

NATIONAL DRUG REGISTER OF UGANDA HUMAN MEDICINES - AUGUST 2018

NDA REGISTRATION NUMBER	LICENSE HOLDER	LOCAL TECHNICAL REPRESENTATIVE	NAME OF DRUG	GENERIC NAME OF DRUG	STRENGTH OF DRUG	MANUFACTURER	COUNTRY OF MANUFACTURE	DOSAGE FORM	PACK SIZE
NDA/MAL/HDP/0002	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	X-SONE-N	DEXAMETHASONE+ NEOMYCIN	0.1W/V+ 0.35W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/0004	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	INRAB 20	RABEPRAZOLE SODIUM	20 MG	AUROBINDO PHARMA LTD-UNIT VII (SEZ), PLOT NO.S1, GREEN INDUSTRIAL PARK, POLEPALLY (V) JEDCHERIA (M), MAHABOOB NAGAR	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0005	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	ALPRAZEC 0.25	ALPRAZOLAM	0.25MG	ACME FORMULATION PVT LTD -ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X4.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0006	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIAMIDE	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/0007	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROCIP SYRUP	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0008	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	OMEPRIC	OMEPRAZOLE DELAYED-RELEASE	20MG	ACME FORMULATION PVT LTD.-ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0009	STALLION LABORATORIES PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	DINASOD-100	DICLOFENAC	100MG	ACME FORMULATION PVT LTD,-ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/0012	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	PENGESIC SR	TRAMADOL HYDROCHLORIDE SR	100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0014	HOVID BHD (IPOH SITE)	UNITED HEALTHCARE DISTRIBUTORS LTD	MONTELAIR 10MG TABLET	MONTELUKAST	10MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0016	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CODIMEX-CT TABLETS	CETIRIZINE DIHYDROCHLORIDE	10MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0017	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	HYCORT	HYDROCORTISONE	100MG	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X7.5 ML VIAL
NDA/MAL/HDP/0021	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	QUINS	QUININE DIHYDROCHLORIDE	300MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJJURAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE,1.0X2.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/0022	AGOG PHARMA LTD	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
NDA/MAL/HDP/0024	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPICLOXA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/0030	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	TRADMIN	TRAMADOL HYDROCHLORIDE	50MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/0031	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFTATIME-SB 1.5	CEFTRIAXONE+SULBACTAM	1000MG+500 MG	MANKIND PHARMA LTD--VILLAGE KISHANPURA P.O JAMNI WALA TEHSIL PAONTA SAHIB DISTT SIRMOUR 173025 HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL
NDA/MAL/HDP/0036	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	DOCETAXEL FOR INJECTION	DOCETAXEL	40MG/ML	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL + 1*6ML SOLVENT FOR RECONSTITUTION
NDA/MAL/HDP/0037	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	L-ASPASE	L-ASPARGINASE	1000 I.U	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/0038	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	ARZI 200	DACARBAZINE FOR INJECTION USP	200MG	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/0039	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	NZYTOP	ETOPOSIDE INJECTION USP	100MG	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL
NDA/MAL/HDP/0041	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECIM	CIMETIDINE	200MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0042	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	CISPLATIN	CISPLATIN	1MG/ML	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL
NDA/MAL/HDP/0043	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL JUNIOR	PARACETAMOL	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0044	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	NAPRO-TAX	PACLITAXEL	6MG/ML	NAPROD LIFE SCIENCE PVT LTD-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA.	INDIA	PARENTERAL ORDINARY OTHER VIALS	1.0X1.0X20.0 ML VIAL

NDA/MAL/HDP/0045	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	PARACETAMOL	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0046	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	ABINGEM	GEMCITABINE	1G	NAPROD LIFE SCIENCES PVT LTD-G-17, MIDC, TARAPUR INDUSTRIAL AREA, BIOSAR THANE, MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/0047	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAMIHOPE ET	EFAVIRENZ + LAMIVUDINE + TENOFOVIR 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
NDA/MAL/HDP/0051	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL ACUPHASE	ZUCLOPENTHIXOL ACETATE	50MG/ML	H. LUNDBECK A/S - OTTILIAVEJ 9,2500 VALBY	DENMARK	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/0053	H. LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FLUANXOL DEPOT	FLUPENTIXOL DECANOATE	20MG/ML	H. LUNDBECK A/S ,,-OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN	DENMARK	PARENTERAL RETARD AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/0054	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	FUNGOAL	CLOTRIMAZOLE	1%W/W	KREMOINT PHARMA PVT LTD---B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/0055	H.LUNDBECK A/S	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOPIXOL DEPOT	ZUCLOPENTHIXOL DECANOATE	200MG/ML	H. LUNDBECK A/S ,,-OTTILIAVEJ 9, DK-2500, VALBY-COPENHAGEN	DENMARK	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/0056	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR QPS	DICLOFENAC	4%W/V	TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL SPRAYS WITHOUT GAS	1.0X30.0 ML BOTTLE

NDA/MAL/HDP/0058	NIRMA LIMITED.	SUPER MEDIC LTD	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
NDA/MAL/HDP/0059	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICAL S 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
NDA/MAL/HDP/0060	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 300 IU/0,5 ML (22 µG/0,5 ML)	FOLLITROPIN ALFA	22 µG/0,5 ML	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY PRE- FILLED PENS	1.0X1.0 CARTRIDGE PREFILLED PEN + 5 NEEDLES FOR INJECTION, 1.0X1.0 CARTRIDGE PREFILLED PEN + 8 NEEDLES FOR INJECTION
NDA/MAL/HDP/0063	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0064	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 450 IU/ IE 0,75 ML (33 µG)	FOLLITROPIN ALFA	33µG/ 0.7ML	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY CARTRIDGES	1.0X1.0 CARTRIDGE PREFILLED PEN + 7 NEEDLES FOR INJECTION, 1.0X1.0 CARTRIDGE PREFILLED PEN + 12 NEEDLES FOR INJECTION
NDA/MAL/HDP/0065	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	ALENDRONATE 70MG	ALENDRONATE SODIUM	70MG	HOVID BHD-LOT 56442 7 1/2 MILES JALAN IPOH / CHEMOR 31200 CHEMOR	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/0069	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATIN	10MG	PFIZER LABORATORIES-GODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/0070	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	LIPITOR	ATORVASTATIN	20MG	PFIZER LABORATORIES-GODECKE MOOSWALDALLE 179090 FR ,PFIZER PHARMACEUTICALS LLC, ROAD 689 KM 1.9 VEGA BAJA, PUERTO RICO	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/0071	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SUMAFIX 100	SUMATRIPTAN SUCCINATE	100MG	AUROBINDO PHARMA LIMITED (UNIT III) - AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD-500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER
NDA/MAL/HDP/0072	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	AMTERICIN	AMPHOTERICIN	50MG	VHB MEDI SCIENCES LTD-PLOT 20, 21, 22 & 49,50, 51. INTEGRATED INDUSTRIAL AREA SECTOR 5, RUDRAPUR, UTTARAKHAND - INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 MG VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/0077	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	X-SONE	DEXAMETHASONE SODIUM PHOSPHATE	0.1 % W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/0079	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	REVOKE 72	LEVONORGESTREL	750MCG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA.,MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/0080	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABWATER	STERILE WATER FOR IRRIGATION	N/A	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY OTHER INFUSIONS	1.0X500.0 ML BOTTLE

NDA/MAL/HDP/0081	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	VEXAPEN-625	AMOXICILLIN + CLAVULANATE	500 MG + 125 MG	ANKUR DRUGS AND PHARMA LTD- UNIT I- VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0082	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	CEPOVEX-50	CEFPODOXIME PROXETIL	50MG	ANKUR DRUGS AND PHARMA LTD- UNIT I- VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/0083	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	ZINNIA-F	LEVONORGESTREL & ETHINYLESTRADIOL + FERROUS FUMARATE	150MCG + 30MCG + 75MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA.,MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X28.0 TABLET BLISTER
NDA/MAL/HDP/0084	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	VEXIME CP-625	CEFUROXIME AXETIL + POTASSIUM CLAVULANATE	500MG + 125MG	ANKUR DRUGS AND PHARMA LTD- UNIT I- VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER
NDA/MAL/HDP/0085	HETERO LABS LTD UNIT IX	ABACUS PHARMA (AFRICA) LIMITED	PIOGEN-30	PIOGLITAZONE HYDROCHLORIDE	30MG	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
NDA/MAL/HDP/0086	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	VEXAPEN -228.5	AMOXICILLIN + CLAVULANATE	200 MG + 28.5 MG	ANKUR DRUGS AND PHARMA LTD- UNIT I- VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0087	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	VEXAPEN CP-457	AMOXICILLIN + CLAVULANATE	400 MG + 57 MG	ANKUR DRUGS AND PHARMA LTD- UNIT I- VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/0088	AGOG PHARMA LTD	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
NDA/MAL/HDP/0089	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	CEPOVEX-200	CEFPODOXIME PROXETIL	200MG	ANKUR DRUGS AND PHARMA LTD- UNIT I-VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0097	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	SAFELEVO 750	LEVOFLOXACIN	750MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0098	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	ATOREM 10	ATORVASTATIN	10MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0099	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	CARBAS	CARBAMAZEPINE	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,1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/0101	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTETRA CAPSULES (THANE)	TETRACYCLINE HYDROCHLORIDE	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0102	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	SILMELT 100	SILDENAFIL CITRATE	100MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER
NDA/MAL/HDP/0103	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	ATOREM 20	ATORVASTATIN	20MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0104	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	SILMELT 50	SILDENAFIL CITRATE	50MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X2.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/0106	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	SAFELEVO	LEVOFLOXACIN	500MG/100ML	MARCK BIOSCIENCES -PLOT NO 876, NH NO 8 HARIYALA KHEDA- 387411 GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0107	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ASUNRA	DEFERASIROX	400MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERSTRASSE	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER

NDA/MAL/HDP/0110	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	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
NDA/MAL/HDP/0111	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	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
NDA/MAL/HDP/0112	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 5MG/160MG	AMLODIPINE + VALSARTAN	5 MG + 160 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERSTRASSE,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
NDA/MAL/HDP/0114	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	BREATHEZY 4	MONTELUKAST SODIUM	4MG	MSN LABORATORIES LTD -PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0116	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	BREATHEZY CW 5	MONTELUKAST SODIUM	5MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0117	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 1.5G	CEFUROXIME SODIUM	1.5G	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL
NDA/MAL/HDP/0118	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 750MG	CEFUROXIME SODIUM	750MG	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL
NDA/MAL/HDP/0119	DAWA LIMITED	SUPER MEDIC LTD	DACOLD	CAFFEINE ANHYDROUS+CHLORPHENIRAMINE MALEATE+PARACETAMOL+PSUDOEPHEDRINE	30MG+4MG+400MG+30MG	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0124	DAWA LIMITED	SUPER MEDIC LTD	AMPECIN	AMPICILLIN TRIHYDRATE	125MG/5ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0125	DAWA LIMITED	SUPER MEDIC LTD	SULPHUR OINTMENT	SULPHUR	10%W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE

NDA/MAL/HDP/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
NDA/MAL/HDP/0127	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/0128	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CORYCARDON	IRBESARTAN + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/0129	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	PIOGEN	PIOGLITAZONE HYDROCHLORIDE	15MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0130	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICAL S LTD.	TRIGAN -D	DICYCLOMINE HYDROCHLORIDE	10MG/ML	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/0139	ANGLIAN NUTRITION PRODUCTS COMPANY	SUPER MEDIC LTD	MOXAFORTE	FLUCLOXACILLIN SODIUM + AMOXICILLIN TRIHYDRATE	250MG + 250MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0141	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT SUSPENSION	NYSTATIN	100,000 I.U/ML	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/0142	PFIZER LAB LTD	LABOREX UGANDA LIMITED	PREVENAR 13	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13- VALENT.ADSORBED)	2.2MCG OF POLYSACCHAR IDE 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)
NDA/MAL/HDP/0143	UNIMED INDIA	METAPLUS (U) LIMITED	SPECTRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	UNIMED INDIA.-UNI-MED HOUSE, 86,MAROL COOPORATIVE INDUSTRIAL ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/0145	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 10	MONTELUKAST SODIUM	10MG	MSN LABORATORIES LTD -PLOT NO. 42 INDUSTRIAL ESTARE BOLLARAM MEDAK DISTRIC 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0146	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CEF2 250	CEFUROXIME AXETIL	250MG	MEDREICH LIMITED UNIT-5-PLOT 45 A & B, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0147	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	CEF 2 500	CEFUROXIME AXETIL	500MG	MEDREICH LIMITED UNIT-5-PLOT 45 A & B, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, TELANGANA INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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, BANGLORE- 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
NDA/MAL/HDP/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
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0157	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RECODIN	CODEINE PHOSPHATE + CHLORPHENIRAMIN E MALEATE	10MG + 4MG /5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0158	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 10	MONTELUKAST SODIUM	10MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0161	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0162	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COSYP-D LINCTUS	DEXTROMETHORPH AN HYDROBROMIDE + CHLORPHENAMINE MALEATE	10MG +4MG /5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0163	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PHENAREN	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/0164	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENPRESS	PROPRANOLOL	40MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0166	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOLE	100MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE

NDA/MAL/HDP/0168	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FEBUDAY	FEBUXOSTAT	80MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0169	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ROSUVAX 10	ROSUVASTATIN	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
NDA/MAL/HDP/0174	GLAXO SMITHKLINE LTD	ERIS LTD	FLIXOTIDE 50	FLUTICASONE PROPIONATE	50MCG	GLAXO WELLCOME S.A.-AVENIDA DE EXTREMADURA 3 09400 ARANDA DE DUERO BURGOS SPAIN	SPAIN	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0175	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	XARELTO 10MG	RIVAROXABAN	10MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0177	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	ILET B2	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG+500 MG	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
NDA/MAL/HDP/0178	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAYTIME AND NIGHT TIME CAPSULE	DAY TIME(PARACETAMOL +CAFFEINE ANHYDROUS+PSEUDOEPHEDRINE HCL) AND NIGHT TIME(PARACETAMOL +CHLORPHENIRAMINE MALEATE)	DAY TIME (500MG + 30MG + 30MG) AND NIGHT TIME (500MG +2MG)	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X8.0 CAPSULE BLISTER
NDA/MAL/HDP/0182	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FEBUDAY 40	FEBUXOSTAT	40MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0186	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BBC SPRAY	BENZOCAINE+BENZYLAMINE+CATALKONIUM CHLORIDE	1.5%W/V+0.15%W/V+0.0413%W/V	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL TOPICAL SPRAYS WITHOUT GAS	1.0X25.0 ML BOTTLE
NDA/MAL/HDP/0187	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON TABLET	TRANEXAMIC ACID	500 MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/0191	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S 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/SYR UPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/0192	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICAL S LIMITED	AMOCOMB CREAM	NEOMYCIN + TRIAMCINOLONE ACETONIDE + GRAMICIDIN	0.25GM + 0.1G + 100000IU + 0.025G/100G	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/0193	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S 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
NDA/MAL/HDP/0196	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	DUOVIR	LAMIVUDINE/ZIDOV UDINE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0201	GLAXO SMITH KLINE LTD	ERIS LTD	FLIXOTIDE 125	FLUTICASONE PROPIONATE	125MCG	GLAXO WELLCOME S.A.-AVENIDA DE EXTREMADURA 3 09400 ARANDA DE DUERO BURGOS SPAIN	SPAIN	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0203	GLAXOSMITHLINE LTD	ERIS 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

NDA/MAL/HDP/0204	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	TIVICAY	DOLUTEGRAVIR SODIUM	50MG	GLAXO OPERATIONS UK LTD-WARE SG120DJ UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/0205	MACLEODS PHARMACEUTICALS LTDS LTD	NORVIK ENTERPRISES LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/0207	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	300MG +300MG	MACLEODS PHARMACEUTICALS LTD---PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401,MACLEODS PHARMACEUTICALS LIMITED (BLOCK -N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH -174101,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/0209	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	ABACAVIR SULPHATE ORAL SOLUTION	ABACAVIR SULPHATE	20MG/ML	HETERO LABS LTD, UNIT III-KALYANPUR, CHAKKAN ROAD, BADDI, DIST. SOLAN, HIMACHAL PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X240.0 ML BOTTLE
NDA/MAL/HDP/0210	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICAL S 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
NDA/MAL/HDP/0212	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICAL S 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
NDA/MAL/HDP/0213	AUROBINDO PHARMA LTD (UNIT VI)	PHILLIPS PHARMACEUTICAL S (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
NDA/MAL/HDP/0217	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PALETHET	ARTEMETHER	80MG/ML	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY I M AMPOULES	2.0X3.0X1.0 ML AMPOULE
NDA/MAL/HDP/0221	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/0222	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	AVIR-200	ACYCLOVIR	500MG	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0223	ABACUS PHARMA LTD	ABACUS PARENTERAL DRUGS LIMITED	TOPCID-150	RANITIDINE	150MG	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/0225	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DIKON PLUS	DICLOFENAC/SALICYLATE/MENTHOL/LINSEED	1%W/W+10%W/W+5%W/W+3%W/W	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G CONTAINER
NDA/MAL/HDP/0227	AMOUM PHARMACEUTICALS LTD	BOOTS PHARMACEUTICALS LIMITED	CYRINOL SYRUP	PHOLCODINE+EPHEDRINE HCL +CARBINOXAMINE MALEATE	4MG+7MG+2MG /5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/0228	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-960	TRIMETHOPRIM/SULFAMETHOXAZOLE	160MG/800MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/0230	STRIDES ARCOLAB LTD	DELMAR ENTERPRISES LIMITED	COMBIART	ARTHEMETHER + LUMEFANTRINE	20MG +120MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKA TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X6.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X18.0 TABLET BLISTER,1.0X1.0X24.0 TABLET BLISTER,1.0X24.0 TABLET BLISTER
NDA/MAL/HDP/0233	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	CEFIMED 400	CEFIXIME TRIHYDRATE	400MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/0235	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 500	CEFUROXIME AXETIL	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP

NDA/MAL/HDP/0236	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CLOB	CLOTRIMAZOLE	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
NDA/MAL/HDP/0237	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 280	ARTEMETHER + LUMEFANTRINE	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
NDA/MAL/HDP/0239	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	KOMEFAN 140	ARTEMETHER + LUMEFANTRINE	20 MG+ 120 MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X3.0 TABLET BLISTER
NDA/MAL/HDP/0243	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	LAMOZID	LAMIVUDINE + ZIDOVUDINE	150MG +300MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/0245	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 4	GLIMEPIRIDE	4MG	CADILA HEALTHCARE LTD -KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0248	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	PANTONEX DR-40	PANTOPRAZOLE	40 MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0250	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DIKON	DICLOFENAC	1%W/W	LINCOLN PHARMACEUTICALS LTD -.10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER
NDA/MAL/HDP/0251	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAMIVUDINE/ZIDOVUDINE/NEVIRAPINE	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	150MG + 300MG + 200MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101,MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/0252	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VAST-40	ATORVASTATIN	40MG	LINCOLN PHARMACEUTICALS LTD -.10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0254	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 5	BISOPROLOL HEMIFUMARATE	5MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250-64293 DARMSTADT, WINTHROP PHARMACEUTICALS(PTY) LTD, -315 WATLOO ROAD, WATLOO, PRETORIA, SOUTH AFRICA (FPP SECONDARY PACKAGING, FPP RELEASE/QC TESTING SITE)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0255	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	CAPETERO 150	CAPECITABINE	150MG	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA(M) MAHABOONNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/0256	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	CAPETERO 500	CAPECITABINE	500MG	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA(M) MAHABOONNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X120.0 TABLET CONTAINER
NDA/MAL/HDP/0257	SANOFI AVENTIS FRANCE	LABOREX UGANDA LIMITED	CORDARONE	AMIODARONE HYDROCHLORIDE	200MG	SANOFI WINTHROP INDUSTRIE-LAGRAGE 33565 CARBON BLANC CEDEX FRANCE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0261	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSAGEN -100	LOSARTAN POTASSIUM	100MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0266	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2.400.000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON
NDA/MAL/HDP/0267	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	PENVIR 750	FAMCICLOVIR	750MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0269	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMISTAT-8	ONDANSETRON	8MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0270	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVIN 500MG	LEVOFLOXACIN HEMIHYDRATE	500MG	HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0271	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BETT	TETANUS VACCINE ADSORBED	40 I.U	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHUR (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X20.0X10.0 ML AMPOULE,1.0X24.0X10.0 ML AMPOULE,1.0X5.0 ML VIAL (10 DOSES)
NDA/MAL/HDP/0272	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVIN 250	LEVOFLOXACIN	250MG	HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOON NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0273	MICRO LABS LTD	LABOREX UGANDA LIMITED	PULMOCEF-1500	CEFUROXIME	1500MG	MICRO LABS LTD--NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/0275	GLAXO SMITHLINE LIMITED	ERIS 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
NDA/MAL/HDP/0276	MICRO LABS LTD	LABOREX UGANDA LIMITED	MELANOV 80	GLICLAZIDE	80MG	MICRO LABS LIMITED-PLOT NO. S-155 TO S 159, VERNA INDUSTRIAL ESTATE, PHASE III VERNA GOA-403 722, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0278	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZINE TABLETS B.P 100MG	CHLORPROMAZINE HYDROCHLORIDE	100MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0283	DAWA LIMITED	SUPER MEDIC LTD	AMPICLO-DAWA	AMPICILLIN + CLOXACILLIN	125 MG + 125 MG	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0284	GLAXO SMITHLINE LIMITED	ERIS 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
NDA/MAL/HDP/0287	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	POWER HEAT	METHYL SALICYLATE BP	15000MG	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
NDA/MAL/HDP/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
NDA/MAL/HDP/0289	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	TETRAS	TETRACYCLINE HYDROCHLORIDE	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	1.0X10000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0290	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	NATOA	MEBENDAZOLE	100MG	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/0292	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	NAZANEEN ANTACID SUSPENSION	ALUMINUM HYDROXIDE + MAGNESIUM HYDROXIDE + SIMETHICONE	3.75 G/ 200 ML + 2.724 G/ 200 ML + 0.399 G/ 200 ML	MILAN LABS PVT LTD-63-67 JAWAHAR CO.OP. INDUSTRIAL ESTATE KAMOTHE,NAVI MUMBAI	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0296	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PRAZITEL TABLETS	PRAZIQUANTEL	600MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0298	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	SEFIXI-50 DRY SYRUP	CEFIXIME	50MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X60.0 ML BOTTLE

NDA/MAL/HDP/0300	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	AB-DOX-100	DOXYCYCLINE	100MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0301	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	MONTE - H 10	MONTELUKAST SODIUM	10MG	HETERO LABS LTD. UNIT (V)-S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0302	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CINAMET-400	CIMETIDINE	400MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0303	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0304	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0305	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFAX-250 DRY SYRUP	CEFALEXIN	250MG/5ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/0310	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	LATREN	PENTOXIFYLLINE	0.5MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0311	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	FENTANYL	FENTANYL CITRATE	50MCG/ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE

NDA/MAL/HDP/0312	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA ORAL SOLUTION 125	CLOXACILLIN	125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0314	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	SUXAMETHONIUM CHLORIDE SOLUTION FOR INJECTION	SUXAMETHONIUM CHLORIDE	50MG/ML	MARTINDALE PHARMA -BAMPTON ROAD, HAROLD HILL,ROMFORD,RM3844	UNITED KINGDOM	ORAL LIQUID ORDINARY LIQUIDS	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0316	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	OFLOXACIN-UF	OFLOXACIN	2MG/ML	YURIA-PHARM, LTD. -18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE..	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0317	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	CIPROFLOXACIN-UF	CIPROFLOXACIN	2MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0318	DAWA LIMITED	SUPER MEDIC LTD	SABULIN	SALBUTAMOL	4MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0320	DAWA LIMITED	SUPER MEDIC LTD	DAZOLE	CLOTRIMAZOLE	1%W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/0322	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-5	NEBIVOLOL HCL	5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0326	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	OSTEBON	CALCIUM + COLECALCIFEROL	250MG + 125 IU	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0327	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FLEXILOR 8	LORNOXICAM	8MG	GLENMARK PHARMACEUTICALS LTD - UNIT III-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0328	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FLEXILOR P	LORNOXICAM + PARACETAMOL	4MG + 500MG	GLENMARK PHARMACEUTICALS LTD - UNIT III-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0330	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASBUTOL-4	SALBUTAMOL	4MG	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
NDA/MAL/HDP/0331	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVOKILZ 500	LEVOFLOXACIN	500MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIIC-PLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0332	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ROSUVAX 20	ROSUVASTATIN 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
NDA/MAL/HDP/0333	KOPRAN LIMITED	TATA UGANDA LIMITED	CLAVAMYN-625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG +125MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0335	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	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
NDA/MAL/HDP/0336	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AS-DP TABLETS	DICYCLOMINE HCL + PARACETAMOL	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
NDA/MAL/HDP/0337	IND-SWIFT	TATA UGANDA LIMITED	SWAZI *500	AZITHROMYCIN	500MG	IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0339	IND-SWIFT	TATA UGANDA LIMITED	SWAZI *250	AZITHROMYCIN	250MG	IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/0340	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	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

NDA/MAL/HDP/0341	IND SWIFT LTD	TATA UGANDA LIMITED	TELSWIFT- H 40	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0342	IND SWIFT LTD	TATA UGANDA LIMITED	TELSWIFT- H 80	TELMISARTAN + HYDROCHLOROTHIAZIDE	80MG + 12.5MG	IND SWIFT LTD-GLOBAL BUSINESS UNIT JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI PUNJAB 140507	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/0343	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	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
NDA/MAL/HDP/0348	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA	BETAMETHASONE SODIUM PHOSPHATE	0.1%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/0349	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	CLAXY 1.2 G	COAMOXICLAV	1.2G	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL
NDA/MAL/HDP/0350	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CETIREN	CETIRIZINE HYDROCHLORIDE	10MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0351	MANKIND PHARM LTD	TATA UGANDA LIMITED	DEPREGDINA	LEVONORGESTREL	1.5MG	ACME FORMULATION PVT LTD.-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/0352	HARLEYS UGANDA LIMITED	HARLEYS UGANDA LIMITED	ANLODIN TABLET 5MG	AMLODIPINE	5MG	Y.S.P.INDUSTRIES(M)SBD,BHD-LOT 3,5,& 7,JALANP/7,SECTION13,KAWASAN PERINDUSTRIAN BANDAR BARUBANGI,43000 KAJANG SELANGOR DARUL EHSAN, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0353	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-10	AMLODIPINE BESILATE	10MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X3.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0354	KOPRAN LIMITED	TATA UGANDA LIMITED	LEVOKOP	LEVOFLOXACIN	500MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0355	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	BICO VITA	THIAMINE HCL + RIBOFLAVIN + PYRIDOXINE HCL + NICOTINAMIDE	10MG + 0.1MG + 1MG + 10MG	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0356	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 500	LEVOFLOXACIN HEMIHYDRATE	500MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61 59320 ENNIGERLOH GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER, 1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0358	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	STREPTOCIN	STREPTOMYCIN SULPHATE	1GM	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/0360	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 20MG	ESOMEPRAZOLE	20MG	ASTRAZENECA AB.-GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X4.0X7.0 TABLET BLISTER, 1.0X7.0 TABLET BLISTER, 1.0X14.0 TABLET CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/0363	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	AGYCIN	AZITHROMYCIN	250MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/0364	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	HALDOL	HALOPERIDOL	5MG/ML	JANSSEN PHARMACEUTICAL NV-TURNHOUTSEWEG 30 B-2340 BEERSE BELGIUM	BELGIUM	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/0365	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	SULFRAN- DS	TRIMETHOPRIM/SULFAMETHOXAZOLE	160MG/800MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/0366	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	AGYCIN 500	AZITHROMYCIN	500MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/0367	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	BG-ZOLE -400	ALBENDAZOLE	400MG	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 CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/0368	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	QUININE DI HYDROCHLORIDE INJECTION	QUININE DIHYDROCHLORIDE	300MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0370	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-H	NEBIVOLOL + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0372	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEZYNCET	LEVOCETIRIZINE	5MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER, 5.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0376	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-D	AMLODIPINE + HYDROCHLOROTHIAZIDE	2.5 MG + 12.5 MG	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0377	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	DUINUM	CLOMIFENE	50MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0380	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AVERNOL	CARVEDILOL	6.25NG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0381	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	EFVIRENZA/EMTRICITABINE/TENOFOVIR	EFVIRENZA + EMTRICITABINE + TENOFOVIR	600MG + 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
NDA/MAL/HDP/0382	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGI PHARM (U) LIMITED	KETAMINE FRESENIUS	KETAMINE HYDROCHLORIDE	50MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY VIALS	1.0X10.0X10.0 ML VIAL

