISTER	28/08/2019
3453	NDA/MAL/HD P/7278	TIL HEALTHCARE PVT LTD	HARLEYS UGANDA LIMITED	NEUTROSEC	DL- METHIONINE + CHOLINE BITARTRATE + THIAMINE MONO NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORI DE + NICOTINAMID E + DEXPANTHEN OL + BIOTIN + FOLIC ACID + CYANOCOBAL AMIN + ALPHA TOCOPHERYL ACETATE	200MG + 200MG +3MG + 3MG + 1.5MG + 22.5MG + 4.5MG + 0.1MG + 0.5MG + 3MCG + 7.5.I.U	TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R- 5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

3454	NDA/MAL/HD P/7283	TIL HEALTHCARE PVT LTD	HARLEYS UGANDA LIMITED	ASTYMIN-M FORTE	L-THREONINE + L-VALINE + DL- METHIONINE + L- ISOLEUCINE + L-LEUCINE + L- PHENYLALANI NE + L- TRYPTOPHAN + L-LYSINE HYDROCHLORI DE + THIAMINE NITRATE + RIBOFLAVIN + PYRIDOXINE HYDROCHLORI DE + NICOTINAMID E + CALCIUM PANTOTHENA TE + FOLIC ACID + CYANOCOBAL AMIN + AS	4.2MG + 6.7MG + 18.4MG + 5.9MG + 18.3MG + 5.0MG + 5.0MG + 25MG + 5MG + 3MG + 1.5MG + 25MG + 5MG+ 0.75MG + 2.5MCG+ 40MG + 2500 IU+ 200 IU + 7.5 IU + 0.1MG+ 20.5MG+ 4MG+ 1.4MG+ 7.425MG+ 3.3MG+ 10MCG	TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R- 5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019
3455	NDA/MAL/HD P/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	25/07/2018

3456	NDA/MAL/HD P/7286	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRIN OPHTHALMIC OINTMENT	TOBRAMYCIN	3MG/G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017
3457	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2017
3458	NDA/MAL/HD P/7288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE FILM COATED TABLETS	DEKXETOPROF 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	31/01/2017

3459	NDA/MAL/HD P/7289	TIL HEALTHCARE PVT LTD	HARLEYS UGANDA LIMITED	PEGLEC	POLYETHYLEN E GLYCOL + SODIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM BICARBONATE + ANHYDROUS SODIUM SULFATE	118.0G +2.93G +1.484G + 3.370G + 11.360G / SACHET	TIL HEALTHCARE PVT LIMITED-PLOT 100, WEST R- 5, SOUTH, SRICITY SEZ, CHERIVE9 (VI), DISTRICT: CHITTOOR 517588 ANDHRA PRADESH-	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X137.15 G SACHET	27/11/2019
3460	NDA/MAL/HD P/7292	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	IBUPLUS SUSPENSION	IBUPROFEN+.P ARACETAMOL	100MG + 125MG / 5ML	LEBEN LABORATORIES PVT LTD .-L-14 PHASE III MIDC AKOLA 444 104	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	27/11/2019
3461	NDA/MAL/HD P/7293	İLKO İLAÇ SANAYİ VE TICARET A. Ş.	CORE ACCESS LTD	ALRINAST	DESLOTATADI NE	5MG	İLKO İLAÇ SANAYİ VE TICARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	29/11/2017

3462	NDA/MAL/HD P/7294	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	VONADAY	EFAVIRENZ + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	600MG + 300MG + 300MG	EMCURE PHARMACEUTICALS LIMITED- PLOT NO. P-2. ITBT PARK, PHASE II, MIDC, HINJWADI PUNE 411057, MHARASHTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	27/11/2019
3463	NDA/MAL/HD P/7295	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	LAMIFEN	TERBINAFINE HYDROCHLORI DE	1%W/W	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	27/11/2019
3464	NDA/MAL/HD P/7296	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDAXONUM 2G	CEFTRIAZONE 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	06/02/2019

3465	NDA/MAL/HD P/7298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-2.5	NEBIVOLOL HYDROCHLORI DE	2.5 MG	MICRO LABS LTD 92 SIPCOT - 92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3466	NDA/MAL/HD P/7301	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	PACLITERO 300	PACLITAXEL	60 MG/ML	HETERO LABS LIMITED UNIT- VI -APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X50.0 ML VIAL	26/09/2018
3467	NDA/MAL/HD P/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	27/11/2019

3468	NDA/MAL/HD P/7303	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXATOL-20	MANNITOL	20%W/V	AXA PARENTERALS LTD-PLOT NO. 936, 937 & 939, VILLAGE KISHANPUR, JAMALPUR ROORKEE-247667, DIST. HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	06/02/2019
3469	NDA/MAL/HD P/7306	HETERO LABS LTD	AIVEEN (U) LIMITED	PACLITERO 100	PACLITAXEL	100 MG/16.7 ML	HETERO LABS LIMITED UNIT- VI -APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DISTRICT) ANDHRA PRADESH-509301, , INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X16.7 ML VIAL	26/09/2018
3470	NDA/MAL/HD P/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	29/05/2019

3471	NDA/MAL/HD P/7308	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	APSIDASE	ACECLOFENAC + PARACETAMO L + SERRATIOPEPT IDASE	100MG + 500MG + 10MG	ACME FORMULATION PVT. LTD-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
3472	NDA/MAL/HD P/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	27/11/2019
3473	NDA/MAL/HD P/7311	JAMJOOM PHARMACEUTICALS COMPANY	MU PHARMA CO- SMC LIMITED	FLUCA OPHTHALMIC SUSPENSION	FLUOROMETH OLON + SODIUM CROMOGLICA TE	1%W/V + 2%W/V	JAMJOOM PHARMACEUTICALS CO.- PLOT NO. ME 1:3, PHASE V, INDUSTRIAL CITY, P.O. BOX 6267 JEEDAH	SAUDI ARABIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE	27/11/2019
3474	NDA/MAL/HD P/7312	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE OINTMENT 5%W/W	POVIDONE IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .- B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X125.0 G TUBE,1.0X250.0 G JAR	01/07/2017

3475	NDA/MAL/HD P/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	27/11/2019
3476	NDA/MAL/HD P/7316	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	I-UP TABLETS	FERROUS ASCORBATE + FOLIC ACID	100MG + 1.5MG	CACHET PHARMACEUTICAL PVT LTD. -VILLAGE-THANA, NEAR BADDI, TEHSIL_NALAGARH, DIST. SOLAN, HIMACHAL PRADESH - 173205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

3477	NDA/MAL/HD P/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	27/11/2019
3478	NDA/MAL/HD P/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	04/02/2019

3479	NDA/MAL/HD P/7320	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CARDISAR HT	VALSARTAN + HYDROCHLOR OTHIAZIDE	160 MG + 25 MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3480	NDA/MAL/HD P/7321	GLENMARK PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	ASCORIL DRY COUGH AND COLD SYRUP	DEXTROMETH ORPHAN HYDROBROMI DE + TRIPROLIDINE HYDROCHLORI DE + PSEUDOEPHE DRINE HYDROCHLORI DE + MENTHOL	10MG + 1.25MG + 30MG + 1.5MG / 5ML	GLENMARK PHARMACEUTICALS LTD .- PLOT E-37, 39, D ROAD, MIDC, SATPUR, NASHIK 422007, MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	27/11/2019

3481	NDA/MAL/HD P/7322	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CARDISAR HT	VALSARTAN + HYDROCHLOR OTHIAZIDE	160MG + 12.5MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD-SY. NO 172 &. 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR MANDAL, RR DIST., HYDERABAD- 500 100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/08/2019
3482	NDA/MAL/HD P/7327	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SURGIPHARM (U) LIMITED	TRAJENTA	LINAGLIPTIN	5MG	WESTWARD COLUMBUS INC. 1809 WILSON ROAD, COLUMBUS OHIO 43228	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
3483	NDA/MAL/HD P/7330	MYLAN LABORATORIES LIMITED	NORVIK ENTERPRISES LIMITED	FAMY-POP	LEVONORGEST REL	0.03MG	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	1.0X3.0X35.0 TABLET BLISTER	27/11/2019

3484	NDA/MAL/HD P/7331	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DIVATOR 10MG TABLET	ATORVASTATI N	10MG	DROGSAN İLAÇLARI 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	29/03/2019
3485	NDA/MAL/HD P/7332	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	DIVATOR 20MG FILM TABLET	ATORVASTATI N	20MG	DROGSAN İLAÇLARI 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	29/03/2019
3486	NDA/MAL/HD P/7333	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TORIDIP 20	LERCANIDIPIN E HYDROCHLORI DE	20MG	TORRENT PHARMACEUTICALS LTD. - AHMEDABAD-MEHSANA HIGHWAY, TAL. KADI, DIST. MEHSANA, INDRAD 382 721, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER	28/11/2019

3487	NDA/MAL/HD P/7334	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ETOVA 400	ETODOLAC	400MG	IPCA LABORATORIESLIMITED- IPCA LABORATORIES LTD P.O SEJANTA DISTRICT RATLAM 457002 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3488	NDA/MAL/HD P/7335	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE 5%	POVIDONE IODINE	5%W/V	G.S PHAMBUTOR PVT LTD .- B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X500. 0 ML BOTTLE,1.0X50.0 ML BOTTLE	01/07/2017
3489	NDA/MAL/HD P/7336	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE GERMICIDE GARGLE 2% MINT	POVIDONE IODINE	2%W/V	G.S PHAMBUTOR PVT LTD- G.S PHAMBUTOR PVT LTD B- 172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL TOPICAL LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	31/01/2018
3490	NDA/MAL/HD P/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	01/07/2017

3491	NDA/MAL/HD P/7338	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	IBUPLUS	IBUPROFEN + PARACETAMO L	400MG + 325MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X2.0X20 .0 TABLET BLISTER	05/12/2019
3492	NDA/MAL/HD P/7339	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 16	CANDESARTA N CILEXETIL	16 MG	AJANTA PHARMA LIMITED-B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018
3493	NDA/MAL/HD P/7340	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HIFEN -200	IBUPROFEN	200MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/11/2019

3494	NDA/MAL/HD P/7341	M/S.MAXHEAL PHARMACEUTICALS(I NDIA)	ABACUS PHARMA (AFRICA) LIMITED	ZITHROHEAL 500	AZITHROMYCI N	500MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER	28/11/2019
3495	NDA/MAL/HD P/7342	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ZEALARGY	RUPATADINE FUMERATE	10 MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3496	NDA/MAL/HD P/7343	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	GLEVIX	LEVOFLOXACI N + SODIUM CHLORIDE	0.5G + 0.9G	WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	28/11/2019

3497	NDA/MAL/HD P/7344	ACULIFE HEALTHCARE	LIFE PHARMA AFRICA 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	29/11/2017
3498	NDA/MAL/HD P/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	28/11/2019
3499	NDA/MAL/HD P/7346	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REZN TABLETS	ZINC SULFATE MONOHYDRA TE	20MG	RENE INDUSTRIES LIMITED- PLOT 680 KAMULI- KIREKA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2017

3500	NDA/MAL/HD P/7350	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	SULCEF	CEFOPERAZON E+ SULBACTUM	1G+1G	MEDOCHEMIE LTD-CENTRAL FACTORY A-1-10 CONSTANTINOPOLEUS STREET 3011 LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 ML VIAL	27/03/2019
3501	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3502	NDA/MAL/HD P/7353	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 500MG	METFORMIN HYDROCHLORI DE	500MG	MERCK KGAA-- FRANKFURTER STR. 250 64293 DARMSTADT GERMANY MERCK SANTÉ S.A.S.-2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE	GERMANY	ORAL SOLID RETARD TABLETS	1.0X6.0X15.0 TABLET BLISTER	28/03/2018

3503	NDA/MAL/HD P/7354	WUHAN FUXING BIOLOGICAL PHARMACEUTICAL CO	KAIYUANTANG (U) LIMITED	OSMOTICARE	SODIUM CHLORIDE	0.9%W/V	WUHAN FUXING BIOPHARMACEUTICAL CO., LTD-NO.9, FUXING ROAD, HANCUAN ECONOMIC & DEVELOPMENT DISTRICT, HUBEI PROVINCE	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X250. 0 ML BOTTLE,1.0X500. 0 ML BOTTLE	28/11/2019
3504	NDA/MAL/HD P/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,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	31/01/2018
3505	NDA/MAL/HD P/7356	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN TABLET 500MG	METFORMIN HYDROCHLORI DE	500MG	HOVID BERHAD-121, JALAN TUNKU ABDUL RAHMAN, 30010 IPOH, PERAK, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X 20.0 TABLET BLISTER	01/07/2017

3506	NDA/MAL/HD P/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	31/01/2018
3507	NDA/MAL/HD P/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	01/07/2017
3508	NDA/MAL/HD P/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 SUSPENSIONS	1.0X150.0 ML BOTTLE,1.0X300. 0 ML BOTTLE,1.0X12.0 X10.0 ML SACHET	28/11/2019

3509	NDA/MAL/HD P/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,1.0X30.0 TABLET BOTTLE	28/11/2019
3510	NDA/MAL/HD P/7363	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	AARON PHARMACEUTICALS LIMITED	INDCLAV 228	AMOXICILLIN+ CLAVULANATE POTASSIUM	200MG+28MG /5ML	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.- VILLAGE & P.O – THANA, TEHSIL – BADDI, DIST- SOLAN, HIMACHAL	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3511	NDA/MAL/HD P/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	01/07/2017

3512	NDA/MAL/HD P/7365	AUROCHEM PHAMACEAUTICALS (1) LTD)	SUPER MEDIC LTD	DOLOACT MR	PARACETAMO L+ DICLOFENAC POTASSIUM+C HLORZOAZO NE	500 MG+50 MG+250 MG	KARALEX PHARMA-58, PALGHAR TALUKA, INDUSTRIAL CO.-OP. ESTATE LTD.PALGHAR –INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3513	NDA/MAL/HD P/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	01/07/2017
3514	NDA/MAL/HD P/7367	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX 100 DS	CEFIXIME	100MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD- -ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3515	NDA/MAL/HD P/7368	OCTOBER PHARMA	ABACUS PHARMA (AFRICA) LIMITED	BRADIPECT	IVABRADINE HYDROCHLORI DE	7.5MG	OCTOBER PHARMA-1ST INDUSTRIAL ZONE, STREET 25 PLOT 190, 6TH OCTOBER CITY CAIRO, ARAB REPUBLIC OF EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	28/11/2019

3516	NDA/MAL/HD P/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 SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3517	NDA/MAL/HD P/7370	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 625	AMOXICILLIN TRIHYDRATE+ POTASSIUM CLAVULANATE	500MG+125M G	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD- UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017

3518	NDA/MAL/HD P/7373	OCHOA LABORATORIES	SUPER MEDIC LTD	FUSIGO CREAM	FUSIDIC ACID	2.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE	01/07/2017
3519	NDA/MAL/HD P/7374	OCHOA LABORATORIES	SUPER MEDIC LTD	FUSIGO-HC CREAM	FUSIDIC ACID +HYDROCORTI SONE ACETATE	2.0 % W/W+1.0 % W/W	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	29/11/2017
3520	NDA/MAL/HD P/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	28/11/2019

3521	NDA/MAL/HD P/7376	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 375	AMOXICILLIN+ POTASSIUM CLAVULANATE	250MG+125M G	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD- UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
3522	NDA/MAL/HD P/7377	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX DS	AMOXICILLIN TRIHYDRATE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD- UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3523	NDA/MAL/HD P/7381	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE ANTISEPTIC CREAM 5%	POVIDONE- IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .- B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X20.0 G TUBE	01/07/2017

3524	NDA/MAL/HD P/7382	TORRENT PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	OLMESAR H 40	OLMESARTAN MEDOXOMIL + HYDROCHLOR OTHIAZIDE	40 MG+12.5 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	27/03/2019
3525	NDA/MAL/HD P/7385	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM DS	CEFUROXIME AXETL	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD- -ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3526	NDA/MAL/HD P/7386	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYLEXIN 125 DS	CEFALEXIN MONOHYDRA TE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD- -ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017

3527	NDA/MAL/HD P/7387	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CEFRIM 250	CEFUROXIME AXETIL	250MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/11/2019
3528	NDA/MAL/HD P/7388	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLA VULANIC ACID	200MG+125M G	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD- -ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET STRIP	01/07/2017
3529	NDA/MAL/HD P/7389	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES -	GAMA PHARMACEUTICALS (U) LIMITED	GAROPRIDE	ITOPRIDE HYDROCHLORI DE	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	28/11/2019
3530	NDA/MAL/HD P/7390	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	CIDOPRAZ	ESOMEPRAZO LE	40MG	ASTRA LIFECARE (INDIA) PVT. LTD'-PLOT 57 / P, SARKHEJ - BAVLA HIGHWAY RAJODA AHMEDABA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X15.0 TABLET BLISTER	28/11/2019

3531	NDA/MAL/HD P/7391	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	TAVIN-EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABIN E	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	25/01/2019
3532	NDA/MAL/HD P/7394	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS 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	28/11/2019
3533	NDA/MAL/HD P/7395	PLANET PHARMACEUTICALS (U) LTD	PLANET PHARMACEUTICALS UGANDA LTD	ACE KIT	MIFEPRISTON E + MISOPROSTOL	200MG + 20MCG	ACME FORMULATION PVT LTD -ROPAR ROAD, NALAGARH DISTT. SOLAN HP- 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER	05/12/2019
3534	NDA/MAL/HD P/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	01/07/2016

3535	NDA/MAL/HD P/7406	PHARMACIE BETHEL	ABACUS PARENTERAL DRUGS LIMITED	ARENA	ADRENALINE	0.1% W/V	LINCOLN PARENTERAL LTD - 11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE	01/07/2017
3536	NDA/MAL/HD P/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	28/11/2019
3537	NDA/MAL/HD P/7408	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS 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	28/11/2019

3538	NDA/MAL/HD P/7409	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARIACT DISPERSIBLE	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 SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER	28/11/2019
3539	NDA/MAL/HD P/7410	MEDOPHARM, INDIA	PLANET PHARMACEUTICALS UGANDA LTD	COTRIMOXAZ OLE TABLETS BP 960 MG	TRIMETHOPRI M +SULPHAMET HOXAZOLE	960MG	MEDOPHARM --34 B, INDUSTRIAL AREA, MALUR - 563160, KARNATAKA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0 X10.0 TABLET BLISTER,1.0X100. 0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	26/09/2018
3540	NDA/MAL/HD P/7411	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARIACT 180- 1080	ARTEMETHER + LUMEFANTRIN E	180MG + 1080MG /60ML	S KANT HEALTHCARE LTD- PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	28/11/2019
3541	NDA/MAL/HD P/7412	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	LARIACT DS	ARTEMETHER + LUMEFANTRIN E	40MG + 240MG	S KANT HEALTHCARE LTD- PLOT NO. 1805, G.I.D.C PHASE III, VAPI 396195, GUJARAT	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0 TABLET BLISTER	28/11/2019

3542	NDA/MAL/HD P/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	28/11/2019
3543	NDA/MAL/HD P/7414	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	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	28/11/2019
3544	NDA/MAL/HD P/7415	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	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	28/11/2019

3545	NDA/MAL/HD P/7416	FDC LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	RESTORS ORAL REHYDRATION SALTS ZINKID CO-PACK(ORANGE FLAVOUR)	ORAL REHYDRATION SALTS + ZINC SULPHATE	MULTI- INGREDIENT	FDC LIMITED - GOA III-PHASE III/A, PLOT NO. L-121/B, SALCETTE, VERNA INDUSTRIAL ESTATE, VERNA, GOA-403722 FDC LTD.-L- 56&L-57, PHASE II- D, VERNA INDUSTRIAL ESTATE, VERNA- 403 722, SALCETE, GOA	INDIA	ORAL SOLID ORDINARY UNIT DOSE POWDERS	1.0X2.0X21.8 G SACHET +(1*10 ALU-PVC BLISTERS ZINC SULPHATE)	28/11/2019
3546	NDA/MAL/HD P/7417	INTAS PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	TELTAS-40	TELMISARTAN	40MG	INTAS PHARMACEUTICALS LTD ...,-CAMP ROAD, SELAQUI, DEHRADUN- 248197, UTTARKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/11/2019

3547	NDA/MAL/HD P/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	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X2.0 ML PRE- FILLED SYRINGE	28/11/2019
3548	NDA/MAL/HD P/7419	INTAS PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	PACLITAXEL	CARBAMAZEPI NE	200MG	INTAS PHARMACEUTICALS LTD ...,-CAMP ROAD, SELAQUI, DEHRADUN- 248197, UTTARKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X16.7 ML VIAL	28/11/2019
3549	NDA/MAL/HD P/7421	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	GESIC ADL 200	IBUPROFEN	200MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

3550	NDA/MAL/HD P/7422	CODAL-SYNTO LTD	RENE PHARMACY LTD	SYNTOCLAV 625MG	AMOXICILLIN TRIHYDRATE+ CLAVULANATE POTASSIUM	500MG+125M G	MEDOCHEMIE LTD - FACTORY B-48 IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2016
3551	NDA/MAL/HD P/7424	NTICALS LTD.	NORVIK ENTERPRISES 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	01/07/2017
3552	NDA/MAL/HD P/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	28/11/2019

3553	NDA/MAL/HD P/7426	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDOFED	GUAIFENESIN + DEXTROMETH ORPHAN HYDROBROMI DE + PSEUDOEPHE DRINE HYDROCHLORI DE AND + TRIPROLIDINE HYDROCHLORI DE	100MG + 15MG + 20MG + 1.25MG/5ML	MEDOCHEMIE ACTORY).....-1- 10 CONSTANTINOPOLEOS STREET, 3011, LIMASSOL	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE	28/11/2019
3554	NDA/MAL/HD P/7427	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	EFAVIRENZ + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	400MG + 300MG + 300MG	CIPLA LTD ,.-PLOT NO. A-33, A-2 (UNIT 1), A42 (UNIT II), MIDC PATALGANGA, DISTRICT-RAIGAD MAHARASHTRA, 410220 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	28/11/2019
3555	NDA/MAL/HD P/7428	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	TELPERZID	TELMISARTAN + HYDROCHLOR OTHIAZIDE	40MG + 12.5MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/11/2019

3556	NDA/MAL/HD P/7429	SAKAR HEALTHCARE LIMITED	ROYAL PHARMA 2011 LIMITED	CEFTRIAZONE	CEFTRIAZONE 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	1.0X1.0 G VIAL + 1*10ML AMPOULE WFI	28/11/2019
3557	NDA/MAL/HD P/7431	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	MOVICOL	MACROGOL 3350 (POLYETHYLEN E GLYCOL)+SODI UM CHLORIDE+SO DIUM BICARBONATE + POTASSIUM CHLORIDE	13.125G+350. 7MG+178.5M G+46.6MG	WIN-MEDICARE PVT. LTD- MODIPURAM-250 110, UTTAR PRADESH,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X13.81 G SACHET	26/09/2018
3558	NDA/MAL/HD P/7432	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	MENAFRIVAC	MENINGOCOCCAL A POLYSACCHAR IDE + 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	28/11/2019

3559	NDA/MAL/HD P/7433	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	KETOSTERIL	MULTIINGRED IENT	MULTIINGRED IENT	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	28/11/2019
3560	NDA/MAL/HD P/7434	NEOMI PHARMACEUTICALS PVT LTD	EUROPA HEALTHCARE (U) LTD	NEOMICEF	CEFTRIAZONE SODIUM	1G	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	28/11/2019
3561	NDA/MAL/HD P/7435	SQUARE FORMULATIONS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ZIMAX	AZITHROMYCI N DIHYDRATE	200MG/5ML	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE	28/11/2019
3562	NDA/MAL/HD P/7436	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEFOTIL PLUS 500	CEFUROXIME AXETIL + CLAVULANATE	500MG + 125MG	SQUARE CEPALOSPORINS LTD..-KALIAKOIR GAZIPUR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER	28/11/2019
3563	NDA/MAL/HD P/7437	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEFOTIL PLUS 250	CEFUROXIME AXETIL + CLAVULANATE	250MG + 62.5MG	SQUARE CEPALOSPORINS LTD..-KALIAKOIR GAZIPUR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/11/2019

3564	NDA/MAL/HD P/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	28/11/2019
3565	NDA/MAL/HD P/7440	MANKIND	TATA UGANDA LIMITED	TOTACEF-1000	CEFEPIME	1000MG	MANKIND PHARMA LTD.- VILLAGE KISHANPURA, POAMTA SAHI DISTRICT SIRMOUR HIMACHAL PRADESH	INDIA	PARENTERAL RETARD DRY VIALS	1.0X1000.0 MG VIAL	28/11/2019
3566	NDA/MAL/HD P/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(MANDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X6.0 ML PRE- FILLED SYRINGE	29/11/2017
3567	NDA/MAL/HD P/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	28/11/2019

3568	NDA/MAL/HD P/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	28/11/2019
3569	NDA/MAL/HD P/7444	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	FRESH EYES	CARMELLOSE SODIUM	0.5%W/V	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	20/12/2018
3570	NDA/MAL/HD P/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	28/11/2019
3571	NDA/MAL/HD P/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	28/11/2019

3572	NDA/MAL/HD P/7448	OCHOA LABORATORIES	SUPER MEDIC LTD	SORID OINTMENT	CALCIPOTRIOL MONOHYDRA TE + BETAMETHAS ONE DIPROPIONAT E	50MCG +0.5MG	AUROCHEM PHAMACEAUTICALS (1) LTD- 58 PALGHAR TALUKA INDUSTRIAL CO-OEPERATIVE ESTATE LTD BOISAR RD PALGHAR DIST THANE 401404 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE	29/11/2017
3573	NDA/MAL/HD P/7449	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ TENOFVIR DF 300/300MG	LAMIVUDINE+ TENOFVIR DISOPROXIL FUMARATE	300MG+300M G	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED--PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3574	NDA/MAL/HD P/7450	OCHOA LABORATORIES	SUPER MEDIC LTD	DOLOACT GEL	KETOPROFEN + CAPSICUM OLEORESIN	2.50%W/W + 0.25%W/W	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE	29/11/2017

3575	NDA/MAL/HD P/7451	AKRITI PHARMACEUTICALS PVT LTD	ROYAL PHARMA 2011 LIMITED	MYTHRO 500	AZITHROMYCI N 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	28/11/2019
3576	NDA/MAL/HD P/7452	OCHOA LABORATORIES	SUPER MEDIC LTD	XTRADERM CREAM	BETAMETHAS ONE DIPROPIONAT E + GENTAMICIN SULFATE + CLOTRIMAZOL E	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	29/11/2017
3577	NDA/MAL/HD P/7453	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANTIDIAZOX	NITAZOXANID E	100MG/5ML	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	01/07/2017
3578	NDA/MAL/HD P/7454	MEDISEL(K) LTD	AIVEEN (U) LIMITED	GIT	ITOPRIDE HYDROCHLORI DE	150MG	CORONA REMEDIES PVT. LTD- VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	OPHTHALMIC DROPS	1.0X1.0X10.0 TABLET BLISTER	28/11/2019

3579	NDA/MAL/HD P/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	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	28/11/2019
3580	NDA/MAL/HD P/7457	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	CIPLADON	PARACETAMO L EFFERVESCE NT	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	28/11/2019
3581	NDA/MAL/HD P/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), MAHABOONNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.42 ML PRE- FILLED SYRINGE (SINGLE DOSE)	28/11/2019

3582	NDA/MAL/HD P/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	28/11/2019
3583	NDA/MAL/HD P/7460	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN SR 75	PREGABALIN	75MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/11/2019
3584	NDA/MAL/HD P/7461	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	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	29/05/2019

3585	NDA/MAL/HD P/7462	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN SR 150	PREGABALIN	150MG	INVENTIA HEALTHCARE PVT LTD -F1-F1/1 ADDITIONAL MIDC AMBERNATH (E) DIST. THANE	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/11/2019
3586	NDA/MAL/HD P/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	28/08/2019
3587	NDA/MAL/HD P/7464	INVENTIA HEALTHCARE PVT LTD	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	28/11/2019
3588	NDA/MAL/HD P/7465	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN DS	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	28/11/2019

3589	NDA/MAL/HD P/7466	HETERO DRUGS LTD	AIVEEN (U) LIMITED	VALSAR HT 80/12.5	VALSARTAN + HYDROCHLOR OTHIAZIDE	80MG + 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	28/11/2019
3590	NDA/MAL/HD P/7467	BROOKES PHARMA (PRIVATE) LIMITED	HARLEYS UGANDA LIMITED	TEZOLE CREAM	KETOCONAZO LE	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	28/08/2019
3591	NDA/MAL/HD P/7468	AKRITI PHARMACEUTICALS PVT LTD	ROYAL PHARMA 2011 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	28/11/2019

3592	NDA/MAL/HD P/7470	AKRITI PHARMACEUTICALS PVT LTD	ROYAL PHARMA 2011 LIMITED	AKSONE	CEFTRIAXONE SODIUM	1G	AKRITI PHARMACEUTICALS PVT LTD-PLOT NO. D-10 & 11, MIDC, JEJURI, TAL. PURANDAR, DIST. PUNE (MAHARASHTRA) INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	28/11/2019
3593	NDA/MAL/HD P/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	PARENTERAL ORDINARY VIALS	1.0X1.0X4.0 ML VIAL	27/11/2019

3594	NDA/MAL/HD P/7472	AMRING FARMA S.R.L	ERIS LTD	BEVACIZUMAB AMRING	BEVACIZUMAB	400 MG/16 ML	SINERGIIUM 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	1.0X1.0X16.0 ML VIAL	27/11/2019
3595	NDA/MAL/HD P/7473	INVENTIA HEALTHCARE PVT LTD	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	27/11/2019
3596	NDA/MAL/HD P/7474	INVENTIA HEALTHCARE PVT LTD	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	27/11/2019
3597	NDA/MAL/HD P/7475	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+ CLOXACILLIN SODIUM	250MG+250M G	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER	01/07/2015