NDA/MAL/HDP/0383	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	MANNITOL FRESENIUS	MANNITOL	20%W/V	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BAG
NDA/MAL/HDP/0384	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	PANCURONIUM BROMIDE FRESENIUS	PANCURONIUM BROMIDE	4MG/2ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0385	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASFORMIN	METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/0386	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-80	ENOXAPARIN SODIUM	80MG/ 0.8ML	EMCURE PHARMACEUTICALS LTD -PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/0388	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP,1.0X250.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0390	PT NOVELL PHARMACEUTICAL LABORATORIES	ECHO PHARMACY (U) LIMITED	TUSSIGON	DEXTROMETHORPHAN HBR/PSEUDOEPHEDRINE/CHLORPHENAMINE/GUAIFENESIN	10MG/30MG/2MG/100MG	PT NOVELL PHARMACEUTICAL LABORATORIES -J1 WANAHERANG NO. 35, TLAJUNG UDIK, GUNUNG MUTRI, BORGO 16962 INDONESIA	INDONESIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0393	NAARI AG	ECHO PHARMACY (U) LIMITED	MISO-KARE	MISOPROSTOL	200MCG	JAGSONPAL PHARMACEUTICALS LTD-PLOT NO.14-16,55-57,SECTOR-5,IIE PANT NAGAR,SIDCUL,RUDRAPUR UDHAM SINGH NAGAR,UTTARAKHAND-263153 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/0397	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-LT	AMLODIPINE + LOSARTAN POTASSIUM	2.5 MG + 50 MG	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0400	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBSOL 1.2	MESALAMINE DELAYED RELEASE	1.2GM	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0401	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAR ENTERPRISES LIMITED	L MONTUS	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	FOURRTS (INDIA) LABORATORIES (PVT) LTD-FOURRTS AVENUE, VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/0402	IVEE AQUA EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYSONE OPHTHALMIC SUSPENSION	HYDROCORTISONE ACETATE	1%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC SUSPENSIONS	5.0 ML VIAL
NDA/MAL/HDP/0403	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	SUPRIDOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NEON LABORATORIES LTD --PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/0404	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED WET COUGH & COLD	TRIPLORIDINE HCL/PSEUDOEPHEDRINE/GUAIPHENESIN	1.25MG/30MG/100MG	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X2.0 L JERRYCAN
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0407	NEON LABARATORIES 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
NDA/MAL/HDP/0408	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	ALGIC - P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0409	NEON LABORATORIES LTD	AIVEEN (U) LIMITED	TYDE-S*	CHLORAMPHENICOL SODIUM SUCCINATE	1G/VIAL	NEON LABORATORIES LTD --PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/0410	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	LDNIL 20	ROSUVASTATIN CALCIUM	20MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0411	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	JADELLA SINE	LEVONORGESTREL	150MG	BAYER PHARMA OY-PANSLONTIE 47 20210 TURK	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X3.0X1.0 IMPLANT STRIP
NDA/MAL/HDP/0412	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	LDNIL 5	ROSUVASTATIN CALCIUM	5MG	MSN LABORATORIES LTD- PLOT NO.42, ANRICH INDUSTRIAL ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0413	NEON LABORATORIES LTD	AIVEEN (U) LIMITED	XSPAS	HYOSCINE BUTYLBROMIDE	20MG/ML	NEON LABORATORIES LTD --PLOT NO. 29, 30, 31, 32, 57 & 60, THE PALGHAR TALUKA - CO-OP ESTATE LTD., BOISAR ROAD, PALGHAR, DIST - THANE - 401404, MAHARASHTRA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/0415	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	RELEX	DIPHENHYDRAMINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SODIUM CITRATE+MENTHOL	14.03MG+138 MG+57.03MG +0.90MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0418	ASTRA ZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 5MG/1000	SAXAGLIPTIN + METFORMIN	5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/0419	ASTRAZENECA	MACNAUGHTON LIMITED	KOMBIGLYZE XR 2.5MG/1000MG	SAXAGLIPTIN + METFORMIN	2.5MG + 1000MG	ASTRAZENECA PHARMACEUTICALS LP.-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/0421	MSN LABORATORIES LTD	STAR PHARMACEUTICALS LTD	PREGASAFE 150	PREGABALIN	150MG	MSN LABORATORIES LTD-PLOT NO.42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0422	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PARAFLAM	IBUPROFEN + PARACETAMOL	100MG + 162.5MG /5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/0424	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZINE TABLETS B.P 25MG	CHLORPROMAZINE	25MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0426	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	150MG +300MG + 200MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/0427	MICRO LABS LTD	LABOREX UGANDA LIMITED	AMLOZAAR -H	LOSARTAN POTASSIUM + AMLODIPINE BESILATE + HYDROCHLOROTHIA ZIDE	50MG + 5MG + 12.5MG	MICRO LABS LTD ...-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0428	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROMOX-400	MOXIFLOXACIN	400MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER
NDA/MAL/HDP/0429	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FLEXON MR	IBUPROFEN + PARACETAMOL + CHLORZOXAZONE	400MG + 325MG + 250MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0430	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO ACECLO PLUS	ACECLOFENAC+PAR ACETAMOL	100MG+500MG	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X15.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0432	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAR ENTERPRISES LIMITED	K MAC ORAL SOLUTION	POTASSIUM CITRATE + MAGNESIUM CITRATE	22MG + 7.5MG	FOURRTS INDIA LABORATORIES PVT. LIMITED-VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/0435	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	LIGNOCAINE HCL FRESENIUS	LIGNOCAINE HYDROCHLORIDE	2%W/V	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY VIALS	1.0X10.0X20.0 ML VIAL
NDA/MAL/HDP/0437	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL NEONATAL FRESENIUS	NALOXONE HYDROCHLORIDE	0.02MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0439	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	NALOXONE HCL FRESENIUS 0.4MG/1ML	NALOXONE HYDROCHLORIDE	0.4MG/1ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/0444	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	NEOSTIGMINE METHYLSUIPHATE FRESENIUS	NEOSTIGMINE METHYLSULPHATE	2.5MG\ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/0449	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD GRANULES	CYANOCOBALAMIN	5MCG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY GRANULES	1.0X10.0X5.0 G SACHET
NDA/MAL/HDP/0453	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMINO GUARD LIQUID	AMINO ACIDS + MULTIVITAMINS	MULTI INGREDIENTS	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0456	LEBEN LABORATORIES PVT. LTD	ANDYCO PHARMACY (UGANDA) LTD	METROLEB	METRONIDAZOLE	125MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0458	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 5MG/80MG	AMLODIPINE + VALSARTAN	5 MG + 80 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERSTRASSE,NOVARTIS FARMACEUTICA SA,-BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/0460	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	7.5MG/ML	ARISTO PHARMACEUTICALS PVT. LIMITED- PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEP PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/0461	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	BEXITROL-F HFA 25/125	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG+125MCG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	TOPICAL EXTERNAL METERED-DOSE PRESSURISED AEROSOLS	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0462	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	DECOMIT 50 HFA	BECLOMETHASONE	50MCG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	TOPICAL EXTERNAL METERED-DOSE PRESSURISED AEROSOLS	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0463	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TOPHEN	PHENYTOIN	100MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X100.0 CAPSULE CONTAINER, 1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0465	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	DECOMIT 100 HFA	BECLOMETHASONE DIPROPIONATE	200MCG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	TOPICAL EXTERNAL METERED-DOSE PRESSURISED AEROSOLS	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0466	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	ALPHIN DS	ALBENDAZOLE	400MG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X50.0 TABLET BLISTER, 1.0X50.0X1.0 TABLET BLISTER
NDA/MAL/HDP/0467	DAWA PHARMACEUTICALS LIMITED	SUPER MEDIC LTD	CURAMOL PLUS	PARACETAMOL/CAF FEINE	500MG/60MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	50.0X2.0 TABLET STRIP
NDA/MAL/HDP/0468	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	CEFUXIT 750	CEFUROXIME	750MG	NECTAR LIFESCIENCES LIMITED-VILL. BHATOLIKALAN, ADJOININGJHARMJRI, P.O BAROTIWALA DIST SOLAN H.P 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL + 10ML WFI AMPOULE
NDA/MAL/HDP/0470	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NOVOMIX 30 FLEXPEN	INSULIN ASPART	100I.U/ML	NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD	DENMARK	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN

NDA/MAL/HDP/0471	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICAL S (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
NDA/MAL/HDP/0472	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	BCG VACCINE (FREEZE DRIED)	BCG VACCINE(FREEZE DRIED)	1.33*100000 C.F.U/0.1ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL,1.0X0.5 ML VIAL
NDA/MAL/HDP/0475	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	TINI-500	TINIDAZOLE	500MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X25.0X4.0 TABLET BLISTER
NDA/MAL/HDP/0477	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	VOMISTAT-4	ONDANSETRON	4MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0480	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ, LAMIVUDINE & TENOFIVIR DISOPROXIL FUMERATE 600/300/300 MG	EFAVIRENZ + LAMIVUDINE + TENOFIVIR 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
NDA/MAL/HDP/0481	BIOCON LTD	ABACUS PHARMA (AFRICA) LIMITED	ERYPRO SAFE 4000	RECOMBINANT HUMAN ERYTHROPOETIN ALPHA	4,000 IU/ML	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA- JIGANI LINK ROAD BANGALORE-560 099 INDIA	INDIA	PARENTERAL ORDINARY CARTRIDGES	1.0X1.0 ML CARTRIDGE
NDA/MAL/HDP/0482	LEBEN LABORATORIES PVT. LTD	ANDYCO PHARMACY (UGANDA) LTD	AZILEB-500	AZITHROMYCIN	500MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X20.0X3.0 TABLET BLISTER

NDA/MAL/HDP/0483	FOUNTIL LIFE SCIENCES PVT LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID TABLETS	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE+ MAGNESIUM TRISILICATE + SIMETICONE	200MG + 250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/0484	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	PILPLAN PLUS	ETHINYLESTRADIOL + LEVONORGESTREL / 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
NDA/MAL/HDP/0486	LEBEN LABORATORIES PVT. LTD	ANDYCO PHARMACY (UGANDA) LTD	ADIFLAM-SR	DICLOFENAC SODIUM	100MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0487	BIOCON LTD	ABACUS PHARMA (AFRICA) LIMITED	BASALOG	INSULIN GLARGINE	100IU/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,1.0X3.0 ML PRE- FILLED SYRINGE,1.0X3.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/0490	SISONKE	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
NDA/MAL/HDP/0491	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EYE DROPS	CHLORAMPHENICOL	0.5% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL
NDA/MAL/HDP/0492	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	ZOLFIN	ACECLOFENAC	100MG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X15.0X20.0 TABLET BLISTER

NDA/MAL/HDP/0493	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/0494	BEXIMCO PHARMACEUTICALS LIMITED	KIMSY MEDS LTD	INFORMET 500	METFORMIN HYDROCHLORIDE	500MG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0496	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MYPRODOL	PARACETAMOL + 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
NDA/MAL/HDP/0497	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL DRY SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0498	BEXIMCO PHARMACEUTICALS LTD	KIMSY MEDS LTD	EVO 500	LEVOFLOXACIN	500MG	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0499	NVS KENYA LTD	SURGIPHARM (U) LIMITED	BANEOCIN OINTMENT	BACITRACIN ZINC+NEOMYCIN SULPHATE	250I.U + 5000I.U	MERCK KGAA & CO.-HOSSLGASSE 20 9800 SPITTAL DRAU/ AUSTRIA	AUSTRIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE
NDA/MAL/HDP/0502	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ GARGLE	IODINATED POVIDONE	2%W/V	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0504	NVS KENYA LTD	SURGIPHARM (U) LIMITED	BANEOCIN POWDER	BACITRACIN/NEOMY CIN SULPHATE	250/5000I.U/5 MG	PHARMAZEUTISCHE FABRIK MONTAVIT GES M.B.H-SALZBERGSTRABE 96 6060 ABSAM/ TYROL,AUSTRIA	AUSTRIA	TOPICAL EXTERNAL POWDERS	1.0X10.0 G CONTAINER
NDA/MAL/HDP/0505	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	75MG	MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARAstra	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0506	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	OPTA-ATROPINE EYE DROPS	ATROPINE SULPHATE	1%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL

NDA/MAL/HDP/0507	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 12.5	CARVEDILOL	12.5 MG	FOURRTS (INDIA) LABORATORIES PVT LTD - PALE YELLOW COLOURED CIRCULAR, UNCOATED TABLET WITH A BREAKLINE ON ONE SIDE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0508	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTARGAN	PROMETHAZINE HYDROCHLORIDE	25MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT 57/P, RAJODA-382220, BAVLA AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/0509	FOURRTS (INDIA) LABORATORIES (PVT) LTD	DELMAW ENTERPRISES LIMITED	FILDILOL 25	CARVEDILOL	25MG	FOURRTS (INDIA) LABORATORIES PVT LTD - PALE YELLOW COLOURED CIRCULAR, UNCOATED TABLET WITH A BREAKLINE ON ONE SIDE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0510	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/0511	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	150MG + 200MG + 300MG	STRIDES ARCOLAB LIMITED .-PLOT 9-12, DEWAN & SONS INDUSTRIAL AREA, VEOOR, PALGHAR, MAHARASHTRA 401404	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/0512	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 10	ATORVASTATIN CALCIUM	10MG	FOURRTS (INDIA) LABORATORIES PVT LTD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0514	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFAKIND-500	CEFUROXIME AXETIL	500MG	BAROQUE PHARMACEUTICALS PVT LTD - 192/2&3, SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0515	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 20	ATORVASTATIN	20MG	FOURRTS (INDIA) LABORATORIES PVT LTD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0517	SANOVI 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)

NDA/MAL/HDP/0518	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CYCLOREN	ACICLOVIR	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/0519	MANKIND PHARM LTD	TATA UGANDA LIMITED	CEFAKIND-250	CEFUROXIME AXETIL	250MG	BAROQUE PHARMACEUTICALS PVT LTD - 192/2&3, SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0520	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FILSTAT 40	ATORVASTATIN CALCIUM	40MG	FOURRTS (INDIA) LABORATORIES PVT LTD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0521	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PAN 40	PANTOPRAZOLE SODIUM	40MG	ALKEM LABORATORIES LTD .- VILLAGE THANA BADDI TEHSIL NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0522	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	VAZORTAN 50	LOSARTAN POTASSIUM	50MG	MEDLEY PHARMACEUTICALS LTD -PLOT NO. 18 AND 19, SURVEY NO. 378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM , DAMAN-396 210, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0524	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	XAFEN-60	FEXOFENADINE HYDROCHLORIDE	60MG	MEDREICH LTD (UNIT III) -SURVEY 4/3 AVALAHALI ANJANAPURA POST OFF KARNAKATA BANGALORE 560 062	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0526	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	AMILEB- 25	AMITRIPTYLINE	25MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER
NDA/MAL/HDP/0527	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	XAFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	MEDREICH LTD (UNIT III) -SURVEY 4/3 AVALAHALI ANJANAPURA POST OFF KARNAKATA BANGALORE 560 062	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0528	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLARY 500	CLARITHROMYCIN	500MG	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0529	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MOXIKIND-CV	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG	MEDOPHARM PVT LTD -NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY- 603203 TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML CONTAINER

NDA/MAL/HDP/0530	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	XAFEN-180	FEXOFENADINE HYDROCHLORIDE	180 MG	MEDREICH LTD (UNIT III) -SURVEY 4/3 AVALAHALI ANJANAPURA POST OFF KARNAKATA BANGALORE 560 062	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0532	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	SARTAN-50	LOSARTAN POTASSIUM	50MG	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0533	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 5	MONTELUKAST SODIUM	5MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0534	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MOXIKIND-CV 375	AMOXICILLIN + POTASSIUM CLAVULANATE	250 MG + 125 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/0536	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	MOXIKIND-CV 625	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/0538	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 180	FEXOFENADINE HYDROCHLORIDE	180 MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0539	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	TELKAST 4	MONTELUKAST 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
NDA/MAL/HDP/0540	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	HYDRICORT	HYDROCORTISONE SODIUM SUCCINATE	100MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL
NDA/MAL/HDP/0541	MICRO LABS LTD	LABOREX UGANDA LIMITED	XONADINE 120	FEXOFENADINE HYDROCHLORIDE	120MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0542	DAWA LIMITED	SUPER MEDIC LTD	PHENBITAL	PHENOBARBITAL	30MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0543	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 2	GLIMEPIRIDE	2MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0544	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0548	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD ---P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0549	ABOTT LABORATORIES S.A (PTY) LTD	LABOREX UGANDA LIMITED	HIDRASEC	RACECADOTRIL	100 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESOIR, 28500 VERNOUILLET, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0550	DAWA LIMITED	SUPER MEDIC LTD	DA-ZEPAM	DIAZEPAM	5MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0552	ABOTT LABORATORIES S.A (PTY) LIMITED	LABOREX UGANDA LIMITED	HIDRASEC INFANTS	RACECADOTRIL	10 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESOIR, 28500 VERNOUILLET, FRANCE	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRANU LES	1.0X16.0 SACHET CARTON
NDA/MAL/HDP/0553	BHARAT SERUMS AND VACCINES LTD	GITTOES PHARMACEUTICAL S 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)

NDA/MAL/HDP/0554	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INDOCAP-25	INDOMETHACIN	25 MG	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0555	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CARZEPIN	CARBAMAZEPINE	200MG	HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0556	ABOTT LABORATORIES S.A (PTY) LTD	LABOREX UGANDA LIMITED	HIDRASEC CHILDREN	RACECADOTRIL	30 MG	LABORATOIRES SOPHARTEX-21 RUE DU PRESSEIR, 28500 VERNUILLET, FRANCE	FRANCE	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X30.0 SACHET CARTON
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0558	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGENTA EYE DROPS	GENTAMICIN SULPHATE	0.3% W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/0559	HOVID BHD	MEDICAL ACCESS (UGANDA) LIMITED	DIABETMIN RETARD	METFORMIN HYDROCHLORIDE	850MG	HOVID BHD-LOT 56442,71/2 MILES JALAN IPOH,PERAK,MALAYSIA	MALAYSIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0560	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GLIMERYL 1	GLIMEPIRIDE	1MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .--P.O BOX 69 AMMAM 11591 JORDAN NUZHAT SAHID AL-RAQEEM NEAR PUBLIC HOUSING SECURITY	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0561	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	FALCIMAX-600	QUININE DIHYDROCHLORIDE	600MG/2ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD.-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0562	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM COTRI	CO-TRIMOXAZOLE	240MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	100.0 ML BOTTLE,60.0 ML BOTTLE
NDA/MAL/HDP/0563	IND SWIFT LTD	TATA UGANDA LIMITED	EZO 40	ESOMEPRAZOLE MAGNESIUM	40MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0565	YURIA PHARM LTD	YURIA PHARM EAST AFRICA LIMITED	AMINOCAPROIC ACID-UF	AMINOCARPROIC ACID	5G/100ML	YURIA-PHARM, LTD.-18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE.	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0566	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL SUSPENSION	CEFUROXIME AXETIL	125MG/5ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJURAT,INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0X50.0 ML BOTTLE
NDA/MAL/HDP/0567	KOTRA PHARMA SDN BDN	UNITED HEALTHCARE DISTRIBUTORS LTD	VAXCEL CEFTRIAZONE 500MG	CEFTRIAXONE	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
NDA/MAL/HDP/0568	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FLUOXIREN	FLUOXETINE	20MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0569	KOTRA PHARMA SDN BDN	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/0570	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LIMITED	TETGLOB 250 I.U	HUMAN TETANUS IMMUNOGLOBULIN	250IU	BHARAT SERUMS AND VACCINES LIMITED,- PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X1.0X2.0 ML VIAL (1 DOSE VIAL)
NDA/MAL/HDP/0571	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL KAOPEC	LIGHT KAOLIN + PECTIN (CITRUS)	1G + 20MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/0572	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	AZARGA	BRINZOLAMIDE + TIMOLOL	10MG/ML + 5MG/ML	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL
NDA/MAL/HDP/0573	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL PARACETAMOL-250	PARACETAMOL	250MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0575	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROMOX	MOXIFLOXACIN	400MG/100ML	AHLCON PARENTERALS (INDIA) LTD-SP-917-918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0576	GLAXO SMITH KLINE LTD	ERIS 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

NDA/MAL/HDP/0578	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	XYKAA RAPID	PARACETAMOL	500MG	TROIKAA PHARMACEUTICALS LIMITED-C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0580	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	MULTINGREDIENT	MULTINGREDIENT	KAMPALA PHARMACEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0582	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO SERA	ACECLOFENAC+PARACETAMOL+SERRATI OPEPTIDASE	100MG + 500MG + 15MG	ARISTO PHARMACEUTICALS PVT LTD-VILLAGE: MAKHNUMAJRA P.O. BHUD BADDI DISTRICT: SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0584	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 1	GLIMEPIRIDE+PIOGLITAZONE+METFORMIN HYDROCHLORIDE	1MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0585	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DOMPERON	DOMPERIDONE	1MG/ML	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/0586	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ONSETT	ONDANSETRON	2MG/ML	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE,1.0X5.0X4.0 ML AMPOULE
NDA/MAL/HDP/0587	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CADIGREL	CLOPIDOGREL	75MG	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0588	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROFORT	PREDNISOLONE ACETATE	1%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/0589	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRIGLIMIPREX 2	GLIMEPIRIDE+PIOGLITAZONE+METFORMIN HYDROCHLORIDE	2MG+15MG+500MG	ARISTO PHARMACEUTICALS PVT LTD---VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0590	BHARAT SERUMS AND VACCINES LTD	GITTOES PHARMACEUTICALS LIMITED	ASNA ANTIVENOM C	B.GABONICA/B.ARIE NTANS/ B.NASICORNIS/ DENDROASPIS/ POLYEPIS/D.ANGUSTICEPS/ N.NIVEA /N.NLGRCOLLIS/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
NDA/MAL/HDP/0592	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCHROME	CROMOLYN SODIUM	2%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X10.0 ML CONTAINER
NDA/MAL/HDP/0593	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PANTOP-D	PANTOPRAZOLE SODIUM SESQUIHYDRATE + DOMPERIDONE CAPSULES	20MG+10MG	ARISTO PHARMACEUTICALS PVT LTD .- MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP,1.0X3.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/0594	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROVISC-2ML PFS	HYPROMELLOSE OPHTHALMIC SOLUTION USP	2%W/V	AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC VIALS	1.0X2.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/0595	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ORNOF	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	ARISTO PHARMACEUTICALS PVT LTD--- VILLAGE MAKHNUMAJRA P.O BHUD BADDI DISTRICT SOLAN (H.P) 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0596	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL-H	TELMISARTAN/HYDROCHLOROTHIAZIDE	40MG/12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/0598	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LIPICURE-20	ATORVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0599	MICRO LABS LTD	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
NDA/MAL/HDP/0600	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	CARVEDI-DENK 6.25	CARVEDILOL	6.25MG	ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRASSE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0603	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	GROMIN SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0605	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	CARVEDI-DENK 25	CARVEDIOL	25MG	ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0609	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	CLOPI-DENK 75	CLOPIDOGREL BESYLATE	75MG	ARTESAN PHARMA GMBH & CO. KG - WENDLANDSTRABE 1,29439 LUCHOW,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0610	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	PYLOR KIT	LANSOPRAZOLE DELAYED RELEASE + CLARITHROMYCIN+ TINIDAZOLE	30MG + 250MG + 500MG	LINCOLN PHARMACEUTICALS LTD -.10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)
NDA/MAL/HDP/0611	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	GALCIPRO 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	GALPHA LABORATORIES LIMITED-VILLAGE – THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0614	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0615	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0617	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	SILVEX	SILVER SULFADIAZINE + CHLORHEXIDINE	1%W/W + 0.2%W/W	LINCOLN PHARMACEUTICALS LTD -.10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE

NDA/MAL/HDP/0618	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0619	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D10	GLUCOSE	10%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/0621	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	ALZER	DONEPEZIL HYDROCHLORIDE	10MG	HETERO LABS LTD. UNIT (V)-439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0623	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GELCID	MAGNESIUM SULPHATE	50%W/V	LINCOLN PHARMACEUTICALS LTD--11 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0X10.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/0626	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC-10	AMLODIPINE BESILATE	10MG	KPI INDUSTRIES (1996) LTD-PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0627	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AMOXIKID	AMOXICILLIN TRIHYDRATE	125MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0630	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEO LORIDIN	DESLOTRADINE	5MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/0633	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIPROGIN	CIPROFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/0634	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	TRISOLIV	ANDROGRAPHOLIDE S/TRICHOLINE CITRATE	50MCG+50MG /ML	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/0635	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-AMIN	AMINOPHYLLINE	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0636	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	REVOKE-1.5	LEVONORGESTREL	1.5MG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA.,MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/0637	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	ZUDICORT	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG + 1MG/G	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/0638	ABACUS PARENTERAL DRUGS LIMITED	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
NDA/MAL/HDP/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
NDA/MAL/HDP/0640	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BIODROXIL 250MG/5ML	CEFADROXIL (ANHYDROUS)	250MG/5ML	SANDOZ GMBH-BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE

NDA/MAL/HDP/0641	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GYNAZOLE	CLOTRIMAZOLE	2%W/W	LINCOLN PHARMACEUTICALS LTD .-10,12,13 TRIMUL ESTATE, NEAR KHATRAJ CHOKADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE
NDA/MAL/HDP/0642	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	BIODROXIL 125MG/5ML	CEFADROXIL (ANHYDROUS)	125MG/5ML	SANDOZ GMBH-BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/0647	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BIODROXIL 1000MG TABLETS	CEFADROXIL (ANHYDROUS)	1000MG	SANDOZ GMBH-BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/0651	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BIODROXIL 500MG	CEFADROXIL (ANHYDROUS)	500MG	SANDOZ GMBH-BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0654	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG/500MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/0657	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN / METFORMIN	50MG / 850MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0658	NVS KENYA LTD	SURGIPHARM (U) LIMITED	GALVUS MET	VILDAGLIPTIN/ METFORMIN	50MG/1000MG	NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X6.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0662	PHARMAVET LTD	DELMAR ENTERPRISES LIMITED	RECTIN 100	INDOMETHACIN	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	1.0X2.0X5.0 SUPPOSITORY STRIP

NDA/MAL/HDP/0663	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GLYCERIN	GLYCERIN	1G	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 STRIP
NDA/MAL/HDP/0665	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	IRBIS-H 150	IRBESARTAN	150MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0666	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	IRBIS-H 300	IRBESARTAN	300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0667	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXEL MICONAZOLE	MICONAZOLE NITRATE	2%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/0668	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TELI 40	TELMISARTAN	40MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0669	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXEL FUNGICORT CREAM	MICONAZOLE NITRATE + HYDROCORTISONE	2% W/W + 1% W/W	KOTRA PHARMA SDN BDN-1, 2, &3, JALANTTC12 CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/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,1.0X5.0X4.0 CAPSULE BLISTER
NDA/MAL/HDP/0671	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/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

NDA/MAL/HDP/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,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0675	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL METRONIDAZOLE 400	METRONIDAZOLE	400MG	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0676	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ONSETT 4	ONDANSETRON	4MG	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0678	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL HYDROCORTISONE CREAM	HYDROCORTISONE	1%W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0688	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	HBB	HYOSCINE BUTYLBROMIDE	10MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/0690	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HEALTHEASE CREAM	BECLOMETHASONE DIPROPIONATE + PHENYLEPHRINE HCL + LIGNOCAINE HCL + CHLOROCRESOL	0.025%W/W + 0.1%W/W + 2.5%W/W + 0.1%W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE
NDA/MAL/HDP/0691	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-20	OLMESARTAN MEDOXOMIL	20 MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0692	DAWA LIMITED	SUPER MEDIC LTD	DAWACLOX -250	CLOXACILLIN SODIUM	250MG	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/0693	DAWA LIMITED	SUPER MEDIC LTD	MOXACIL -250	AMOXICILLIN 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
NDA/MAL/HDP/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
NDA/MAL/HDP/0696	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	RITONAVIR	RITONAVIR	100MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/0700	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	VAXIRAB N	INACTIVATED RABIES VIRUS(PITMAN MOORE STRAIN)	>2.5 I.U	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL + 1ML AMPOULE OF WFI(1 DOSE VIAL)
NDA/MAL/HDP/0702	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	SEPTOCIN	STREPTOMYCIN SULPHATE	1GM	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL

NDA/MAL/HDP/0703	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	DICLODAY GEL	DICLOFENAC DIETHYLAMINE+ LINSEED OIL+ METHYL SALICYLATE +MENTHOL	11.6MG + 30MG + 100MG + 50MG	KREMOINT PHARMA PVT LTD---B-8 ADDITIONAL AMBERNATH MIDC OPP. ANAND NAGAR POLICE CHECK POST AMBERNATH (E) DIST THANE 421 506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/0704	HETERO LABS LTD UNIT IX	ABACUS PHARMA (AFRICA) LIMITED	M-FLOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA,HETERO LABS LTD-UNIT II & III BADDI THE NALAGARH DIST SOLAN H.P	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 10.0X1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/0705	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ACICLOVIR	ACICLOVIR	5%W/W	LINCOLN PHARMACEUTICAL LIMITED- TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE
NDA/MAL/HDP/0706	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 5	ROSUVASTATIN	5MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0707	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0710	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 20	ROSUVASTATIN	20MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0712	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/0713	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 20	PANTOPRAZOLE SODIUM SESQUIHYDRATE	20MG	ADVANCE PHARMA GMBH...WALLENRODER STR.12-14, 13435 BERLIN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/0715	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	PANTO-DENK 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	ADVANCE PHARMA GMBH...WALLENRODER STR.12-14, 13435 BERLIN	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/0716	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-1	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	1MG + 500MG	LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0718	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	GLYMET-2	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG + 500MG	LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0719	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 4000	RECOMBINANT HUMAN ERYTHROPOIETIN	4000 I.U	WOCKHARDT LIMITED --WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.4 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/0720	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 400 DROPS	COLECALCIFEROL	400 I.U/ML	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/0721	MISSION PHARMA	METRO PHARMACEUTICALS LIMITED	ARH-A	ARTEMETHER	80MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X2.0X3.0X1.0 ML AMPOULE,1.0X1.0X6.0 ML AMPOULE
NDA/MAL/HDP/0722	FDC LTD	AIVEEN (U) LIMITED	IOTIM 0.5%	TIMOLOL MALEATE	0.5% W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/0724	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	NIZORAL	KETOCONAZOLE	200MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0725	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	SPASMOTROY 40	DROTAVERINE HYDROCHLORIDE	40MG	TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0726	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	T DOL RAPID	TRAMADOL HYDROCHLORIDE	50MG	TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X10.0 TABLET STRIP

NDA/MAL/HDP/0727	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	STOMACH FIT SYRUP	BISMUTH AMMONIUM CITRATE+BELLADON A DRY EXTRACT+THYMOL+ MENTHOL	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
NDA/MAL/HDP/0733	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYNAC	ACECLOFENAC	100MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0734	ANHIU	MAISHA MEDICAL SUPPLIES LIMITED	OMMED -20	OMEPRAZOLE	20MG	MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/0736	MEDOCHEMIE LTD	BOOTS PHARMACEUTICAL S LIMITED	MABRON 50	TRAMADOL HYDROCHLORIDE	50MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0737	SANOFI AVENTIS	LABOREX UGANDA LIMITED	TAXOTERE 80MG	DOCETAXEL TRIHYDRATE	80MG/4ML	SANOFI-AVENTIS DEUTSCHLAND GMBH - INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X4.0 ML VIAL
NDA/MAL/HDP/0738	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CIPRIND-500	CIPROFLOXACIN	500MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X200.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/0739	SANOFI AVENTIS	LABOREX UGANDA LIMITED	TAXOTERE 20MG	DOCETAXEL TRIHYDRATE	20MG/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH- INDUSTRIEPARK HOESCHST,BRUNINGSTRASSEN BUIDING,H65065926, FRANKFURT AM MAIN	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0 ML VIAL

NDA/MAL/HDP/0740	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	COTRIM	CO-TRIMOXAZOLE	960MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X17.0X6.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0741	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDOCIPRIN	CIPROFLOXACIN	500MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0742	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	BROT	METFORMIN HYDROCHLORIDE	500MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0743	INTRACIN PHARMACEUTICAL PVT LTD	VEERAM HEALTHCARE (U) LIMITED	TRY-PZ	PIPERACILLIN+TAZO BACTAM	5MG+500MG	INTRACIN PHARMACEUTICAL PVT LTD-C-1, B-53, G.I.D.C ESTATE, NADIAD – 387001 GUJARAT, INDIA.,	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL
NDA/MAL/HDP/0746	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DTS-Z KIT	TABLET-ZINC, SACHET-NACL + KCL + TRISODIUM CITRATE + ANHYDROUS GLUCOSE	TABLET-54.89MG , SACHET 1.3G + 0.75G + 1.45G + 6.75G	COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X4.0X10.3 G SACHET + 1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0747	MEDIPHARM INDUSTRIES LTD	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, BWEYOGGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY OTHER SOLID SPECIAL FORMS	1.0X20.8 G SACHET + 60 ML BOTTLE
NDA/MAL/HDP/0748	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 15MG	RIVAROXABAN	15MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X14.0 TABLET BLISTER

NDA/MAL/HDP/0749	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEROGRAM 1000	MEROPENEM	1000MG	AURONEXT PHARMA PVT LTD.-A- 1128 RIICO INDUSTRIAL AREA, PHASE III, DISTALWAR, BHIWADI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/0750	BAYER PHARMA	SURGIPHARM (U) LIMITED	XARELTO 20MG	RIVAROXABAN	20MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/0751	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN	ACECLOFENAC	100MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0752	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	NUCLEO C.M.P FORTE	CYTIDINE + URIDINE	10MG + 6MG	FERRER INTERNACIONAL S.A --GRAN VIA CARLOS III 94 08028 BARCELONA	SPAIN	PARENTERAL ORDINARY DRY PRE-FILLED PENS	1.0X3.0 ML AMPOULE + 1 *2ML CLEAR GLASS AMPOULES FOR SOLVENT
NDA/MAL/HDP/0753	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MEROGRAM 500	MEROPENEM	500MG	AURONEXT PHARMA PRIVATE LIMITED,-A-1128, RIICO INDUSTRIAL AREA, PHASE-III,BHIWADI-301019, DISTRICT- ALWAR (RAJASTHAN), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/0754	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	TORAS DENK 10	TORASEMIDE	10MG	DENK PHARMA GMBH &CO.KG--PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0755	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	T- DOL	TRAMADOL HYDROCHLORIDE	50MG/ML	TROIKAA PHARMACEUTICALS LTD-THOL VILLAGE, DIST. MEHSANA- 382728, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/0756	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 100	TOLPERISONE	100MG	CADILA HEALTHCARE LTD-PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0757	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TOLFREE 150	TOLPERISONE	150MG	CADILA HEALTHCARE LTD-PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0759	MICRO LABS LTD	LABOREX UGANDA LIMITED	COTRIMOXAZOLE	COTRIMOXAZOLE	960MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/0760	STRIDES	SUPER PHARMACEUTICALS LIMITED	CEFAX	CEFTRIAXONE	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL

NDA/MAL/HDP/0761	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	BENZILIN	BENZATHINE BENZYL PENICILLIN	2.4MEGA/VIAL	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X2.4 MU VIAL
NDA/MAL/HDP/0764	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 5	AMLODIPINE	5MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/0765	PHARM ACCESS AFRICA LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	LEVOPLANT	LEVONORGESTREL	75MG	SHANGHAI DAHUA PHARMACEUTICAL CO. LTD-CHANG ZENG FARM, CHONGMING COUNTY, SHANGHAI	CHINA	PARENTERAL RETARD IMPLANTS	1.0X10.0X2.0 ROD IMPLANT
NDA/MAL/HDP/0768	FDC LTD	AIVEEN (U) LIMITED	PYRIMON EYE DROP	DEXAMETHASONE/C FLORAMPHENICOL	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
NDA/MAL/HDP/0769	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	AMPIL-1000	AMPICILLIN	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON
NDA/MAL/HDP/0770	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	AMPIL-500	AMPICILLIN	500MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL
NDA/MAL/HDP/0772	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 150	PREGABALIN	150MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0773	HEBEI NOVASCON TRADING CO. LTD	RENE PHARMACY LTD	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	ANHUI CHENGSHI MEDICINE MANUFACTURE CO. LTD-INDUSTRIAL AREA, BENGBU CITY, ANHUI PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE
NDA/MAL/HDP/0775	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIGABA - 75	PREGABALIN	75MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0776	FREDUN PHARMACEUTICALS LTD	PLANET PHARMACEUTICALS UGANDA LTD	FREMOL TABLETS	PARACETAMOL TABLETS	500MG	FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIAN INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0.0 TABLET CONTAINER

NDA/MAL/HDP/0779	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	VITAFIL Z	CHROMIUM + ZINC + THIAMINE + RIBOFLAVINE + PYRIDOXINE + FOLIC ACID + NICOTINAMIDE + ASCORBIC ACID	1.667MG + 42MG + 12MG + 11.5MG + 3.6MG + 1.2MG + 52.5MG + 165MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPURUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0780	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA TABLETS	ATORVASTATIN	10MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X1.0X7.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0784	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HEMOSAN	FERROUS FUMERATE	300MG	COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0787	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV DRY SYRUP	AMOXICILLIN + CLAVULANIC ACID	250 MG + 62.5 MG/5 ML	MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0792	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AS-V	PHENOXYMETHYL PENICILLIN	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	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/0794	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	AMYGDEX	TOBRAMYCIN/DEXA METHASONE	3MG+1MG/ML	REMINGTON PHARMACEUTICALS (PVT) LTD- 18KM, MULTAN ROAD, LAHORE 53800, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/0795	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-250	PHENOXYMETHYL PENICILLIN POTASSIUM	250MG	MILAN LABORATORIES (INDIA) PVT LTD .- PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0796	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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

NDA/MAL/HDP/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
NDA/MAL/HDP/0798	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLO-H 10	AMLODIPINE BESILATE	10MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0802	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE HCT 5MG/160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/0806	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	SQUARE ZINC	ZINC SULPHATE	20MG	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0808	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	ISOFLURANE	ISOFLURANE	250ML	PIRAMAL ENTERPRISES LTD, INDIA-DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0809	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	PARAPAED	PARACETAMOL	120MG/5ML	PINEWOOD LABORATORIES LTD-BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	IRELAND	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0811	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	DOLOWIN -SR	ACECLOFENAC	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/0814	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	CANCYT	CYTARABINE	100MG/5ML	NAPROD LIFE SCIENCES (PVT) LIMITED-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL
NDA/MAL/HDP/0815	NAPROD LIFE SCIENCES PVT LTD	AIVEEN (U) LTD - WILSON ROAD	ABINGEM-200	GEMCITABINE	200MG	NAPROD LIFE SCIENCES PVT LTD-G-17, MIDC, TARAPUR INDUSTRIAL AREA, BIOSAR THANE, MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X200.0 MG VIAL

NDA/MAL/HDP/0816	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 2	GLIMEPIRIDE	2MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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, 1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0821	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	GLIMEPIRIDE DENK 3	GLIMEPIRIDE	3MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0822	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXCIN-500	CLOXACILLIN SODIUM FOR INJECTION	500MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 G VIAL
NDA/MAL/HDP/0823	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TRAP TABLETS	TRAMADOL HCL + PARACETAMOL	37.5MG+325 MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0827	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	CLANOXY 1.2	AMOXICILLIN + CLAVULANATE	1000 MG + 200 MG	GALPHA LABORATORIES LTD-AT: ALKEM LABORATORIES LTD PLOT 167/2 MAHATMA UDYOG NAGAR AMALIYA DAMAN 396210	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL 1*20ML VIAL OF WFI
NDA/MAL/HDP/0830	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 25 MCG	LEVOTHYROXINE SODIUM	25 MCG	MERCK KGAA - -FRANKFRUTER STRASSE 250, D-64293,DARMSTADT- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BLISTER, 1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/0832	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 100MCG	LEVOTHYROXINE	100MCG	MERCK KGAA - -FRANKFRUTER STRASSE 250, D-64293,DARMSTADT- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER, 1.0X1.0X30.0 TABLET BLISTER
NDA/MAL/HDP/0834	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VOMI-6	DOXYLAMINE SUCCINATE & PYRIDOXINE HYDROCHLORIDE	10MG + 10MG	LINCOLN PHARMACEUTICALS LIMITED.- TRIMUL ESTATE NEAR KHATRAJ CHOKADI KHATRAJ 382721 GHANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/0836	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CALBONE-500	CALCIUM CARBONATE + COLECALCIFEROL	1250MG + 250 I.U	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0841	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ETHOMID	ETHIONAMIDE	250MG	MACLEODS PHARMACEUTICALS LTD.-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/0842	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	SAC	SECNIDAZOLE	1000MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/0843	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	COXERIN	CYCLOSERINE	250MG	MACLEODS PHARMACEUTICALS LTD.-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/0845	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	OLEVO-500	LEVOFLOXACIN	500 MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0846	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MOXIMAC	MOXIFLOXACIN	400MG	MACLEODS PHARMACEUTICALS LTD--PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/0848	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MACROZIDE 500	PYRAZINAMIDE	500MG	MACLEODS PHARMACEUTICALS LTD---PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER

NDA/MAL/HDP/0849	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	MONOPAS-4G	PARA-AMINOSALICYLATE SODIUM	60%W/W	MACLEODS PHARMACEUTICALS LTD---PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401	INDIA	ORAL SOLID RETARD GRANULES	1.0X30.0X4.0 G SACHET
NDA/MAL/HDP/0850	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LCT KIT	LANSOPRAZOLE + CLARITHROMYCIN + TINIDAZOLE	30MG + 250MG + 500MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)
NDA/MAL/HDP/0852	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	KAPOCIN-1G	CAPREOMYCIN	1000MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON
NDA/MAL/HDP/0854	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-50	BECLOMETASONE	50MCG PER ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0855	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LAZINE	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0856	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	KANAMAC-1000	KANAMYCIN	1G	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1000.0 MG VIAL
NDA/MAL/HDP/0857	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID-V6 VAGINAL TABLETS	CLOTRIMAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP
NDA/MAL/HDP/0858	ASTRAZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	5MG	ASTRAZENECA AB,-GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/0860	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	FLOXSAFE 400	MOXIFLOXACIN HYDROCHLORIDE	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

NDA/MAL/HDP/0861	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	PROZINE	PROMETHAZINE	25MG/ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	2.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/0862	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR- 200	BECLOMETASONE	200MCG PER ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA, BADDI-NALAGARH ROAD TEHSIL BADDI, DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/0864	HETERO LABS LTD UNIT IX	ABACUS PHARMA (AFRICA) LIMITED	PANTIN-40	PANTOPRAZOLE SODIUM	40 MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0866	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	LIZOLID	LINEZOLID	2MG/ML	AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X300.0 ML BOTTLE, 1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0867	HETERO LABS LTD UNIT IX	ABACUS PHARMA (AFRICA) LIMITED	PANTIN-20	PANTOPRAZOLE SODIUM	20MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0868	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	VARMIKA-500	AMIKACIN	500MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13, M.N DESAI PETROL PUMP, SARKHEJ-BAVLA ROAD, VILLAGE CHANGODAR DIST AHMEDABAD 382-213, GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/0869	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	LARTRM	ARTEMETHER	80MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13, M.N DESAI PETROL PUMP, SARKHEJ-BAVLA ROAD, VILLAGE CHANGODAR DIST AHMEDABAD 382-213, GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE
NDA/MAL/HDP/0870	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TROY-K	PHYTOMENADIONE	10MG/ML	TROIKAA PHARMACEUTICALS LIMITED-THOL, DIST. MEHSANA-382728, GUJARAT, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE

NDA/MAL/HDP/0871	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	DEXA	DEXAMETHASONE 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
NDA/MAL/HDP/0873	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0879	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	TRIBES FORTE FILM COATED TABLETS	THIAMINE + PYRIDOXINE + CYANOCOBALAMIN	200MG + 50MG +1000MCG	COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0882	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/2.5MG	METFORMIN + GLIBENCLAMIDE	500MG + 2.5MG	MERCK SANTE S.A.S-CENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER
NDA/MAL/HDP/0883	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOVANCE 500MG/5MG	METFORMIN + GLIBENCLAMIDE	500MG + 5MG	MERCK SANTE S.A.S-CENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOR VERT 45400 SEMOY	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER,1.0X4.0X15.0 TABLET BLISTER
NDA/MAL/HDP/0889	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DNS	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5% W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/0894	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/0895	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH	SODIUM HYALURONATE	10MG/1ML	VIRCHOW BIOTECH PVT, LTD-SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X2.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/0897	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	DEBRIDACE	PAPAIN + UREA	521700UNITS+ 100MG/G	VIRCHOW BIOTECH PVT, -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/0898	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSAGEN 50	LOSARTAN POTASSIUM	50MG	HETERO LABS LTD (UNIT-V)-SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0899	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	VIRIAXONE	CEFTRIAZONE	1G	INJECTCARE PARENTERALS PVT. LTD.- PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML VIAL WFI
NDA/MAL/HDP/0900	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	LAPSONE	DAPSONE	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,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/0903	GLAXO WELLCOME(KENYA) LTD	ERIS LTD	ZANTAC	RANITIDINE	50MG/2ML	GLAXO SMITHKLINE MANUFACTURING S.P.A .-STARDA PROVINCIALE ASOLANA 90, 43056 SAN POLO DI TORRILE (PARMA)	ITALY	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/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

NDA/MAL/HDP/0905	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECPOD	CEFPODOXIME PROXETIL	200MG	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/0906	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	IONSIL	SILVER NITRATE	0.2%W/W	VIRCHOW BIOTECH PVT, -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/0907	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	CEFUAXIT	CEFUROXIME AXETIL	250MG	NECTAR LIFE SCIENCES LTD--UNIT VI BHATOLIKALAN DIST SOLAN H.P	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/0908	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYOPT PLUS	SODIUM HYALURONATE	11.9MG/0.85 ML	VIRCHOW BIOTECH PVT, -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT TELANGANA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.85 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/0909	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	FIXINECT	CEFIXIME	100MG	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/0911	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HEALACE	RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR -B	100MCG/G	VIRCHOW BIOTECH PVT, LTD-SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DIST	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/0914	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	OSTEOTIDE	TERIPARATIDE [RECOMBINANT HUMAN PARATHYROID HORMONE (1-34)] INJECTION	250MCG/ML	VIRCHOW BIOTECH PVT LTD -SURVEY NO. 172, PART GAGILLAPUR, QUTHBULLAPUR, R.R, DISTRICT ANDHRA PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X3.0 ML VIAL
NDA/MAL/HDP/0915	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXICILLIN + CLAVULANIC ACID	875 MG + 125 MG	SANDOZ GMBH-BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X2.0 TABLET STRIP
NDA/MAL/HDP/0920	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	BUPITROY HEAVY	BUPIVACAINE HYDROCHLORIDE	5MG/ML	TROIKAA PHARMACEUTICALS LTD.-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0X4.0 ML VIAL

NDA/MAL/HDP/0926	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-375	AMOXICILLIN +CLAVULANATE POTASSIUM	250MG + 125MG	MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET STRIP,1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/0928	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	INSTACLOP 75	CLOPIDOGREL	75MG	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/0929	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DUOQUIN	DIHYDROARTEMISIN IN + PIPERAQUINE PHOSPHATE	40MG +320MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X1.0X9.0 TABLET BLISTER,10.0X1.0X8.0 TABLET BLISTER
NDA/MAL/HDP/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,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X1.0 ML AMPOULE
NDA/MAL/HDP/0937	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VALAZYD H 92.5	VALSARTAN/HYDRO CHLOROTHIAZIDE	80MG/12.5MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0938	FEROZSONS LABORATORIES LTD	TOP UNIVERSAL MEDICARE LIMITED	ESOMEGA 20MG	ESOMEPRAZOLE AS MAGNESIUM TRIHYDRATE PELLETS	20MG	FEROZSONS LABORATORIES LTD-AMANGARH-NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/0939	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ARH	ALPHA -BETA ARTEETHER	150MG /2ML	SAKAR HEALTHCARE PVT. LTD-PLOT 10/13 SAKHEJ-BAVLA ROAD, AHMEDABAD,GUJRAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE
NDA/MAL/HDP/0940	FEROZSONS LABORATORIES LTD	TOP UNIVERSAL MEDICARE LIMITED	ESOMEGA 40MG	ESOMEPRAZOLE AS MAGNESIUM TRIHYDRATE PELLETS	40MG	FEROZSONS LABORATORIES LTD-AMANGARH-NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/0941	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA	AZITHROMYCIN	200MG/5ML	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/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,GUJRAT,INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X3.0 ML AMPOULE
NDA/MAL/HDP/0943	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	STREPTOMYCIN INJECTION BP	STREPTOMYCIN	1G	MACLEODS PHARMACEUTICALS LTD--PLOT 25-27 SURVEY NO. 366 PREMIER INDUSTRIAL ESTATE KACHIGAM DAMAN	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0X1.0 G VIAL

NDA/MAL/HDP/0945	CLARIS LIFE SCIENCES LIMITED	REDDYS PHARMA LIMITED	ZOFEX	OFLOXACIN	2 MG/ML	CLARIS OTSUKA LIMITED-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0946	ASTRAZENECA	MACNAUGHTON LIMITED	TENORETIC	ATENOLOL + CHLORTHALIDONE	100 MG + 25 MG	ASTRA ZENEC A UK LIMITED-SILK ROAD BUSINESSPARK,MACCLESFIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/0948	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA SYRUP 5MG/5ML	LORATADINE	5MG/5ML	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/0949	JULPHAR GULF PHARMACEUTICAL INDUSTRIES	GAMA PHARMACEUTICAL S (U) LIMITED	VANCOLON	VANCOMYCIN	0.5G/VIAL	JULPHAR GULF PHARMACEUTICAL INDUSTRIES-DIGDIGA AREA, AIR PORT ROAD P.O BOX 977 RAS-AL KHAIMAH UAE	UNITED ARAB EMIRATES	PARENTERAL ORDINARY I V VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/0950	JULPHAR GULF PHARMACEUTICAL INDUSTRIES	GAMA PHARMACEUTICAL S (U) LIMITED	EPOTIN	ERYTHROPOIETIN	4000I.U	JULPHAR GULF PHARMACEUTICAL INDUSTRIES-DIGDIGA AREA, AIR PORT ROAD P.O BOX 977 RAS-AL KHAIMAH UAE	UNITED ARAB EMIRATES	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X10.0 PREFILLED SYRINGE CARTON
NDA/MAL/HDP/0951	NEON LABARATORIES LTD	AIVEEN (U) LIMITED	NORAD	STERILE NORADRENALINE CONCENTRATE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/0957	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	LYRED SYRUP	VITAMINE A + VITAMINE E ACETATE + ASCORBIC ACID + SELENIUM + ZINC	2500 IU + 10 IU + 50MG + 35MCG + 3MG	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE

NDA/MAL/HDP/0959	AJANTA PHARMA LTD 310	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN DISPERSIBLE 20/120	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGABAD	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER, 1.0X30.0X12.0 TABLET BLISTER,1.0X30.0 X6.0 TABLET BLISTER
NDA/MAL/HDP/0963	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD	ARTESUNATE+AMO DIAQUINE	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
NDA/MAL/HDP/0964	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 25 / 67.5	ARTESUNATE + AMODIAQUINE	25 MG + 67.5 MG	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/0966	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CLOFENAC DT	DICLOFENAC SODIUM	50MG	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0967	I CARE PHARMA LIMITED	VITACARE LTD	STREPTOMYCIN	STREPTOMYCIN	1G	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/0969	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-2.5	AMLODIPINE BESILATE	2.5MG	EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0971	I CARE PHARMA LIMITED	VITACARE LTD	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1MU	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY I M VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON
NDA/MAL/HDP/0972	PHARCO PHARMACEUTICALS COMPANY LTD	ECHO PHARMACY (U) LIMITED	AZOMYCIN	AZITHROMYCIN 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/SYRUPS/DROPS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/0974	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3	CEFIXIME	100MG/5ML	SQUARE CEPHALOSPORINS LTD-KALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/0975	PHARCO PHARMACEUTICALS	ECHO PHARMACY (U) LIMITED	CETRAK SYRUP	CETIRIZINE DIHYDROCHLORIDE	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
NDA/MAL/HDP/0977	PHARCO PHARMACEUTICALS	ECHO PHARMACY (U) LIMITED	CETRAK	CETIRIZINE DIHYDROCHLORIDE	10MG	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 FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0978	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	AMBROX 75 SR CAPSULE	AMBROXOL	75MG	SQUARE PHARMACEUTICALS LIMITED- KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0980	PHARCO PHARMACEUTICALS	ECHO PHARMACY (U) LIMITED	AZOMYCIN	AZITHROMYCIN	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
NDA/MAL/HDP/0981	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC SR TABLETS	DICLOFENAC SODIUM	100MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0982	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASMETO-10	METOCLOPRAMIDE	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
NDA/MAL/HDP/0983	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ANADOL CAPSULES	TRAMADOL HYDROCHLORIDE	50MG	SQUARE PHARMACEUTICALS LIMITED- KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/0984	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICAL S LTD.	JOVAN T20	TADALAFIL	20MG	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0986	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CONVENTIN	GABAPENTIN	100MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/0987	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ALATROL TABLETS	CETIRIZINE	10MG	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0988	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CADITOR 20	ATORVASTATIN	20MG	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0989	ROYAL GROUP	HARLEYS UGANDA LIMITED	DICLOFENAC SODIUM	DICLOFENAC	75MG/3ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	10.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/0990	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FUSIDERM CREAM	FUSIDIC ACID	2%W/W	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/0995	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	FLUCOMOL	PARACETAMOL + PHENYLEPHRINE HCL + DEXTROMETHORPHAN HBR + CHLORPHENIRAMINE MALEATE	250MG + 5MG + 10MG + 2MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFR VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/0997	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GENUPHIL	GLUCOSAMINE SULPHATE SODIUM CHLORIDE+METHYLSULPHONYLMETHANE+CHONDROITIN SULPHATE	375MG+375MG+300MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/0998	ROYAL GROUP	HARLEYS UGANDA LIMITED	QUININE DIHYDROCHLORIDE INJECTION	QUININE DIHYDROCHLORIDE	600MG/2ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA,GRAND PHARMACEUTICAL (CHINA) CO. LTD--LAKE ROAD NELL JINYINHU ECOLOGICAL PARKDONG XI HU DISTRICT, WUHAN, HEBEI PROVINCE.	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/0999	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	THIOEVA	THIOTIC ACID	600MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1000	TROIKAA PHARMACEUTICALS LTD	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
NDA/MAL/HDP/1001	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	THIOTACID ACID	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
NDA/MAL/HDP/1002	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CIPROCIN T 750	CIPROFLOXACIN	750MG	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1006	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TRIPRIDE-2	GLIMEPIRIDE + PIOGLITAZONE+ METFORMIN	2MG+15MG+500MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1007	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZINCOS DISPERSIBLE TABLETS 20MG	ZINC SULPHATE	20MG	COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1009	TROIKAA PHARMACEUTICALS LTD	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
NDA/MAL/HDP/1010	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASDOPA TABLETS	METHYLDOPA	250MG	ASTRA LIFECARE (INDIA) PVT. LTD-PLOT 57/P, SARKHEJ-BAVLA HIGHWAY, RAJODA 382 220, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1011	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DABORAL SYRUP	AMINOSIDINE	125MG/5ML	COSMOS LIMITED, KENYA-RANGWE ROAD, OFF LUNGA ROAD, INDUSTRIAL AREA NAIROBI - KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/1012	NEON LABORATORIES 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

NDA/MAL/HDP/1013	NEON LABORATORIES 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
NDA/MAL/HDP/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
NDA/MAL/HDP/1018	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM CHLOR	CHLORAMPHENICOL	250MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,100 0.0 CAPSULE CONTAINER,250. 0 CAPSULE CONTAINER,500. 0 CAPSULE CONTAINER,1.0X 10.0 CAPSULE CONTAINER
NDA/MAL/HDP/1020	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	PA-12	PARACETAMOL SUSTAINED RELEASE	1000MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID RETARD LAYERED TABLETS	1.0X10.0X1.0X12 .0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1023	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	ZINNIA P	LEVONORGESTREL + ETHINYLESTRADIOL	150MCG + 30MCG	MYLAN LABORATORIES LIMITED.--PLOT NO. 1606-1609, SARIGAM INDUSTRIAL AREA, GIDC, SARIGAM, TAL-UMERGAM, DIST VALSAD, 396155, GUJARAT, INDIA.,MYLAN LABORATORIES LIMITED..-PLOT NO.20 & 21, PHARMEZ, SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 08A, NEAR VILLAGE MATODA, TAL-SANAND, AHMEDABAD, GUJARAT, INDIA 382213	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/1025	SANOFI –AVENTIS DEUTSCHLAND	LABOREX UGANDA LIMITED	INSUMAN COMB 30	INSULIN HUMAN	100IU/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH - INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X3.0 ML PRE- FILLED SYRINGE

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/1031	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOXIFLOX	MOXIFLOXACIN	400MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/1032	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ARTHRFREE 20	LEFLUNOMIDE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1033	FAES FARMA S.A	LABOREX UGANDA LIMITED	DYNAMOGEN	GLUTODINE (CYPROHEPTADINE ALPHA-KETOGLUTARATE) + ARGININE ASPARTATE	3MG +1G	FAES FARMA, S.A -MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X20.0X10.0 ML SACHET
NDA/MAL/HDP/1034	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX	AMOXICILLIN	250MG/5ML	VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1035	GUILIN PHARMACEUTICAL CO.LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/1037	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	LAMIVUDINE + TENOFOVIR	LAMIVUDINE+TENOF OVIR DISOPROXIL FUMARATE	300MG+300MG	AUROBINDO PHARMA LTD-UNIT VII (SEZ), PLOT NO.S1, GREEN INDUSTRIAL PARK, POLEPALLY (V) JEDCHERIA (M), MAHABOOB NAGAR	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/1038	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3	CEFIXIME TRIHYDRATE	200MG	SQUARE CEPHALOSPORINS LTD-KALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER

NDA/MAL/HDP/1040	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	CEF-3 DS	CEFIXIME TRIHYDRATE	400MG	SQUARE CEPHALOSPORINS LTD-KALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1042	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 80/12.5	TELMISARTAN +HYDROCHLOROTHI AZIDE	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
NDA/MAL/HDP/1043	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	FLEXI 100	ACECLOFENAC	100MG	SQUARE PHARMACEUTICALS LTD-KALIAKOIR	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1044	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANGINET 80MG	VALSARTAN	80MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1045	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	ZIMAX 500	AZITHROMYCIN	500MG	SQUARE CEPHALOSPORINS LTD-KALIAKOIR, GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/1047	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 180MG	FEXOFENADINE	180MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER
NDA/MAL/HDP/1048	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EXOFEN 120MG	FEXOFENADINE	120MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER
NDA/MAL/HDP/1049	AGOG PHARMA LTD.	GITTOES PHARMACEUTICAL S LIMITED	AGOVATE	BETAMETHASONE VALERATE	0.1%W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE

NDA/MAL/HDP/1050	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	AMTAS-10	AMLODIPINE	10MG	INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1052	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	MICLOGEN	MICONAZOLE NITRATE+NEOMYCIN SULPHATE+CLOBETA SOL 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
NDA/MAL/HDP/1053	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN-125 DT	AMOXICILLIN	125MG	MILAN LABORATORIES (INDIA) PVT LTD .- PLOTS 63,67,87,35,36,64,65, JAWAHAR CO-OP IND. ESTATE LTD, KAMOTHE, PANVEL (NAVI MUMBAI)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1054	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/1055	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	ROZITTA 40	ROSUVASTATIN CALCIUM	40MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/1056	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	AGOVATE-N OINTMENT	BETAMETHASONE + NEOMYCIN	0.1%W/W + 0.5% W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE
NDA/MAL/HDP/1057	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	FIXINECT-200MG	CEFIXIME	200MG	NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP

NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1062	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	VANCONEX-CP	VANCOMYCIN	500MG	VENUS REMEDIES LIMITED-UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI BADDI (HP) 173205 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/1065	BLISS GVS PHARMA LIMITED	DELMAR 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
NDA/MAL/HDP/1067	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	IBUPARA	IBUPROFEN+PARACE TAMOL	200MG+ 250MG/10ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1069	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	K-ONE INJECTION	PHYTOMENADIONE	10MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/1071	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/25MG	VALSARTAN + HYDROCHLOROTHIAZIDE	160 MG + 25 MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1072	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 80/12.5MG	VALSARTAN + HYDROCHLOROTHIAZIDE	80MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD .-57 UBAYBIN MUAATH STREET AL RAGEEM-SAHAB, AMMAN, JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/1073	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-250	BECLOMETASONE	250MCG PER ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER

NDA/MAL/HDP/1074	NECTAR LIFESCIENCES LTD	SUPER MEDIC LTD	CEFUAXIT	CEFUROXIME	500MG	NECTAR LIFE SCIENCES LTD-VILL. BHATOLIKALAN, ADJOINING JHARMJRI, E.P.I.P TEL. NALAGARH, DISTT. SOLAN, H.P.-173205 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1075	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECPIME	CEFEPIME	1000MG	NECTAR LIFESCIENCES LTD UNIT VI-BHATOLIKALAN P.O BAROTIWALA DISTT SOLAN HIMACHAL PRADESH 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*10 ML WATER FOR INJECTION
NDA/MAL/HDP/1076	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST 4MG	MONTELUKAST SODIUM	4MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1077	NECTAR LIFESCIENCES LTD	AIVEEN (U) LIMITED	NECTRAM	CEFTRIAZONE	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
NDA/MAL/HDP/1078	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT INFUSION	LEVOFLOXACIN HEMIHYDRATE	500MG	AHLCON PARENTERALS (INDIA) LTD-SP-917-918, PHASE-III BHIWADI-301019, ALWAR, RAJASTHAN	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1079	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOG-QUINE SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1080	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF 250 TABLETS	CEFUROXIME AXETIL	250MG	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/1082	DAWA LIMITED	SUPER MEDIC LTD	DACOF PAEDIATRIC	DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE + MENTHOL	75MG + 28.5MG + 0.55MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1083	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	CHOCOFER SYRUP	IRON + FOLIC ACID	50MG + 0.5MG /5ML	GALPHA LABORATORIES LIMITED-VILLAGE – THANA BADDI, TEHSIL BADDI SOLAN HIMACHAL PRADESH-173 205 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/1084	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAMIN E 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
NDA/MAL/HDP/1086	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	SYNOGEN TABLETS	DIACERIN + METHYL SULPHONYL METHANE + GLUCOSAMINE SULPHATE	50MG +250MG + 750MG	NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1087	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/1088	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	RESTUM	CEFUROXIME SODIUM	750MG	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL
NDA/MAL/HDP/1093	STRIDES ARCOLAB LTD	DELMAN ENTERPRISES LIMITED	EMTRICITABINE + TENOFIVIR DISOPROXIL FUMARATE	EMTRICITABINE+TEN OFIVIR DISOPROXIL FUMARATE	200MG+300M G	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1094	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-100	CEFIXIME	100MG/5ML	MICRO LABS LTD--NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1095	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTINE-20	EBASTINE	20MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1098	IDA FOUNDATION	KIMSY MEDS LTD	PRAZIQUANTEL	PRAZIQUANTEL USP	600MG	MICRO LABS LTD ...-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/1099	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	MOMATE F CREAM	FUSIDIC ACID+MOMETASON E 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
NDA/MAL/HDP/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
NDA/MAL/HDP/1101	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O 100	CEFIXIME	100MG	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
NDA/MAL/HDP/1102	MATRIX UGANDA LTD	ROYAL PHARMA 2011 LIMITED	OVUREX	CLOMIPHENE	50MG	Y.S.P INDUSTRIES (M) SDN BDH - LOT 3,5 & 7 P/7 SECTION 13 KAWASAN PERINDUSTRIAN BANDAR BARU BANGI 43000 KAJANG SELANGOR DARUL EHSAN	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1104	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	LIPIDUCE 10	ATORVASTATIN	10MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1105	DAWA LIMITED	SUPER MEDIC LTD	DERMAZINE PLUS	SILVER SULPHADIAZINE AND CHLORHEXIDINE GLUCONATE	1%W/W / 10.0%W/W	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1106	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIACEREIN	DIACEREIN	50MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X2.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/1107	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDNA) (PAEDIATRIC))	HEPATITIS B VACCINE(RDNA)	10MCG /0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X25.0X5.0 ML VIAL (10 DOSES),1.0X10.0 X0.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/1109	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CPM	CHLORPHENIRAMINE MALEATE	2MG/5ML	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/1111	DAWA LIMITED	SUPER MEDIC LTD	FAST-ACT GEL	DICLOFENAC + DIETHYLAMINE + METHYL SALICYLATE + LINSEED OIL + MENTHOL CRYSTALS	1.16%W/W + 10%W/W + 3%W/W + 5%W/W	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/1113	MACK BROWN PHARMACEUTICALS 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
NDA/MAL/HDP/1114	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TRANGEL ULTRA	DICLOFENAC/METHYL SALICYLATE/MENTHOL/CAPSICUM OLEORESIN	10MG/80MG/60MG/0.15MG	NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER
NDA/MAL/HDP/1116	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	VITAL ESSENTIAL BALM	MENTHOL + CAMPHOR + PEPPERMINT OIL + EUCALYPTUS OIL + CLOVE OIL+ CINNAMON +WINTER GREEN OIL	140MG + 140MG + 80MG +80MG +40MG +40MG +120MG	NEM LABORATORIES LIMITED-133 KRISHNA IND. ESTATE, VASAI (E), THANE – 401 210, MAHARASHTRA – INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X24.0 G CONTAINER
NDA/MAL/HDP/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