3598	NDA/MAL/HD P/7476	AKRITI PHARMACEUTICALS PVT LTD	ROYAL PHARMA 2011 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	27/11/2019
3599	NDA/MAL/HD P/7477	CHEPLAPHARM ARZNEIMITTEL GMBH	LABOREX UGANDA LIMITED	ROHYPNOL	FLUNITRAZEP AM	1 MG	CENEXI S.A.S-52, RUE MARCEL ET JACQUES GAUCHER 94120 FONTENAY- SOUS-BOIS- FRANCE	FRANCE	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2019
3600	NDA/MAL/HD P/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	01/07/2017
3601	NDA/MAL/HD P/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	27/11/2019

3602	NDA/MAL/HD P/7480	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	AMOKLAVIN BID	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	200MG + 28.5MG/5ML	SPECPHARM HOLDINGS (PTY) LTD. -15TH ROAD, HALFWAY HOUSE, 1685	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	27/11/2019
3603	NDA/MAL/HD P/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	01/07/2017
3604	NDA/MAL/HD P/7482	OCHOA LABORATORIES	SUPER MEDIC LTD	FUSIGO-B CREAM	FUSIDIC ACID BP AND BETAMETHAS ONE VALERATE BP	2.0%W/W+0.1 %W/W	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	29/11/2017
3605	NDA/MAL/HD P/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	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL	27/11/2019

3606	NDA/MAL/HD P/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	27/11/2019
3607	NDA/MAL/HD P/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	27/11/2019
3608	NDA/MAL/HD P/7486	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA AM 5/20	AMLODIPINE BESYLATE + ATORVASTATI N 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	27/11/2019
3609	NDA/MAL/HD P/7487	ATCO LABORATORIES LTD	HARLEYS UGANDA LIMITED	BETASALIC	BETAMETHAS ONE DIPROPIONAT E + 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	27/11/2019

3610	NDA/MAL/HD P/7488	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FINTAS 5	FINASTERIDE	5MG	INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3611	NDA/MAL/HD P/7489	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DOLUTEGRAVI R, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE	DOLUTEGRAVI R + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE,1.0X90.0 TABLET BOTTLE,1.0X100. 0 TABLET BOTTLE,1.0X180. 0 TABLET BOTTLE	27/11/2019
3612	NDA/MAL/HD P/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	01/07/2017

3613	NDA/MAL/HD P/7491	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	CIPRO-DENK 750	CIPROFLOXACIN HYDROCHLORIDE	750MG	ALLPHAMED PHARBIL ARZNEIMITTEL GMBH. - HILDEBRANDSTRABE 12 37081 GOTTINGEN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017
3614	NDA/MAL/HD P/7492	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CYPRODINE	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	LINCOLN PHARMACEUTICAL LIMITED..-LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	28/08/2019
3615	NDA/MAL/HD P/7493	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CEFRAZ 200	CEFIXIME TRIHYDRATE	200 MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHVAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/11/2019

3616	NDA/MAL/HD P/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	29/05/2019
3617	NDA/MAL/HD P/7495	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	MEBEX	MEBENDAZOL E	100MG	LINCO N PHARMACEUTICALS LIMITED-TRIMUL ESTATE KHATRAJ KALOL GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	28/08/2019
3618	NDA/MAL/HD P/7496	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEFTRON 500 MG IM/IV INJECTION	CEFTRIAXONE SODIUM	500 MG/VIAL	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT- KALIAKOIR GAZIPUR	BANGLADESH	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON	27/11/2019

3619	NDA/MAL/HD P/7497	NAPP PHARMACEUTICALS LIMITED	SURGIPHARM (U) LIMITED	FLUTIFORM INHALER	FLUTICASONE PROPIONATE + FORMOTEROL FUMARATE DIHYDRATE	125MCG + 5MCG	FISONS LTD (ALSO KNOWN AS SANOFI-AVENTIS) --72 LONDON ROAD, HOLMES CHAPEL CHEWE, CHESHIRE CW4 8BE, UNITED KINGDOM	UNITED KINGDOM	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0X120.0 METERED DOSE CANNISTER	07/11/2018
3620	NDA/MAL/HD P/7498	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELDOL 100	CELECOXIB	200 MG	AUROBINDO PHARMA LTD- UNIT VII ,/-SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019

3621	NDA/MAL/HD P/7499	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELDOL 200	CELECOXIB	200 MG	AUROBINDO PHARMA LTD- UNIT VII ,/-SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019
3622	NDA/MAL/HD P/7500	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICALS LIMITED	DICLOZONE MR TABLETS	DICLOFENAC POTASSIUM + PARACETAMO L + CHLORZOXA Z 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	27/11/2019

3623	NDA/MAL/HD P/7501	GENERAL PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DEXAGEN	DEXAMETHAS ONE SODIUM PHOSPHATE	0.01%W/V	GENERAL PHARMACEUTICALS LTD (UNIT II)-KAROLSURICHALA, MOUCHAK, KALIAKOIR, GAZIPUR	BANGLADESH	OPHTHALMIC LIQUIDS	1.0X1.0X5.0 ML VIAL	27/11/2019
3624	NDA/MAL/HD P/7502	AMRING FARMA S.R.L	ERIS LTD	CLINDABIOX	CLINDAMYCIN PHOSPHATE	100 MG	FARMAPRIM LTD-5, CRINILOR STREET, PORUMBENI, CRIULENI DISTRICT, MD-4829	ROMANIA	VAGINAL SUPPOSITORIES	1.0X1.0X3.0 PESSARY BLISTER	27/11/2019
3625	NDA/MAL/HD P/7503	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DUTABIT 0.5	DUTASTERIDE	0.5 MG	AUROBINDO PHARMA LTD- UNIT VII ,/-SY. NO'S 411, 425, 434, 435 & 458, PLOT NO. S1 (PART), SPECIAL ECONOMIC ZONE (PHARMA), APIIC, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE JEDEHERLA MANDAL, MAHABOOB NAGAR DISTRICT-509302, ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	27/11/2019

3626	NDA/MAL/HD P/7507	ZIM LABORATORIES LTD	ABACUS PHARMA (AFRICA) LIMITED	FINEVIT-D3 2000	CHOLECALCIFE ROL (VITAMIN D3)	2000 IU	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET STRIP	27/11/2019
3627	NDA/MAL/HD P/7508	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	FREGOUT 40	FEBUXOSTAT	40 MG	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	1.0X1.0X10.0 TABLET BLISTER	27/11/2019
3628	NDA/MAL/HD P/7509	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TOREZA 10	ROSUVASTATI N	10MG	MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT LUPIN LTD-PLOT NO. 6A, SECTOR 17, SPECIAL ECCOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER	27/03/2019

3629	NDA/MAL/HD P/7510	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	IMAVIR EYE OINTMENT	ACYCLOVIR	3%	AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN, JORDAN MMAN, JORDAN	JORDAN	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	29/05/2019
3630	NDA/MAL/HD P/7511	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TOREZA 20	ROSUVASTATI N	20MG	MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT LUPIN LTD-PLOT NO. 6A, SECTOR 17, SPECIAL ECCOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	27/03/2019

3631	NDA/MAL/HD P/7512	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	TOREZA 40	ROSUVASTATI N	40MG	MERCK KGAA-PHARMA PRODUCTION DARMSTADT - FRANKFURTER STRABE 250, D-64293, DARMSTADT LUPIN LTD-PLOT NO. 6A, SECTOR 17, SPECIAL ECCOMIC ZONE, MIHAN, NAGPUR 441108, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019
3632	NDA/MAL/HD P/7513	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	FREGOUT 80	FEBUXOSTAT	80 MG	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	1.0X1.0X10.0 TABLET BLISTER	27/11/2019

3633	NDA/MAL/HD P/7514	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 500	LEVOFLOXACIN HEMIHYDRATE	500 MG	ILKO İLAC SANAYİ VE TİCARET A.Ş-3.ORGANİZE SANAYİ BOLGESİ, BÜYÜK KAYACIK MAH. KUDDİSİ CAD.23 SOKAKNO. 1 42050 SELÇUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	27/11/2019
3634	NDA/MAL/HD P/7515	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	HEPBEST	PREGABALIN + NORTRIPTYLINE (AS HYDROCHLORIDE)	75MG + 10MG	MYLAN LABORATORIES LTD- PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE II, SECTOR III, PITHAMPUR -454775; DIST; DHAR; MADHYA PRADESH;	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	27/11/2019

3635	NDA/MAL/HD P/7516	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	ILFLOX 750	LEVOFLOXACIN HEMIHYDRATE	750 MG	İLKO İLAÇ SANAYİ VE TİCARET A.Ş-3.ORGANİZE SANAYİ BOLGESİ, BÜYÜK KAYACIK MAH. KUDDİSİ CAD.23 SOKAKNO. 1 42050 SELÇUKLU, KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	27/11/2019
3636	NDA/MAL/HD P/7517	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS 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	27/11/2019
3637	NDA/MAL/HD P/7518	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICALS 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	27/11/2019

3638	NDA/MAL/HD P/7519	MACLEODS PHARMACEUTICALS LTDS LTD	NORVIK ENTERPRISES LIMITED	LEVOFLOXACI N	LEVOFLOXACI N HEMIHYDRATE	250 MG	MACLEODS PHARMACEUTICALS LTD - BLOCK N2, VILLAGE THEDA, P.O. LODHI MAJRA, TEHSIL BADDI, DIST. SOLAN, HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER	27/11/2019
3639	NDA/MAL/HD P/7520	DAWA LIMITED	SUPER MEDIC LTD	LEVOXCIN	LEVOFLOXACI N HEMIHYDRATE	750 MG	DAWA LIMITED -16633- 00620, RUARAKA, BABA DOGO ROAD, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER	27/11/2019
3640	NDA/MAL/HD P/7521	HETERO LABS LTD	AIVEEN (U) LIMITED	LISOF	LEDIPASVIR + SOFOSBUVIR	90MG + 400MG	HETERO LABS LIMITED (UNIT V)-SY NO. 436,440, 441 & 458, APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M), MAHABOONNAGAR, DISTRICT ANDHRA PRADESH 509301	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET BOTTLE	27/11/2019

3641	NDA/MAL/HD P/7522	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	DOLUTEGRAVI R	DOLUTEGRAVI R	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	28/03/2019
3642	NDA/MAL/HD P/7523	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	LEVOFLOX- DENK 5 MG/ML	LEVOFLOXACI N HEMIHYDRATE	5MG/ML	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH-- INDUSTRIESTR. 3 34212 MELSUNGEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL	01/07/2017
3643	NDA/MAL/HD P/7524	AMMAN PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROSTAN	LATANOPROST + TIMOLOL MALEATE	0.005% W/V + 0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC LIQUIDS	1.0X2.5 ML VIAL	27/11/2019
3644	NDA/MAL/HD P/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	27/11/2019

3645	NDA/MAL/HD P/7526	CORONA REMEDIES PVT. 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	27/11/2019
3646	NDA/MAL/HD P/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	27/11/2019
3647	NDA/MAL/HD P/7528	I-CARE PHARMA LTD	AIVEEN (U) LIMITED	MANIGRA PLUS	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORI DE	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	27/11/2019

3648	NDA/MAL/HD P/7529	FDC LTD	AIVEEN (U) LIMITED	MOSI EYE DROPS	MOXIFLOXACI N HYDROCHLORI DE	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	27/11/2019
3649	NDA/MAL/HD P/7530	HETERO LABS LTD	AIVEEN (U) LIMITED	DOLUTEGRAVI R TABLETS 50MG	DOLUTEGRAVI R	50MG	HETERO LABS LTD UNIT III-22- 110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET CONTAINER	07/11/2018
3650	NDA/MAL/HD P/7533	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ASUNATE 60	ARTESUNATE	60 MG	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*5ML 0.9%W/W SODIUM CHLORIDE SOLUTION AMPOULE + 1*1ML 5.0%W/W SODIUM BICARBONATE SOLUTION AMPOULE	26/09/2018

3651	NDA/MAL/HD P/7535	ACME FORMULATION PVT. LTD.	MARIE STOPES UGANDA LIMITED	MARIPRIST	MIFEPRISTON E + 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	28/08/2019
3652	NDA/MAL/HD P/7536	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	NETVAICAIN	BUPIVACAINE HYDROCHLORI DE + DEXTROSE	5MG + 80MG /ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X10.0X4. 0 ML AMPOULE,1.0X1 0.0X4.0 ML AMPOULE,1.0X1. 0X5.0X5.0X4.0 ML AMPOULE	01/07/2017
3653	NDA/MAL/HD P/7538	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABUVAC	BUPIVACAINE HYDROCHLORI DE	0.5 % W/V	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X4.0 ML AMPOULE	27/03/2019
3654	NDA/MAL/HD P/7539	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	COUGH LINCTUS	CHLORPHENIR AMINE	2MG/5ML	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1000.0 ML JERRYCAN,1.0X2 00.0 ML BOTTLE	01/07/2011

3655	NDA/MAL/HD P/7541	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	CHLORHEXIDI NE SCRUB	CHLORHEXIDI NE GLUCONATE	4%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1000.0 ML JERRYCAN	01/07/2012
3656	NDA/MAL/HD P/7544	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	GLYCERIN OF BORAX	GLYCERINE+B ORAX	12%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3657	NDA/MAL/HD P/7546	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1.0 L JERRYCAN	01/07/2012
3658	NDA/MAL/HD P/7548	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	IODINE TINCTURE	IODINE + POTASSIUM IODIDE	2.5%W/V+2.5 %W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X22.0 ML BOTTLE	01/07/2013
3659	NDA/MAL/HD P/7552	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	MAGNESIUM TRISILICATE MIXTURE	MAGNESIUM TRISILICATE + LIGHT MAGNESIUM CARBONATE + SODIUM BICARBONATE	250MG + 250MG + 250MG/5ML	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2010

3660	NDA/MAL/HD P/7554	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	POVIDONE IODINE BP	POVIDONE IODINE	10%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X100 0.0 ML JERRYCAN	01/07/2013
3661	NDA/MAL/HD P/7556	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	SEVASTAT	CETRIMIDE + CHLORHEXIDI NE	3%W/V+0.3% W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE	01/07/2012
3662	NDA/MAL/HD P/7559	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	SURGICAL SPIRIT	METHYL SALICYLATE	0.5%V/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL SPIRITS	1.0X100.0 ML BOTTLE	01/07/2011
3663	NDA/MAL/HD P/7560	SEV PHARMACEUTICALS LIMITED	SEV PHARMACEUTICALS LIMITED	VIOLGENT	CRYSTAL VIOLET	0.5%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X25.0 ML BOTTLE	01/07/2014
3664	NDA/MAL/HD P/7571	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FILM-COATED TABLET	THIAMINE MONONITRAT E + PYRIDOXINE HCL + CYANOCOBAL AMINE	97MG + 50MG + 100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
3665	NDA/MAL/HD P/7586	OCHOA LABORATORIES	SUPER MEDIC LTD	CLEAR-T GEL	CLINDAMYCIN PHOSPHATE + TRETINOIN	1.0%W/W + 0.025%W/W	AUROCHEM LABORATORIES LTD -PLOT 08 PALGHAR 401404 MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/11/2017