NDA/MAL/HDP/1122	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCHLOR EAR DROPS	CHLORAMPHENICOL	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
NDA/MAL/HDP/1123	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPAR	PARACETAMOL	500 MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/1124	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGO SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	AGOG PHARMA LTD-PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0X500.0 ML BOTTLE
NDA/MAL/HDP/1125	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROXONE 1000	CEFTRIAXONE	1000MG	A-UNIT VI, SY. NO 329/39, 329/	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/1127	FEROZSONS LABORATORIES LTD	TOP UNIVERSAL MEDICARE LIMITED	CLARION TABLETS 500MG	CLARITHROMYCIN	500MG	FEROZSONS LABORATORIES LTD-AMANGARH-NOWSHERA, (KHYBER PAKHTOONKHWA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1128	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BTC KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	LINCOLN PHARMACEUTICALS L.T.D-TRIMUL ESTATE KHATRAJ 382721 GHANDINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY COMBINATION PACK TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1130	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	KLARO-500	CLARITHROMYCIN TABLETS	500MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1132	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	M-CALZ	CALCIUM CITRATE +MAGNESIUM HYDROXIDE + ZINC SULPHATE + COLECALCIFEROL	1000MG+100MG+4MG+200.I.U	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/1133	MEDIPHARM INDUSTRIES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDICOL SUSPENSION	CHLORAMPHENICOL	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/1139	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	AGOVATE	BETAMETHASONE	0.1%W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1140	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	AGOVATE-N	BETAMETHASONE+N EOMYCIN 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
NDA/MAL/HDP/1141	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CALBONE	CALCIUM CARBONATE + COLECALCIFEROL	250MG+125MG/5ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1142	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CANDIZOL	CLOTRIMAZOLE	1%W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1143	LINCOLN P'CAL'S LTD	METRO PHARMACEUTICALS LIMITED	LOSA-H	LOSARTAN + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1147	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	VALAZYD	VALSARTAN	80MG	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
NDA/MAL/HDP/1148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT	MONTELUKAST	10MG	CADILA HEALTH CARE LIMITED -PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1149	UNIVERSAL CORPORATION LTD	DELMAW ENTERPRISES LIMITED	NEUROBA	GABAPENTIN	300MG	UNIVERSAL CORPORATION LTD..-PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/1154	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	BACQUIRE	IMIPENEM + CILASTATIN	500MG + 500MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED- INDUSTRIAL AREA NO.3, A.B. ROAD DEWAS, 455001 (MP), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML VIAL
NDA/MAL/HDP/1156	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FUNGICIP	CLOTRIMAZOLE	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
NDA/MAL/HDP/1157	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	TRETINON	TRETINOIN	0.05%W/W	Y.S.P.INDUSTRIES(M)SBD,BHD-LOT 3,5,& 7,JALANP/7,SECTION13,KAWASAN PERINDUSTRIAN BANDAR BARUBANGI,43000 KAJANG SELANGOR DARUL EHSAN, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1159	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	VOREN	DICLOFENAC SODIUM	50MG	Y.S.P.INDUSTRIES(M)SBD,BHD-LOT 3,5,& 7,JALANP/7,SECTION13,KAWASAN PERINDUSTRIAN BANDAR BARUBANGI,43000 KAJANG SELANGOR DARUL EHSAN, MALAYSIA	MALAYSIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP,1.0X10.0X 10.0 SUPPOSITORY STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/1166	PANACEA BIOTEC LTD	ABACUS PHARMA (AFRICA) LIMITED	DOLZERO	TRAMADOL HYDROCHLORIDE + PARACETAMOL	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
NDA/MAL/HDP/1167	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	METOCLOPRAMIDE INJECTION	METOCLOPRAMIDE	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2 .0 ML AMPOULE
NDA/MAL/HDP/1168	DAWA LIMITED	SUPER MEDIC LTD	DAWA-CORT CREAM	HYDROCORTISONE	1%W/W	DAWA LTD -BABA DOGO ROAD, RUARAKA P.O.BOX 16633-00620, NAIROBI KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1169	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	NEBI 5	NEBIVOLOL HYDROCHLORIDE	5MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER

NDA/MAL/HDP/1171	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	BETNEW EYE / EAR DROP	BETAMETHASONE+N EOMYCIN	0.1%W/W+0.5 %W/W	CIRON DRUGS & PHARMACEUTICALS PVT LTD.-N-118 MIDC TARAPUR BOISAR DIST THANE 401 506 MAHARASHTRA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/1172	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	20MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD.-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL,1.0X30.0 ML VIAL
NDA/MAL/HDP/1176	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	FUNGISAFE	TERBINAFINE HYDROCHLORIDE	1%W/W	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY,KALYOUBIA CAIRO EGYPT	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1178	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/1179	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	OVITRELLE	CHORIOGONADOTROPIN ALFA	250MCG/0.5ML	MERCK SERONO SA-1170 AUBONNE(SWITZERLAND),MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY	SWITZERLAND	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/1184	DAWA LIMITED	SUPER MEDIC LTD	DACOF MUCOLYTIC	SALBUTAMOL + BROMHEXINE + GUAIPHENESIN + MENTHOL	2.0MG + 4.0MG +100MG + 1.0MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1185	DAWA LIMITED	SUPER MEDIC LTD	DACOF DRY	DIPHENHYDRAMINE + DEXTROMETHORPHAN + MENTHOL	12.5MG + 6.5MG + 1.10MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1186	DAWA LIMITED	SUPER MEDIC LTD	DACOF EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE + SODIUM CITRATE + MENTHOL	14.0MG + 135.0MG + 57.0MG + 1.10MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/1187	GALPHA LABORATORIES LTD	AIVEEN (U) LIMITED	KEFTAZ-1000	CEFTAZIDIME	1 G	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST-SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL + 1*10 ML WATER FOR INJECTION
NDA/MAL/HDP/1188	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	GMYCIN-80	GENTAMYCIN SULPHATE	80MG/2ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR,ANHUI CHENGSHI PHARMACEUTICAL CO. LTD,- NO.5068 HUAISHANG ROAD,HEBEI NEW AREA INDUSTRIAL PARK, BENGBU,ANHUI,CHINA.	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE
NDA/MAL/HDP/1189	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	DICLOMAX-75	DICLOFENAC SODIUM	75MG/ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/1194	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PISA	PIPERACILLIN + TAZOBACTAM	4000MG/VIAL + 500MG/VIAL	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X30.0 ML VIAL
NDA/MAL/HDP/1195	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	ALTRINE	CETIRIZINE	5MG/5ML	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE
NDA/MAL/HDP/1196	UNIVERSAL CORPORATION LTD	DELMAR ENTERPRISES LIMITED	ACNESOL	TRETINOIN	0.05%W/W	UNIVERSAL CORPORATION LTD.-PLOT 13777 CLUB ROAD, PAST KIKUYU	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE
NDA/MAL/HDP/1202	MEDIPHARM INDUSTRIES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/1205	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	EFAVIRENZ	EFAVIRENZ	600MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1206	THE METHOLATUM CO. LTD	HARLEYS UGANDA LIMITED	DEEP RELIEF	IBUPROFEN + MENTHOL	5%W/W + 3% W/W	THE MENTHOLATUM CO. LTD. -1 REDWOOD AVE PEEL PARK CAMPUS EAST KILBRIDE	UNITED KINGDOM	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X50.0 G CONTAINER,1.0X 15.0 G CONTAINER,1.0X 30.0 G CONTAINER
NDA/MAL/HDP/1208	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	VISCO LIQUID	ALGINIC ACID + MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE + SIMETHICONE	100 MG + 250 MG + 125 MG + 50 MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.II MANDIDEEP 462046 RAISEN MADHYA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X200.0 ML BOTTLE
NDA/MAL/HDP/1209	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (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
NDA/MAL/HDP/1211	ASTRA ZENECA	MACNAUGHTON LIMITED	BRILINTA	TICAGRELOR	90MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1212	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/1214	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	NUCLEO C.M.P FORTE	CYTIDINE+URIDINE	5MG+3MG	FERRER INTERNACIONAL, S.A-JOAN BUCSALA 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER
NDA/MAL/HDP/1215	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GYNANFORT VAGINAL PESSARY	METRONIDAZOLE+N EOMYCIN SULPHATE+NYSTATI N	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
NDA/MAL/HDP/1217	SANOFI AVENTIS	LABOREX UGANDA LIMITED	INSUMAN BASAL	RECOMBINANT HUMAN INSULIN	100 IU/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH - INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X3.0 ML CARTRIDGE,1.0X 5.0 ML VIAL

NDA/MAL/HDP/1218	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE-50	ARTESUNATE	50MG	BLISS INDASI LIFESCINCES PRIVATE LIMITED - PLOT 73-76 SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN 396 210, INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP
NDA/MAL/HDP/1219	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	TORAS-DENK 5	TORASEMIDE	5MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1220	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BLISTER
NDA/MAL/HDP/1223	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X25.0 G TUBE
NDA/MAL/HDP/1224	KOTRAPHARMA (M) SDN.BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VAXCEL CEFTRIAXONE	CEFTRIAXONE	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
NDA/MAL/HDP/1225	AMOUN PHARMACEUTICAL COMPANY	BOOTS PHARMACEUTICALS LIMITED	MOSEDIN PLUS SR	PSEUDOEPHEDRINE HYDROCHLORIDE + 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, KALYOUBIA CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1226	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	SALBUTAMOL	SALBUTAMOL	4MG	STRIDES ARCOLAB LIMITED .-DEWAN & SONS IND. AREA, VEOOR, PALGHAR, MAHARASTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/1227	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	FUNGISAFE	TERBINAFINE HCL	250MG	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-OBOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET STRIP
NDA/MAL/HDP/1228	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	LUMETHER	ARTEMETHER + LUMEFANTRINE	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

NDA/MAL/HDP/1230	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	LOXAMP	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1231	NORVIK ENTERPRISES LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOX 125	AMOXYCILLIN	125MG/5ML	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1232	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOCILLIN 125	AMPICILLIN	125 MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1234	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	BISACODYL TABLETS BP	BISACODYL	5MG	MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1238	PHARMACARE 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
NDA/MAL/HDP/1239	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PECTYLIN-C	DIPHENHYDRAMINE HYDROCHLORIDE+AMMONIUM HYDROCHLORIDE+SODIUM CITRATE+MENTHOL	14MG+135MG+57MG+1.1MG	IPCA LABORATORIES LTD-SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1240	BRICVED LTD	BOOTS PHARMACEUTICALS LIMITED	CETIRIZINE HYDRCHLORIDE	CETIRIZINE HYDROCHLORIDE	5MG/5ML	PINEWOOD LABORATORIES LTD. - BALLYMACARBRY, CLONMEL, TIPPERARY, IRELAND	IRELAND	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/1243	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	LEVO DENK 250	LEVOFLOXACIN HEMIHYDRATE	250MG	ROTTENDORF PHARMA GMBH-OSTENFELDER STRASSE 51-61 59320 ENNIGERLOH GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1244	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	FLEXILOR SR	LORNOXICAM	16MG	GLENMARK PHARMACEUTICALS LTD - UNIT III-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -174 101 INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1245	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	FLEXILOR P8	LORNOXICAM + PARACETAMOL	8MG + 500MG	GLENMARK PHARMACEUTICALS LTD - UNIT III-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -174 101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1246	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	GLEMONT CT 4	MONTELUKAST	4MG	GLENMARK PHARMACEUTICALS LTD-VILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1247	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PROCIP	CYPROHEPTADINE	4MG	AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1250	STRIDES ARCOLAB LIMITED	DELMAW ENTERPRISES LIMITED	STRIMOL EXTRA	PARACETAMOL+CAF FEINE	500MG+30MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAWADICROSS ANEKAL TALUK BANYALURE-562106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1252	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	ZOY	SILDENAFIL	50MG	TORQUE PHARMACEUTICALS PVT LTD-VILL ISSAPUR P.O DAPPAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1254	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM TABLETS	CO-TRIMOXAZOLE	480MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/1256	SIRMAXO CHEMICALS PVT LTD	SUPER MEDIC LTD	SANQUAD PVP T	POVIDONE IODINE	10%W/W	SIRMAXO CHEMICALS PVT LTD-PLOT NO. E-35. TARAPRU MIDC BOISAR, THANE, MUMBAI, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X500.0 ML BOTTLE,1.0X100.0 ML BOTTLE

NDA/MAL/HDP/1258	GLAXO WELLCOME(KENYA),LTD	ERIS LTD	MYOGLIN CAPSULES	CHLORZOXAZONE/P ARACETAMOL	250MG/300M G	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1260	BLISS GVS PHARMA LIMITED	DELMAR ENTERPRISES LIMITED	DIABETA	GLIBENCLAMIDE	5MG	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	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1264	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUCYCLINE EYE OINTMENT	TETRACYCLINE HYDROCHLORIDE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE,1.0X3.5 G TUBE
NDA/MAL/HDP/1265	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	COMBIPLEX	VITAMIN B1 + VITAMIN B2 + NICOTINAMIDE + VITAMIN B6	1.0 MG + 1.0 MG + 15 MG + 0.5 MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1272	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	GAMA PHARMACEUTICAL S (U) LIMITED	MEBO HERBAL OINTMENT	B-SITOSTEROL	0.25%W/W	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA, P.O.BOX: 997,RAS AL KHAIMAH, U.A.E.	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/1274	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN	250MG	NABIQASIM INDUSTRIES (PVT) LTD-- 17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/1275	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 10 F.C TABLETS	NIFEDIPINE	10MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1277	SANOTI AVENTIS	LABOREX UGANDA LIMITED	INSUMAN RAPID	INSULIN HUMAN	100 IU/ML	SANOI-AVENTIS DEUTSCHLAND GMBH- INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY S C VIALS	1.0X5.0 ML VIAL
NDA/MAL/HDP/1278	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	D-ARTEPP	DIHYDROARTEMESI NIN + 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

NDA/MAL/HDP/1282	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	LOSABERG	LOSARTAN POTASSIUM	50MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX- DS 100	CEFIXIME	100MG/5ML	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/1290	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANIX 400 CAP	CEFIXIME	400MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1293	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEGRA - 100	SILDENAFIL CITRATE	100MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1294	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	ULTRAVIST 370	IOPROMIDE	370MG/ML	BAYER SCHERING PHARMA AG-1334231, BERLIN	GERMANY	PARENTERAL ORDINARY VIALS	1.0X100.0 ML VIAL,1.0X50.0 ML VIAL
NDA/MAL/HDP/1295	SHAIGAN PHARMACEUTICALS (PVT) LTD	HEALTHCARE LTD.	ZEPAR	ALBENDAZOLE	200MG	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/1297	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLMY 40	OLMESARTAN	40MG	CADILA HEALTHCARE LIMITED--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
NDA/MAL/HDP/1298	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FORTE	THIAMINE MONONITRATE/ PYRIDOXINE/ CYANOCOBALAMIN	245.5MG/ 250MG/ 1.4MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1299	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE PLUS-1000	CEFTRIAXONE+SULBACTAM	1000MG+500 MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL
NDA/MAL/HDP/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

NDA/MAL/HDP/1301	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	COSAMINE PLUS	GLUCOSAMINE 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
NDA/MAL/HDP/1302	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	HIPEN CAPSULES	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1,SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1307	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ARBITEL 40	TELMISARTAN	40MG	MICRO LABS LTD --57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1310	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN-300	CLINDAMYCIN	300MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1312	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	SLIPIZEM- 2.5	DIAZEPAM	2.5MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/1315	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZES0Z-20	ESOMEPRAZOLE	20MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1324	MACK BROWN PHARMACEUTICALS 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
NDA/MAL/HDP/1325	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE

NDA/MAL/HDP/1326	IDA	KIMSY MEDS LTD	CO-TRIMOXAZOLE 480MG	CO-TRIMOXAZOLE	480MG	MEDOPHARM--34-B, INDUSTRIAL AREA, MALUR 563 160 KARNATAKE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER
NDA/MAL/HDP/1328	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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)
NDA/MAL/HDP/1329	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	VITAVITE	MULTI-INGREDIENT	VITAMINS AND MINERALS	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER
NDA/MAL/HDP/1330	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	RAPICLAV-625	AMOXYCILLIN+CLAV ULANIC 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
NDA/MAL/HDP/1331	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N OINTMENT	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X5.0 G TUBE
NDA/MAL/HDP/1334	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	30MG	MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARAstra	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER,1.0X30.0 CAPSULE CONTAINER
NDA/MAL/HDP/1335	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	PREGATAS	PREGABALIN	75MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1336	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	45MG	MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARAstra	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER, CAPSULE CONTAINER

NDA/MAL/HDP/1337	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	FOURTS B	THIAMINE +RIBOFLAVIN + PYRIDOXINE + NICOTINAMIDE + FOLIC ACID + ASCORBIC ACID + COLECALCIFEROL + ACETYL CYSTEINE + GLYCINE + GLUTAMIC ACID + CHROMIUM + VANADIUM + ZINC + SELENIUM	10MG + 10MG + 3MG + 50MG + 1MG + 75MG + 400IU + 25MG +25MG +MG +200MCG + 100MCG + 55MG +100MCG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1341	AUROLAB	SWASTIK PHARMACEUTICAL LTD	G-FLOX	GATIFLOXACIN SESQUIHYDRATE	0.3%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI – 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC LIQUIDS	1.0X5.0 ML VIAL
NDA/MAL/HDP/1342	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL CEPHALEXIN 250	CEPHALEXIN MONOHYDRATE	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
NDA/MAL/HDP/1344	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S LIMITED	LIDOCAINE	LIDOCAINE	2%W/V	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/1345	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	SWICH-200	CEFPODOXIME	200MG	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1347	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	ORNILOX	ORNIDAZOLE + OFLOXACIN	500MG + 200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1348	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1351	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ATORIN	ATORVASTATIN CALCIUM	20MG	MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1352	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PLATFREE	CLOPIDOGREL	75MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1353	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	KITPYLO - C	LANSOPRAZOLE + TINIDAZOLE + CLARITHROMYCIN	30MG +500MG + 250MG	MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)
NDA/MAL/HDP/1354	PFIZER LABS LIMITED	LABOREX UGANDA LIMITED	ARTHROTEC	DICLOFENAC SODIUM + MISOPROSTOL	50MG + 200MCG	PIRAMAL HEALTHCARE UK LTD--WHALTON ROAD MORPETH NORTHUMBERLAND NE613 YA UK	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1356	GLAXO SMITH KLINE LTD	ERIS LTD	REQUIP PD 24 HOUR 2 MG	ROPINIROLE	2MG	GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/1357	GLAXO SMITH KLINE LTD	ERIS LTD	REQUIP PD 24 HOUR 4 MG	ROPINIROLE	4MG	GLAXO WELLCOME S.A ARANDA-ARANDA AVDA EXTREMADURA 3, 09400 ARANDA DE DUERO BURGOS	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/1359	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC-100 SR	DICLOFENAC SODIUM	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID RETARD CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/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 NAACL AMPOULE + 1*1ML OF 5%W/V NAHCO3 AMPOULE
NDA/MAL/HDP/1362	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	BACTOCLAV-1000	AMOXICILLIN + CLAVULANATE	875 MG + 125 MG	MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X7.0 TABLET STRIP
NDA/MAL/HDP/1366	F. HOFFMANN- LA ROCHE LTD	LABOREX UGANDA LIMITED	HERCEPTIN 440MG	TRASTUZUMAB	440MG	F. HOFFMANN LA-ROCHE-WURMISWEG CH-4303 KAISERAUGST	SWITZERLAND	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X440.0 MG VIAL ,2OZML VIAL OF SOLVENT
NDA/MAL/HDP/1367	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1368	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D5	GLUCOSE	5%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/1369	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO-PACK ORANGE FLAVOUR	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X2.0X20.8 G SACHET + 1.0 *10.0 TABLET BLISTER
NDA/MAL/HDP/1370	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	STERILIZED WATER FOR INJECTION	WATER FOR INJECTION	NEUTRAL	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE,1.0X10.0 ML AMPOULE,1.0X7.5 ML AMPOULE
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1375	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	VALODIN CAPSULES	CEPHADRINE	250MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X4.0 CAPSULE BLISTER

NDA/MAL/HDP/1377	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	WATER FOR INJECTION	WATER FOR INJECTION	N/A	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML AMPOULE
NDA/MAL/HDP/1380	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT CREAM	HYDROCORTISONE	1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/1381	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE,/ ZIDOVUDINE TABLETS	LAMIVUDINE,+ ZIDOVUDINE	150MG+300MG	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
NDA/MAL/HDP/1382	HOVID BERHAD	UNITED HEALTHCARE DISTRIBUTORS LTD	INOX CAPSULES	ITRACONAZOLE	100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER
NDA/MAL/HDP/1383	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOFEN GEL	KETOPROFEN	2.5%W/W	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/1387	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAN-30	LANSOPRAZOLE	30MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQI DEHRADUN	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/1390	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	5MG	IPR PHARMACEUTICALS INC,-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1392	ASTRA ZENECA	MACNAUGHTON LIMITED	ZOLADEX	GOSERELIN	3.6MG	ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 PREFILLED SYRINGE CARTON

NDA/MAL/HDP/1393	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANFUR	CEFUROXIME	500MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1394	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANPIME -1000	CEFEPIME	1000MG	SANCE LABORATORIES PRIVATE LTD-PB NO. 2 ELAPPUNKAL JN, KOOZLUVANAL , 686 523, PALA, KOTTAYAM DISTRICT, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X15.0 ML VIAL
NDA/MAL/HDP/1395	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG IV	ESOMEPRAZOLE	40MG/5ML	ASTRA ZENECA--KVARNBERGAGATAN12, SE-151 SODERTALIJE	SWEDEN	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL, 1.0X10.0X5.0 ML VIAL
NDA/MAL/HDP/1397	ASTRAZENECA	MACNAUGHTON LIMITED	PLENDIL	FELODIPINE	10MG	ASTRAZENECA AB,-GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1399	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ASTHALIN	SALBUTAMOL	100MCG/DOSE	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE -II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/1400	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 500	METFORMIN HYDROCHLORIDE	500MG	INVENTIA HEALTHCARE PRIVATE LIMITED-F1-F1/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST), DISTRICT THANE, 421 0506, DIST. THANE, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER
NDA/MAL/HDP/1402	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PANFOR SR 1000	METFORMIN HYDROCHLORIDE	1000MG	INVENTIA HEALTHCARE PRIVATE LIMITED-F1-F1/1, ADDITIONAL AMBERNATH MIDC, AMBERNATH (EAST), DISTRICT THANE, 421 0506, DIST. THANE, MAHARASHTRA, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1.0X5.0X20.0 TABLET BLISTER
NDA/MAL/HDP/1403	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/1404	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	NAPRODOX-10	DOXORUBICIN HCL	100MG	NAPROD LIFE SCIENCES (PVT) LIMITED-PLOT G-17/1 MIDC TARAPUR BOISAR, DIST. THANE-401506 MAHARASTRA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL

NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/1409	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICAL S LIMITED	ROMYCIN	AZITHROMYCIN	200MG/5ML	NABIQASIM INDUSTRIES (PVT) LTD-- 17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X15.0 ML BOTTLE
NDA/MAL/HDP/1411	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	CIPUM	CHLORPHENIRAMIN E	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
NDA/MAL/HDP/1413	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	PODINE MOUTH WASH	POVIDONE IODINE	0.1%W/V	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/1415	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND	CANDESARTAN	32MG	ASTRA ZENECA SWEDEN OPERATIONS- TABLET PRODUCTION SE-151 85, GARTUNAVAGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1417	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/1418	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	AMINOPHYLLINE TABLETS	AMINOPHYLLINE	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
NDA/MAL/HDP/1419	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 10	LISINOPRIL	10MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER
NDA/MAL/HDP/1420	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	SODIUM CHLORIDE + GLUCOSE	SODIUM CHLORIDE + GLUCOSE	0.9%W/V + 5%W/V	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184 NAIROBI	KENYA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE

NDA/MAL/HDP/1422	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BINOZYT 500MG	AZITHROMYCIN MONOHYDRATE	500MG	SANDOZ SRL LTD-LIVEZENI STREET 7A540472 TARGU MURES ROMANIA	ROMANIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1423	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CURAM	AMOXYCILLIN + POTASSIUM CLAVULANATE	500MG+125M G	SANDOZ GMBH-BIOCHEMIESTRASSE 10, A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X7.0X2.0 TABLET BLISTER
NDA/MAL/HDP/1425	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM	COTRIMOXAZOLE	240MG/5ML	LEBEN LABORATORIES PVT. LTD-L-4, PHASE -III, M.I.D.C,	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE
NDA/MAL/HDP/1426	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	METROLEB	METRONIDAZOLE	200MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1427	AGOG PHARMA LTD.	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/1431	INTAS PHARMACUITICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 10	TORSEMIDE	10MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1432	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORAMPHENICOL EAR DROPS	CHLORAMPHENICOL	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
NDA/MAL/HDP/1433	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NORISTERAT	NORETHISTERONE ENANTATE	200MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0 ML PRE- FILLED SYRINGE,1.0X10 0.0X1.0 ML AMPOULE

NDA/MAL/HDP/1436	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CONCOR 10	BISOPROLOL HEMIFUMARATE	10MG	MERCK KGAA-250 FRANKFRUTER STRASSE 250-64293 DARMSTADT, WINTHROP PHARMACEUTICALS(PTY) LTD,-315 WATLOO ROAD, WATLOO, PRETORIA, SOUTH AFRICA (FPP SECONDARY PACKAGING, FPP RELEASE/QC TESTING SITE)	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1445	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	AXONE 1000	CEFTRIAXONE SODIUM	1000MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL
NDA/MAL/HDP/1446	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN B COMPLEX	VITAMINS B1 + B2 + B6 + NIACINAMIDE	0.5 MG + 0.5MG + 7.5MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/1447	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITONA PLUS	VITAMINS + MINERALS	MULTI-INGREDIENT	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/1448	HEBEI NOVASCOR TRADING CO. LTD	RENE PHARMACY LTD	VITAMIN B INJECTION	VIT B1 + VIT B2 + VIT B6 + NICOTINAMIDE + CALCIUM DEXTROPANTOTHENATE	20MG + 2MG + 2MG + 30MG + 1MG /2ML	ANHUI CHENGSHI MEDICINE MANUFACTURE CO. LTD-INDUSTRIAL AREA, BENGBU CITY, ANHUI PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE
NDA/MAL/HDP/1449	SHAIGAN PHARMACEUTICALS (PVT) LTD	HEALTHCARE LTD.	ZEPAR SUSPENSION	ALBENDAZOLE	200MG/5ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/1450	GLAXOSMITHKLINE LIMITED LIKONI	UNITED HEALTHCARE DISTRIBUTORS LTD	VOLTAREN EMULGEL 1%	DICLOFENAC DIETHYLAMMONIUM	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
NDA/MAL/HDP/1451	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN INJECTION	DICLOFENAC	25MG/ML	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE
NDA/MAL/HDP/1452	ASTRA ZENECA	MACNAUGHTON LIMITED	ZESTORETIC	LISINAPRIL/HYDROCHLOROTHIAZIDE	20MG/12.5MG	ASTRAZENECA MACCLESFIELD-CHESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/1453	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZESQZ-40	ESOMEPRAZOLE	40MG	MADRAS PHARMACEUTICALS -137-B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI – 600 096, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1454	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PAINEX	PARACETAMOL + ASPIRIN + CAFFEINE	500MG + 400MG + 50 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP
NDA/MAL/HDP/1455	IDA	KIMSY MEDS LTD	LIDOCAINE HCL 5% & DEXTROSE 7.5% INJECTION	LIDOCAINE HCL 5%+DEXTROSE 7.5%	50MG +75MG/ML	GLAND PHARMA LTD -D.P.PALLY, DUNDIGAU POST NEAR GANDIMAISAMMA CROSS ROAD, QUTHBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD - 500043, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/1456	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	SUCRAFIL O GEL	SUCRALFATE + OXETACAINE	10MG + 0.2MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/1458	STRIDES ARCOLAB LTD	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
NDA/MAL/HDP/1459	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 200	NILOTINIB	200MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1461	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	CLAVICIN	AMOXICILLIN + POTASSIUM CLAVULANATE	500MG + 100MG	STRIDES ARCOLAB LTD -BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X600.0 MG VIAL
NDA/MAL/HDP/1463	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ARISTOZYME LIQUID	DIASTASE+PEPSIN	50MG+10MG	ARISTO PHARMACEUTICALS PVT. LIMITED- PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE

NDA/MAL/HDP/1464	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ORNIDA	ORNIDAZOLE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED- PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/1465	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLFAST	DICLOFENAC POTASSIUM	50MG	MIPHARM S.P.A -VIA BERNARDO QUARANTA, 12-20141, MILANO ITALY.	ITALY	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X3.0 G SACHET
NDA/MAL/HDP/1466	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	MATADOR	LEVOFLOXACIN	500MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X7.0 TABLET BLISTER
NDA/MAL/HDP/1468	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID CAPSULES	OMEPRAZOLE	20MG	CADILA HEALTHCARE LTD-PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA, S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL SOLID RETARD CAPSULES	1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/1469	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 125	AMOXICILLIN	125MG/5ML	VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1472	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	FORTUM INJECTION	CEFTAZIDIME	1GM	GLAXOSMITHKLINE LTD MANUFACTURING SPA-VERONA	ITALY	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/1474	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGODIC	DICLOFENAC DIETHYLAMINE	1%W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/1476	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	SEPTOL	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	1%W/W + 0.20W/W	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1478	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA	SILDENAFIL	50MG	AJANTA PHARMA LTD -B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1481	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTROGYL	METRONIDAZOLE	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

NDA/MAL/HDP/1482	SANOPI PASTEUR	LABOREX UGANDA LIMITED	STAMARIL PASTEUR	YELLOW FEVER VIRUS 17D-204 STRAIN(LIVE ATTENUATED)	NLT 1000 I.U	SANOPI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF SOLVENT IN PRE-FILLED SYRINGE
NDA/MAL/HDP/1484	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	CLYCIN.V	CLINDAMYCIN	2%W/W	SHAIGAN PHARMACEUTICALS (PVT) LIMITED- 14 KM ADYALA RD, RAWALPINDI, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL OTHER CREAMS	1.0X40.0 G TUBE + APPLICATOR
NDA/MAL/HDP/1485	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DICLOFEN 25	DICLOFENAC	25MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	RECTAL SYSTEMIC SUPPOSITORIES	1.0X10.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1487	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	SCHERIPROCT SUPPOSITORIES	PREDNISOLONE CAPROATE/ CINCHOCAINE HYDROCHLORIDE	1.3MG/ 1MG	BAYER HEALTH CARE MANUFACTURING S.R.L S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X12.0 SUPPOSITORY STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/1491	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	BILTRICIDE TABLETS	PRAZIQUANTEL	600MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER,1.0X10.0 TABLET BOTTLE
NDA/MAL/HDP/1492	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 75 INJECTION	DICLOFENAC SODIUM	25MG/ML	HAUPT PHARMA WULFING GMBH.- BETHELNER LANDSTR. 18, 31028 GRONAU, GERMANY.	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/1494	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	PEITEL 0.25%	PREDNICARBATE	0.25%W/W	FERRER INTERNACIONAL, S.A-JOAN BUCSALA 1-9, 08173 SANT CUGAT DEL VALLES, BARCELONA, SPAIN	SPAIN	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE

NDA/MAL/HDP/1495	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	PELOX-400	PEFLOXACIN	400MG	WOCKHARDT LIMITED --PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/1497	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE
NDA/MAL/HDP/1499	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMETHAZINE	PROMETHAZINE HYDROCHLORIDE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/1500	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ATRIPLA	EFAVIRENZ+EMTRICITABINE + TENOFOVIR	600MG +200MG+300 MG	PATHEON INC-MISSISSAUGA, ON L5N 7K9 CANADA	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1501	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CURAQUIN SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1503	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT CREAM	HYDROCORTISONE+ CINCHOCAINE	0.5%W/W + 0.5%W/W	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL OTHER CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1505	GLAXOSMITHKLINE	ERIS 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
NDA/MAL/HDP/1506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	WEPOX 2000	RECOMBINANT HUMAN ERYTHROPOIETIN	2000 IU	WOCKHARDT LIMITED --WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/1508	DAWA LIMITED	SUPER MEDIC LTD	WOMNIL	ALBENDAZOLE	200MG/5ML	DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/1510	JOHNSON & JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LISTERINE ANTISEPTIC	THYMOL + ALCOHOL 95%	12.78MG/20ML + 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
NDA/MAL/HDP/1514	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	100MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X6.0 TABLET BLISTER

NDA/MAL/HDP/1516	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL P	TRAMADOL/ PARACETAMOL	37.5MG/ 325MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1517	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	VEST MENTAMU BALM	COMPOUND METHYLSALICYLATE	MULTI INGREDIENT	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/1520	CLARIS INJECTABLES LTD	REDDYS PHARMA LIMITED	FLUCANOL	FLUCONAZOLE	2MG/ML	CLARIS INJECTABLES LIMITED--- CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL
NDA/MAL/HDP/1522	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/1523	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN	AMPICILLIN	125MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1524	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	125 MG / 5 ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1525	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BENDEX	ALBENDAZOLE	20MG/5ML	CIPLA LTD-VERNA INDUSTRIAL ESTATE, GOA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/1526	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	GAMALATE B6	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC 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