3666	NDA/MAL/HD P/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	27/11/2019
3667	NDA/MAL/HD P/7588	OCHOA LABORATORIES	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 PHAMACEAUTICALS (1) LTD- 58 PALGHAR TALUKA INDUSTRIAL CO-OEPERATIVE ESTATE LTD BOISAR RD PALGHAR DIST THANE 401404 INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE	29/11/2017
3668	NDA/MAL/HD P/7589	OCHOA LABORATORIES	SUPER MEDIC LTD	LACX SYRUP	LACTULOSE	10G/15ML	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100. 0 ML BOTTLE	29/11/2017
3669	NDA/MAL/HD P/7591	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	ONCOMIDE	CYCLOPHOSPH OMIDE	1000 MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 ML VIAL	27/11/2019

3670	NDA/MAL/HD P/7592	KHANDELWAL LABORATORIES PVT LIMITED	SURGIPHARM (U) LIMITED	ONCOMIDE	CYCLOPHOSPH OMIDE	500 MG	KHANDELWAL LABORATORIES PVT. LTD-B- 1, WAGLE INDUSTRIAL ESTATE, THANE – 400 604 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML VIAL	27/11/2019
3671	NDA/MAL/HD P/7593	AMRING PHARMA	ERIS LTD	PARACETAMO L AMRING	PARACETAMO L	10 MG/ML	CLARIS INJECTABLES LIMITED VASANA-CHACHARWADI, TAL-SANAND-382 213, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE	27/11/2019
3672	NDA/MAL/HD P/7595	AMMAN PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOPROST	LATANOPROST	0.005% W/V	AMMAN PHARMACEUTICALS INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE, SAHAB, AMMAN	JORDAN	OPHTHALMIC VIALS	1.0X2.5 ML VIAL	27/11/2019
3673	NDA/MAL/HD P/7596	INTERNATIONAL ORGANIZATION FOR MIGRATION	AIVEEN (U) LTD - WILSON ROAD	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	27/11/2019

3674	NDA/MAL/HD P/7597	CODAL-SYNTO LTD	RENE PHARMACY LTD	SYNTOCLAV	AMOXICILLIN SODIUM + CLAVULANIC ACID	1000MG + 200MG	MEDOCHEMIE LTD - FACTORY B-48 IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	01/07/2017
3675	NDA/MAL/HD P/7598	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	RABEFLUX- DSR	RABEPRAZOLE SODIUM + DOMPERIDON E	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	27/11/2019

3676	NDA/MAL/HD P/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	27/11/2019
3677	NDA/MAL/HD P/7600	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	NO COLD SYRUP	PARACTAMOL + PHENYL HYDROCHLORI DE + CHLORPHENA MINE MALEATE + SODIUM CITRATE	125MG + 5MG + 1MG + 60MG / 5ML	CRIS PHARMA (INDIA) LIMITED-E-11, UPSIDC INDUSTRIAL AREA, SELAQUI, DEHRADUN, UTTARAKHAND INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X60.0 ML BOTTLE	27/11/2019

3678	NDA/MAL/HD P/7601	AMRING FARMA S.R.L	ERIS LTD	RITUXIMAB AMRING	RITUXIMAB	500 MG/50 ML	SINERGIIUM 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	1.0X1.0X50.0 ML VIAL	27/11/2019
3679	NDA/MAL/HD P/7602	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	ROSICARD 10	ROSUVASTATI N CALCIUM	10 MG	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	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
3680	NDA/MAL/HD P/7603	RAINBOW LIFE SCIENCES PVT.LTD.	EUROPA HEALTHCARE (U) LTD	ROSICARD 5	ROSUVASTATI N CALCIUM	5 MG	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	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

3681	NDA/MAL/HD P/7604	INVENTIA HEALTHCARE PVT LTD	EUROPA HEALTHCARE (U) LTD	SEGABIN M 150	PREGABALIN + METHYLCOBA LAMIN	150MG + 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	27/11/2019
3682	NDA/MAL/HD P/7605	GUFIC LIFESCIENCES PRIVATE LTD	EUROPA HEALTHCARE (U) LTD	STRIPOLE	PANTOPRAZO LE SODIUM SESQUIHYDRA TE	40 MG	GUFIC LIFESCIENCES PRIVATE LIMITED- SURVEY NO. 171, N.H. NO-8, NEAR FRID, KABILPORE, CITY- NAVSARI-396424, DIST. NAVSARI, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*10ML SODIUM CHLORIDE SOLUTION 0.9% W/V	27/11/2019
3683	NDA/MAL/HD P/7607	FDC LTD	AIVEEN (U) LIMITED	TEARMAX EYE DROPS	CARMELLOSE SODIUM	5MG/ML	FDC LIMITED, WALUJ .-PLOT NO. B-8, MIDC, INDUSTRIAL AREA, WALUJ 431136 DIST AURANGABAD	INDIA	OPHTHALMIC LIQUIDS	1.0X1.0X10.0 ML VIAL	27/11/2019

3684	NDA/MAL/HD P/7608	RAINBOW LIFE SCIENCES PVT LTD	EUROPA HEALTHCARE (U) LTD	TELMICARD 40	TELMISARTAN	40 MG	GLOBELA PHARMA PVT.LTD.- PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT- 394230,GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
3685	NDA/MAL/HD P/7609	RAINBOW LIFE SCIENCES PVT LTD	EUROPA HEALTHCARE (U) LTD	TELMICARD 80	TELMISARTAN	80 MG	GLOBELA PHARMA PVT.LTD.- PLOT NO.357,G.I.D.C SACHIN ROAD NO.3,SURAT- 394230,GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019
3686	NDA/MAL/HD P/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	27/11/2019
3687	NDA/MAL/HD P/7611	FERRING GMBH	MACNAUGHTON LIMITED	PABAL	CARBETOCIN	100MCG/ML	FERRING GMBH.-11, WITTLAND	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL	01/07/2017
3688	NDA/MAL/HD P/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	27/11/2019

3689	NDA/MAL/HD P/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, 1.0X2.0X 7.0 TABLET BLISTER	26/11/2019
3690	NDA/MAL/HD P/7616	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	XIMEPROX	CEFPODOXIME PROXETIL	100MG/5ML	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X15.0 ML BOTTLE	26/11/2019
3691	NDA/MAL/HD P/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 + TENOFIVIR DISOPROXIL FUMARATE	600 MG + 300 MG + 300 MG	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED--PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018
3692	NDA/MAL/HD P/7618	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	XIMEPROX 200	CEFPODOXIME PROXETIL	200MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER	26/11/2019

3693	NDA/MAL/HD P/7629	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	NOMOPIL 2	REPAGLINIDE	2MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	26/11/2019
3694	NDA/MAL/HD P/7632	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 2.5 MG FILM- COATED TABLETS	BISOPROLOL FUMARATE	2.5MG	LEK S.A.-16 PODLIPIE STR. 95- 010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2017
3695	NDA/MAL/HD P/7634	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL	BISOPROLOL	5 MG	LEK S.A.-16 PODLIPIE STR. 95- 010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER	01/07/2017
3696	NDA/MAL/HD P/7656	A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SPASMOMEN	OTILONIUM BROMIDE	40MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA CAMPO DI PILE, L'AQUILA (AQ), ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER	01/07/2017
3697	NDA/MAL/HD P/7663	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR	ENTECAVIR MONOHYDRA TE	1.0MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1- 7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2017

3698	NDA/MAL/HD P/7671	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DICHLOR-25	CHLORTHALID ONE	25MG	IPCA LABORATORIES LTD,PLOT NO. T-139 - SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3699	NDA/MAL/HD P/7673	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	80MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E- 08210 BARBERA DEL VALLES BARCELONA SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3700	NDA/MAL/HD P/7674	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLEVOX	LEVOFLOXACI N HEMIHYDRATE	5G/L	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2017

3701	NDA/MAL/HD P/7675	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	160MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E- 08210 BARBERA DEL VALLES BARCELONA SPAIN	SPAIN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3702	NDA/MAL/HD P/7683	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DESLORATADI NE	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER	01/07/2017
3703	NDA/MAL/HD P/7686	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT EYE/EAR DROPS	GENTAMICIN SULPHATE	0.3W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE	01/07/2017

3704	NDA/MAL/HD P/7688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORI DE	850MG	NKUNZI PHARMACEUTICALS- 259 DAVIDSON ROAD, WADEVILLEGERMISTON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X300.0 TABLET CONTAINER,1.0X 60.0 TABLET CONTAINER,1.0X 4.0X15.0 TABLET BLISTER	01/07/2017
3705	NDA/MAL/HD P/7695	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	CORTUM 500	CEFUROXIME AXETIL	500MG	AKUMS DRUGS & PHARMACEUTICALS LTD.- PLANT III, PLOT NO. 19, 20, 21, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3706	NDA/MAL/HD P/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	01/07/2017

3707	NDA/MAL/HD P/7705	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	OTICLOR	CEFACLO R MONOHYDRA TE	125MG/5ML	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	29/11/2019
3708	NDA/MAL/HD P/7708	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	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	01/07/2017
3709	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X50.0X2.0 ML AMPOULE	01/07/2017
3710	NDA/MAL/HD P/7711	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 850 MG	METFORMIN HYDROCHLORI DE	850MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

3711	NDA/MAL/HD P/7712	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	MEBASTIN	MEBHYDROLI N	500MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	29/11/2019
3712	NDA/MAL/HD P/7713	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	TIMOZIN	TIEMONIUM METHYLSULFA TE	50MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X10.0X5.0 TABLET BLISTER	29/11/2019
3713	NDA/MAL/HD P/7716	CORE ACCESS LIMITED	CORE ACCESS LTD	ALRINAST 2.5 MG / 5 ML SYRUP	DES Loratidine	2.5 MG / 5 ML	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE	29/11/2017
3714	NDA/MAL/HD P/7721	SANOFI-AVENTIS KENYA	LABOREX UGANDA LIMITED	MAALOX LEMON FLAVORING	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	175MG + 200MG + 25MG/ 5ML	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X250.0 ML BOTTLE,1.0X355. 0 ML BOTTLE	01/07/2017

3715	NDA/MAL/HD P/7722	SANOFI-AVENTIS KENYA	LABOREX UGANDA LIMITED	MAALOX MINT FLAVORING	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE	175MG + 200MG/ 5ML	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 - ,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X355.0 ML BOTTLE,1.0X250. 0 ML BOTTLE	01/07/2017
3716	NDA/MAL/HD P/7724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHI N [CORRESPONDI NG TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU]	75 IU + 75 IU/ 4ML VIAL	FERRING (PTY) LTD- WITTLAND II 24146 KIEL	GERMANY	PARENTERAL ORDINARY DRY VIALS	10.0X4.0 ML VIAL 10*1ML CLEAR COLOURLESS GLASS AMPOULES CONTAINING 9.0MG/ML OF NACL	01/07/2017
3717	NDA/MAL/HD P/7728	NORVATIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	LINEX	LACTOBACILL US ACIDOPHILUS + BIFIDOBACTER IUM INFANTIS + ENTEROCOCC US 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	01/07/2017

3718	NDA/MAL/HD P/7735	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL 400	PARACETAMO L + IBUPROFEN	325MG + 400MG	AJANTA PHARMA LIMITED PAITHAN-MANUFACTURING UNIT B-4/5/6 MIDC PAITHAN DISTRICT AURANGABAD 431 148 MAHARASTRA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3719	NDA/MAL/HD P/7740	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	METHICOWEL 1500	METHYLCOBA LAMIN	1500 MCG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE	01/07/2017
3720	NDA/MAL/HD P/7747	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	THERMODOL	PARACETAMO L	1.0%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.-2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2017

3721	NDA/MAL/HD P/7751	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX COUGH SYRUP	BROMHEXINE HYDROCHLORI DE + DEXTROMETH ORPHAN HYDROBROMI DE + AMMONIUM CHLORIDE	8MG + 10MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2017
3722	NDA/MAL/HD P/7760	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 10	OLANZAPINE	10MG	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND PSYCHOTROPICS INDIA LTD PLOT--NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3723	NDA/MAL/HD P/7784	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	LORATOL	LORATADINE	5MG/5ML	NOBEL ILAC DUZCE- SANAYIINVE TICARET A.S SANCAKLAR 81100 DUZCE	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2017

3724	NDA/MAL/HD P/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	01/07/2009
3725	NDA/MAL/HD P/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	01/07/2016
3726	NDA/MAL/HD P/7906	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	IVMOL	PARACETAMO L	10MG/ML	AXA PARENTERAL LIMITED- PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	01/07/2016

3727	NDA/MAL/HD P/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 NACL AMBER GLASS AMPOULE	01/07/2017
3728	NDA/MAL/HD P/7912	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	GLIMEWEL M- 1	GLIMEPIRIDE + METFORMIN HYDROCHLORI DE	1MG + 500MG	AKUMS DRUGS & PHARMACEUTICALS LTD -- 19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017
3729	NDA/MAL/HD P/8009	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	GRISO-500	GRISEOFULVIN	500MG	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	01/07/1998

3730	NDA/MAL/HD P/8010	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	METROZOLE TABLETS	METRONIDAZ OLE	200MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2001
3731	NDA/MAL/HD P/8015	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	D-FEN	DICLOFENAC SODIUM	25MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X3.0 ML AMPOULE,1.0X1 0.0X1.0X10.0X3. 0 ML AMPOULE	01/07/2011
3732	NDA/MAL/HD P/8021	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	LAMIVIR-150 TABLETS	LAMIVUDINE	150MG	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	1.0X10.0X10.0 TABLET BLISTER,1.0X60.0 TABLET BOTTLE	01/07/2001
3733	NDA/MAL/HD P/8022	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG +50MG + 60MG	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	1.0X60.0 TABLET BOTTLE	01/07/2016

3734	NDA/MAL/HD P/8023	DENK PHARMA GMB H & CO. KG	BENLE CONSULT LIMITED	AMOXICLAV- DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBH- BRITENBACHSTR ASSE 13 D- 13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER	01/07/2011
3735	NDA/MAL/HD P/8032	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	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	01/07/2011
3736	NDA/MAL/HD P/8043	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BİLİM PHARMACEUTICALS- GOSB 41480 GEBZE- KOCAELİ/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER	01/07/2017
3737	NDA/MAL/HD P/8061	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 25MG	PREGABALIN	25 MG	PFIZER GMBH ARZEIMTELWORK - MOOSWADALLE 179090, FREIBERG GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER	01/07/2007
3738	NDA/MAL/HD P/8062	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	PROSTIN E2	DINOPROSTO NE	3MG	PHARMACIA AND UPJOHN S.P.A-RIJWSWEG 12, B-2870 PUURS	BELGIUM	VAGINAL TABLETS	1.0X4.0 TABLET STRIP	01/07/1997
3739	NDA/MAL/HD P/8073	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TRILEPTAL	OXCARBAZEPI NE	300MG	NOVARTIS PHARMA SPA,- TORRE ANNUNZIATA ITALY	ITALY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X50.0 TABLET CONTAINER	01/07/1997

3740	NDA/MAL/HD P/8078	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 100/270	ARTESUNATE + AMODIAQUIN E	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	01/07/2011
3741	NDA/MAL/HD P/8082	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE + LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	60MG + 30MG	MYLAN LABORATORIES LIMITEDD ,-F-4 & F-12,MIDC, MALEGAON,SIRRRAR, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2016
3742	NDA/MAL/HD P/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,1.0X 100.0X10.0 CAPSULE BLISTER,1.0X500. 0 CAPSULE CONTAINER,1.0X 250.0 CAPSULE CONTAINER	01/07/1997
3743	NDA/MAL/HD P/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 SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2001

3744	NDA/MAL/HD P/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,1.0X 10.0X10.0 CAPSULE BLISTER	01/07/1997
3745	NDA/MAL/HD P/8093	CIPLA LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DUOVIR-N	ZIDOVUDINE + LAMIVUDINE + NEVIRAPINE	300MG + 150MG + 200MG	CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2010
3746	NDA/MAL/HD P/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.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2016
3747	NDA/MAL/HD P/8096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYL PENICI LLIN SODIUM	2.4MEGA/ VIAL	REYOUNG PHARMACEUTICAL CO. LTD- NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG PROVINCE P.R. 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON	01/07/2011

3748	NDA/MAL/HD P/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	01/07/2016
3749	NDA/MAL/HD P/8100	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMPICLOX	AMPICILLIN/ CLOXACILLIN	250MG/5ML	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/1997
3750	NDA/MAL/HD P/8102	THE JORDANIAN PHAMACUITICALS MANUFACTURIES LTD	PHARMA TREAT COMPANY LTD	VOMINORE	MECLOZINE HYDROCHLORI DE + PYRIDOXINE HCL	25MG + 50MG	JORDANIAN PHARMACEUTICAL MANUFACTURING COMPANY-AL-RAZI SITE, UM AL—AMAD	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER	07/01/2005
3751	NDA/MAL/HD P/8103	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	WELQUINE 500	LEVOFLOXACI N	500MG	AKUMS DRUGS & PHARMACEUTICALS LTD.- PLANT III, PLOT NO. 19, 20, 21, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER	01/07/2016

3752	NDA/MAL/HD P/8104	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 40	TELMISARTAN	40MG	PSYCHOTROPICS INDIA LTD- PLOT NO. 46 & 49 SECTOR - 6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3753	NDA/MAL/HD P/8105	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	XERIN	LEVOCETIRIZIN E HYDROCHLORI DE + MONTELUKAS T 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	01/07/2017
3754	NDA/MAL/HD P/8108	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS	GLUCOSE ANHYDROUS+ TRISODIUM CITRATE+SODI UM CHLORIDE+PO TASSIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G	: MEDIPHARM INDUSTRIES LTD-PLOT 65, KAKAJJO ROAD, BWEYOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X25.0 G SACHET	01/07/2017

3755	NDA/MAL/HD P/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,100.0X1 0.0 TABLET BLISTER	01/07/2017
3756	NDA/MAL/HD P/8110	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	R.B.TONE SYRUP	MULTI- INGREDIENT	N/A	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	1.0X1.0X200.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE	01/07/2000
3757	NDA/MAL/HD P/8116	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES 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	01/07/2013

3758	NDA/MAL/HD P/8119	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	HALOPERIDOL DECANOATE	HALOPERIDOL DECANOATE	50MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE,1.0X1 0.0X1.0 ML AMPOULE	01/07/2017
3759	NDA/MAL/HD P/8121	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	SWISSQUINE	QUININE	300MG/ML	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	01/07/2011
3760	NDA/MAL/HD P/8125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	GAMA PHARMACEUTICALS (U) LIMITED	MATADOR	LEVOFLOXACI N	500MG	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD, - NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER	01/07/2009

3761	NDA/MAL/HD P/8126	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	TRIDOSIL	AZITHROMYCI N	500MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0 TABLET BLISTER	29/11/2019
3762	NDA/MAL/HD P/8127	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	LIDOCAINE HYDROCHLORI DE	LIDOCAINE HYDROCHLORI DE	2% W/V	SWISS PARENTERALS LTD- 809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL	01/07/2016
3763	NDA/MAL/HD P/8129	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ATOREG 20	ATORVASTATI N CALCIUM	20MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD.-SY. NO. 172 & 173,PARK ROAD, DULAPALLY VILLAGE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

3764	NDA/MAL/HD P/8130	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	DEGRA 100	SILDENAFIL CITRATE	100MG	DEVA HOLDING A. S.- ÇERKEZKÖY ORGANİZE SANAYİ BOLGESİ. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER	30/05/2018
3765	NDA/MAL/HD P/8131	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	DEGRA	SILDENAFIL CITRATE	50MG	DEVA HOLDING A. S.- ÇERKEZKÖY ORGANİZE SANAYİ BOLGESİ. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER	01/07/2017
3766	NDA/MAL/HD P/8135	BAL PHARMA LIMITED	SHREEJI PHARMACEUTICALS LIMITED	REGAMOL	PARACETAMO L	500MG	BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE- PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2017

3767	NDA/MAL/HD P/8136	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	ONASERON	ONDANSETRO N	8MG/4ML	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	PARENTERAL ORDINARY AMPOULES	1.0X5.0X4.0 ML AMPOULE	26/11/2019
3768	NDA/MAL/HD P/8138	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	OTICLOR 500	CEFACLOX R	500MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X4.0 CAPSULE BLISTER	26/11/2019
3769	NDA/MAL/HD P/8139	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	SEASONIX	LEVOCETIRIZIN E DIHYDROCHLO RIDE	5MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/11/2019
3770	NDA/MAL/HD P/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	01/07/2017

3771	NDA/MAL/HD P/8143	NAARI LTD	ECHO PHARMACY (U) LIMITED	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	01/07/2013
3772	NDA/MAL/HD P/8144	NAARI LTD	ECHO PHARMACY (U) LIMITED	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	01/07/2016
3773	NDA/MAL/HD P/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	01/07/2017

3774	NDA/MAL/HD P/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	01/07/2017
3775	NDA/MAL/HD P/8147	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 5	MONTELUKAS T SODIUM	5 MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER	01/07/2017
3776	NDA/MAL/HD P/8148	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILL IN	FLUCLOXACILL IN	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	30/05/2018
3777	NDA/MAL/HD P/8150	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	20MG	NOVARTIS PHARMA STEIN AG-CH. 4002 STEIN, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017

3778	NDA/MAL/HD P/8151	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGO-C (THANE)	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,1.0X 10.0X10.0 TABLET STRIP	01/07/2005
3779	NDA/MAL/HD P/8152	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	15MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3780	NDA/MAL/HD P/8153	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ASNORBIN- 1000	VITAMIN C	1000MG	BLISS GVS PHARMA LTD,- PLOT 10, SURVEY NO. 38/1, DEWAN UDYONG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X4.0 TABLET BLISTER	26/11/2019

3781	NDA/MAL/HD P/8154	AGOG PHARMA LTD	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	01/07/2013
3782	NDA/MAL/HD P/8155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER	01/07/2017
3783	NDA/MAL/HD P/8156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILU S TYPE B CONJUGATE VACCINE	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILU S TYPE B CONJUGATE VACCINE	25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+ 11MCG	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLThER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0X5 .0 ML VIAL (10 DOSE VIAL)	01/07/2014

3784	NDA/MAL/HD P/8157	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	D LYTE- PLAIN	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE + POTASSIUM CHLORIDE	13.50G + 2.60G + 2.90G +1.50G/ 1L	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X20.5 G SACHET	01/07/2016
3785	NDA/MAL/HD P/8159	AUROBINDO PHARMA LIMITED (UNIT III)	GITTOES PHARMACEUTICALS LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	AUROBINDO PHARMA LIMITED (UNIT III) -AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD- 500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2017
3786	NDA/MAL/HD P/8160	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250M G+250MG+25 0MG+125MG/ 15ML	STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2017

3787	NDA/MAL/HD P/8162	BHARAT SERUMS AND VACCINES LTD	ABACUS PHARMA (AFRICA) LIMITED	HUMOG 75 HP	HIGHLY PURIFIED MENOTROPHI N [CORRESPONDI NG TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU] /150 I.U	75 IU + 75 IU/ 150 I.U VIAL	BHARAT SERUMS AND VACCINES LTD- PLOT NO. K- 27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*1 ML AMPOULE OF 0.9%W/V NACL	01/07/2017
3788	NDA/MAL/HD P/8170	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250M G+250MG+25 0MG+125MG/ 15ML	STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2017
3789	NDA/MAL/HD P/8172	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	COAMOX- ACINO 1000	AMOXICILLIN + CLAVULANIC ACID	875MG + 125 MG	LEK PHARMACEUTICALS- PREVALJE SITE, PERZONALI 47, S1-2391, PREVALJE	SLOVENIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	01/07/2006

3790	NDA/MAL/HD P/8178	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NYSTAGO TABLETS	NYSTATIN	500,000I.U	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET BOTTLE,1.0X10.0 X10.0 TABLET BLISTER	01/07/2005
3791	NDA/MAL/HD P/8180	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL TABLETS 500MG	PARACETAMO L	500MG	COSMOS LIMITED -RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER	01/07/1997
3792	NDA/MAL/HD P/8188	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	150MG + 300MG + 200MG	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	1.0X60.0 TABLET BOTTLE	01/07/2011

3793	NDA/MAL/HD P/8190	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE TABLETS	LAMIVUDINE	150 MG	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 TABLETS	1.0X60.0 TABLET BOTTLE	01/07/2005
3794	NDA/MAL/HD P/8191	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DIDANOSINE DELAYED- RELEASE	DIDANOSINE DELAYED- RELEASE	400MG	AUROBINDO PHARMA LTD- UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X30.0 CAPSULE BOTTLE	01/07/2009

3795	NDA/MAL/HD P/8193	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	ECOX 400	ETHAMBUTOL	400MG	MACLEODS PHARMACEUTICALS LTD.- PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. MACLEODS PHARMACEUTICALS LTD- - PLOT 25-27, SURVEY NO. 306, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT)- 396210, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2005
3796	NDA/MAL/HD P/8194	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	SOLONEX-100	ISONIAZID	100MG	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,1.0X100 0.0 TABLET CONTAINER,1.0X 24.0X28.0 TABLET BLISTER	01/07/2005

3797	NDA/MAL/HD P/8195	NTICALS LTD.	NORVIK ENTERPRISES 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 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 STRIP,1.0X24.0X 28.0 TABLET BLISTER,1.0X3.0X 28.0 TABLET BLISTER	01/07/2005
3798	NDA/MAL/HD P/8197	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN	AMIKACIN SULPHATE	500MG/2ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL	01/07/2017

3799	NDA/MAL/HD P/8198	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX DROPS	MULTI- INGREDIENT	MULTI- INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE	01/07/1999
3800	NDA/MAL/HD P/8199	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX SYRUP	MULTIVITAMI N/ 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	01/07/2000
3801	NDA/MAL/HD P/8200	MEDIPHARM SALES LIMITED	MEDIPHARM INDUSTRIES (E.A) LTD	ORS ORANGE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G / SACHET	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGERERE P.O.BOX 6218,KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.4 G SACHET	01/07/2017

3802	NDA/MAL/HD P/8201	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CENTROZINE	CETIRIZINE HYDROCHLORI DE	5MG/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD- -N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	01/07/2017
3803	NDA/MAL/HD P/8202	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	ISONIAZID	ISONIAZID	300MG	MACLEODS PHARMACEUTICALS LTD.- PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA. OXALIS LABS--VILLAGE THEDA,P.O.LODHIMAJRA ,TEHSIL BADDI,DIST .SOLAN (HIMACHAL PRADESH) - 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X24.0 X28.0 TABLET BLISTER	01/07/2017

3804	NDA/MAL/HD P/8204	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	DOPAMINE HCL FRESENIUS	DOPAMINE HYDROCHLORI DE	200MG/5ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD KORSTEN PORT ELIZABETH 6020	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE	01/07/2017
3805	NDA/MAL/HD P/8206	BRAWN LABORATORIES LTD	ESCORTS PHARMACEUTICALS LIMITED	BRULEXIN	CEFALEXIN MONOHYDRA TE	125MG/5ML	BRAWN LABORATORIES LTD.- 13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	01/07/2017
3806	NDA/MAL/HD P/8207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;- SCHAFFHAUSERSTRASSE CH 4332 STEIN- SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0 VIAL CARTON	01/07/2017
3807	NDA/MAL/HD P/8208	CIRON DRUGS & PHARMACEUTICAL PVT LTD	RENE PHARMACY LTD	CHLORAMPHE NICOL SODIUM SUCCINATE	CHLORAMPHE NICOL SODIUM SUCCINATE	1G	CIRON DRUGS AND PHARMACEUTICALS PVT LTD- N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0X1.0 G VIAL	01/07/2007

3808	NDA/MAL/HD P/8210	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	HYDROCORTIS ONE SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTIS ONE	100MG	CIRON DRUGS & PHARMACEUTICALS PVT LTD- -N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL	01/07/2007
3809	NDA/MAL/HD P/8211	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCO- ASTHALIN SYRUP	SALBUTAMOL + BROMHEXINE	2MG/5ML + 4MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2010
3810	NDA/MAL/HD P/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	01/07/1998

3811	NDA/MAL/HD P/8213	FDC LTD	AIVEEN (U) LIMITED	ZOCON 200	FLUCONAZOLE	200MG	FDC LTD.-L-56/L-57,PHASE II-D, VERNA INDUSTRIAL ESTATE,VERNA-403722, SALTETE,GOA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET BLISTER	01/07/2001
3812	NDA/MAL/HD P/8216	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	SEFOTAX	CEFOTAXIME SODIUM	1G	SWISS PARENTERALS LTD, UNIT- II-PLOT NO. 402,412- 414 KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST: AHMEDABAD	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	01/07/2017
3813	NDA/MAL/HD P/8218	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECLOPHEN 12.5	DICLOFENAC SODIUM	12.5MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2017
3814	NDA/MAL/HD P/8221	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NEMADOL	TRAMADOL HYDROCHLORI DE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPIRA 3 BARA	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE	01/07/2017

3815	NDA/MAL/HD P/8222	MICRO LABS LTD	LABOREX UGANDA LIMITED	LUBREX	SODIUM CARBOXYMET HYL CELLULOSE	0.5%W/V	MICRO LABS LTD ...-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIIL NADU	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	01/07/2017
3816	NDA/MAL/HD P/8224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT OINTMENT	GENTAMICIN SULFATE	0.3%W/W	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE	01/07/2017
3817	NDA/MAL/HD P/8225	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	ARTELIN 60	ARTESUNATE	60MG	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*1 ML AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION B.P + 1*5 ML AMPOULE OF 0.9%W/V NACL	01/07/2017

3818	NDA/MAL/HD P/8226	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	SALRES	SALBUTAMOL SULPHATE	120.5MCG/SP RAY	DEVA HOLDING A. S.- ÇERKEZKÖY ORGANIZE SANAYİ BOLGESİ. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER	01/07/2017
3819	NDA/MAL/HD P/8227	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ALZER 5	DONEPEZIL HYDROCHLORI DE	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 FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X3.0X 1.0X10.0 TABLET BLISTER	01/07/2017
3820	NDA/MAL/HD P/8231	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ANASTROZOLE DENK	ANASTROZOLE	1MG	HAUPT PHARMA GMBH & CO KG- SCHLEEBRUGGENKAMP 15, 48159 MUNSTER, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017