NDA/MAL/HDP/1527	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV	AMOXICILLIN + CLAVULANATE POTASSIUM	200MG + 28.5MG/ 5ML	MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1528	MICRO LABS LTD	LABOREX UGANDA LIMITED	BACTOCLAV-625	AMOXYCILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X6.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1529	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PROVIRON	MESTEROLONE	25MG	BAYER PHARMA A.G-PRODUKTIONS KG DOBERRENSTRASSE 20 99427 WEIMAR	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1532	BF BIOSCIENCES LTD	TOP UNIVERSAL MEDICARE LIMITED	NOVAPRESSIN	TERLIPRESSIN	1MG/VIAL	BF BIOSCIENCES LTD. -RAIWIND,PAKISTAN	PAKISTAN	PARENTERAL ORDINARY VIALS	1.0X1.0 MG VIAL
NDA/MAL/HDP/1533	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	5D	GLUCOSE	50G/L	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/1534	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	PARACETAMOL	PARACETAMOL	500MG	SHANDONG XIER KANGTAI PHARMACEUTICAL CO LTD-YANZHOU CITY, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1539	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LIMITED	K-TRIM	SULFAMETHOXAZOLE + TRIMETHOPRIM	200MG + 40MG	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1540	STRIDES ARCOLAB LTD	DELMAR ENTERPRISES LIMITED	NAT-E 400	VITAMIN E	400I.U	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BOTTLE

NDA/MAL/HDP/1543	MEDIPHARM INDUSTRIES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PROMAZINE ELIXIR	PROMETHAZINE HYDROCHLORIDE	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
NDA/MAL/HDP/1544	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	PROMETHAZINE HYDROCHLORIDE B.P	PROMETHAZINE HCL	25MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1546	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LANPRO	LANSOPRAZOLE	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
NDA/MAL/HDP/1547	MYLAN LABORATORIES LIMITED.	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
NDA/MAL/HDP/1549	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	PREDNICOL EYE DROPS	PREDNISOLONE/CHL ORAMPHENICOL	5MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/1551	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	CALOSHELL-500	CALCIUM CARBONATE + VITAMIN D3	1250MG + 250IU	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1552	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICAL S LTD	BLUDROX TABLETS, DISPERSIBLE	CEFADROXIL	125MG	BLUE CROSS LABORATORIES LIMITED-A-12 MIDC AMBAD-NASHIK-422010 MAHARASHTRA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP

NDA/MAL/HDP/1553	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	VIFEX	SALBUTAMOL + BROMHEXINE + GUAIFENESIN	1MG/5ML+2MG/5ML+50MG/5ML	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1554	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL CETIRIZINE	CETIRIZINE DIHYDROCHLORIDE	5MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/1555	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	GALSCRUB	CHLORHEXIDINE	4%W/W	GALENTIC PHARMA PVT. LIMITED -R-673, TTC MIDC, RUBALE, THANE BELAPUR NAVI MUMBAI 400 701 INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/1556	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	DOMI UP	ONDASENTRON	2MG/ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE, NEAR KHATRAJ CHOLADI, P.O. KHATRAJ-382721 TA: KALOL, DIST. GANDHINAGAR, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/1557	GLAXOSMITHKLINE	ERIS LTD	SYNFLORIX VACCINE	PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES (1,5,6B,7F,9V,14,23F) + (4,18C,19F) + PROTEIN D+TETANUS TOXOID+DIPHTHERIA TOXOID CARRIER PROTEINS AND ALUMINIUM PHOSPHATE	1MCG+3MCG+13MCG+8MCG+5MCG+0.5MG	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE),1.0X100.0 X0.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/1558	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	GABBRORAL	AMINOSIDINE SULPHATE	250MG	PHARMACIA AND UPJOHN S.P.A-RIJKSWEG 12, B-2870 PUURS	BELGIUM	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET STRIP
NDA/MAL/HDP/1559	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DOLOMOL	PARACETAMOL	500MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X100.0X1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1563	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	AMOXIL	AMOXYCILLIN	125MG/5ML	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1565	COSMOS LTD	ASTRA PHARMA (U) LIMITED	SALBUT SYRUP 2MG/5ML	SALBUTAMOL	2MG/5ML	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE
NDA/MAL/HDP/1566	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/1568	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM	AMOXICILLIN AND CLAVULANATE POTASSIUM	156.25MG	ALKEM LABORATORIES LTD-PLOT 167/1 VILLABE DAHBEL AMALIYA DAMAN 396210	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1569	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	KALETRA	LOPINAVIR+RITONA VIR	80MG + 20MG	ABBOTT LABORATORIES LTD- QUEENSBOROUGH, KENT ME11 SEL	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X160.0 ML BOTTLE
NDA/MAL/HDP/1570	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM AMOXY	AMOXYCILLIN	125MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1571	BHARAT SERUMS AND VACCINES LTD	GITTOES PHARMACEUTICAL S LIMITED	RHOCLONE	MONOCLONAL ANTI- D IMMUNOGLOBULIN	300MCG	BHARAT SERUMS AND VACCINES LIMITED,- PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL (1 DOSE VIAL)
NDA/MAL/HDP/1574	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AMTAS-5	AMLODIPINE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X2.0X7.0 TABLET BLISTER,10.0X10. 0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/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,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1577	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	SPIROMIDE	SPIRONOLACTONE + FRUSEMIDE	50MG+20MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/1581	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	PANTOTAB	PANTOPRAZOLE	40MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1582	LINCON PHARMACEUTICALS LIMITED	METRO PHARMACEUTICALS LIMITED	CEEPRO-500	CIPROFLOXACIN	500MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1583	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	ABZEE	ALBENDAZOLE	200MG/5ML	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/1585	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	UDIHEP FORTE	URSODEOXYCHOLIC ACID	300MG	WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1588	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	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
NDA/MAL/HDP/1589	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	CENTACID SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE+SIMETHICONE	40MG+200MG +250MG/5ML	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X170.0 ML BOTTLE
NDA/MAL/HDP/1591	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	CENTIPAR ELIXIR	PIPERAZINE CITRATE	750ML/5ML	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/1605	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ASPIRIN TABLETS	ACETYL SALICYLIC ACID	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/1615	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APCALIS SX	TADALAFIL	20MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X2.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1618	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	AMOXYDAR	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1620	IRAN MEDICAL GROUP COMPANY	UNEED GLOBAL GROUP LIMITED	LORAXONE	CEFTRIAXONE	1000MG	EXIR PHARMACEUTICAL FACTORY-2ND KM, BORUJERD, RU	IRAN	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL
NDA/MAL/HDP/1627	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID-V GEL	CLOTRIMAZOLE	2%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	VAGINAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/1631	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE ORAL SUSPENSION	NEVIRAPINE	50MG/5ML	AUROBINDO PHARMA LTD-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

NDA/MAL/HDP/1632	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1.2G	AMOXICILLIN SODIUM + CLAVULANATE POTASSIUM	1000MG +200MG	ALKEMS LABORATORIES LIMITED-PLOT 167/1 MAHATMA GHANDHI, UDYOG NAGAR, DABHEL, AMALIYA DAMAN- 396 210 UTTARANCHAL, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/1635	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICAL S LTD.	ORITAXIM 1000MG INJECTION	CEFOTAXIME SODIUM	1GM	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/1636	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICAL S LTD.	VIGAMOX	MOXIFLOXACIN	5MG/ML	S.A.ALCON COUVREUR N.V-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/1638	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLADAZOLE	SECNIDAZOLE	500MG	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-OBOUR CITY, EGYPT.	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1639	GLAXO SMITHLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL EXTRA	PARACETAMOL + 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
NDA/MAL/HDP/1641	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	UNIENZYME C MPS	NICOTINAMIDE+SIM ETHICONE+PAPAIN+ FUNGAL DIASTASE+CHARCOAL	25MG+50MG+30MG+20MG+75MG	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1642	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	EUCHLOR-1000	CHLORAMPHENICOL SODIUM SUCCINNATE B.P	1G	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/1645	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTAZOLE	MEBENDAZOLE	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 TABLET CONTAINER
NDA/MAL/HDP/1646	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE TABLETS	METRONIDAZOLE+DI LOXANIDE	200MG+250MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER

NDA/MAL/HDP/1650	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL CR 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID RETARD TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1652	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	VALPARIN CHRONO 300	SODIUM VALPROATE	300MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/1656	ANHIU	MAISHA MEDICAL SUPPLIES LIMITED	AZIGYL-500	AZITHROMYCIN	500MG	MEDICO REMEDIES PVT LIMITED-8 & 9 DEWAN & SONS, UDYOG NAGAR PALGAR, DISTRICT THANE MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X100.0X10.0 TABLET STRIP
NDA/MAL/HDP/1661	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA 100/25	LOPINAVIR/RITONAVIR	100MG/25MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.-KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/1663	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ALCID-PINK	ALUMINIUM HYDROXIDE/MAGNESIUM TRISILICATE	400MG+400MG/50ML	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X400.0 ML BOTTLE,1.0X160.0 ML BOTTLE
NDA/MAL/HDP/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,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/1670	SANOFI AVENTIS	LABOREX UGANDA LIMITED	AMARYL 4	GLIMIPIRIDE	4MG	AVENTIS PHARMA-AVENTIS PHARMA, 315 WALTLOO ROAD, SILVERTON 0127 PRETORIA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1673	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/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	MERCK & CO. INC-SUMNEYTOWN PIKE, P.O BOX 4, WEST POINT, PENNSYLVANIA, U.S. 19486, USA	UNITED STATES	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE), 1.0X10.0X0.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/1676	KOPRAN LIMITED	TATA UGANDA LIMITED	CLOXIN-250	CLOXACILLIN	250MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER, 1.0X1000.0 CAPSULE CONTAINER, 1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1677	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ZIDOVUDINE	ZIDOVUDINE	300MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/1678	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE SODIUM SUCCINATE	100MG/VIAL	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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, 1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1682	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	TOFLOX-200	OFLOXACIN	200MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1683	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	VOREN PLUS	DICLOFENAC	10MG/ML	Y.S.P INDUSTRIES (M) SDN BDH - LOT 3,5 & 7 P/7 SECTION 13 KAWASAN PERINDUSTRIAN BANDAR BARU BANGI 43000 KAJANG SELANGOR DARUL EHSAN	MALAYSIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE, 1.0X45.0 G TUBE
NDA/MAL/HDP/1684	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	IBUN-200	IBUPROFEN	200MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI, KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1686	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	QUININE SULPHATE	QUININE SULPHATE	300MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI, KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1687	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ALLDOX	DOXYCYLINE	100MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1690	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORIDE	1MG/ML	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1691	WIDE SPECTRUM ENTERPRISES (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZITHRORIV	AZITHROMYCIN	500MG	RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER

NDA/MAL/HDP/1692	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX 50MG/5ML SUSPENSION	CEFPODOXIME PROXETIL	50MG/5ML	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/1693	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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
NDA/MAL/HDP/1694	GLAXO WELLCOME(KENYA),LTD	ERIS LTD	BETNOVATE CREAM	BETAMETHASONE VALERATE	0.1%W/W	GLAXOSMITHKLINE HARMIRE - GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/1697	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	FINALLERG	CETIRIZINE DIHYDROCHLORIDE	10MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1698	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	AZEE-500	AZITHROMYCIN	500MG	CIPLA LTD.-VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1701	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FORMIN	METFORMIN HYDROCHLORIDE	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1702	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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
NDA/MAL/HDP/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
NDA/MAL/HDP/1705	IND-SWIFT	TATA UGANDA LIMITED	METSWIFT	METFORMIN	500MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1707	XEPA SOUL PATTISON (M) SDN BHD	DELMAR ENTERPRISES LIMITED	FEBRICOL TABLETS	PARACETAMOL / PSEUDOEPHEDRINE / CHLORPHENIRAMINE	500MG / 30MG /2MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BLD -1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1708	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	DENTAMOL	ACETAMINOPHEN	500MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1709	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	LUCIN CREAM	HYDROCORTISONE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE,1.0X15.0 G TUBE,1.0X5.0 G TUBE
NDA/MAL/HDP/1711	KOPRAN LIMITED	TATA UGANDA LIMITED	AMYN-250	AMOXYCILLIN	250MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/1712	I CARE PHARMA LIMITED	VITACARE LTD	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/1713	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LUMITER	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	MACLEODS PHARMACEUTICALS LTD -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.,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
NDA/MAL/HDP/1714	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	REMICOL EAR DROPS	CHLORAMPHENICOL	1%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OTIC DROPS	1.0X10.0 ML BOTTLE

NDA/MAL/HDP/1715	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCOLYN SYRUP	AMMONIUM CHLORIDE+CHLORPHENIRAMINE+DEXTROMETHORPHAN+BROMOHXINE	50MG+2MG+5MG+4MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA,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
NDA/MAL/HDP/1723	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT MULTIVITAMIN	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
NDA/MAL/HDP/1724	GLAXOSMITHKLINE LTD	ERIS LTD	AVAMYS NASAL SPRAY	FLUTICASONE FUROATE	27.5MCG/ACTUATION	GLAXO OPERATIONS UK LTD---HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/1725	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL CREAM 1%	CLOTRIMAZOLE	1%W/W	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1726	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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)
NDA/MAL/HDP/1727	MISSION PHARMA	JOINT MEDICAL STORE (UPMB - UCMB)	TETRACYCLINE HYDROCHLORIDE	TETRACYCLINE HYDROCHLORIDE	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
NDA/MAL/HDP/1728	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DELISPRIN 75MG	ASPIRIN	75MG	ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0X14.0 TABLET STRIP
NDA/MAL/HDP/1730	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCIN	500MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1731	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDIVEN-S OINTMENT	BETAMETHASONE VALERATE + SALICYLIC ACID	0.05%W/W + 3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE

NDA/MAL/HDP/1732	MICRO LABS LTD	LABOREX UGANDA LIMITED	CEFEX-250	CEPHALEXIN	250MG	MICROLABS LIMITED-PLOT NO. 121-124, KIADB, BOMMASANDRA , -JIGNI LINK ROAD, ANEKUL TALUK,BANGALORE, KARNATAKA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1734	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMOMINT	COMPOUND MAGNESIUM TRISILICATE	500MG	TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,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 TABLET CONTAINER
NDA/MAL/HDP/1736	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	KLERIMED	CLARITHROMYCIN	500MG	MEDOCHÉMIE LTD-1-10 CONSTANTINOUPOLEOS TREET 3011 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/1738	ALCON PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TEARS NATURELE II	NATURAL TEARS	15ML	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/1739	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MELOX	MELOXICAM	15MG	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1741	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEOPRED-P	PREDNISOLONE ACETATE + NEOMYCIN SULPHATE+ POLYMYXIN-B	5MG/ML +5MG/ML + 1M I.U/ML	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1743	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	DAPRIL	LISINAPRIL DIHYDRATE	10MG	MEDOCHÉMIE LTD-1-10 CONSTANTINOUPOLEOS TREET 3011 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1745	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIGEN	GENTAMYCIN SULPHATE	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1746	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	PRAZIQUANTEL	PRAZIQUANTEL USP	600MG	CSPC OUYI PHARMACEUTICAL CO.LTD. LIMITED-NO. 276, WEST ZHONGSTAN ROAD, SHIJIAZHANG, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/1747	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN H 50	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1748	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-500	AZITHROMYCIN	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0 CAPSULE BLISTER
NDA/MAL/HDP/1749	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX	VITAMIN B COMPLEX	N/A	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/1750	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIFLOX	NORFLOXACIN	0.3%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1751	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIFUCIN	FUSIDIC ACID	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X5.0 ML AMPOULE
NDA/MAL/HDP/1754	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIMOL	TIMOLOL MALEATE	0.5%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/1755	MEMPHIS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOPAGON TABLETS	BROMOCRIPTINE	2.5MG	MEMPHIS COMPANY--8 EL SAWAH STREET, CAIRO. EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1756	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APRICROM	SODIUM CROMOGLYCATE	2%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1758	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APICORT	PREDNISOLONE ACETATE	0.12%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1760	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEODEX	NEOMYCIN +DEXAMETHASONE	0.5%W/V + 0.1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES-AMMAN PHARMACEUTICAL INDUSTRIES-KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OTIC DROPS	1.0X1.0X10.0 ML VIAL

NDA/MAL/HDP/1762	AMMAN PHARMACEUTICAL INDUSTRIES	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APITROPIN	ATROPINE	1%W/V	AMMAN PHARMACEUTICALS INDUSTRIES .- KING ABDULLAH II, INDUSTRIAL ESTATE,SAHAB, AMMAN, JORDAN	JORDAN	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/1763	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	ASPIRIN TABLETS BP	ACETYL SALICYLIC ACID	300MG	LABORATORY & ALLIED LTD.-PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/1764	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FRESH BURST LISTERINE	ALCOHOL + THYMOL	95 % W/V + 12 MG	JOHNSON&JOHNSON PTY LTD.-241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X500.0 ML CONTAINER
NDA/MAL/HDP/1765	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	RILIF PLUS	ACECLOFENAC + PARACETAMOL	100MG + 500MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1766	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COLDEASE CAPSULES	PARACETAMOL+CAF FEINE CITRATE+CHLORPHE NIRAMINE MALEATE+PSEUDOE PHEDRINE HYDROCHLORIDE	400MG+30MG +4MG+30MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1767	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PROSTEROL	ALFUZOSIN HYDROCHLORIDE	10MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1768	GLAXO SMITHKLINE LTD(ITALY)	ERIS LTD	ULTIVA INJECTION 2MG	REMIFENTANIL	2MG	GLAXOSMITHKLINE LTD MANUFACTURING SPA-VERONA	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/1769	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	ENGERIX-B VACCINE	HEPATITIS B SURFACE ANTIGEN	10MCG/ML	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X10.0X0.5 ML VIAL (1 DOSE),1.0X25.0X0.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/1770	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	DIOVAN 160MG TABLETS	VALSARTAN	160MG	NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET STRIP

NDA/MAL/HDP/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
NDA/MAL/HDP/1772	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	GESTID TABLETS	COMPOUND MAGNESIUM TRISILICATE	385MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED,-INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X4.0 TABLET BLISTER
NDA/MAL/HDP/1773	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT 500	LEVOFLOXACIN HEMIHYDRATE	500MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 500MG CAPSULES	AMOXYCILLIN TRIHYDRATE	500MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SOLUTION	POVIDONE IODINE	10.0G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE
NDA/MAL/HDP/1780	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/1781	ASTRAZENECA	MACNAUGHTON LIMITED	ARIMIDEX	ANASTROZOLE	1MG	ASTRAZENECA PHARMACEUTICALS LP-NEWARK, DELAWARE	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1782	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	PER 5ML: 15MG + 90MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE
NDA/MAL/HDP/1783	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAEOVATE OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X15.0 G TUBE

NDA/MAL/HDP/1784	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	AZICURE-500	AZITHROMYCIN	500MG	MACLEODS PHARMACEUTICALS LIMITED (BLOCK –N1)-VILLAGE THEDA, P.O. LODHI MAJRA,TEHSIL BADDI, HIMACHAL PRADESH - 174101,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1785	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	ACTION TABLETS	ACETYL SALICYLATE + CAFFEINE + PARACETAMOL	600 MG + 50 MG + 400 MG	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
NDA/MAL/HDP/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
NDA/MAL/HDP/1790	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNITRIM TABLET	CO-TRIMOXAZOLE	480MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X250. 0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER
NDA/MAL/HDP/1792	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	LIPODAR	ATORVASTATIN	20MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/1795	KOPRAN LIMITED	TATA UGANDA LIMITED	AMPIK-250	AMPICILLIN	250MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER

NDA/MAL/HDP/1796	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA 250	AZITHROMYCIN	250 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/1797	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	AMPICILLIN+CLOXACILLIN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/1799	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	SECZOL DS	SECNIDAZOLE	1GM	INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1801	LABORATORY AND 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
NDA/MAL/HDP/1803	ASTRA ZENECA AB	MACNAUGHTON LIMITED	NEXIUM 40MG	ESOMEPRAZOLE	40MG	ASTRAZENECA AB.-GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER,1.0X14.0 TABLET CARTON,1.0X28.0 TABLET CARTON
NDA/MAL/HDP/1805	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORIDE	50MG + 1000MG	AESICA QUEENSBOROUGH LTD .-NORTH ROAD, QUEENSBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X14.0 TABLET BLISTER

NDA/MAL/HDP/1806	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICAL S LTD	BLUMOX P	AMOXYCILLIN	125MG	BLUE CROSS LABORATORIES LIMITED-A-12 MIDC AMBAD-NASHIK-422010 MAHARASHTRA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0X2.0 TABLET STRIP
NDA/MAL/HDP/1807	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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/SYR UPS/DROPS	1.0X8.0 ML BOTTLE
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1809	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOVIT-6	PYRIDOXINE	25MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1810	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	AGOTRI	TRIFLUOPERAZINE	5MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/1812	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN TABLETS	QUININE SULPHATE	300MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1815	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	SUPIROCIN OINTMENT	MUPIROCIN	2%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL OTHER OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/1816	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	DRESS UP CREAM	NEOMYCIN SULPHATE	0.5%W/W	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE

NDA/MAL/HDP/1819	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CINAMET-200	CIMETIDINE	200MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1821	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL 500 TABLETS	MEFENAMIC ACID	500MG	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1822	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	EPHEDRINE	EPHEDRINE HYDROCHLORIDE	30MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/1824	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	GLANDIN E2 GEL	DINOPROSTONE	0.5MG	NABIQASIM INDUSTRIES (PVT) LTDv-17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X3.0 G TUBE WITH STERILE CATHETER
NDA/MAL/HDP/1825	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	COLDEASE SYRUP	PARACETAMOL+CHLORPHENIRAMINE MALEATE+PSEUDOPHEDRINE HYDROCHLORIDE	120MG+2MG+15MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1826	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	LOGICAN-200	FLUCONAZOLE	200MG	WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X4.0 CAPSULE BLISTER
NDA/MAL/HDP/1827	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ALBASOL SUSPENSION	ALBENDAZOLE	200MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/1828	ASTRAZENECA	MACNAUGHTON LIMITED	TENORET	ATENOLOL + CHLORTHALIDONE	50 MG + 12.5 MG	ASTRA ZENECA UK LIMITED-SILK ROAD BUSINESS PARK,MACCLESFIELD,CHESHIRE SK10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/1832	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	DICLOAS	DICLOFENAC SODIUM	50MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X5.0X20.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/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

NDA/MAL/HDP/1838	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	ABZEE	ALBENDAZOLE	400MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/1839	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	FEVEREX	PARACETAMOL	500MG	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	1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/1840	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	OVA-MIT	CLOMIPHENE	50MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1841	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL CREAM	CLOTRIMAZOLE	1%W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1842	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	SUGAQUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICALS INDUSTIES- PLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1843	USV 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
NDA/MAL/HDP/1844	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	SULFAMETHOXAZOLE / TRIMETHOPRIM	SULFAMETHOXAZOL E / TRIMETHOPRIM	800MG /160MG	GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/1848	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	PARATAL	PARACETAMOL	500MG	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/1849	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CIFIN	CIPROFLOXACIN	0.2%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1850	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	400MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/1851	PHILLIPS PHARMACEUTICALS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CAPSIFENAC GEL	CAPSAICIN + DICLOFENAC + LEVOMENTHOL + METHYL SALICYLATE	0.438 G + 0.335 G + 0.135 G + 0.918 G	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE,1.0X1.0X10.0 G TUBE
NDA/MAL/HDP/1852	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	VERCEF ORAL SUSPENSION	CEFACLOX	125MG/5ML	RANBAXY LABORATORIES-LABORATORIES LIMITED INDUSTRIAL AREA 3 DEWAS 455001	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1853	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AERIUS ORAL SOLUTION	DESLOXATADINE	0.5MG/ML	MSD (PTY) LTD- LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA,SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	BELGIUM	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X150.0 ML BOTTLE
NDA/MAL/HDP/1856	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROPRANOLOL TABLETS B.P. 40MG	PROPRANOLOL HYDROCHLORIDE	40MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1861	GUILIN PHARMACEUTICALS CO LTD	STAR PHARMACEUTICALS LTD	SULFAMETHOXAZOLE / TRIMETHOPRIM	SULFAMETHOXAZOLE / TRIMETHOPRIM	400MG /80MG	GUILIN PHARMACEUTICAL CO.LTD.-NO.43 QUILIDIAN ROAD GUILIN 541002, GUANGXI, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/1863	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ORACURE GEL	LIDOCAINE HCL+CETYL PYRIDINIUM 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

NDA/MAL/HDP/1864	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	PATANOL	OLOPATADINE HYDROCHLORIDE	0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL
NDA/MAL/HDP/1865	FDC LTD	AIVEEN (U) LIMITED	MYCODERM-C POWDER	CLOTRIMAZOLE	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
NDA/MAL/HDP/1866	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	NIZORAL	KETOCONAZOLE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1867	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	LEVATEX TABLETS	LEVAMISOLE HYDROCHLORIDE	40MG	CYANO PHARMA(P)-115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	500.0 TABLET CONTAINER,1.0X 10.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1868	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ZIDOVUDINE	ZIDOVUDINE	300MG	AUROBINDO PHARMA LTD-UNIT VII (SEZ), PLOT NO.S1, GREEN INDUSTRIAL PARK, POLEPALLY (V) JEDCHERIA (M), MAHABOOB NAGAR	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/1869	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	STOCRIN 200	EFAVIRENZ	200MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA,MERCK SHARP & DOHME.- WAADERWAG 39, POSTBUS 581. 2003 PC HAARLEM	NETHERLANDS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X90.0 TABLET BOTTLE
NDA/MAL/HDP/1873	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	JANUMET	SITAGLIPTIN + METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/1877	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MINT-O-COOL	DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE	120MG + 250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER
NDA/MAL/HDP/1879	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYL PENICILLIN	250MG	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1880	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1881	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1882	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	250MG	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0X10.0 CAPSULE BLISTER,1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1886	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM QUIN TABLETS	CHLOROQUINE PHOSPHATE	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1887	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL	PARACETAMOL	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,100.0 TABLET CONTAINER,250.0 TABLET CONTAINER,500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1888	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM QUIN SYRUP	CHLOROQUINE PHOSPHATE	80MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1889	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PRED SOL	PREDNISOLONE	5MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON,1.0X10.0 TABLET CARTON
NDA/MAL/HDP/1891	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	LEVOMAC 500	LEVOFLOXACIN	500MG	MACLEODS PHARMACEUTICALS LTD -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER
NDA/MAL/HDP/1892	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LEVOMAC 250	LEVOFLOXACIN	250MG	MACLEODS PHARMACEUTICALS LTD -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0X5.0 TABLET BLISTER
NDA/MAL/HDP/1893	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	TRIKA 0.25 TABLETS	ALPRAZOLAM	0.25MG	UNICHEM LABORATORIES LTD--PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1894	KOPRAN LIMITED	TATA UGANDA LIMITED	TRIM-480	CO-TRIMOXAZOLE	480MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/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 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1898	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	ZAPACID - 30	LANSOPRAZOLE	30MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1899	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	TUSPRESS COUGH SUPPRESSANT	MULTI-INGREDIENT	MULTI-INGREDIENT	INDOCO REMEDIES LTD - 0-L-14 VERNA INDUSTRIAL AREA, VERNA, GOA-403722	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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,1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/1901	AJANTA PHARMA LTD 310	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL	IBUPROFEN + PARACETAMOL	100MG + 162.5 MG /5ML	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1902	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMODIUM	LOPERAMIDE HYDROCHLORIDE	2MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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	1.0X1.0X1.0 ML AMPOULE
NDA/MAL/HDP/1905	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	OXYTOCIN INJECTION	OXYTOCIN	10I.U/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE,1.0X100.0X1.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/1908	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OLMY 20	OLMESARTAN	20MG	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

NDA/MAL/HDP/1911	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CODIENE PHOSPHATE TABLETS BP 30	CODEINE PHOSPHATE	30MG	COSMOS LIMITED -RANGWA ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1912	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM	ALBENDAZOLE	200MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/1914	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CHLORPHENIRAMINE	CHLORPHENIRAMINE	4MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/1915	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/1919	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDIDERM CREAM	BECLOMETASONE/C LOTRIMAZOLE/GENTAMYCIN	0.025%W/W+ 1%W/W+0.1% W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/1922	IPCA LABORATORIES LIMITED	MEDVIN PHARMA LIMITED	AZIFAST-500	AZITHROMYCIN	500MG	IPCA LABORATORIES LTD-SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER
NDA/MAL/HDP/1923	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	BETAMETHASONE	BETAMETHASONE	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
NDA/MAL/HDP/1924	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO (SHIJIAZHANG) PHARMACEUTICAL CO LTD-NO. 47 FENGSHOU ROAD SHIJIAZHANG,CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X500.0 MG VIAL
NDA/MAL/HDP/1925	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	G - ALFENAC- P	ACECLOFENAC + PARACETAMOL	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

NDA/MAL/HDP/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
NDA/MAL/HDP/1928	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX	ALGINIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG + 250MG +250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1929	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTORVA 40	ATORVASTATIN	40MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1931	ASTRAZENECA	MACNAUGHTON LIMITED	ZOLADEX LA	GOSERELIN ACETATE	10.8MG	ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	PARENTERAL RETARD PRE-FILLED SYRINGES	1.0X10.8 MG IMPLANT
NDA/MAL/HDP/1934	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR SUSPENSION	CHLORAMPHENICOL	125MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1935	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	SULPHA KREAM-N	SULPHANILAMIDE	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
NDA/MAL/HDP/1936	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON EXPECTORANT	CHLORPHENIRAMINE MALEATE + AMMONIUM CHLORIDE	MULTINGREDIENT	GLAXO WELLCOME (KENYA) LTD-KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1937	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	AUROBINDO PHARMA LIMITED (UNIT III) - AURO HOUSE, 313, BUCHUPALLY, QUTHUBULLAPAR(M), RR DISTRICT HYDERABAD-500090, ANDHERA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1938	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	INFULGAN	PARACETAMOL	10MG/ML	YURIA-PHARM, LTD.-18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE.	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X20.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/1941	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	RABELOX IV	RABEPRAZOLE	20MG/VIAL	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL
NDA/MAL/HDP/1942	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMCLOREN	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/1943	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 2.6	NITROGLYCERIN (CONTROLLED RELEASE)	2.6MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD TABLETS	1.0X25.0 TABLET CONTAINER
NDA/MAL/HDP/1946	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	SOLUDOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGAR ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	10.0X10.0 TABLET STRIP
NDA/MAL/HDP/1948	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	500MG	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER,1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/1952	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NIZORAL	KETOCONAZOLE	20MG/G	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X80.0 ML BOTTLE
NDA/MAL/HDP/1953	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	RANTAB-150	RANITIDINE	150MG	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	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1954	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	RAPEED-20	RABEPRAZOLE	20MG	ALKEM LABORATORIES LTD .-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X1.0X10.0 TABLET STRIP

NDA/MAL/HDP/1955	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	MILCILLIN	AMPICILLIN	250MG	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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 CAPSULE CONTAINER
NDA/MAL/HDP/1957	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	MILCILLIN	AMPICILLIN	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1960	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	DIFENAC	DICLOFENAC SODIUM	50MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD -PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1962	GLAXO SMITHKLINE LTD(ITALY)	ERIS LTD	NIMBEX	CISATRACURIUM BESYLATE	2MG/ML	GLAXOSMITHKLINE S.P.A -STRADA PROVINCIALE ASOLANA 9	ITALY	PARENTERAL ORDINARY VIALS	2.5 ML VIAL,1.0X10.0 ML VIAL
NDA/MAL/HDP/1963	MILAN LABERATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	DICLOFENAC GEL	DICLOFENAC	1%W/W	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X35.0 G TUBE