3821	NDA/MAL/HD P/8235	IMMUCOR	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	01/07/2017
3822	NDA/MAL/HD P/8239	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	UMBIPRO GEL	CHLORHEXIDI NE	4%W/W	GLAXO OPERATIONS UK LTD-- -HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	TOPICAL EXTERNAL GELS AND SOLS	1.0X7.0 SACHET CARTON	01/07/2017
3823	NDA/MAL/HD P/8243	OCHOA LABORATORIES	SUPER MEDIC LTD	TRANEXAMIC ACID + MEFENAMIC ACID	TRANEXAMIC ACID + MEFENAMIC ACID	500MG + 250MG	AUROCHEM LABORATORIES (I) PVT LTD--8 PALGHAR TALUKA INDUSTRIAL CO-OP ESTATE LTD PALGHAR 401 404 DIST THANE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	01/07/2017
3824	NDA/MAL/HD P/8244	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 440	TRASTUZUMA B (R-DNA ORIGIN)	440MG	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X440.0 MG VIAL ,1X2X10ML VIALS OF WFI	01/07/2017

3825	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE	01/07/2017
3826	NDA/MAL/HD P/8250	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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,1.0X30.0 X6.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER	01/07/2017
3827	NDA/MAL/HD P/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	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL,1.0X10.0X1 00.0 ML VIAL	01/07/2017

3828	NDA/MAL/HD P/8254	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF- CV	CEFIXIME TRIHYDRATE + CLAVULANIC ACID	200MG + 125MG	MICRO LABS LIMITED, BOMMASANDRA -PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET STRIP	01/07/2017
3829	NDA/MAL/HD P/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	01/07/2017

3830	NDA/MAL/HD P/8274	HETERO LABS LTD	AIVEEN (U) LIMITED	BICATERO 50	BICALUTAMID E	50MG	HETERO LABS LTD (UNIT-VI)- "SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013
3831	NDA/MAL/HD P/8275	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	LETERO	LETROZOLE	2.5MG	HETERO LABS LTD (UNIT-VI)- "SY.NO. 439, 440 & 458,APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT ANDHRA PRADESH-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013

3832	NDA/MAL/HD P/8276	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	GEMTERO 1G	GEMCITABINE	1G	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOONNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL	01/07/2013
3833	NDA/MAL/HD P/8278	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	ANATERO	ANASTROZOLE	1MG	HETERO LABS LTD, UNIT VI, INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGER DISTRICT ANDHRA PRADESH-509301, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	01/07/2013

3834	NDA/MAL/HD P/8279	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	GENTACIN	GENTAMICIN SULPHATE	80MG/2ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382- 213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X6.0X2.0 ML AMPOULE IN BLISTERS	01/07/2013
3835	NDA/MAL/HD P/8282	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BINOZYT 500	AZITHROMYCI N	500MG	SANDOZ SRL LTD-LIVEZENI STREET 7A540472 TARGU MURES ROMANIA	ROMANIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER	01/07/2016
3836	NDA/MAL/HD P/8283	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	QUINAS	QUININE SULPHATE BP	300MG	ASTRA LIFE CARE(INDIA) PVT LTD-PLOT NO. 57/P, SARKHEJ – BAVLA HIGHWAY, POST. RAJODA – 382220, TALUKA: BAVLA, DIST. AHMEDABAD	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER	01/07/2009

3837	NDA/MAL/HD P/8287	PHARCO PHARMACEUTICALS	GAMA PHARMACEUTICALS (U) LIMITED	DERMATIN 1% POWDER	CLOTRIMAZOL E+ZINC OXIDE	0.01G + 2.500G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	TOPICAL EXTERNAL POWDERS	1.0X10.0 G CONTAINER	01/07/2003
3838	NDA/MAL/HD P/8293	NAARI LTD	ECHO PHARMACY (U) 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 COMBINATION PACK TABLETS	1.0X1.0 TABLET BLISTER + 1.0X4.0 TABLETS OF MISOPROSTOL	28/08/2019
3839	NDA/MAL/HD P/8297	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ISONIAZIDE TABLETS	ISONIAZID	100MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1000.0 TABLET CONTAINER	01/07/2001

3840	NDA/MAL/HD P/8302	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	SIMFEN 400MG	IBUPROFEN	400MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER	01/07/2008
3841	NDA/MAL/HD P/8307	NAME AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED	ROYAL PHARMA 2011 LIMITED	METFORMIN 500	METFORMIN	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED (755793)- PLOT 9-12,DEWAN & SONS INDUSTRIAL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	01/07/2008
3842	NDA/MAL/HD P/8309	INDUS PHARMA PVT LTD	HEALTHCARE LTD.	SNOLIP 20MG	ATORVASTATI N	20MG	INDUS PHARMA (PVT) LTD ,- PLOTS NO. 64, 65, 66 & 67, SECTOR -27, KORANGI INDUSTRIAL AREA, KARACHI - 74900	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	01/07/2010

3843	NDA/MAL/HD P/8312	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TRICORT 40	TRIAMCINOLO NE ACETONIDE	40MG/ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL	29/11/2017
3844	NDA/MAL/HD P/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	01/07/2017

3845	NDA/MAL/HD P/8316	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVI R 50 MG/ LAMIVUDINE 300 MG/ TENOFIVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFIVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	"AUROBINDO PHARMA LIMITED-UNIT –VII, SEZ, TSIIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P & 458/P, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT -509 302 TELANGANA STATE, INDIA"	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	30/05/2018
3846	NDA/MAL/HD P/8317	ACULIFE HEALTHCARE	LIFE PHARMA AFRICA LIMITED	MERONIR 500	MEROPENEM	500MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*10ML AMPOULE OF WFI	29/11/2017

3847	NDA/MAL/HD P/8318	ACULIFE HEALTHCARE	LIFE PHARMA AFRICA LIMITED	B-CANE HEAVY	BUPIVACAINE HYDROCHLORI DE BP	5 MG/ML	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0 ML AMPOULE	29/11/2017
3848	NDA/MAL/HD P/8319	KOPRAN LIMITED	TATA UGANDA LIMITED	ERYKO-250	ERYTHROMYCI N 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,1.0X100 0.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER	29/11/2017
3849	NDA/MAL/HD P/8320	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	STACEF 1 GM	CEFTRIAXONE SODIUM	1 GM	NATIONAL HEALTHCARE PVT. LTD.-(WORKS: STERILE BLOCK) CHHATAPIPRA-3, BARA, NEPAL	NEPAL	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	29/11/2017
3850	NDA/MAL/HD P/8321	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROSTAR- 200 CAPSULES	PROGESTERO NE	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,1.0X3.0X 10.0 CAPSULE BLISTER	31/01/2018

3851	NDA/MAL/HD P/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	29/11/2017
3852	NDA/MAL/HD P/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,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER (EMBOSSSED WITH "GOU NOT FOR SALE" & NON- EMBOSSSED)	29/11/2017
3853	NDA/MAL/HD P/8331	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TORSINEX-20	TORSEMIDE	20MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017

3854	NDA/MAL/HD P/8332	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	AZITRO 500 MG	AZITHROMYCI N	500MG	DEVA HOLDING A. S.- ÇERKEZKÖY ORGANİZE SANAYİ BÖLGESİ. KARAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TÜRKİYE	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER	29/11/2017
3855	NDA/MAL/HD P/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	29/11/2017
3856	NDA/MAL/HD P/8337	DEUTSCHE LABS INC	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 120 MG	ARTESUNATE	120 MG	BLISS INDAS LIFESCIENCE P. LTD.-PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*2 ML AMPOULE OF SODIUM BICARBONATE + 1*10 ML VIAL OF 0.9%W/V SODIUM CHLORIDE	29/11/2017

3857	NDA/MAL/HD P/8340	NTICALS LTD.	NORVIK ENTERPRISES 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	29/11/2017
3858	NDA/MAL/HD P/8341	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR +COBICISTAT+ EMTRICISTABI NE+TENOFVI R ALAFENAMIDE	150MG + 150MG + 200MG + 10MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018
3859	NDA/MAL/HD P/8342	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	ANCOLIN 75	PREGABALIN	75MG	ZIM LABORATORIES LIMITED- B-21/22 MIDC AREA KALMESHWAR 441501, DIST NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	30/05/2018

3860	NDA/MAL/HD P/8343	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMO L BP(IMMEDIAT E RELEASE)+ PARACETAMO L BP(EXTENDED RELEASE)	325MG+675M G	TROIKAA PHARMACEUTICALS LTD .- SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,2.0X10.0 TABLET BLISTER	01/07/2014
3861	NDA/MAL/HD P/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	29/11/2017
3862	NDA/MAL/HD P/8348	İLKO İLAÇ SANAYİ VE TICARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5M G	IRBESARTAN + HYDROCHLOR OTHIAZIDE	300MG + 12.5MG	İLKO İLAÇ SANAYİ VE TICARET 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	29/11/2017

3863	NDA/MAL/HD P/8352	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE	DEXKETOPROF EN TROMETAMOL	50MG/2ML	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L-VIA SETTE SANTI 3, 50131 FIRENZE	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 AMPOULE CARTON,1.0X6.0 AMPOULE CARTON,1.0X20. 0 AMPOULE CARTON,1.0X5.0 AMPOULE CARTON	26/11/2019
3864	NDA/MAL/HD P/8353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NURIFER CAPSULES	CARBONYL IRON + FOLIC ACID + VITAMIN B12 + VITAMIN C + ZINC SULFATE MONOHYDRA TE	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.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	29/11/2017
3865	NDA/MAL/HD P/8354	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZORUXA	ZOLEDRONIC ACID	5MG/100ML	GLAND PHARMA LIMITED 143-148-D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE	29/11/2017

3866	NDA/MAL/HD P/8357	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	FRESENIUS PROPOVEN 1%	PROPOFOL	1% W/V	FRESENIUS KABI AUSTRIA GMBH PLANT GRAZ- HAFNERSTRASSE 36 A-8055 GRAZ AUSTRIA FRESENIUS KABI AB PLANT UPPSALA- RAPSGATAN 7S-75174 UPPSALA SWEDEN	AUSTRIA	PARENTERAL ORDINARY OTHER INFUSIONS	1.0X10.0X20.0 ML VIAL,1.0X10.0X5 0.0 ML VIAL,1.0X10.0X1 00.0 ML VIAL	29/11/2017
3867	NDA/MAL/HD P/8359	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ASUNATE 120	ARTESUNATE	120MG	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*10 ML SODIUM CHLORIDE IN GLASS AMPOULE + 1*2 ML SODIUM BICARBONATE IN GLASS AMPOULE	29/11/2017
3868	NDA/MAL/HD P/8393	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NACLOR EYE DROPS 10ML	CHLORAMPHE NICOL	0.5% W/V	NATIONAL HEALTHCARE PVT. LTD.--WORKS: STERILE BLOCK CHHATAPIPIRA-3, BARA, NEPAL	NEPAL	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE	29/11/2017

3869	NDA/MAL/HD P/8394	NTICALS LTD.	NORVIK ENTERPRISES 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,1.0X 3.0X28.0 TABLET BLISTER	29/11/2017
3870	NDA/MAL/HD P/8395	NTICALS LTD.	NORVIK ENTERPRISES LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG DISPERSABLE TABLETS	RIFAMPICIN + ISONIAZID	75MG + 50MG	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,1.0X 3.0X28.0 TABLET BLISTER	29/11/2017
3871	NDA/MAL/HD P/8396	MARIE STOPE INTERNATIONAL	MARIE STOPE 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	29/11/2017

3872	NDA/MAL/HD P/8407	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 20	TORSEMIDE	20MG	INTAS PHARMACEUTICALS LTD -CAMP ROAD, SELAQUI – 248 197 DEHRADUN (UK)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	29/11/2017
3873	NDA/MAL/HD P/8408	NAARI AG	ECHO PHARMACY (U) LIMITED	PENEM-N	MEROPENEM	1000MG	NITIN LIFE SCIENCES LIMITED.-RAMPUR ROAD, PAONTA SAHIB, SIRMOUR- 173025, H.P,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML VIAL	26/11/2019
3874	NDA/MAL/HD P/8409	SUPER MEDIC LTD.	SUPER MEDIC LTD	KPANJEC	PANTOPRAZO LE SODIUM	40MG	SAMRUDH PHARMACEUTICALS PVT LTD- J-174, J-168 & J-168/1, MIDC, TARAPUL, BOISAR, DIST THANE-401506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL	26/11/2019
3875	NDA/MAL/HD P/8411	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	RHEUMAC GEL	DICLOFENAC	1%W/W	LABORATORY & ALLIED LTD-- PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE	29/11/2017

3876	NDA/MAL/HD P/8424	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	HAEMRICH	FERRIC AMMONIUM CITRATE+ FOLIC ACID+PYRIDO XINE HCL + THIAMINE HCL + NICOTINAMID E	50MG + 0.55MG +2.4MG + 1.2MG +11MG /5ML	LINCOLN PARENTERAL LTD- 11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE	01/07/2017
3877	NDA/MAL/HD P/8432	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECLOPHEN	DICLOFENAC SODIUM	100MG	PHARCO PHARMACEUTICALS- KILO 31 ALEXANDRIA-CAIRO DESERT ROAD AMRIYA ALEXANDRIA	EGYPT	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP	01/07/2017
3878	NDA/MAL/HD P/8434	DAWA LIMITED	SUPER MEDIC LTD	DACINAZOLE	MICONAZOLE NITRATE	2%W/W	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	01/07/2009
3879	NDA/MAL/HD P/8443	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	EKON-D TABLETS	CETIRIZINE	10 MG	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0X 12.0 TABLET STRIP	01/07/2001

3880	NDA/MAL/HD P/8468	THEON PHARMACEUTICALS LIMITED	AIVEEN (U) LIMITED	THEOMOX- 500	AMOXICILLIN	500 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	31/01/2018
3881	NDA/MAL/HD P/8477	WOCKHARDT LTD	ABACUS PHARMA (AFRICA) LIMITED	GLARITUS 100IU/ML	INSULIN GLARGINE	100IU/ML	WOCKHARDT LIMITED -- WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY CARTRIDGES	1.0X3.0 ML CARTRIDGE	31/01/2018
3882	NDA/MAL/HD P/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	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE	31/01/2018
3883	NDA/MAL/HD P/8483	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE 2MG	GLIMEPIRIDE	2MG	LEK S.A--U1, PODLIPIE 16, 95- 0140 STRYKOW POLAND	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER	31/01/2018

3884	NDA/MAL/HD P/8487	BAL PHARMA LIMITED	SHREEJI PHARMACEUTICALS LIMITED	EMTRIM FORTE	SULFAMETHO XAZOLE + TRIMETHOPRI M	800MG + 160MG	BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE- PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	31/01/2018
3885	NDA/MAL/HD P/8488	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CEFRAZ 200	CEFIXIME TRIHYDRATE	200MG	ZIM LABORATORIES LIMITED- B-21122, MIDC AREA, KALMESHWAR -441 501, DIST. NAGPUR,INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER	31/01/2018
3886	NDA/MAL/HD P/8490	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9% W/V	ALTHEA PHARMA PVT LTD -- PLOT NO. 374 SHED NO. E.,ALPHA INDUSTRIAL PARK , ATHIYAWAD DABHEL ,NANI DAMAN (U.T) 396210, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE	31/01/2018

3887	NDA/MAL/HD P/8491	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CETROTIDE 0.25MG	CETRORELIX	0.25MG	ABBOTT BIOLOGICALS B.V VEERWEG -12,NL-8121 AA OLST THE NETHERLANDS PIERRE FABRE MEDICAMENT - AQUITAINE PHARM INTERNATIONAL SITE 1	FRANCE	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON	31/01/2018
3888	NDA/MAL/HD P/8493	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25MG	EMTRICITABIN E/TENOFOVIR ALAFENAMIDE	200MG + 25 MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9 ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61,59320 ENNIGERLOH,GERMANY	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE	31/01/2018

3889	NDA/MAL/HD P/8494	KOTRA PHARMA (M) SDN,BHD	ABACUS PHARMA (AFRICA) LIMITED	VAXCEL CEFOBACTAM	CEFOPERAZON E SODIUM+SULB ACTAM SODIUM	500MG + 500MG	KOTRA PHARMA (M) SDN.BHD,-1,2 & 3 JALAN TTC 12 CHENG INDUSTRIAL ESTATE 75250 MELAKA	MALAYSIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	31/01/2018
3890	NDA/MAL/HD P/8497	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM 500	CEFUROXIME AXETIL	500 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD -- UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.- HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	31/01/2018
3891	NDA/MAL/HD P/8502	MEDREICH PLC	LABOREX UGANDA LIMITED	FLEMING	AMOXICILLIN + POTASSIUM CLAVULANATE	400MG/5ML + 57MG/5ML	MEDREICH STERILAB LTD- 12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X70.0 ML BOTTLE	01/07/2009

3892	NDA/MAL/HD P/8504	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LEDVIR	LEDIPASVIR + SOFOSBUVIR	90MG + 400MG	MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X28.0 TABLET BOTTLE	29/11/2017
3893	NDA/MAL/HD P/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	01/07/2017
3894	NDA/MAL/HD P/8565	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SULTOLIN HFA INHALER	SALBUTAMOL SULFATE	100MCG/PUFF	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT- KALIAKOIR GAZIPUR	BANGLADESH	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 DOSE CANNISTER	29/11/2019
3895	NDA/MAL/HD P/8566	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZINOWEL	AZITHROMYCI N	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	29/11/2019

3896	NDA/MAL/HD P/8569	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	TERBINOL®	TERBINAFINE HYDROCHLORI DE	1%W/W	NOBEL İLAÇ SAN. VE TIC. A.Ş- SANCAKLAR, DÜZCE, 81100	TURKEY	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE	26/11/2019
3897	NDA/MAL/HD P/8602	MAVID PHARMACEUTICALS LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	KOFLIN COUGH FLU LINCTUS	CHLOPHENIRA MINE	2MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
3898	NDA/MAL/HD P/8603	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAGNESIUM TRISILICATE SUSPENSION	SODIUM BICARBONATE + LIGHT MAGNESIUM CARBONATE + MAGNESIUM	250 MG + 250 MG + 250 MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE	01/07/2005
3899	NDA/MAL/HD P/8604	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	PYODINE	POVIDINE- IODINE	10 %W/V	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE	01/07/2005
3900	NDA/MAL/HD P/8605	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6 %W/V	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X250.0 ML BOTTLE	01/07/2005

3901	NDA/MAL/HD P/8606	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	DIPHEX COUGH EXPECTORANT	DIPHENHYDRA MINE HYDROCHLORI DE + SODIUM CITRATE + AMMONIUM CHLORIDE	0.014 MG / 5 ML + 0.057 MG / 5 ML + 0.135 MG / 5 ML	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE	01/07/2005
3902	NDA/MAL/HD P/8611	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	SURGICAL SPIRIT	MULT- INGREDIENT	N/A	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE	01/07/2005
3903	NDA/MAL/HD P/8615	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	CALAMINE LOTION	CALAMINE + ZINC OXIDE	0.75 MG / 5 ML + 0.25 MG / 5 ML	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	TOPICAL EXTERNAL SUSPENSIONS	1.0X100.0 ML BOTTLE	01/07/2005
3904	NDA/MAL/HD P/8617	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID'S KEVLON	CHLORHEXIDI NE GLUCONATE 20% + CETRIMIDE	0.015 G / 5 ML +0.15 G / 5 ML	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X125.0 ML BOTTLE	01/07/2007

3905	NDA/MAL/HD P/8637	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	AGYCIN	AZITHROMYCI N DIHYDRATE	40MG/ML	BLISS GVS PHARMA LTD- PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA- INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X1.0X15.0 ML BOTTLE	28/03/2018
3906	NDA/MAL/HD P/8641	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TELI H	TELMISARTAN + HYDROCHLOR OTHIAZIDE	40MG + 12.5MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER	28/03/2018
3907	NDA/MAL/HD P/8643	SWISS PARENTERALS PVT LTD	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	BLISS INDAS LIFESCIENCE P. LTD.-PLOT 73-76, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3	28/03/2018

3908	NDA/MAL/HD P/8644	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	LOOBID SUSPENSION	OFLOXACIN + ORNIDAZOLE	50MG + 125MG / 5ML	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE	28/03/2018
3909	NDA/MAL/HD P/8648	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	UNODEX PLUS	TERBUTALINE SULPHATE + BROMHEXINE HYDROCHLORI DE + GUAIFENESIN	2.5MG + 8MG + 100MG	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	28/03/2018
3910	NDA/MAL/HD P/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,1.0X2.0X 1.0X5.0 TABLET BLISTER	28/03/2018

3911	NDA/MAL/HD P/8653	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	LEFLOXIN 500	LEVOFLOXACIN HEMIHYDRATE	500MG	ZIM LABORATORIES LTD-B- 21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018
3912	NDA/MAL/HD P/8655	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 1000MG	METFORMIN HYDROCHLORIDE	1000MG	MERCK KGAA-- FRANKFURTER STR. 250 64293 DARMSTADT GERMANY MERCK SANTÉ S.A.S.-2 RUE DU PRESOIR VERT 45400 SEMOY FRANCE	GERMANY	ORAL SOLID RETARD TABLETS	1.0X4.0X15.0 TABLET BLISTER, 1.0X6.0X 10.0 TABLET BLISTER	28/03/2018
3913	NDA/MAL/HD P/8658	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 1000MG	METFORMIN HYDROCHLORIDE	1000MG	LEK S.A.-16 PODLIPIE STR. 95- 010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER	28/03/2018
3914	NDA/MAL/HD P/8659	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 500MG	METFORMIN HYDROCHLORIDE	500MG	LEK S.A.-16 PODLIPIE STR. 95- 010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER	01/07/2010

3915	NDA/MAL/HD P/8660	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	VEMLIDY	TENOFOVIR ALAFENAMIDE	25MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018
3916	NDA/MAL/HD P/8661	AUROBINDO PHARMA LTD	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 MAHABOONNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	28/03/2018
3917	NDA/MAL/HD P/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 GLUCONATE	5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	28/03/2018

3918	NDA/MAL/HD P/8684	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMEDA)	GAMA PHARMACEUTICALS (U) LIMITED	MEGAFEN N	IBUPROFEN	100MG/5ML	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)- SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE	26/11/2019
3919	NDA/MAL/HD P/8685	MSN LABORATORIES PRIVATE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	RANCV 500	RANOLAZINE	500 MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	30/05/2018
3920	NDA/MAL/HD P/8689	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD -- H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE	30/05/2018

3921	NDA/MAL/HD P/8690	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ARTESUNATE SUPPOSITORIE S 100MG	ARTESUNATE	100MG	CIPLA LIMITED.,-PLOT NO.D- 7 MIDC INDUSTRIAL AREA, KURKUMBH,DIST:PUNE 413802,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X2.0 BLISTER CARTON	26/09/2018
3922	NDA/MAL/HD P/8691	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 1000	LEVETIRACETA M	1000MG	REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018
3923	NDA/MAL/HD P/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	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL	30/05/2018
3924	NDA/MAL/HD P/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	30/05/2018

3925	NDA/MAL/HD P/8696	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BABY COL	SIMETICONE	40MG/0.6ML	PHARCO PHARMACEUTICALS- KILO 31 ALEXANDRIA-CAIRO DESERT ROAD AMRIYA ALEXANDRIA	EGYPT	ORAL LIQUID ORDINARY EMULSIONS	1.0X1.0X15.0 ML BOTTLE	30/05/2018
3926	NDA/MAL/HD P/8698	ZHUHAI KINHOO PHARMACEUTICAL CO., LTD	SWASTIK PHARMACEUTICAL LTD	KIN-CEF	CEFTRIAXONE SODIUM	1G	ZHUHAI KINHOO PHARMACEUTICAL CO., LTD.- BIO-INDUSTRY ZONE, GOLDEN COAST, ZHUHAI, GUANGDONG, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL	28/08/2019
3927	NDA/MAL/HD P/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	30/05/2018

3928	NDA/MAL/HD P/8743	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ISONIAZID	ISONIAZID	300 MG	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X24.0X28.0 TABLET BLISTER	01/07/2010
3929	NDA/MAL/HD P/8768	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMEDA)	GAMA PHARMACEUTICALS (U) LIMITED	ORDESCA	DESLORATADI NE	5MG	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)- SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019
3930	NDA/MAL/HD P/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	26/11/2019

3931	NDA/MAL/HD P/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	29/05/2019
3932	NDA/MAL/HD P/8780	HETERO DRUGS LTD	AIVEEN (U) LIMITED	STATINOR 10	ROSUVASTATI N CALCIUM	10 MG	HETERO LABS LIMITED UNIT V-TSIIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) -509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/03/2019

3933	NDA/MAL/HD P/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	26/11/2019
3934	NDA/MAL/HD P/8782	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	STATINOR 5	ROSUVASTATI N	5MG	HETERO LABS LIMITED UNIT V-TSIC FORMULATION SEZ, S.NO 439, 440, 441 & 458 POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR (DIST) -509301, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER	07/11/2018
3935	NDA/MAL/HD P/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	26/11/2019
3936	NDA/MAL/HD P/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	26/11/2019

3937	NDA/MAL/HD P/8785	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVCEF SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	ASSOCIATED BIOTECH- KRISHANPURA, P. O GURUMAJRA, BADDI, DIST. SOLAN	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	26/11/2019
3938	NDA/MAL/HD P/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	26/11/2019
3939	NDA/MAL/HD P/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	26/11/2019
3940	NDA/MAL/HD P/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	26/11/2019
3941	NDA/MAL/HD P/8795	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 60/360	ARTEMETHER + LUMEFANTRIN E	60MG + 360MG	AJANTA PHARMA LIMITED-B- 4/5/6 MIDC PAITHAN DISTRICT AURANGABAD MAHARASHTRA STATE INDIA 431 128	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X1.0X6. 0 TABLET BLISTER	26/11/2019

3942	NDA/MAL/HD P/8796	PSYCHOTROPICS INDIA LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	AMITRIP-25	AMITRIPTYLIN E HYDROCHLORI DE	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	26/11/2019
3943	NDA/MAL/HD P/8797	TENTH OF RAMADAN FOR PHARMACEUTICALS INDUSTRIES AND DIAGNOSTICS REAGENTS(RAMEDA)	GAMA PHARMACEUTICALS (U) LIMITED	COLONA	MEBEVERINE HYDROCHLORI DE + SULPIRIDE	100MG + 25MG	TENTH OF RAMADAN FOR PHARMACEUTICAL INDUSTRIES & DIAGNOSTIC REAGENTS (RAMEDA)- SECOND INDUSTRIAL ZONE, PLOT NO.5 SIXTH OF OCTOBER- EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019
3944	NDA/MAL/HD P/8803	SQUARE PHARMACEUTICALS LTD.(CHEMICALS DIVISION)	GAMA PHARMACEUTICALS (U) LIMITED	MOXACLAV 625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG + 125MG	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X6.0 TABLET BLISTER	26/11/2019
3945	NDA/MAL/HD P/8807	SQUARE PHARMACEUTICALS LTD.(CHEMICALS DIVISION)	GAMA PHARMACEUTICALS (U) LIMITED	MOXACLAV FORTE	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	400MG/5ML + 57.5 /5ML	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X35.0 ML BOTTLE	26/11/2019

3946	NDA/MAL/HD P/8808	SQUARE PHARMACEUTICALS LTD.(CHEMICALS DIVISION)	GAMA PHARMACEUTICALS (U) LIMITED	MOXACLAV	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	125MG/5ML + 31.25MG/5ML	SQUARE PHARMACEUTICALS LIMITED.-SQUARE ROAD, SALGARIA, PABNA	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	26/11/2019
3947	NDA/MAL/HD P/8814	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACRIPTEGA	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR 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	30/05/2018
3948	NDA/MAL/HD P/8815	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	ZIMAGRA – ODS 50	SLIDENAFIL CITRATE	50 MG	ZIM LABORATORIES LTD-B- 21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	OTHER SYSTEMIC SPECIAL SOLIDS	1.0X1.0X10.0 SACHET CARTON	30/05/2018

3949	NDA/MAL/HD P/8816	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABPARA	PARACETAMO L	1%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BOTTLE	30/05/2018
3950	NDA/MAL/HD P/8818	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-PF	LEVOFLOXACI N 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	30/05/2018
3951	NDA/MAL/HD P/8819	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D SYRUP	DES Loratadi NE	5MG/5ML	AKUMS DRUGS & PHARMACEUTICALS LTD- PLANT II-PLOT NO.22, SECTOR 6-A, IIE, SIDCUL, RANIPUR,DISTRICT: HARIDWAR 249 403, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE	30/05/2018

3952	NDA/MAL/HD P/8820	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	T-DOL P RAPID	TRAMADOL HYDROCHLORI DE + PARACETAMO L	37.5MG + 325MG	TROIKAA PHARMACEUTICALS LTD .-C- 1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	30/05/2018
3953	NDA/MAL/HD P/8822	ABACUS PARENTERAL DRUGS LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	ALIDO	LIDOCAINE HYDROCHLORI DE	2%W/V	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL	30/05/2018
3954	NDA/MAL/HD P/8823	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	EPCLUSA	SOFOSBUVIR + VELPATASIR	400MG + 100MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018

3955	NDA/MAL/HD P/8824	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEPAFLAM	NEPAFENAC	0.1% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD- N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML VIAL	30/05/2018
3956	NDA/MAL/HD P/8825	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LAXALINK	LACTULOSE	3.35G/5ML	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X150.0 ML BOTTLE	30/05/2018
3957	NDA/MAL/HD P/8826	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR SULFATE AND LAMIVUDINE TABLETS FOR ORAL SUSPENSION 120/60 MG	ABACAVIR SULFATE + LAMIVUDINE	120MG + 60MG	CIPLA LIMITED -PLOT NO A – 33, A – 2 (UNIT – I), MIDC PATALGANGA, DISTRICT RAIGAD, 410 220 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X1.0X60.0 TABLET BOTTLE	30/05/2018