NDA/MAL/HDP/1964	MILAN LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	CLONEX	CLOTRIMAZOLE	1%W/W	MILAN LABORATORIES -PLOT NOS 63, 67 & 87, JAWAHAR CO-OP. INDUSTRIAL ESTATE LTD., KAMOTHE, PANVEL (NAVI MUMBAI).	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/1966	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	PARACIN	PARACETAMOL	500MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1969	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SR 75MG	DICLOFENAC SODIUM	75MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY-NA	ITALY	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/1970	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	CETRAMAC	CETIRIZINE	10MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/1974	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	CEFROTIL	CEFUROXIME AXETIL	500MG	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1975	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	BET-CODERM N	BETAMETHASONE + NEOMYCIN	0.1 W/W + 0.5 W/W	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/1976	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	OROGEL	CHOLINE SALICYLATE+LIGNOC AINE HCL+BENZALKONIUM CHLORIDE	8.7%W/W+2% W/W+0.01%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE
NDA/MAL/HDP/1977	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	LOSA-H	LOSARTAN + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/1984	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	CIALIS	TADALAFIL	20MG	LILLY SA, AVDA DE LA INDUSTRIA-LILLY SA, AVDA DE LA INDUSTRIA, 30 28108 ALCOBENDAS - MADRID	SPAIN	ORAL SOLID ORDINARY TABLETS	2.0X2.0 TABLET BLISTER
NDA/MAL/HDP/1985	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	PROXIMEXA ORAL SUSPENSION 250MG/5ML	CEFUROXIME AXETIL	250MG/5ML	GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE
NDA/MAL/HDP/1987	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	FOMYCETIN	CHLORAMPHENICOL	250MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1989	FERRER INTERNACIONAL S.A	LABOREX UGANDA LIMITED	DERMOFIX	SERTAONAZOLE 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
NDA/MAL/HDP/1990	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TAGERA FORTE	SECNIDAZOLE	1G	UNICHEM LABORATORIES LTD---C31 & 32 INDUSTRIAL AREA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/1991	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	TETRACYCLINE	TETRACYCLINE	250MG	SHANDONG XIER KANGTAI PHARMACEUTICAL CO LTD-YANZHOU CITY, CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/1992	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	UNIKPEF	PEFLOXACIN	400MG	J.B CHEMICALS-ANKLESHWAR, GUJARAT 393002 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/1994	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	PANUM 40	PANTOPRAZOLE	40MG	J.B. CHEMICALS AND PHARMACEUTICALS LTD .-128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X3.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/1999	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CARBATOL 200	CARBAMAZEPINE	200MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 2.0X 5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2000	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	CALCIGARD RETARD	NIFEDIPINE(SR)	20MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID RETARD TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2003	GLAXO SMITHKLINE LTD(ITALY)	ERIS LTD	PROTEDEX 1G	CEFTRIAXONE	1G	GLAXOSMITHKLINE LTD MANUFACTURING SPA-VERONA	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/2004	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	R.B.TONE	FERROUS GLUCONATE + VITAMIN C + VITAMIN B12 + VITAMIN B1 + VITAMIN B2 + VITAMIN B6 + CALCIUM PANTOTHENATE + VITAMIN B3 + FOLIC ACID + DIBASIC CA PO4 + 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
NDA/MAL/HDP/2005	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	KAMAGRA-100	SILDENAFIL CITRATE	100MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIAL AREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2008	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- CREAM	CLOTRIMAZOLE + BECLOMETASONE DIPROPIONATE CREAM	1%W/W + 0.025%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 , D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2009	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ZITHROX	AZITHROMYCIN	200MG/5ML	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X15.0 ML BOTTLE, 1.0X30.0 ML BOTTLE

NDA/MAL/HDP/2011	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/2012	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID -B- LOTION	CLOTRIMAZOLE + BECLOMETHASONE DIPROPIONATE	1% + 0.025%	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/2016	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	CANDID CREAM	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/2018	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	ORAXIN SYRUP	CYPROHEPTADINE+T RICHOLINE CITRATE	2MG+275MG	CENTAUR PHARMACEUTICALS LTD,-- KARASWADA MAPUSA GOA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2020	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	QUINE	QUININE SULPHATE	300MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER
NDA/MAL/HDP/2021	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	PREGVIT ZINC	MULTIVITAMIN/MINERALS	MULT-INGREDIENT	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X12.0X2.0 CAPSULE BLISTER
NDA/MAL/HDP/2022	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	TORACTIN	CYPROHEPTADINE	2MG/5ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE

NDA/MAL/HDP/2024	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	NEXPRO - 40	ESOMEPRAZOLE MAGNESIUM TABLET	40MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/2026	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 10MG	AMLODIPINE BESYLATE	10MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2027	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CO-ANGINET 160/12.5MG	VALSARTAN + HYDROCHLOROTHIAZIDE	160MG + 12.5MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2028	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	SELANZ - SR	LANSOPRAZOLE	30MG	SEARLE PAKISTAN LIMITED-PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2033	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ANGIZAAR-50	LOSARTAN POTASSIUM	50MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/2035	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NEOSIDAR	SULPHADOXINE + PYRIMETHAMINE	500MG + 25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X50.0X3.0 TABLET BLISTER
NDA/MAL/HDP/2036	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN REGULAR	HUMAN INSULIN	100IU	ELI LILLY & COMPANY-LILLY TECHNOLOGY CENTER, 1555 S HARDING, INDIANAPOLIS, INDIANA, 46221,LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY SC VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE

NDA/MAL/HDP/2037	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	STOCRIN 50	EFAVIRENZ	50MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA,MERCK SHARP & DOHME.- WAADERWAG 39, POSTBUS 581. 2003 PC HAARLEM	NETHERLANDS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/2039	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	RANITIDINE INJECTION USP	RANITIDINE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/2040	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0X12.0 TABLET BLISTER,1.0X3.0X8.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/2043	COSMOS LTD	ASTRA PHARMA (U) LIMITED	DIASTOP TABLETS	ATTAPULGITE/ ALUMINIUM HYDROXIDE	N/A	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP
NDA/MAL/HDP/2045	CLARIS INJECTABLES LTD	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
NDA/MAL/HDP/2046	COSMOS LTD	ASTRA PHARMA (U) LIMITED	LORHISTINA	LORATADINE	10MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2047	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	RITONAVIR	RITONAVIR	100MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER,1.0X 30.0 TABLET BOTTLE
NDA/MAL/HDP/2050	NORVATIS PHARMA AG- SWITZERLAND	KARURI PHARMACEUTICAL S LTD.	ISOPTO CARPINE 2%	PILOCARPINE	2%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/2051	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON TABLETS	CHLORPHENIRAMIN E MALEATE	4MG	GLAXO WELLCOME (KENYA) LTD-KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/2053	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ASOMEX-5	AMLODIPINE BESILATE	5MG	EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2055	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	ARTESUN	ARTESUNATE	120MG	GUILIN PHARMACEUTICAL CO.,LTD-NO 43 QILIDIAN ROAD GUILIN 541002, GUANGXI	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
NDA/MAL/HDP/2056	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	BRO-ZEDEX	TERBUTALINE SULPHATE +BROMHEXINE HYDROCHLORIDE+G UAIPHENESIN+MEN THOL	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
NDA/MAL/HDP/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
NDA/MAL/HDP/2061	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	ADSOCARB TABLETS	ACTIVATED CHARCOAL	250MG	CYANO PHARMA(P)-115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER

NDA/MAL/HDP/2063	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROGYNON FE	LEVONORGESTREL / ETHINYLESTRADIOL.	0.15MG / 0.03MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER
NDA/MAL/HDP/2066	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	METHOTREXATE	METHOTREXATE	2.5MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2067	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET	CETIRIZINE DIHYDROCHLORIDE	10MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2068	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	DOMADOL	TRAMADOL HYDROCHLORIDE	50MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2069	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SK DERM	BETAMETHASONE + CLOTRIMOXAZOLE + GENTAMYCIN	0.05%W/W + 1%W/W + 0.1%W/W	S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/2070	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MIRENA	LEVONORGESTREL	52MG	BAYER OY-PANSIONATE 47 20210 TURKU FINLAND	FINLAND	PARENTERAL RETARD IMPLANTS	1.0X1.0 IMPLANT CARTON
NDA/MAL/HDP/2071	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFAMOR DRY SYRUP	CEFALEXIN	125MG/5ML	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2073	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES VACCINE LIVE ATTENUATED(FREEZE-DRIED)	MEASLES VIRUS	NOT LESS THAN 1000CCID50/DOSE	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML AMPOULE OF STERILE WATER FOR INJECTION,1.0X10.0 DOSE VIAL + 5ML AMPOULE OF STERILE WATER FOR INJECTION
NDA/MAL/HDP/2074	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOXIN ORAL SUSPENSION	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2075	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOPRED	PREDNISOLONE	5MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/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 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2077	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	30MG/5ML	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2080	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	BETAMETHASONE VALERATE	BETAMETHASONE 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
NDA/MAL/HDP/2081	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	COMPOUND SODIUM LACTATE	SODIUM LACTATE+SODIUM CHLORIDE+POTASSIUM CHLORIDE+ CALCIUM CHLORIDE DIHYDRATE	0.32G+0.6G+0.04+0.027/100 ML	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184	KENYA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE

NDA/MAL/HDP/2083	BIOLOGICAL E. LTD	GITTOES PHARMACEUTICALS LIMITED	BEVAC	PURIFIED HEPATITIS B SURFACE ANTIGEN	20MCG	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHAR (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY VIALS	1.0X35.0X1.0 ML VIAL (1 DOSE VIAL),1.0X24.0X10.0 ML VIAL (10 DOSE VIAL)
NDA/MAL/HDP/2085	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CHLORHEXIDINE GLUCONATE SOLUTION	CHLORHEXIDINE GLUCONATE	20%W/V	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE,1.0X1.0 L JERRYCAN,1.0X5.0 L JERRYCAN
NDA/MAL/HDP/2086	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	BENDAS	ALBENDAZOLE	200MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, SARKEJ BAVLA HIGHWAY RAJODA AHMEDABAD 382220, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET STRIP
NDA/MAL/HDP/2087	ABBVIE LOGISTICS BV	MEDICAL ACCESS (UGANDA) LIMITED	NORVIR	RITONAVIR	100MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/2089	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN XR 500MG	METFORMIN HCL EXTENDED RELEASE	500MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2090	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	CIPROREN	CIPROFLOXACIN	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2091	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CAMSTON	CLOTRIMAZOLE	1%W/W	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES LTD-PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/2093	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TRIGAN-D TABLET	PARACETAMOL + DICLOFENAC	500MG + 20MG	CADILA PHARMACEUTICALS LTD ...-1389 DHOKA GUJARAT STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP
NDA/MAL/HDP/2094	MICRO LABS LTD	LABOREX UGANDA LIMITED	LEVOBACT-750	LEVOFLOXACIN HEMIHYDRATE	750MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2095	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL	PARACETAMOL	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/2099	XEPA SOUL PATTISON (M) SDN BHD	DELMAN ENTERPRISES LIMITED	HYDROCORTISONE 1% CREAM	HYDROCORTISONE	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
NDA/MAL/HDP/2100	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	ORALCON - F	LEVONORGESTREL & ETHINYLESTRADIOL+ 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
NDA/MAL/HDP/2101	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDISPRIN	ACETYL SALICYLIC ACID	75MG	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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, VIRGONAG BANGALORE-560 049, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER

NDA/MAL/HDP/2104	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG + 50MG + 60MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/2105	MEDREICH PLC	LABOREX UGANDA LIMITED	FLEMING 156MG/5ML	AMOXYCILLIN + CLAVULANATE POTASSIUM	125 MG + 31.5 MG/5 ML	MEDREICH LIMITED --UNIT I-12TH MILE, OLD MADRAS ROAD, VIRGONAGAR BANGALORE-560 049, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2107	MEDREICH PLC	LABOREX UGANDA LIMITED	AMEDIN 10	AMLODIPINE	10 MG	MEDREICH STERILAB LIMITED--AVAILAHALI, BANGALORE-560 062 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X14.0X2.0 TABLET BLISTER
NDA/MAL/HDP/2111	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/2112	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/2115	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTRIM	CO-TRIMOXAZOLE	480MG	ASTRA LIFE CARE (INDIA) PVT LIMITED-57/P RAJODA 382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/2118	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	RIFAFOURE E-275	RIFAMPICIN+ISONIAZID+PYRAZINAMIDE +ETHAMBUTOL	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

NDA/MAL/HDP/2120	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MEGAPIME	CEFEPIME	1G	ALKEM LABORATORIES LTD.-VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.0 G VIAL
NDA/MAL/HDP/2123	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/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
NDA/MAL/HDP/2129	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	500MG/125MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/2130	IPCA LABORATORIES	MEDVIN PHARMA LIMITED	ZERODOL-LA	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
NDA/MAL/HDP/2132	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LOPINAVIR/ RITONAVIR	LOPINAVIR/ RITONAVIR	200MG/ 50MG	AUROBINDO PHARMA LTD-UNIT III-SURVEY NO.313,BACHUPALLY VILLAGE,QUTHUBULLAPUR MANDAL R.R DISTRICT(A.P),INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET CONTAINER
NDA/MAL/HDP/2133	NOVO NORDISK	STAR PHARMACEUTICALS LTD	ACTRAPID	HUMAN INSULIN	100 I.U/ML	NOVO NORDISK PHARMA-NOVO ALLE	DENMARK	PARENTERAL ORDINARY SC VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/2135	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/2136	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	SEDIPROCT SUPOSITORY	HYDROCORTISONE+ CINCHOCAINE+ ESCULOSIDE+ FRAMYCETIN	5MG + 5MG +10MG +10MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	TOPICAL EXTERNAL SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/2141	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	INFLAZONE	MULTIINGREDIENT	N/A	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE

NDA/MAL/HDP/2143	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRISEOFIL	GRISEOFULVIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2144	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICOTIL	TENOXICAM	20MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X3.0 VIAL CARTON + 1*3*2ML WFI AMPOULE
NDA/MAL/HDP/2145	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	METFIL 500	METFORMIN	500MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/2147	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	LABOREX UGANDA LIMITED	DICLOFEN -50	DICLOFENAC	50MG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2149	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT DEPOT	HYDROXYPROGESTE RONE HEXANOATE	250MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/2150	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN MIXTURE	HUMAN INSULIN	70/30 I.U	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,- INDIANA 46285 USA	UNITED STATES	PARENTERAL ORDINARY S C VIALS	1.0X4.0 ML VIAL,1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/2151	USV 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
NDA/MAL/HDP/2154	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GLYNASE	GLIPIZIDE	5MG	FREDUN PHARMACEUTICALS LIMITED--- 14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2159	SANOFI PASTEUR	LABOREX UGANDA LIMITED	VAXIGRIP	INFLUENZA VIRUS STRAINS H1N1 + H3N2 + B	15MCG + 15MCG + 15MCG	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE)

NDA/MAL/HDP/2160	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ACEM-500	CLARITHROMYCIN	500MG	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2161	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX CREAM	ACICLOVIR	5%W/W	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE
NDA/MAL/HDP/2165	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TRAMAREN	TRAMADOL HYDROCHLORIDE	50MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2167	BAYER AG	SURGIPHARM (U) LIMITED	MYCOSPOR SOLUTION	BIFONAZOLE	10MG	BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY	GERMANY	TOPICAL EXTERNAL LIQUIDS	1.0X15.0 ML BOTTLE,1.0X50.0 ML BOTTLE
NDA/MAL/HDP/2168	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICAL S LIMITED	HYDROCORTISONE INJECTION	HYDROCORTISONE SODIUM SUCCINATE	100MG	ROTEX MEDICA GMBH-BUNSENSTRASSE 4 TRITTAU	GERMANY	PARENTERAL ORDINARY DRY VIALS	1.0X8.0 ML VIAL
NDA/MAL/HDP/2170	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ALSARTAN-AM	LOSARTAN + AMLODIPINE	50MG + 5MG	ARISTO PHARMACEUTICALS PVT. LIMITED- PLOT NO. 208, NEW INDUSTRIAL AREA NO. II, MANDIDEEP-462046, DIST. - RAISEN, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/2171	IDA	KIMSY MEDS LTD	CO-TRIMOXAZOLE	CO-TRIMOXAZOLE	100MG/200 MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR- 635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2173	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICAL S LTD	GLEVO-500	LEVOFLOXACIN	500MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET BLISTER
NDA/MAL/HDP/2175	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PARAFIZZ	PARACETAMOL	500MG	CIPLA LTD .-PLOT NO. 9, 10 AND 15, INDORE SPECIAL ECONOMIC ZONE, PHASE -II, PITHAMPUR, DISTRICT DHAR, PIN CODE: 454775, MADHYA PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0X4.0 TABLET STRIP,1.0X4.0X4.0 TABLET STRIP
NDA/MAL/HDP/2176	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RISPITAS-2	RISPERIDONE	2MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2177	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM ERYMYCIN	ERYTHROMYCIN ESTOLATE	125MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2178	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/2179	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICAL S LIMITED	PENICIN	BENZYPENICILLIN	1MEGA	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON
NDA/MAL/HDP/2180	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PEN V	PHENOXYMETHYLPE NICILLIN	125MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2181	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM PHEN	PHENOXYMETHYLPE NICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	100.0 TABLET CONTAINER,100.0 TABLET CONTAINER,500.0 TABLET CONTAINER,250.0 TABLET CONTAINER
NDA/MAL/HDP/2183	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OCID I.V.	OMEPRAZOLE	40MG/VIAL	CADILA HEALTHCARE LTD-PLOT 203-213, KUNDAIM INDUSTRIAL ESTATE, GOA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/2184	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM QUIN MIXTURES	QUININE	100MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2185	GLAXOSMITHKLINE LTD	ERIS 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)
NDA/MAL/HDP/2186	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL DIPHENHYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	7MG+67.5MG /5ML	KOTRA PHARMA-BHD 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2187	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	VOMIZ	ONDANSETRON	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

NDA/MAL/HDP/2188	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PREDNISOLONE	PREDNISOLONE	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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2189	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL BETAMETHASONE	BETAMETHASONE	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,1.0X5.0 G TUBE
NDA/MAL/HDP/2191	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	KLOXY	CLOXACILLIN	250MG	LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2194	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CALCIUM D SYRUP	CALCIUM CARBONATE/VITAMIN D	250MG+125IU /5ML	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/2195	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	EUDERM CREAM	UREA	10%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X45.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/2197	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	WHITFIELD'S OINTMENT	BENZOIC ACID + SALICYLIC ACID	6%W/W + 3%W/W	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE
NDA/MAL/HDP/2199	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EUTHYROX 50MCG	LEVOTHYROXINE SODIUM	50MCG	MERCK KGAA - -FRANKFRUTER STRASSE 250, D-64293,DARMSTADT- GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER,1.0X1.0X30.0 TABLET BLISTER
NDA/MAL/HDP/2203	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	MYCORIL 100 VAGINAL TABLETS	CLOTRIMAZOLE	100MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	VAGINAL TABLETS	1.0X2.0X3.0 PESSARY STRIP
NDA/MAL/HDP/2204	IND SWIFT LTD	TATA UGANDA LIMITED	ATSTAT	ATORVASTATIN	100MG	IND SWIFT LTD-GBU JAWAHARPUR OFF NH-21 DERABASSI DIST MOHALI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2205	IND SWIFT LTD	TATA UGANDA LIMITED	C-SWIFT	CETIRIZINE HCL	10MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2206	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	NETRA CORT	HYDROCORTISONE 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
NDA/MAL/HDP/2208	KOTRA PHARMA SDN BDN	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL CEPHALEXIN	CEPHALEXIN MONOHYDRATE	500MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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 ML BOTTLE
NDA/MAL/HDP/2212	DENK PHARMA	BENLE CONSULT LIMITED	CIPRO-DENK 500	CIPROFLOXACIN	500MG	ALLPHARMED PHARBIL ARZNEIMITTEL GMBH-12 D377081	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2216	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	5MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/2217	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMINOPHYLINE	AMINOPHYLLINE	20MG	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE
NDA/MAL/HDP/2218	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	ZINECTIL-100	CHLORPROMAZINE	100MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/2219	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	PRIMOLUT N	NORETHISTERONE	5MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X30.0 TABLET CONTAINER

NDA/MAL/HDP/2220	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 5	AMLODIPINE BESYLATE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2223	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZATHINE PENICILLIN INJECTION	BENZATHINE PENICILLIN	2400000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X2.4 MU VIAL
NDA/MAL/HDP/2224	VOGEN LABORATORIES LTD	BUFFALO HEALTH CARE LTD	DURAMOX 500	AMOXICILLIN	500MG	VOGEN LABORATORIES LTD-70, M.HERACLEOUS STR. AYIOS ATHANASIOS INDUSTRIAL AREA, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2226	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	HEPA-MERZ GRANULES	L-ORNITHINE-L-ASPARTATE	3G/5G	WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL LIQUID ORDINARY OTHER POWDERS/GRANULES	1.0X10.0X5.0 G SACHET
NDA/MAL/HDP/2230	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX CHERRY FLAVOUR	ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG +250MG + 250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/2231	MEDIPHARM INDUSTRIES LTD	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
NDA/MAL/HDP/2232	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	UNICAST	MONTELUKAST	10MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2233	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.25MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE-151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL

NDA/MAL/HDP/2235	WOCKHARDT LTD	TATA UGANDA LIMITED	WOSULIN-N	INSULIN HUMAN(RECOMBINANT DNA ORIGIN)	100IU/ML	WOCKHARDT-WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X10.0 ML VIAL
NDA/MAL/HDP/2236	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL 200	CARBAMAZEPINE	200MG	NOVARTIS FARMA S.P.A.-VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA, ITALY	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2237	WOCKHARDT LTD	TATA UGANDA LIMITED	WOSULIN-30/70	INSULIN HUMAN(RECOMBINANT DNA ORIGIN)	100I.U/ML	WOCKHARDT LIMITED --WOCKHARDT BIOTECH PARK, H14/2, M.I.D.C, WALUJ, AURANGABAD 431136 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X3.0 ML VIAL
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2239	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TEGRETOL ORAL SUSPENSION	CARBAMAZEPINE	20MG/ML	DELPHARMA HUNINGUE S.A.S-26, RUE DE LA CHAPELLE, 68330 HUNINGUE, FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/2240	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	DIOVAN 80	VALSARTAN	80MG	NOVARTISPHARMA AG -LICHTSTRASSE 35 CH-4056 BASEL SWITZERLAND. NOVARTISPHARMA STEIN AG SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X1.0X28.0 TABLET STRIP
NDA/MAL/HDP/2241	IVEE AQUA EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYPHENOCOL EYE DROPS	CHLORAMPHENICOL	0.5%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	5.0 ML VIAL,10.0 ML VIAL
NDA/MAL/HDP/2242	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CYCLOVAX 200 TABLETS	ACYCLOVIR	200MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2243	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	SIMDOL TABLETS	PARACETAMOL	500MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/2244	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYDEXNICOL EYE DROPS	DEXAMETHASONE/C H LORAMPHENICOL	0.1% & 1%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE

NDA/MAL/HDP/2245	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	X-PEL	MEBENDAZOLE	100MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2247	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ESOMAC	ESOMEPRAZOLE	20MG	OKASA PHARMA PVT LTD-L-2, ADDITIONAL M.I.D.C. AREA, SATARA SATARA-415004, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2249	WOCKHARDT LTD	TATA UGANDA 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
NDA/MAL/HDP/2250	GALENTIC PHARMA LTD	NORVIK ENTERPRISES LIMITED	CANDIGEN	CLOTRIMAZOLE	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
NDA/MAL/HDP/2252	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	500MG	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/2253	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	INDOMETHACIN	INDOMETHACIN	25MG	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2254	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	BURN CUR CREAM	ACRIFLAVINE/THYMOL	N/A	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/2256	GLAXOSMITH KLINE LTD	ERIS 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/SYRUPS/DROPS	1.0X1.0X70.0 ML BOTTLE

NDA/MAL/HDP/2258	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	TENOFOVIR DISOPROXIL + LAMIVUDINE + EFAVIRENZ	300MG/300MG/600MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASHTRA, GREEN STONE LIMITED-PLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE, 1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2263	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 10 PLUS	AMINO ACIDS/ELECTROLYTES	10%W/V+10%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BAG
NDA/MAL/HDP/2264	TATA UGANDA LIMITED	TATA UGANDA LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	GLAND PHARMA LTD -D.P.PALLY, DUNDIGAU POST NEAR GANDIMAISAMMA CROSS ROAD, QUTHBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD - 500043, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/2265	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) LIMITED	TENOFOVIR/ LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG + 300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) 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
NDA/MAL/HDP/2267	MYLAN LABORATORIES LIMITED.	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	TENOFOVIR DISOPROXIL FUMARATE + LAMIVUDINE	300MG+300MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE

NDA/MAL/HDP/2269	DAWA LIMITED	SUPER MEDIC LTD	DAWAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	DAWA PHARMACEUTICALS LIMITED-PLOT 7879, BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2270	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	ZITHROCIN 500	AZITHROMYCIN	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
NDA/MAL/HDP/2271	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	ARTEMETHER 20MG/LUMEFANTRINE 120MG	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X6.0 TABLET BLISTER,1.0X30.0X18.0 TABLET BLISTER,1.0X30.0X24.0 TABLET BLISTER,1.0X10.0X1.0X6.0 TABLET BLISTER,1.0X10.0X2.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER,1.0X30.0X4.0X6.0 TABLET BLISTER,1.0X30.0X3.0X6.0 TABLET BLISTER,1.0X30.0X2.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X10.0X4.0X6.0 TABLET BLISTER

NDA/MAL/HDP/2272	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CLARANTA -500	CLARITHROMYCIN	500MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2274	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	PARACETAMOL TABLETS 500MG	PARACETAMOL	500MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD--KAITEE ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2276	MEDREICH PLC	LABOREX UGANDA LIMITED	FUNGRAL	KETOCONAZOLE	200MG	MEDRIECH STERILAB LTD,BANGALORE-MEDRIECH STERILAB LTD, AVALAHALLI BANGALORE 560062	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2280	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	BETADROP-N	BETAMETHASONE + NEOMYCIN	0.1 %W/V + 0.5 %W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL
NDA/MAL/HDP/2281	SURGE LAB (PVT) LIMITED	JEET PHARMACEUTICAL S 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
NDA/MAL/HDP/2282	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	PROPAN	PROPRANOLOL	40MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2283	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA TETANUS PERTUSIS	DIPHTHERIA TOXOID+TETANUS TOXOID+B.PERTUSIS ADSORBED ON ALUMINIUM PHOSPATE	>25LF(>30IU)+>5LF(>40IU)+<16OU(>4PU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE)

NDA/MAL/HDP/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
NDA/MAL/HDP/2285	MEDREICH PLC	LABOREX UGANDA LIMITED	BRUMED	IBUPROFEN	100MG/5ML	MEDRIECH STERILAB LTD-AVALAHALLI BANGALORE-560 049, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2287	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	ZINNAT	CEFUROXIME AXETIL	250MG	GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON
NDA/MAL/HDP/2289	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORAMPHENICOL	CHLORAMPHENICOL	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 CAPSULE CONTAINER
NDA/MAL/HDP/2290	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/2291	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/2292	MEDREICH PLC	LABOREX UGANDA LIMITED	FLEMING 1200	AMOXYCILLIN + CLAVULANATE POTASSIUM	100 MG + 200 MG	NATCO PHARMA LTD-VIJAYAPUR, NORTH NAGARIJUNA SAGA,INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5.0X20.0 ML VIAL
NDA/MAL/HDP/2293	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIOCON	TIOCONAZOLE	1%W/W	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/2295	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	ROZITTA 10	ROSUVASTATIN CALCIUM	10MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP

NDA/MAL/HDP/2296	ERIS LTD	BENLE CONSULT LIMITED	RANI-DENK 150	RANITIDINE	150MG	DENK PHARMA GMBH &CO.KG-PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CONTAINER
NDA/MAL/HDP/2297	DAWA LIMITED	SUPER MEDIC LTD	SABULIN SYRUP	SALBUTAMOL SULPHATE	2MG/5ML	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2298	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	SAFELEVO 500	LEVOFLOXACIN	500MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2299	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	ROZITTA 20	ROSUVASTATIN CALCIUM	20MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/2303	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 5/6.25	BISOPROLOL + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/2304	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 10/6.25	BISOPROLOL + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/2305	MERCK PHARMACEUTICAL MANUFACTURING (PYT) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ZIAK 2.5/6.25	BISOPROLOL + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/2306	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MICROLUT	LEVONORGESTREL	0.03MG	BAYER WEIMER GMBH-DOBEREINERSTRASSE 20, D-99427 WEIMER 2.BAYER PHARMA AG 13342, BERLIN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X35.0 TABLET BLISTER
NDA/MAL/HDP/2307	THE ARAB P'CAL MANUFACTURING CO.	GOODMAN INTERNATIONAL LTD	ZOCIN SUSPENSION	AZITHROMYCIN	200MG/5ML	ARAB PHARMACEUTICAL MANUFACTURING INDUSTRIES --KING ABDULAH 2ND STREET / INDUSTRIAL AREA BUILDING NO. 1 AL-BUHAIRAH / SULT-JORDAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X15.0 ML BOTTLE,1.0X22.5 ML BOTTLE

NDA/MAL/HDP/2312	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 625	AMOXICILLIN + CLAVULANIC ACID	500 MG + 125 MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2313	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAVOMID 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2315	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-50	CEFIXIME	50MG/5ML	MICRO LABS LIMITED, BOMMASANDRA - PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2317	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASMOL	PARACETAMOL	500MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2318	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE-4	GLIMEPIRIDE	4MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2319	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL	PARACETAMOL	120MG/5ML	COSMOS LIMITED-RANGWE ROAD, OFF LUNGA ROAD - INDUSTRIAL AREA NAROB	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2320	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ERO-125	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2321	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN CHESTY	ORCIPRENALINE+BR OMHEXINE	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

NDA/MAL/HDP/2322	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TREFLUCAN	FLUCONAZOLE	150MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X1.0 CAPSULE STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/2325	IDA FOUNDATION	KIMSY MEDS LTD	PARAMOMYCIN	PARAMOMYCIN	375MG/ML	GLAND PHARMA LTD -D.P PALLY DUNDIGAL POST QUTBULLAPUR MANDAL RANGA REDDY DISTRICT HYDERABAB 500043	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/2326	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	SYLATE-500	ETAMSYLATE	50MG	EMCURE PHARMACEUTICALS LTD-LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI BRAHMANA JAMMU (J&K) 18113	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X6.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/2330	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	COARTEM	ARTEMETHER + LUMEFANTRINE	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 IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - 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,1.0X3.0X8.0 TABLET BLISTER,1.0X30.0 X12.0 TABLET BLISTER,1.0X30.0 X18.0 TABLET BLISTER

NDA/MAL/HDP/2333	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII DIPHTHERIA & TETANUS VACCINE ADSORBED(PEDIATRIC)	DIPHTHERIA TOXOID+TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	>25LF(>30IU)+>5LF(>40IU) ADSORBED ON ≥1.5MG	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0 ML VIAL (20 DOSES),1.0X5.0 ML VIAL (10 DOSES),1.0X0.5 ML AMPOULE (1 DOSE)
NDA/MAL/HDP/2334	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII MEASLES MUMPS & RUBELLA	MEASLES VIRUS+MUMPS VIRUS+RUBELLA VIRUS	NLT 1000 CCID50+NLT 5000 CCID50 +NLT1000 CCID50	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 DOSE VIAL + 0.5ML OF THE DILUENT
NDA/MAL/HDP/2335	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	AGOBEN TABLETS(THANE)	MEBENDAZOLE	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2337	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUOXETIL-500	CEFUROXIME AXETIL	500MG	A-UNIT VI, SY. NO 329/39, 329/	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2338	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X70.0 ML BOTTLE
NDA/MAL/HDP/2339	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT-375	AMOXICILLIN + CLAVULANATE POTASSIUM	250 MG + 125 MG	AUROBINDO PHARMA LTD, UNIT XII,- SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X20.0 X5.0 TABLET BLISTER

NDA/MAL/HDP/2342	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT-625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	AUROBINDO PHARMA LTD, UNIT XII,- SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X5.0 TABLET BLISTER
NDA/MAL/HDP/2346	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ABACAVIR SULFATE ORAL SOLUTION	ABACAVIR SULPHATE	20MG/ML	AUROBINDO PHARMA LTD-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
NDA/MAL/HDP/2348	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	HEPATITIS B VACCINE(RDNA) ADULT	HEPATITIS B VACCINE(RDNA) ADULT	20MCG/ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X10.0 ML VIAL (10 DOSE VIAL),1.0X50.0X1.0 ML VIAL (1 DOSE VIAL)
NDA/MAL/HDP/2349	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	D-LYTE	ANHYDROUS GLUCOSE + SODIUM CHLORIDE + TRISODIUM CITRATE DIHYDRATE + POTASSIUM CHLORIDE	2.7G + 0.52G/ 200ML + 0.58G/ 200ML + 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 UNIT DOSE POWDERS	1.0X200.0 ML SACHET,1.0X100.0 ML SACHET,1.0X500.0 ML SACHET
NDA/MAL/HDP/2350	ASTRA ZENECA AB	MACNAUGHTON LIMITED	PULMICORT TURBUHALER	BUDESONIDE	200MCG	ASTRAZENECA AB,-GARTUNA & SNACKVIKEN STOCKHOLM	SWEDEN	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X100.0 DOSE CANNISTER
NDA/MAL/HDP/2352	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP DAY TIME	PARACETAMOL/PSEUDOEPHEDRINE HCL/CAFFEINE	500MG+30MG +30MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/2353	ASTRA ZENECA	MACNAUGHTON LIMITED	NEXIUM	ESOMEPRAZOLE (AS MAGNESIUM TRIHYDRATE)	10MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY GRANULES	1.0X28.0 SACHET CARTON
NDA/MAL/HDP/2354	STRIDES ARCOLAB LIMITED	DELMAR ENTERPRISES LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	STRIDES ARCOLAB LIMITED -36/7 SURAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE

NDA/MAL/HDP/2356	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	QUININE	QUININE DIHYDROCHLORIDE	600MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/2357	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	TRABILIN- 50 CAPSULES	TRAMADOL	50MG	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2359	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ASPIREM 75	ASPIRIN	75MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X28.0 TABLET BLISTER
NDA/MAL/HDP/2361	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CLAREM 500	CLARITHROMYCIN	500MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2363	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GENTAMICIN SULPHATE	GENTAMICIN SULPHATE	80MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/2365	STRIDES ARCOLAB LIMITED	DELMAW ENTERPRISES LIMITED	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	30MG+50MG+60MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2367	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2368	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DERMIDEX CREAM	MICONAZOLE NITRATE	2%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2370	IVEE AQUA EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYBETANEOCIN EYE DROPS	BETAMETHASONE + ENOMYCIN	0.1 %W/V + 0.35 %W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE,1.0X5.0 ML BOTTLE
NDA/MAL/HDP/2371	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOPIZONE CREAM	FUSIDIC ACID + BETAMETHASONE VALERATE	20MG/G+1MG /G	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2373	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	CLOBEN SKIN CREAM	CLOTRIMAZOLE/ BECLOMETASONE	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
NDA/MAL/HDP/2374	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PYRAZINAMIDE TABLETS	PYRAZINAMIDE	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
NDA/MAL/HDP/2375	GLAXO SMITHLINE LIMITED	ERIS 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
NDA/MAL/HDP/2376	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	METCHEK-500	METFORMIN	500MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2377	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	R-LOCK TABLETS	RANITIDINE	150MG	CADILA HEALTHCARE LTD -KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2378	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/2383	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/2384	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CLARIX 500	CLARITHROMYCIN	500MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER

NDA/MAL/HDP/2385	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	COZEPAM 5MG	DIAZEPAM	5MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/2387	DAWA LIMITED	SUPER MEDIC LTD	VERMOUT	MEBENDAZOLE	100MG/5ML	DAWA LIMITED -BABA DOGO RWARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/2390	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN	DIHYDROARTEMISIN IN/ 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/SYR UPS/DROPS	1.0X80.0 ML BOTTLE
NDA/MAL/HDP/2394	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	STOCRIN	EFAVIRENZ	600MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD-XUNQIAO, LINHAI, ZHEJIANG PROVINCE 317024 PEOPLES' REPUBLIC OF CHINA,MERCK SHARP & DOHME B.V- WAARDENWEG 392031 BN, HAARLEM	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/2395	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/2399	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	VOLINI	MULTI INGREDIENT	MULTI INGREDIENT	SUN PHARMACEUTICALS INDUSTRIES LIMITED-INDUSTRIAL AREA 3, A.B ROAD, MADHYA, INDIA	INDIA	TOPICAL EXTERNAL OTHER GELS/SOLS	1.0X1.0X30.0 G TUBE
NDA/MAL/HDP/2400	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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

NDA/MAL/HDP/2401	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/2402	IDA FOUNDATION	KIMSY MEDS LTD	PRAZIQUANTEL	PRAZIQUANTEL	600MG	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/2404	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	LOSAR 50	LOSARTAN POTASSIUM	50MG	UNICHEM LABORATORIES LTD---VILLAGE BHATAULI KALA, BADDI HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2405	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	ERYTHROMYCIN STEARATE	ERYTHROMYCIN STEARATE	250MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/2408	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON TONIC	MULTI-INGREDIENT	MULTI-INGREDIENT	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/2409	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICAL S LTD.	DEPLATT	CLOPIDOGREL	75MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382721, TAL KADI, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2410	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	DOXYREN	DOXYCYCLINE	100MG	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2411	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	POVIDONE IODINE + METRONIDAZOLE	5%W/W + 1%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X10.0 G TUBE,1.0X100.0 G TUBE,1.0X250.0 G TUBE
NDA/MAL/HDP/2414	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCIL	AMPICILLIN	125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2415	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SOLINA TABLETS	DIAZEPAM	5MG	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2416	IDA	KIMSY MEDS LTD	SODIUM STIBOGLUCONATE INJECTION	SODIUM STIBOGLUCONATE	100MG/ML	ALBERT DAVID LTD .-15-CHITTARANJAN AVE. KOLKATA	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/2422	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	TAMIGEN-S EYE/EAR DROPS	GENTAMICIN SULPHATE+DEXAMETHASONE	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
NDA/MAL/HDP/2423	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	ATORIN	ATORVASTATIN	10MG	MEDLEY PHARMACEUTICALS LTD,-PLOT 18 & 19 SURVEY NO 378/7 & 379/ 2&3 ZARI CAUSEWAY ROAD KACHIGAM	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2426	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	PROBEX SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X225.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2427	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	CLONEM	CLOTRIMAZOLE	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
NDA/MAL/HDP/2428	ERIS LTD	BENLE CONSULT LIMITED	CLOTRI-DENK 1% CREAM	CLOTRIMAZOLE	1%W/W	RUBIEPHARM ARZNEIMITTEL GMHH--BRUDER-GRIMU, STRABE 62, GERMANY	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/2429	ERIS LTD	BENLE CONSULT LIMITED	CLOTRI-DENK 100 VAGINAL	CLOTRIMAZOLE	100MG	DENK PHARMA GMBH & CO.KG-PRINZREGENTSTR.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

NDA/MAL/HDP/2431	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 200	BUDESONIDE + FORMOTEROL FUMARATE	200MCG/6MCG	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0 CANNISTER CARTON
NDA/MAL/HDP/2432	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FORMONIDE 100	BUDESONIDE + FORMOTEROL FUMARATE	100MCG+6MCG	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/2434	STRIDES SHASUN LIMITED .	DELMAW 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
NDA/MAL/HDP/2437	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	RISDONE	RISPERIDONE	1MG/ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2438	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC	ACECLOFENAC	100MG	INTAS PHARMACEUTICALS LTD-CAMP ROAD SELAQUI DEHRADUN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2440	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL KIDS	PARACETAMOL	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2451	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN 75 SR	DICLOFENAC SODIUM	75 MG	MEPHA LTD,-DORNACHESTRASSE 114 CH-4147, AESCH, BASEL	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2452	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED CHEST COUGH SYRUP (NON DROWSY)	GUAIFENESIN + MENTHOL	100MG/5ML + 1.1MG/5ML	REGAL PHARMACEUTICALS-PLOT 7879/18 BABA DOGO ROAD NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2453	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	NORVIR	RITONAVIR	80MG/ML	AESICA QUEESNBOROUGH LTD- NORTH RD. QUEENSBOROUGH KENT	UNITED KINGDOM	ORAL LIQUID ORDINARY LIQUIDS	1.0X90.0 ML BOTTLE

NDA/MAL/HDP/2455	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	ARTEQUIN 600/750 LACTAB	ARTESUNATE + MEFLOQUINE	200 MG + 250 MG	MEPHA LTD,-DORNACHESTRASSE 114 CH-4147, AESCH, BASEL	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/2458	XEPA SOUL PATTISON (M) SDN BHD	DELMAN ENTERPRISES LIMITED	PRISTINEX 2% CREAM	KETOCONAZOLE	2%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	2.0X15.0 G TUBE
NDA/MAL/HDP/2459	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	P2	LEVONORGESTREL	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
NDA/MAL/HDP/2460	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS 2MG	BENZHEXOL HCL	2MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/2462	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	HISTALIN SYRUP	CHLORPHENIRAMINE MALEATE/PROMETHAZINE/DIPHENHYDRAMINE/EPHEDRINE/AMMONIUM CHLORIDE/SODIUM CITRATE	1.0MG+2.5MG+5.0MG+7.5MG+90.0MG+48.0MG/5ML.	REGAL PHARMACEUTICALS LTD..-PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN
NDA/MAL/HDP/2467	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	NOKLOT	CLOPIDOGREL	75MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2470	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	EURAX	CROTAMITON	10%W/W	NOVARTIS CONSUMER HEALTH INC -ZYMA SA-CH- 1260 NYON SWITZERLAND	SWITZERLAND	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/2471	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.1% NASAL DROPS	XYLOMETAZOLINE	0.1%W/V	NOVARTIS CONSUMER HEALTH SA-CH-1260 NYON SWITZERLAND	SWITZERLAND	NASAL SYSTEMIC DROPS	1.0X10.0 ML BOTTLE

NDA/MAL/HDP/2472	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TRAN-GEL	DICLOFENAC DIETHYLAMMONIUM	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
NDA/MAL/HDP/2473	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NUGREL	CLOPIDOGREL	75MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2474	SANOFI PASTEUR	LABOREX UGANDA LIMITED	TYPHIM VI	POLYSACCHARIDES OF SALMONELLA TYPHI(TY2 STRAIN)	25MCG	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE)
NDA/MAL/HDP/2475	WIN-MEDICURE LTD	SURGIPHARM (U) LIMITED	URGENDOL INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE,1.0X2.0 ML AMPOULE
NDA/MAL/HDP/2476	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	DERIVA AQUEOUS GEL	ADAPALENE	0.1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/2477	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	LOGICAN-150	FLUCONAZOLE	150MG	WIN-MEDICARE PRIVATE LIMITED-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM - 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X1.0 CAPSULE BLISTER
NDA/MAL/HDP/2478	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL PLUS	PARACETAMOL+DICLOFENAC	500MG+50MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2479	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH-250 CAP	CEPHALEXIN	250MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2481	GALENTIC PHARMA (PVT)LTD	NORVIK ENTERPRISES LIMITED	NETRACORT	HYDROCORTISONE	1%W/W	GALENTIC PHARMA PVT LIMITED-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI MUMBAI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X20.0 G TUBE
NDA/MAL/HDP/2489	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	UMETAC-150	RANITIDINE	150MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2492	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PROFIL 25	PROMETHAZINE HYDROCHLORIDE	25MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/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
NDA/MAL/HDP/2500	MACLEODS PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	CHLORAMPHENICOL SODIUM SUCCINATE INJECTION BP	CHLORAMPHENICOL SODIUM SUCCINATE	1G	MACLEODS PHARMACEUTICALS LTD -PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM DAMAN (UT), INDIA.	INDIA	PARENTERAL RETARD DRY VIAL	1.0X1.0 G VIAL
NDA/MAL/HDP/2502	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	PROBETA N EYE DROP	BETAMETHASONE + NEOMYCIN	0.1%W/V+0.5 %W/V	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X7.5 ML VIAL
NDA/MAL/HDP/2504	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	RESTOCIN	PARACETAMOL + CHLORPHENIRAMINE MALEATE + CAFFEINE + PHENYLEPHRINE HCL	500MG+ 2MG+ 2MG + 30MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET STRIP
NDA/MAL/HDP/2505	GLAXO WELLCOME(KENYA),LTD	ERIS LTD	BETNOVATE OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	GLAXOSMITHKLINE HARMIRE - GLAXOSMITHKLINE HARMIRE ROAD BARNARD CASTLE DURHAM	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/2506	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	NADOXIN	NADIFLOXACIN	1%W/W	WOCKHARDT LTD -VILLAGE KUNJHAL P.O BAROTIWALA DIST SOLAN HIMACHAL PRADESH	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/2508	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	HYOSCINE	HYOSCINE	20MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO.3986 MINZHU ROAD NINGBO CITY ZHEJIANG	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/2509	BETA HEALTHCARE	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
NDA/MAL/HDP/2510	PANACEA BIOTEC LTD	ABACUS PHARMA (AFRICA) 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

NDA/MAL/HDP/2511	GLAXO SMITHKLINE LTD(ITALY)	ERIS LTD	ULTIVA INJECTION 3MG	REMIFENTANIL	3MG	GLAXOSMITHKLINE LTD MANUFACTURING SPA-VERONA	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/2512	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	DICLOFENAC SODIUM INJECTABLE SOLUTION	DICLOFENAC SODIUM	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3 .0 ML AMPOULE
NDA/MAL/HDP/2513	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIPEN DRY SYRUP	PHENOXYMETHYLPE NICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2515	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	SIMFEN 200 TABLETS	IBUPROFEN	200MG	STRIDES ARCOLAB LIMITED-DEWAN & SONS IND. AREA,VEOOR, PALGHAR, MAHARASTRA,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
NDA/MAL/HDP/2516	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNIAMP DRY SUSPENSION	AMPICILLIN	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2519	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/2521	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2522	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PANTAZ TABLETS	PANTOPRAZOLE	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
NDA/MAL/HDP/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

NDA/MAL/HDP/2524	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PRIMODIL-5	AMLODIPINE BESYLATE	5MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI 08AUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2525	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 100 RETARD	DICLOFENAC SODIUM	100MG	DENK PHARMA GMBH &CO.KG--PRINZREGENTSTR.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
NDA/MAL/HDP/2526	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN COMBI PACK	CLOTRIMAZOLE	500MG & 1 %W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	VAGINAL COMBINATION PACK TABLETS	1.0X1.0 PESSARY BLISTER + 1*20G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/2528	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LABESTEN	CLOTRIMAZOLE	1%W/W	LABORATORY & ALLIED LTD.---PLOT 209/10349 OFF MOMBASA RD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X1.0X15.0 G TUBE,1.0X1.0X20.0 G TUBE
NDA/MAL/HDP/2529	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/2545	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICAL S LTD.	TOBREX	TOBRAMYCIN	0.3%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/2549	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	AZY-250	AZITHROMYCIN	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
NDA/MAL/HDP/2552	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	CAROFIT	VITAMIN C/ VITAMIN A/ ZINC SULPHATE	150MG/10MG /75MG	AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2553	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICAL S LTD	ESOZ-20	ESOMEPRAZOLE	20MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X10.0 TABLET STRIP

NDA/MAL/HDP/2554	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	ESDZ	ESOMEPRAZOLE	40MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET STRIP,1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/2555	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PHENOBARBITONE TABLETS BP 30MG	PHENOBARBITONE	30MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/2556	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	TRUVADA	EMTRICITABINE/TENOFOVIR	200MG/300MG	PATHEON INC-ADDRESS: 2100 SYNTEX COURT, MISSISSAUGA, ONTARIO L5N 7K9 COUNTRY: CANADA,TAKEDA GMBH-16515 ORANIENBURG GERMANY,ASPEN PHARMACARE-7 FAIRCLOUGH ROAD KORSTEN PORT ELIZABETH, 6020 SOUTH AFRICA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/2557	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	EPSITRON 25 TABLETS	CAPTOPRIL	25MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2558	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MYCOREN SUSPENSION	NYSTATIN	100000 I.U/ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL TOPICAL SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/2559	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ERYTHROREN	ERYTHROMYCIN STEARATE	250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/2562	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	TRABILIN-100	TRAMADOL	100MG/2ML	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/2565	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC INJECTION	TRAMADOL HYDROCHLORIDE	50MG/ML	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE,1.0X5.0X2.0 ML AMPOULE

NDA/MAL/HDP/2566	MEDREICH PLC	LABOREX UGANDA LIMITED	ZEBEN	ALBENDAZOLE	400MG	MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X1.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/2567	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CIPROBID-500	CIPROFLOXACIN	500MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA,S.KANT HEALTHCARE LIMITED--PLOT NO. 1802-1805,GIDC PHASE II-396195,DIST.VALSAD,GUJARAT,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2568	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	ZINNAT	CEFUROXIME AXETIL	500MG	GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED KINGDOM	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X50.0 TABLET CARTON
NDA/MAL/HDP/2569	SANOFI AVENTIS	LABOREX UGANDA LIMITED	NO-SPA	DROTAVERINE HYDROCHLORIDE	40MG/2ML	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO. LTD CSANYIKVOLGY SITE-CSANYIKVOLGY, P.O.BOX 565.3510, MISKOLC, HUGARY	HUNGARY	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/2570	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	AMOXAPEN 250 CAPSULES	AMOXYCILLIN	250MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2571	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	180 MG + 1080 MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X30.0 ML BOTTLE
NDA/MAL/HDP/2575	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	MYTEKA	MONTELUKAST 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
NDA/MAL/HDP/2576	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEQUINE TABLETS	CHLOROQUINE PHOSPHATE	250MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/2577	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TOPCEF 200	CEFIXIME	200MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2578	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT TABLETS	MAGNESIUM TRISILICATE+ALUMINIUM HYDROXIDE	250MG+120MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X50.0X2.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	ARTEQUIN 300/375 LACTAB	ARTESUNATE + MEFLOROQUINE	300 MG + 375 MG	MEPHA LTD,-DORNACHESTRASSE 114 CH-4147, AESCH, BASEL	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/2580	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	HEDON TABLETS	PARACETAMOL + ASPIRIN + CAFFEINE	250 MG+ 300 MG + 30 MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA,LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA,MILAN LABORATORIES (INDIA) PVT LTD - -63,67,87,35,36, 64, 65 JAWAHAR CO-OP INDUSTRIAL ESTATE KAMOTHE, PANVEL NAVI MUMBAI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP
NDA/MAL/HDP/2581	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AVAS-10	ATORVASTATIN	10MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2582	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROXETIL-250	CEFUROXIME AXETIL	250MG	AUROBINDOM 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 TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2591	SWISS PHARMACEUTICAL PUT LTD	HEALTHCARE LTD.	VITAGLOBIN SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	SWISS PHARMACEUTICALS PVT LTD-A159 SINDH INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2595	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	ZEPILÉN	CEFAZOLIN	1000MG	MEDOCHÉMIE LTD COGOLS FACILITY-1-10 CONSTANTINOUPOLEOS STREET, ZAKAKI, LIMASSOL, CYPRUS	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/2596	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	URISEPTIC	NALIDIXIC ACID	500MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2597	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 250	PARACETAMOL	250MG	RUBIEPHARM ARZNEIMITTEL GMHH - GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/2600	IND SWIFT LTD	TATA UGANDA LIMITED	CLARIE-OD	CLARITHROMYCIN(EXTENDED RELEASE)	500MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X1.0X7.0 TABLET BLISTER
NDA/MAL/HDP/2601	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 750MG	CEFUROXIME	750MG	MEDOCHÉMIE LTD COGOLS FACILITY-1-10 CONSTANTINOUPOLEOS STREET, ZAKAKI, LIMASSOL, CYPRUS	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/2602	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM BID	AMOXICILLIN + CLAVULANIC ACID	200 MG + 28.5 MG/ 5 ML	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2603	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	VIRADAY	TENOFOVIR + EMTRICITABINE + EFAVIRENZ	300 MG + 200 MG + 600 MG	CIPLA LTD .-PLOT NO. S-103 TO S-105, S-107 TO S-112, L-147 TO L-1147-1, VERNA ELECTRONIC CITY GOA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/2604	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/2606	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICAL S (U) LIMITED	PROTAS 40	ESOMEPRAZOLE	40MG	SQUARE PHARMACEUTICALS LIMITED--DHAKA UNIT KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2607	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	FLOTAL	ALFUZOSIN HCL	10MG	SUN PHARMACEUTICAL INDUSTRIES LTD-VILLAGE GANGUWALA, PAONTA SAHIB,173 025,DISTRICT SIRMOUR HIMACHAL PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2610	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S LIMITED	ATROPINE	ATROPINE	1MG/ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/2612	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	RENIRON	MULTI-INGREDIENT	MULTI-INGREDIENT	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2614	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DIALIN	LOPERAMIDE HCL	2MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2617	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICAL S LTD	BLUDROX TABLETS DISPERSABLE	CEFADROXIL	250MG	BLUE CROSS LABORATORIES LIMITED-A-12 MIDC AMBAD-NASHIK-422010 MAHARASHTRA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP
NDA/MAL/HDP/2628	MICRO LABS LTD	LABOREX UGANDA LIMITED	AZILIDE-500	AZITHROMYCIN	500MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/2640	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	BENZYL BENZOATE APPLICATION	BENZYL BENZOATE	25%W/W	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	TOPICAL EXTERNAL LOTIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2641	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE 250MG	CEFUROXIME AXETIL	250MG	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY,FACTORY C-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIALAREA 4101 AGIOS ATHANASSIOUS LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/2642	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MEDOXANUM	CEFTRIAZONE	1G	MEDOCHEMIE LTD-1-10 CONSTANTINOPOLEOS TREET 3011 LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 10 ML AMPOULE WFI
NDA/MAL/HDP/2643	FREDUN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	NEOPHIL -100 TABLETS	AMINOPHYLLINE	100MG	FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIA INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/2645	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANZIDIME 1000	CEFTAZIDIME	1000MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/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,1.0X1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/2648	E DENK OHG	BENLE CONSULT LIMITED	PARA DENK 125	PARACETAMOL	125MG	RUBIEPHARM ARZNEIMITTEL GMHH - GERMANY	GERMANY	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP,1.0X2.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/2650	DENK PHARMA	BENLE CONSULT LIMITED	VIT-B-DENK	THIAMINE HCL + PYRIDOXINE HCL	100MG + 200MG	DENK PHARMA GMBH & CO.- PRINZREGENTENSTR. 79, 81675 MÜNCHEN, GÖLLSTR. 1, 84529 TITTMONING, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET CARTON,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2651	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	RINAVIT SYRUP	MULTIVITAMIN	MULTI-INGREDIENT	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2652	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	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

NDA/MAL/HDP/2653	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/2654	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICAL S 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
NDA/MAL/HDP/2656	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	100MG	SHANDONG XIER KANGTAI PHARMACEUTICAL CO. LTD-PRIVATE ECONOMY ZONE,YANZHOU DISTRICT,SHANDONG, CHINA PR	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2670	CLARIS INJECTABLES LTD	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
NDA/MAL/HDP/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
NDA/MAL/HDP/2672	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICAL S LIMITED	LIDOCAINE	LIDOCAINE	2%W/V	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY VIALS	1.0X25.0X20.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/2675	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	LIBITUS PLUS SYRUP	TERBUTALINE/ BROMHEXINE/ GUAIPHENESIN	1.25MG/ 4MG/ 50 MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2679	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ALERID SYRUP	CETIRIZINE HYDROCHLORIDE	5MG/5ML	CIPLA LIMITED-PLOT NO 9 & 10, PHARMA ZONE, PHASE II, INDORE SPECIAL ECONOMIC ZONE, PITHAMPUR, DIST: DHAR, MADHYA PRADESH – 454 775, INDIA.	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/2680	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMPIREN CAPSULES	AMPICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER

NDA/MAL/HDP/2681	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMOXIREN	AMOXICILLIN TRIHYDRATE	250MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER
NDA/MAL/HDP/2683	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAMIN C	ASCORBIC ACID	100MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2685	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL(SUSPENSION)	PARACETAMOL	120MG/5ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X 60.0 ML BOTTLE
NDA/MAL/HDP/2686	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	AMOXYDAR FORTE	AMOXICILLIN TRIHYDRATE	250MG/5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/2692	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RAMITAS 5	RAMIPRIL	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/2695	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAN ENTERPRISES LIMITED	IDUMSTRA	PARACETAMOL + IBUPROFEN + CAFFEINE	325MG + 200MG + 40MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2696	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LIMITED	AMPHOTRET	AMPHOTERICIN B	50MG	BHARAT SERUMS AND VACCINES LTD- PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON

NDA/MAL/HDP/2697	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	LUCIN OINTMENT	HYDROCORTISONE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/2698	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AZICIN-500	AZITHROMYCIN	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
NDA/MAL/HDP/2699	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 12.5	CARVEDILOL	12.5 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2702	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	EUGLIM 2	GLIMEPIRIDE	2MG	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 STRIP
NDA/MAL/HDP/2703	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT 312.50	CO-AMOXICLAV (AMOXYCILLIN TRIHYDRATE+POTASSIUM CLAVUNATE)	250+62.50MG / 5ML	AUROBINDO PHARMA LTD, UNIT XII,- SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2704	MACLEODS PHARMACEUTICALS LTD	ROYAL PHARMA 2011 LIMITED	PRIMACORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	MACLEODS PHARMACEUTICALS LTD-MAHIM ROAD, NEAR KULDEEP NAGAR REGAR(WO MAHARASHTRA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X100.0 MG VIAL
NDA/MAL/HDP/2705	ASTRAZENECA	MACNAUGHTON LIMITED	PULMICORT NEBULISER	BUDESONIDE	0.5MG/ML	ASTRA ZENECA SWEDEN OPERATIONS LIQUID PRODUCTION - KVARNBERGAGATANLZ SE-151-85,SWEDEN	SWEDEN	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X4.0X5.0X2.0 ML VIAL
NDA/MAL/HDP/2706	SOLVAY PHARMACEUTICALS BV	STAR PHARMACEUTICALS LTD	DUSPATALIN	MEBEVERINE HCL	135MG	SOLVAY PHARMACEUTICALS PV-VEERVEG 12 8121 AA 0187 NETHERLAND	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X5.0 TABLET BLISTER
NDA/MAL/HDP/2707	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMCLOXA	CLOXACILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	100.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,1000.0 CAPSULE CONTAINER,10.0 CAPSULE CONTAINER

NDA/MAL/HDP/2708	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	HYPER TABLETS	PROPRANOLOL HYDROCHLORIDE	40MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 2.0X50.0 TABLET BLISTER
NDA/MAL/HDP/2710	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/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
NDA/MAL/HDP/2714	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	ANAFRANIL	CLOMIPRAMINE	25MG	NOVARTIS PHARMA SPA, TORRE ANNUNZIATA ITALY-NA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/2715	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE	LAMIVUDINE	150MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/2717	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	OCUMYCIN EYE OINTMENT	CHLORAMPHENICOL	1%W/W	CENTAUR PHARMA PVT. LTD-PLOT 39-41, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA INDIA	INDIA	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE
NDA/MAL/HDP/2719	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	LORASED	LORATADINE	10MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/2720	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 250MG POWDER FOR ORAL SUSPENSION	AMOXICILLIN +FLUCLOXACILLIN	125MG/5ML+ 125MG/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X80.0 ML BOTTLE
NDA/MAL/HDP/2721	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRIMAFEN TABLET	IBUPROFEN + PARACETAMOL	400MG + 325MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2722	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	NO SORES	CHOLINE SALICYLATE/LIDOCAINE	8.7%W/W+2% W/W	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X10.0 G TUBE

NDA/MAL/HDP/2724	UNEEED GLOBAL GROUP LIMITED	ASTRA PHARMA (U) LIMITED	CHLORAMPHENICOL 250MG CAPSULES BP	CHLORAMPHENICOL	250MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD--KAITEE ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2726	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	QUININE INJECTION	QUININE DIHYDROCHLORIDE	600MG/2ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD-KAIFA ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/2730	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	TRICLOVERA	MEDROXYPROGESTERONE ACETATE	150MG/ML	PT TUNGGAIDAMAN ABDI,-J1.JEND.YANI NO.7 JAKARTA TIMUR	INDONESIA	PARENTERAL ORDINARY I M VIALS	1.0X20.0X1.0 ML VIAL
NDA/MAL/HDP/2734	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	AMLODAR-10	AMLODIPINE BESILATE	10MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/2735	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICALS (U) LIMITED	FORCE	CEFTIOXIME	1G	SQUARE PHARMACEUTICALS LIMITED--DHAKA UNIT KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL + 1*10 ML AMPOULE WFI
NDA/MAL/HDP/2736	IDA	KIMSY MEDS LTD	FUROSEMIDE	FUROSEMIDE	20MG/2ML	GLAND PHARMA LTD -GLAND PHARMA LTD D.P PALLY DUNDIGAL HYDERABAD	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0 AMPOULE CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/2739	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	BISANOL TABLET	HYOSCINE BUTYLBROMIDE	10MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2745	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENFORMIN	METFORMIN HYDROCHLORIDE	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2746	ERIS LTD	BENLE CONSULT LIMITED	ACYCLOVIR DENK 200	ACYCLOVIR	200MG	DENK PHARMA GMBH &CO.KG-PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X25.0 TABLET BLISTER
NDA/MAL/HDP/2749	CLARIS LIFESCIENCE LTD	REDDYS PHARMA LIMITED	HESTAR-200 PENTASTARCH	HYDROXYETHYLSTAR CH	6%W/V	CLARIS OTSUKA PRIVATE LIMITED-N3	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/2751	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	FLUDAC CAPSULES	FLUOXETINE HCL	20MG	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X20.0 CAPSULE BLISTER
NDA/MAL/HDP/2753	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	PRASIL	METOCLOPRAMIDE HYDROCHLORIDE	10MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X50.0X1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/2756	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	CYTOTEC	MISOPROSTOL	200MCG	PIRAMAL HEALTHCARE LIMITED-WALTON ROAD MORPETH NORTHUMBERLAND NE 613YA	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/2760	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED DRY COUGH SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+D EXTROMETHORPHAN+SODIUM CITRATE+MENTHOL	14MG+6.5MG +57MG+2MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2761	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	TRIFLUOPERAZINE	TRIFLUOPERAZINE HYDROCHLORIDE	5MG	REMEDICA LIMITED,-LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2765	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	HAEM F	FOLIC ACID+ VITAMIN B12+IRON AMMONIUM CITRATE	1MG+5MCG+200MG/15ML	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/2767	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	PHENOXYMETHYLPENICILLIN TABLETS BP	PHENOXYMETHYLPE NICILLIN	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