3958	NDA/MAL/HD P/8827	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	SOFGEN	SOFOSBUVIR	400 MG	HETERO LABS LIMITED UNIT- VI --APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR DIST - 509301, TELANGANA, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X28.0 TABLET BOTTLE	30/05/2018
3959	NDA/MAL/HD P/8828	HELSINN BIREX PHARMACEUTICALS	SURGIPHARM (U) LIMITED	ALOXI	PALONOSTER ON HYDROCHLORI DE	50MCG/5ML	PIERRE FABRE MEDICAMENT PRODUCTION - -AQUITAINE PHARM INTERNATIONAL 1, AVENUE DE BEARN 64320 IDRON FRANCE HELSIN BIREX PHARMACEUTICAL LTD --DAMASTOWN MULHUDDART DUBLIN 15 IRELAND	FRANCE	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	27/11/2019

3960	NDA/MAL/HD P/8829	BYANSI SERVICES LTD	AIVEEN (U) LIMITED	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	DOLUTEGRAVI R SODIUM + LAMIVUDINE + TENOFVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	HETERO LABS PRIVATE LIMITED UNIT III-SURVEY NO. 51, PLOT 22-110, INDUSTRIAL DEVELOPMENT AREA (I.D.A) JEEDIMETLA, HYDERABAD-500 055, TELANGANA STATE	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE	20/12/2018
3961	NDA/MAL/HD P/8830	HETERO LABS LTD	AIVEEN (U) LIMITED	IRBIS-HT	IRBESARTAN + HYDROCHLOR OTHIAZIDE	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	26/11/2019

3962	NDA/MAL/HD P/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	26/11/2019
3963	NDA/MAL/HD P/8836	EXP HAR S.A. ZONING INDUSTRIEL DE NIVELLES SUD	SURGIPHARM (U) LIMITED	GASTRICID	FAMOTIDINE BP + MAGNESIUM HYDROXIDE BP + CALCIUM CARBONATE BP	10 MG + 165 MG + 800 MG	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA- 410209,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0 TABLET STRIP	07/11/2018

3964	NDA/MAL/HD P/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	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER	26/11/2019
3965	NDA/MAL/HD P/8839	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTH RICH	FERRIC AMMONIUM CITRATE + FOLIC ACID + VITAMIN B1 HCL + VITAMIN B6 HCL + NICOTINAMID E + 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	26/11/2019
3966	NDA/MAL/HD P/8843	SQUARE PHARMACEUTICALS LTD.	GAMA PHARMACEUTICALS (U) LIMITED	CEFOTIL 500	CEFUROXIME AXETIL	500MG	SQUARE PHARMACEUTICALS LIMITED - DHAKA UNIT- KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER	26/11/2019

3967	NDA/MAL/HD P/8845	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS 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	26/11/2019
3968	NDA/MAL/HD P/8915	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 120 MG	ETORICOXIB	120 MG	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD-- P.O. BOX 69 AMMAN 11591 - AL-RAGEEM SAHAB - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER	25/07/2018
3969	NDA/MAL/HD P/8916	NTICALS LTD.	NORVIK ENTERPRISES 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	25/07/2018

3970	NDA/MAL/HD P/8917	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-2 LLW TABLETS	RIFAMPICIN + ISONIAZID	150MG + 75MG	SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018
3971	NDA/MAL/HD P/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	25/07/2018
3972	NDA/MAL/HD P/8919	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-4 TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMID E + ETHAMBUTOL HYDROCHLORI DE	150MG + 75MG + 400MG + 275MG	SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER	25/07/2018

3973	NDA/MAL/HD P/8920	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERO NE	90MG/APPLIC ATOR	FLEET LABORATORIES LTD -- 94 RICKMANSWORTH ROAD, WATFORD, HERT, WD18 7JJ, UNITED KINGDOM	UNITED KINGDOM	VAGINAL GELS AND SOLS	1.0X1.0X15.0 POUCH CARTON	25/07/2018
3974	NDA/MAL/HD P/8927	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA AND TETANUS VACCINE (ADSORBED REDUCED ANTIGEN(S) CONTENT)	DIPHThERIA TOXOID + TETANUS TOXOID	2 LF (NOT LESS THAN 2 IU) + 8.8 LF (NOT LESS THAN 20 IU)/ 0.5ML	BIOLOGICAL E. LIMITED-- PLOT NO.1 SHAPOORJI PALLONJI BIOTECH PARK PHASE II, KOLTHUR VILLAGE, SHAMEERPET, MANDAL, R.R. DISTRICT, ANDRA PRADESH 500078, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X24.0X1.0X10 .0 DOSE VIAL,1.0X48.0X1. 0 DOSE VIAL	25/07/2018

3975	NDA/MAL/HD P/8928	CODAL-SYNTO LTD	RENE PHARMACY LTD	SYNTOCLAV	AMOXICILLIN TRIHYDRATE + CLAVULANIC ACID	125MG+31.25 MG / 5ML	MEDOCHEMIE LTD - FACTORY B-48 IAPETOU STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	25/07/2018
3976	NDA/MAL/HD P/8933	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	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	25/07/2018
3977	NDA/MAL/HD P/8934	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CYCLO P EYE DROPS	CYCLOPENTOL ATE HYDROCHLORI DE	1.0%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL	25/07/2018

3978	NDA/MAL/HD P/8939	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL PLUS	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	1.0X50.0X1.0X4. 0 TABLET BLISTER	25/07/2018
3979	NDA/MAL/HD P/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	25/07/2018
3980	NDA/MAL/HD P/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	25/07/2018

3981	NDA/MAL/HD P/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), MAHABOBNAGAR, DISTRICT ANDHRA PRADESH 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019
3982	NDA/MAL/HD P/8944	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICALS LTD	GAMOK 625MG	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD- OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER	25/07/2018

3983	NDA/MAL/HD P/8946	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICALS LTD	GAMOK 0.6G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	500MG + 100MG	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD- OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X0.6 G VIAL	25/07/2018
3984	NDA/MAL/HD P/8947	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICALS LTD	GAMOK 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1G + 0.2G	SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD- OSD WORKSHOP OF ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, SECOND MEDICAL ZONE DATONG, SHANXI, CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.2 G VIAL	25/07/2018

3985	NDA/MAL/HD P/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	26/09/2018
3986	NDA/MAL/HD P/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	26/09/2018
3987	NDA/MAL/HD P/9057	GUILIN PHARMACEUTICAL CO.LTD	PHILLIPS PHARMACEUTICALS (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	26/09/2018

3988	NDA/MAL/HD P/9058	GUILIN PHARMACEUTICAL CO.LTD	PHILLIPS PHARMACEUTICALS (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	26/09/2018
3989	NDA/MAL/HD P/9059	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	METRO PHARMACEUTICALS LIMITED	CLASSMOX DROPS	AMOXICILLIN TRIHYDRATE	125MG/ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD --UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.- HARIDWAR, UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X10.0 ML BOTTLE	26/09/2018
3990	NDA/MAL/HD P/9062	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 32	CANDESARTAN CILEXETIL	32 MG	AJANTA PHARMA LIMITED-B- 4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/09/2018

3991	NDA/MAL/HD P/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	26/09/2018
3992	NDA/MAL/HD P/9065	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOFLEX - 250	CEFALEXIN MONOHYDRA TE	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	26/09/2018

3993	NDA/MAL/HD P/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	26/09/2018
3994	NDA/MAL/HD P/9129	MS PHARMA JORDAN CO.LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LOXAMOX	LEVOFLOXACIN HEMIHYDRATES	250MG/50ML	MS PHARMA - JORDAN-PLOT NO. 356, STREET NO. 6, KING ABDULLAH II BIN AL- HUSSEIN INDUSTRIAL ESTATE, SOUTH- WESTERN EDGE SAHAB ZONE.	JORDAN	PARENTERAL ORDINARY INFUSION BAGS	1.0X50.0 ML BAG	28/11/2019
3995	NDA/MAL/HD P/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	26/11/2019

3996	NDA/MAL/HD P/9131	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	TRIDOSIL	AZITHROMYCI N DIHYDRATE	250MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0 TABLET BLISTER	26/11/2019
3997	NDA/MAL/HD P/9132	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	PANTONIX 40	PANTOPRAZO LE	40MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER	26/11/2019
3998	NDA/MAL/HD P/9133	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	SEASONIX	LEVOCETIRIZIN E	2.5MG/5ML	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE	26/11/2019
3999	NDA/MAL/HD P/9134	INCEPTA PHARMACUTICALS LIMITED	ECHO PHARMACY (U) LIMITED	ONASERON	ONDANSETRO N	8MG	INCEPTA PHARMACEUTICALS LTD .-DEWAN IDRIS ROAD, BARA RANGAMATIA, ZIRABO, SAVAR-DHAKA	BANGLADESH	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019

4000	NDA/MAL/HD P/9135	ILKO ILAC SAN,VE.TICARET.A.S,	CORE ACCESS LIMITED	QUELEPT	QUETIAPINE	100MG	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 TABLETS	1.0X3.0X10.0 TABLET BLISTER	26/11/2019
4001	NDA/MAL/HD P/9136	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	I-CEF DPS	CEFIXIME	50MG/5ML	CORONA REMEDIES PVT. LTD- VILLAGE JATOLI, POST OFFICE- OACHGHAT, TEHSIL, SOLAN, DISTT. SOLAN (H.P) 173223	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X100.0 ML BOTTLE	26/11/2019
4002	NDA/MAL/HD P/9137	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	DOM R	RABEPRAZOLE SODIUM + DOMPERIDON E 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	26/11/2019

4003	NDA/MAL/HD P/9138	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	L-THROX 50	LEVOTHYROXI NE 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	26/11/2019
4004	NDA/MAL/HD P/9139	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	L THROX 100	LEVOTHYROXI NE 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	26/11/2019
4005	NDA/MAL/HD P/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	26/11/2019

4006	NDA/MAL/HD P/9141	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	RABZOLE	RABEPRAZOLE SODIUM + LEVOSULPIRID E	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	26/11/2019
4007	NDA/MAL/HD P/9142	THEON PHARMACEUTICALS LIMITED	AIVEEN (U) LIMITED	THEOFIX -50 DS	CEFIXIME TRIHYDRATE	50MG/5ML	THEON PHARMACEUTICALS LTD ,-VILLAGE SAINI MAJRA, TEHSIL, NALAGARH, DIST. SOLAN HP	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SY RUPS/DROPS	1.0X60.0 ML BOTTLE	26/11/2019
4008	NDA/MAL/HD P/9143	MSN LABORATORIES PRIVATE LIMITED,	PLANET PHARMACEUTICALS UGANDA LTD	PALOHALT	PALONOSETR ON HYDROCHLORI DE	0.25MG/5ML	MSN LABORATORIES (PVT) LTD-FORMULATIONS DIVISION-PLOT NO. 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, SANAGAREDDY DISTRICT- 502-325- TELENGANA,	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	26/11/2019

4009	NDA/MAL/HD P/9144	MAXHEAL PHARMACEUTICALS INDIA LIMITED,	ABACUS PHARMA (AFRICA) LIMITED	BUSCOPRIN	HYOSCINE BUTYL BROMIDE	10MG	MAXHEAL PHARMACEUTICALS INDIA LIMITED-J-7, MIDC, TERAPUR INDUSTRIAL AREA, BOISAR 401506 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER	26/11/2019
4010	NDA/MAL/HD P/9145	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SURGIPHARM (U) LIMITED	METALYSE®	TENECTAPLAS E	50MG/10ML	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG.,- BIRKENDORFER STRASSE 65, 88397, BIBERACH AN DER RISS	GERMANY	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL	27/11/2019
4011	NDA/MAL/HD P/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,1.0X24.0 X28.0 TABLET BLISTER,1.0X100 0.0 TABLET BOTTLE	27/11/2019
4012	NDA/MAL/HD P/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),1.0X1.0 X5.0 ML VIAL (2 DOSES)	27/11/2019

4013	NDA/MAL/HD P/9148	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SURGIPHARM (U) LIMITED	TWYNSTA	TELMISARTAN + AMLODIPINE	80MG + 5MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRABE 51-61, 59320 ENNIGERLOH	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	27/11/2019
4014	NDA/MAL/HD P/9149	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SURGIPHARM (U) LIMITED	TWYNSTA	TELMISARTAN + AMLODIPINE	80MG + 10MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRABE 51-61, 59320 ENNIGERLOH	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER	27/11/2019
4015	NDA/MAL/HD P/9150	SERUM INSTITUTE OF INDIA PVT LTD	NORVIK ENTERPRISES LIMITED	PNEUMOCOC CAL POLYSACCHAR IDE CONJUGATE VACCINE	SEROTYPES 1+ 5+ 9V+14+19A+1 9F+23F+7F+6A AND SEROTYPE 6B	2MCG AND 4MCG / 0.5ML	SERUM INSTITUTE OF INDIA PVT LTD .-212/2, HADAPSAR, PUNE- 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X0.5 ML VIAL,1.0X50.0X2. 5 ML VIAL	27/11/2019
4016	NDA/MAL/HD P/9163	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	UMESTATIN- 10	ATORVASTATI N CALCIUM	10 MG	UMEDICA LABORATORIES PVT. LTD-PLOT 221-GIDC, 2ND PHASE, VAPI 396195 GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER	27/11/2019

4017	NDA/MAL/HD P/9165	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	VAGID-100	CLOTRIMAZOL E	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	27/11/2019
4018	NDA/MAL/HD P/9166	HETERO LABS LTD	AIVEEN (U) LIMITED	VIRDAC 30	DACLATASVIR DIHYDROCHLO RIDE	30 MG	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	1.0X28.0 TABLET BOTTLE	27/11/2019

4019	NDA/MAL/HD P/9167	AICA LABORATORIES COMPANY	ECHO PHARMACY (U) LIMITED	ZOLEDRONIC ACID	ZOLEDRONIC ACID MONOHYDRA TE	4 MG	BEU PHARMACY LABORATORIES LIORAD-27A STREET NUMBER 26402 BETWEEN 264 AND 268, SAN AGUSTIN, LA LISA	CUBA	PARENTERAL ORDINARY DRY VIALS	1.0X25.0 VIAL CARTON	27/11/2019
4020	NDA/MAL/HD P/9168	AMRING FARMA S.R.L	ERIS LTD	ZOLEDRONIC ACID	ZOLEDRONIC MONOHYDRA TE	0.8 MG/ML	CLARIS INJECTABLES LIMITED- VASANA-CHACHARWADI, TAL-SANAND-382 213, INDIA	CUBA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL	27/11/2019
4021	NDA/MAL/HD P/9169	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	PROCTICAD	LACTITOL MONOHYDRA TE	10 GM/15ML	CADILA PHARMACEUTICALS LIMITED-1389, TRASAD ROAD, DHOLKA- 382225, DIST: AHMEDAD, GUJARAT STATE, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE,1.0X200. 0 ML BOTTLE	27/11/2019