NDA/MAL/HDP/2768	ALCON PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ECONOPRED PLUS	PREDNISOLONE ACETATE	1%W/W	ALCON (PUETRO RICO) LABORATORIES-INC USA	UNITED STATES	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/2770	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	RELISURE	MEFENAMIC ACID	250MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2772	ASTRAZENECA	MACNAUGHTON LIMITED	TENORMIN	ATENOLOL	100MG	ASTRA ZENECA UK LIMITED-SILK ROAD BUSINESS PARK,MACCLESFIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/2773	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	BISPANOL ELIXIR	HYOSCINE-N-BUTYLBROMIDE	5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2774	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	BACTIFLOX NEO 500	CIPROFLOXACIN	500MG	ACINO PHARMA AG.-DORNACHERSTRASSE 114, CH-4147 AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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 TABLET CONTAINER,14.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/2777	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/12.5MG TABLETS	VALSARTAN + HYDROCHLOROTHIAZIDE	160MG + 12.5MG	NOVARTIS PHARMA AG-SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/2779	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE SURGICAL SCRUB	POVIDONE IODINE	7.5%W/V	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X450.0 ML BOTTLE
NDA/MAL/HDP/2780	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 160/25MG TABLETS	VALSARTAN + HYDROCHLOROTHIAZIDE	160 MG + 25MG	NOVARTIS PHARMA AG-SCHAFFHAUSERSTRASSE 4332 STEIN SWITZERLAND,NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER

NDA/MAL/HDP/2781	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	CARVETAS 6.25	CARVEDILOL	6.25MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2782	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	KWINIL	QUININE DIHYDROCHLORIDE	300MG/ML	INTAS PHARMACEUTICALS LTD .-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	20.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/2783	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 25MG	DICLOFENAC SODIUM	25MG	DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/2787	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	AMOXICILLIN TABLETS FOR ORAL SUSPENSION	AMOXICILLIN	125MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X10.0 TABLET STRIP,1.0X2.0X10.0 TABLET STRIP,1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/2788	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	MULTIVITAMIN TABLETS	MULTIINGREDIENT	N/A	RENE INDUSTRIES LIMITED-PLOT 680, KAMULI ROAD, KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2790	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	TG-TOR 20	ATORVASTATIN	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
NDA/MAL/HDP/2790	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	TG-TOR 20	ATORVASTATIN	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
NDA/MAL/HDP/2792	UNICHEM LABORATORIES LIMITEDV	EUROPA HEALTHCARE (U) LTD	TG-TOR 10	ATORVASTATIN	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

NDA/MAL/HDP/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
NDA/MAL/HDP/2796	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN SODIUM	1,000,000I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/2797	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	LUMAREN	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X8.0 TABLET BLISTER
NDA/MAL/HDP/2798	UMEDICA LABS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	OMEGARD	OMEPRAZOLE	20MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2799	IVEE AQUA EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYCHLORNICOL EAR DROPS	CHLORAMPHENICOL	5%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84, ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER, KENYA	KENYA	OTIC DROPS	1.0X5.0 ML BOTTLE, 1.0X10.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2802	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	TASOL	CLOBETASOL	0.05%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2805	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NIFELAT 20R TABLETS	NIFEDIPINE	20MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0 X10.0 TABLET BLISTER

NDA/MAL/HDP/2806	RENE INDUSTRIES LIMITED	RENE PHARMACY LTD	PHENOBARBITONE TABLETS	PHENOBARBITONE	30MG	CYANO PHARMA(P)-115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2807	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	100 MG + 270 MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X3.0 TABLET BLISTER,1.0X20.0X6.0 TABLET BLISTER
NDA/MAL/HDP/2809	BLISS GVS PHARMA LIMITED	DELMAR ENTERPRISES LIMITED	MAITRI	PEG 1500BP/ PEG 1000BP	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
NDA/MAL/HDP/2811	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	SULPHUR OINTMENT	SULPHUR PRECIPITATED	10%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X25.0 G TUBE
NDA/MAL/HDP/2812	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	CO-ARTESIANE	BETA ARTEMETHER + LUMEFANTRINE	180 MG/60ML + 1080 MG/60ML	MANUFACTURING PACKAGING FARMACIA APPELHOF OUDEHASK-NETHERLANDS	NETHERLANDS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2813	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	INTACYCLINE SKIN OINTMENT	TETRACYCLINE HYDROCHLORIDE	3%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/2816	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-100 TABLETS	ATENOLOL	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2820	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	VALODIN 500MG CAPSULES	CEPHADRINE	250MG	HILTON PHARMA (PVT) LTD-PLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X6.0 CAPSULE STRIP
NDA/MAL/HDP/2821	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DIOLIN-M	GLIBENCLAMIDE+METFORMIN HYDROCHLORIDE TABLETS	5MG+500MG	LINCOLN PHARMACEUTICAL LIMITED..- LINCOLN PHARMACEUTICALS LIMITED, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP

NDA/MAL/HDP/2826	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PIRITON SYRUP	CHLORPHENIRAMINE MALEATE	4MG/10ML	GLAXOSMITHKLINE-LIKONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X2.0 L BOTTLE
NDA/MAL/HDP/2830	MEDIPHARM SALES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	QUINIMIX MIXTURE	QUININE HYDROCHLORIDE	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD (BWEYOGGERERE)	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2832	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN 100 RECTOCAP	DICLOFENAC	100MG	R P SCHERER GMBH & CO. EBERBACH BALEN- R P SCHERER GMBH & CO. EBERBACH BALEN	GERMANY	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/2835	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	SOLUDINE-M	POVIDONE IODINE / METRONIDAZOLE	5%W/W / 1%W/W	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X20.0 G TUBE, 1.0X125.0 G TUBE
NDA/MAL/HDP/2837	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	GRAMOFIL TABLETS	NALIDIXIC ACID	500MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2838	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 120	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	120MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/2848	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROGENTA OINTMENT	BETAMETHASONE /GENTAMICIN SULPHATE	0.5MG/G+1.0 MG/G	SCHERING-PLOUGH LABONV-INDUSTRIE PARK 30, B-220 HEIST-OP-DEN-BERG, BELGIUM	CANADA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE, 1.0X30.0 G TUBE
NDA/MAL/HDP/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	1.0X3.0X1.0 ML AMPOULE
NDA/MAL/HDP/2852	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	LEK-500	LEVOFLOXACIN HEMIHYDRATE	500MG	BLUECROSS LABORATORIES LIMITED-A-12,M.I.D.C,NASHIK MAHARASHTRA 422010	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2858	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIBROCIL	PHENYLEPHRINE + DIMETHINDENE MALEATE	0.25% W/V + 0.025% W/V	NOVARTIS CONSUMER INT. INC.-ZYMASA-CH-1260, NYON SWITZERLAND	SWITZERLAND	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/2863	KWALITY AFRO-ASIA LTD	KWALITY AFRO ASIA LIMITED	K-MOL	PARACETAMOL	120MG/5ML	KWALITY AFROASIA LTD-KAWEMPE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/2868	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR 50	LOSARTAN POTASSIUM	50MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 X7.0 TABLET BLISTER
NDA/MAL/HDP/2869	GLAXO SMITHKLINE LTD	ERIS 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)
NDA/MAL/HDP/2873	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HELIGO KIT	TINIDAZOLE/CLARIT HROMYCIN/LANSOP RAZOLE	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
NDA/MAL/HDP/2875	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	OTRIVIN 0.05% NASAL DROPS	XYLOMETAZOLINE	0.05%W/V	NOVARTIS CONSUMER HEALTH SA-CH-1260 NYON SWITZERLAND	SWITZERLAND	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/2878	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOIN 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
NDA/MAL/HDP/2879	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OFLIN-200	OFLOXACIN	200MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER,1.0X2.0X 10.0 TABLET BLISTER,1.0X10.0 X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2880	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CARBIMAZOLE 5	CARBIMAZOLE	5MG	REMEDICA LIMITED,-LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2882	TATA UGANDA LIMITED	TATA UGANDA LIMITED	HYOSCINE BROMIDE	HYOSCINE BROMIDE	20MG/ML	GLAND PHARMA LTD -D.P PALLY DUNDIGAL POST QUTBULLAPUR MANDAL RANGA REDDY DISTRICT HYDERABAB 500043	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/2884	NOVARTIS PHARMA SERVICES INC	ERIS LTD	HYCAMTIN	TOPOTECAN HYDROCHLORIDE	4MG	GLAXOSMITHKLINE MANUFACTURING S.P.A-STRADA PROVINCIALE ASOLANA, 9043056 SAN POLO DI TORRILE,PARMA ITALY	ITALY	PARENTERAL ORDINARY VIALS	1.0X5.0X17.0 ML VIAL
NDA/MAL/HDP/2885	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FORECOX-TRAC	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL	150MG + 75MG+ 400MG + 275MG	MACLEODS PHARMACEUTICALS LTD -.PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X6.0 TABLET BLISTER,1.0X24.0 X28.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2888	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	SUCCICORT	HYDROCORTISONE 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
NDA/MAL/HDP/2890	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL N	BETAMETHASONE+N EOMYCIN	1MG/G+5MG/G	KPI INDUSTRIES (1996) LTD-PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2891	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TORVAST 20	ATORVASTATIN	20MG	MACLEODS PHARMACEUTICALS LTD -.PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2893	DAWA LIMITED	SUPER MEDIC LTD	STOPACID SUSPENSION	MAGNESIUM TRISILICATE + ALUMINIUM HYDROXIDE	250MG/5ML + 120MG/5ML	DAWA-PLOT 7879, BABA DOGO ROAD RUARAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2894	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MUCOGEL SUSPENSION	DRIED ALUMINIUM HYDROXIDE + MAGNESSUM HYDROXIDE + OXETHAZINE	8G/100ML + 2G/100ML + 0.2 G/100ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO EIPICO-10TH OF RAMADAN CITY-FIRST INDUSTRIAL AREA -EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X125.0 ML BOTTLE
NDA/MAL/HDP/2896	KPI INDUSTRIES(1996) LTED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	MCG CREAM	MICONAZOLE NITRATE BP + CLOBETASOL PROPIONATE BP + GENTAMYCIN SULPHATE	2.0%W/W + 0.05%W/W + 0.1 %W/W	KPI INDUSTRIES (1996) LTD-PLOT NO.M444B STRETCHER RD, NTINDA, KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE,1.0X25.0 G TUBE
NDA/MAL/HDP/2897	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	STORILAT	CARBAMAZEPINE	200MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2898	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TORVAST 10	ATORVASTATIN	10MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2900	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-O-200	CEFIXIME	200MG	MICRO LABS LIMITED, BOMMASANDRA - PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2903	STRIDES ARCOLAB 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
NDA/MAL/HDP/2904	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	NELTOLON SOLUTION	BIFONAZOLE	10MG	PHARMATHEN LTD.-6 DERVENAKION STR. 153 51 PALLINI-GREECE	GREECE	TOPICAL EXTERNAL LIQUIDS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/2905	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BRONCHOPHANE SYRUP	GUAIPHENESIN+EPHEDRINE HYDROCHLORIDE+DIPHENHYDRAMINE HYDROCHLORIDE+DEXTROMETHORPHAN	50MG+7.5MG +5MG+4.58MG	EGYPT INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. EIPICO-10TH STREET RAMADAN CITY, FIST INDUSTRIES ARE	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X125.0 ML BOTTLE
NDA/MAL/HDP/2906	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RIFAMPICIN/ISONIAZID/ETHAMBUTOL	RIFAMPICIN+ISONIAZID+ETHAMBUTOL	150MG+75MG +275MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER
NDA/MAL/HDP/2907	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART DS	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/2908	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	PAINGO MEDICATED CREAM	METHYLSALICYLATE +CAPSICUM OLEORESIN+TURPENTINE OIL	15%W/W + 1%W/W + 1.47%W/W	NEM LABORATORIES PVT LTD-133 VASAI RD(E) 401 162 SB MARG. LOWER PAREL MUMBAI	INDIA	TOPICAL EXTERNAL CREAMS	1.0X2.0X15.0 G TUBE
NDA/MAL/HDP/2910	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	TENVIR EM	TENOFOVIR DISOPROXIL FUMARATE + EMTRICITABINE	300MG+200MG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/2911	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL LORATADINE	LORATADINE	10MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/2914	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CHLOROCIDE SYRUP	CHLORAMPHENICOL PALMITATE	125MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/2915	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	TREXOL	METHOTREXATE	50MG	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL
NDA/MAL/HDP/2917	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CETAMOL TABLETS	PARACETAMOL	500MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X100.0 X10.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/2919	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ODIMONT 5	MONTELUKAST	5MG	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2920	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	TRANSLIPO -C CREAM	CLOTRIMAZOLE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X20.0 G TUBE,1.0X10.0 G TUBE
NDA/MAL/HDP/2923	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	COLD PLUS SYRUP	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE 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
NDA/MAL/HDP/2926	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	TETRACYCLINE 250MG CAPSULES BP	TETRACYCLINE	250MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD--KAITEE ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/2934	ASTRA LIFE CARE PVT LTD	ASTRA PHARMA (U) LIMITED	ASTOLON	PREDNISOLONE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/2937	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	PEN-A-CLOX CAPSULES	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2938	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CLOXIL-250 CAPSULES	CLOXACILLIN	250MG	AUROBINDO PHARMA LIMITED UNIT - SURVEY NO. 314, BACHUPALLY, QUTHUBULLAPUR (MANDAL), R.R - DISTRICT, HYDERABAD – 500 072, AP – INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2939	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTODIUM	LOPERAMIDE HYDROCHLORIDE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/2941	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORVA 20	ATORVASTATIN	20MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X5.0X 7.0 TABLET BLISTER
NDA/MAL/HDP/2942	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARGISSEPT CREAM	CHOLRHEXIDINE GLUCONATE/SILVER SULPHADIAZINE	0.2%W/W / 1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X10.0 G TUBE
NDA/MAL/HDP/2943	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	SCHERIPROCT OINTMENT	PREDNISOLONE CAPROATE + CINCHOCAINE HYDROCHLORIDE	1.9MG/G + 5MG/G	BAYER HEALTH CARE MANUFACTURING S.R.I - S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	RECTAL SYSTEMIC UNIT DOSE OINTMENTS AND PASTES	1.0X10.0 G TUBE
NDA/MAL/HDP/2945	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ONCET	CETIRIZINE DIHYDROCHLORIDE	10MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2946	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO ORAL SUSPENSION(THANE)	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
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X250.0 BLISTER CARTON
NDA/MAL/HDP/2948	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	METFORMIN DENK 850	METFORMIN HYDROCHLORIDE	850MG	DENK PHARMA GMBH &CO.KG--PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X15.0 TABLET BLISTER,1.0X8.0X15.0 TABLET BLISTER
NDA/MAL/HDP/2949	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	FUNGNIL V TABLET	CLOTRIMAZOLE	100MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP
NDA/MAL/HDP/2950	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	XALATAN	LATANOPROST	0.005%W/V	PFIZER MANUFACTURING -NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE
NDA/MAL/HDP/2951	BLISS GVS PHARMA LIMITED	DELMAN ENTERPRISES LIMITED	LONART FORTE TABLETS	ARTEMETHER + LUMEFANTRINE	40 MG + 240 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/2954	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	VELORIN 100 F.C TABLETS	ATENOLOL	100MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2955	SHAIGAN PHARMACEUTICALS (PVT) LTD	HEALTHCARE LTD.	CLOZOX	CLOTRIMAZOLE	2%W/W	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	VAGINAL CREAMS	1.0X1.0X35.0 G TUBE + TWO APPLICATORS

NDA/MAL/HDP/2956	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	TRANLOK 500MG TABLETS	TRANEXAMIC ACID	500MG	ARISTO PHARMACEUTICALS PVT LIMITED- PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2957	MEDIPHARM SALES (E.A) LTD	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
NDA/MAL/HDP/2959	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	CETAMOL SYRUP	PARACETAMOL	120MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/2960	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	400MG/57MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GRANULES	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/2961	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	OFTALMOLOSA CUSI ERYTHROMYCIN 0.5%	ERYTHROMYCIN	0.5%W/W	ALCON CUSI SA-CAMIL FABRA 58 08320 EL MASNOUR BARCELONA	SPAIN	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE
NDA/MAL/HDP/2962	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASTIDIN	CIMETIDINE	200MG	ASTRA LIFE CARE (INDIA) PVT LIMITED-57/P RAJODA 382220 BAVIA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/2970	ABACUS PHARMA (AFRICA) 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

NDA/MAL/HDP/2971	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	LEFRA-20 TABLETS	LEFLUNOMIDE	20MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,T EH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2972	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	ANTIMIN SYRUP	LORATIDINE	5MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2974	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	TRAVATAN	TRAVOPROST	4µG/ML	ALCON COUVREUR NV-RIJKSWEIG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X2.5 ML VIAL
NDA/MAL/HDP/2978	SANOFI PASTEUR	LABOREX UGANDA LIMITED	TETAVAX	TETANUS VACCINE	40 I.U	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE)
NDA/MAL/HDP/2979	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM N CREAM	BETAMETHASONE VALERATE + NEOMYCIN	0.1%W/W + 0.5%W/W	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/2980	BLISS GVS PHARMA LIMITED	DELMAR ENTERPRISES LIMITED	LONART TABLETS	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X3.0X8.0 TABLET BLISTER
NDA/MAL/HDP/2981	SHAIGAN PHARMACEUTICALS (PVT) LTD	HEALTHCARE LTD.	STAMIN	CETIRIZINE DIHYDROCHLORIDE	1MG/ML	SHAIGAN PHARMACEUTICALS (PVT) LTD-14TH KM, ADYALA ROAD, RAWALPINDI-PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/2982	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	NEURO-FORTE TABLETS	VITAMIN B1 + VITAMIN B6 + VITAMIN B12	200MG + 50MG + 1MG	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2983	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FORCAN-200	FLUCONAZOLE	200MG	CIPLA LTD -PLOT NO. L-139, VERNA, GOA 403 722 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X1.0X4.0 CAPSULE BLISTER
NDA/MAL/HDP/2986	GLAXO WELLCOME(KENYA) LTD	ERIS LTD	OXYBRAL SR	VINCAMINE	30MG	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	EGYPT	ORAL SOLID RETARD CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/2987	STRIDES ARCOLAB LTD	DELMAR ENTERPRISES LIMITED	SALDOPA	METHYLDOPA	250MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAVADI CROSS ANECAL TULK BANGALORE 562 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/2990	MICRO LABS LTD	LABOREX UGANDA LIMITED	PULMOCEF-500	CEFUROXIME AXETIL USP	500MG	MICRO LABS LTD--NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X4.0 TABLET BLISTER
NDA/MAL/HDP/2991	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	LIPOR	ATORVASTATIN	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
NDA/MAL/HDP/2992	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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)
NDA/MAL/HDP/2993	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	TRAVOCORT	DIFLUCORTOLONE VALERATE + ISOCONAZOLE NITRATE	0.1% + 1% W/W	BAYER HEALTH CARE MANUFACTURING S.R.I S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/2995	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	GALLOP	LOPERAMIDE HYDROCHLORIDE USP	2MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/2997	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	ACENAC TABLETS	ACECLOFENAC	100 MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2998	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	FITIN-5	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO 18 & 19, SURVEY NO. 378/7& 8,379/2&3 ZARI BHAUSEWAY ROAD,, KACHIGAM, DAMAN-396 210	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/2999	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	AMOXICILLIN	AMOXICILLIN TRIHYDRATE	250MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO. LTD-NO. 6 HUANXING RD ZNONGHU SHIJIAZHUANG	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER

NDA/MAL/HDP/3002	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	KELVIN	PARACETAMOL	500MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/3007	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	TORTAS 5	TORSEMIDE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3008	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/3009	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	SULBACTOMAX 1.5G	CEFTRIAXONE+SULBACTAM	1000MG+500MG	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/3011	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	GYNEST	CLOTRIMAZOLE	100MG	ASTRA LIFE CARE (INDIA) PVT-PLOT 57 ROJADA382220, BAVLA AHMEDABAD INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3012	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL TABLETS	DICLOFENAC SODIUM	50MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/3015	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA-50 TABLETS	SILDENAFIL	50MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3017	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	LIDOCAINE INJECTION	LIDOCAINE HYDROCHLORIDE	20MG/ML	ZHEJIANG RUIXIN PHARMACEUTICALS CO LTD-KAIFA ROAD TIANNING IDOUS ZONE LISHUI CITY	CHINA	PARENTERAL ORDINARY VIALS	1.0X25.0X20.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3021	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	GLIBENCLAMIDE TABLETS	GLIBENCLAMIDE	5MG	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3023	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	AGOTRAX	LEVAMISOLE HYDROCHLORIDE	40MG	AGOG PHARMA LTD.-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X10.0X1.0X3.0 TABLET STRIP,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/3024	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	LAMIVUDINE + NEVIRAPINE + ZIDOVUDINE	150MG + 200MG + 300MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/3026	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL DETROMETHORPHAN-15 SYRUP	DEXTROMETHORPHAN HYDROBROMIDE	15MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3031	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMETHASONE	DEXAMETHASONE	0.5MG	AGOG PHARMA LTD.-NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/3032	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	XYLO-ACINO 0.05%	XYLOMETAZOLINE	0.05%W/V	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/3033	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	PENAMOX	AMOXICILLIN	125MG/5ML	MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/3043	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	FEBREX TABLETS	PARACETAMOL	500MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/3044	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PIRICAM-20 CAPSULES	PIROXICAM	20MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3045	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	BRAMESTON 2.5	BROMOCRIPTINE MALEATE	2.5MG	REMEDICA LIMITED,-LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3046	GLAXO SMITHLINE LIMITED	ERIS 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/SYR UPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/3047	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAMIVUDINE+ ZIDOVUDINE	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
NDA/MAL/HDP/3048	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	TRIMAGO-DS TABLETS	SULFAMETHOXAZOLE/TRIMETHOPRIM	800MG/160MG	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET CONTAINER,1.0X3.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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

NDA/MAL/HDP/3051	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	BETROZOLE	DILOXANIDE FUROATE/METRONIDAZOLE	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
NDA/MAL/HDP/3054	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	NOSIC	DOXYLAMINE SUCCINATE + PYRIDOXINE HYDROCHLORIDE	10MG+10MG	INDOCO REMEDIES LTD - 0--L-14 VERNA INDUSTRIAL AREA, VERNA, GOA-403722	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3056	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASCAF	CHLORAMPHENICOL	250MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, SARKEJ BAVLA HIGHWAY RAJODA AHMEDABAD 382220, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER, 1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/3057	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	COLD-A-GO CAPSULES	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + DIPHENHYDRAMINE + CAFFEINE	400MG + 5MG + 12.5MG + 30MG	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER, 1.0X10.0 X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3060	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	KETOS TABLET	KETOCONAZOLE USP	200 MG	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER, 1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/3062	CIPLA	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE,ZIDOVUDINE, 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

NDA/MAL/HDP/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 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3067	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	PROMAGO SYRUP	PROMETHAZINE	5MG/5ML	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3068	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTACHLOR EYE DROPS	CHLORAMPHENICOL	0.5%W/V	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/3070	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	AMBRODIL	AMBROXOL HYDROCHLORIDE	30MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEP PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3072	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL TABLETS(THANE)	PARACETAMOL	500 MG	AGOG PHARMA LIMITED-PLOT NO.33,SECTOR II,THE VASAI TALUKA INDL.CO-OP ESTATE LTD.VASAI(E) DIST.THANE,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3073	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	50MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X14.0 TABLET STRIP
NDA/MAL/HDP/3076	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 40	TELMISARTAN	40MG	ARISTO PHAMACUTLAB PVT LTD-PLOT NO.208 NEW INDUSTRIAL AREA NO.2 MANIDIDEEP 462.046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/3077	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN HC CREAM	CLOTRIMAZOLE + HYDROCORTISONE	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
NDA/MAL/HDP/3078	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB ALLERGY CONGESTION	PARACETAMOL/ CHLORPHENIRAMINE/ EPHEDRINE	500MG/ 2MG/ 30MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/3080	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	CO-AMOX ACINO 156.25	CO-AMOXICLAV	125MG+31.25 MG/ 5ML	LEK D.D PREVALJE SDOVENIA-DORNACHERSTASSE 144 P.O.BOX 445,CH 4147 AESCH (BASEL) SWITZERLAND	SWITZERLAND	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3083	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS 80	TELMISARTAN	80MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEEP PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/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

NDA/MAL/HDP/3085	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD TABLETS	PARACETAMOL+PHE NYLEPHRINE HCL+CAFFEINE+CHL ORPHENIRAMINE HYDROCHLORIDE	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
NDA/MAL/HDP/3087	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	SULPHATRIM TABLETS B.P. 480	CO-TRIMOXAZOLE	480MG	LINCOLN PHARMACEUTICAL LIMITED- TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/3088	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PILL 72	LEVONORGESTREL	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
NDA/MAL/HDP/3090	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME PROXETIL	100MG/5ML	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/3091	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	ONDI	ONDANSETRON	2MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10- 13,M.N DESAI PETROL PUMP,SARKHEJ- BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/3092	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG/160MG/12.5MG	AMLODIPINE + VALSARTAN + HYDROCHLOROTHIA ZIDE	10MG + 160MG +12.5MG	NOVARTIS PHARMA STEIN AG- SCHAFFHARVSRERTRASSE 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
NDA/MAL/HDP/3095	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	AMPHEN SUSPENSION	CHLORAMPHENICOL PALMITATE	125MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3097	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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

NDA/MAL/HDP/3098	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MOSEDIN	LORATADINE	5MG/5ML	AMOUN PHARMACEUTICALS CO. S.A.E-1ST INDUSTRIAL ZONE, EL-BOUR CITY, EGYPT.	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3099	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZONA 0.1% CREAM	HYDROCORTISONE 17-BUTYRATE	0.1%W/W	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE
NDA/MAL/HDP/3101	DAWA LIMITED	SUPER MEDIC LTD	DACOLD SYRUP	PARACETAMOL + PSEUDOEPHEDRINE HCL + CHLORPHENIRAMINE MALEATE	120MG/5ML+ 10MG/5ML+2 MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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	1.0X5.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/3105	CADILA HEALTHCARE LTD	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
NDA/MAL/HDP/3106	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	LABOREX UGANDA LIMITED	PENAMOX	AMOXICILLIN	250MG/5ML	MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3108	IPCA LABORATOIES LTD	MEDVIN PHARMA LIMITED	ZERODOL	ACECLOFENAC	100MG	IPCA LABORATORIES LTD-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
NDA/MAL/HDP/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
NDA/MAL/HDP/3111	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CALPOL	PARACETAMOL	120MG/5ML	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE

NDA/MAL/HDP/3112	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	BUPROL 400MG	IBUPROFEN BP	400 MG	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
NDA/MAL/HDP/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
NDA/MAL/HDP/3116	LABORATORY AND 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
NDA/MAL/HDP/3117	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE SODIUM SUCCINATE	100MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL, 1.0X50.0X100.0 MG VIAL
NDA/MAL/HDP/3118	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LUMARTEM	ARTEMETHER /LUMEFANTRINE	20MG /120MG	QUALITY CHEMICAL INDUSTRIES LIMITED. - PLOT NO. 1-7 LUZIRA INDUSTRIAL PARK, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X24.0 TABLET BLISTER, 1.0X30.0X18.0 TABLET BLISTER, 1.0X30.0X24.0 TABLET BLISTER, 1.0X30.0X12.0 TABLET BLISTER, 1.0X30.0X6.0 TABLET BLISTER, 1.0X1.0X18.0 TABLET BLISTER, 1.0X1.0X12.0 TABLET BLISTER, 1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3122	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GROVIT	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

NDA/MAL/HDP/3123	BLISS GVS PHARMA LIMITED	DELMAR ENTERPRISES LIMITED	RECTOL 250 SUPPOSITORY	PARACETAMOL BP	250 MG	BLISS GVS PHARMA LIMITED-PLOT NO. 10/11 SURVEY NO.39/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/3125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	AMLODAR 5	AMLODIPINE BESILATE	5MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3134	PANACEA BIOTEC LTD	ABACUS PHARMA (AFRICA) LIMITED	TOFF PLUS	PARACETAMOL+CHLORPHENIRAMINE MALEATE+ DEXTROMETHORPHAN + PHENYLEPHRINE	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
NDA/MAL/HDP/3136	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3139	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	OMEDAR	OMEPRAZOLE	20MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/3140	GLAXO SMITHKLINE LTD	ERIS LTD	ULTIVA INJECTION 1MG	REMIFENTANIL	1ML	GLAXOSMITHKLINE LTD MANUFACTURING SPA-VERONA	ITALY	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/3144	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ULSEC	OMEPRAZOLE	20MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/3145	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AMOXICAP	AMOXYCILLIN	500MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3147	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ARISTO TELVAS-H 40/12.5	TELMISARTAN/HYDR OCHLOROTHIAZIDE	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
NDA/MAL/HDP/3148	BAYER AG	SURGIPHARM (U) LIMITED	ALKA-SELTZER	ACETYL SALICYLIC ACID + SODIUM HYDROGEN CARBONATE + CITRIC ACID	342 MG + 1625 MG + 965 MG	BAYER AG -D-51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X72.0 TABLET STRIP,1.0X10.0 TABLET STRIP,1.0X20.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER
NDA/MAL/HDP/3150	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	MTX-VHB	METHOTREXATE	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
NDA/MAL/HDP/3151	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	CLOTRINE 100 MG PESSARIES	CLOTRIMAZOLE	100MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP
NDA/MAL/HDP/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

NDA/MAL/HDP/3155	MEDREICH PLC	LABOREX UGANDA LIMITED	BIOFERON	FERRIC AMMONIUM CITRATE + CYANOCOBALAMIN + 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 HOBBI NELAMANGALA TALUKI BANGALORE RURAL	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/3156	PFIZER LABORATORIES (PTY)	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN FOR COLDS	PSEUDOEPHEDRINE HCL + IBUPROFEN	30MG + 200MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/3158	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	GLIBEX-5	GLIBENCLAMIDE	5MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/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,1.0X100.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3163	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 50MG	DICLOFENAC SODIUM	50MG	DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY STRIP
NDA/MAL/HDP/3165	MEDREICH PLC	LABOREX UGANDA LIMITED	MUCODIL EXPECTORANT	TERBUTALINE SULPHATE +BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2.5MG + 8MG + 100MG	MEDREICH LTD-4/3 OFF KANAPURA ROAD, AVALAHALLI, A, TEJKAMAL PHARMACEUTICAL PVT, SURVEY NO.6/2 ALADAHALLI,SOMAPURAHOBIL,NELAMANGALA TALUK,BANGALORE RURAL-562111,INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3166	PHARMACARE LTD	BETA HEALTHCARE UGANDA LIMITED	SEPTRIN	TRIMETHOPRIM + SULPHAMETHOXAZOLE	40MG/5ML + 200MG/5ML	GLAXO WELLCOME EGYPT CO. S.A.E-CAIRO	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/3173	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOCILLIN 250	AMPICILLIN	250MG	MEDOPHARM PVT LTD -NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY-603203 TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3177	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	BETADERM CREAM	BETAMETHASONE VALERATE	0.1%W/W	ATCO LABORATORIES PVT LTD-B-18,S.I.T.E KARACHI 75700, PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X5.0 G TUBE
NDA/MAL/HDP/3178	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENDURIC TABLETS	BENDROFLUMETHIAZIDE	5MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/3179	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	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
NDA/MAL/HDP/3180	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	LOFIN 500	METFORMIN HYDROCHLORIDE	500MG	M.J BIOPHARM PVT LTD --L-7 MIDC INDUSTRIAL AREA, DIST . RAIGAD , TALOJA , NAVI MUMBAI	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3185	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	AMINOPHYLLINE INJECTION	AMINOPHYLLINE	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0X10.0 ML AMPOULE,1.0X10.0X10.0 ML AMPOULE
NDA/MAL/HDP/3186	IDA FOUNDATION	KIMSY MEDS LTD	PARACETAMOL	PARACETAMOL	500MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/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

NDA/MAL/HDP/3192	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ANZAVIR-R	ATAZANAVIR + RITONAVIR	300 MG + 100 MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/3196	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	MOTINORM	DOMPERIDONE	10MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/3197	ERIS LTD	BENLE CONSULT LIMITED	TRIAM-DENK 40 INJECTION	TRIAMCINOLONE ACETONIDE	40 MG/ML	DENK PHARMA, GOLLSTR.,-1-D-845 529 TITTMONING GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/3198	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPEN-125	PHENOXYMETHYL 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/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3199	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ISENTRESS	RALTEGRAVIR	400MG	ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD -ZHEJIANG HUAHAI PHARMACEUTICAL CO LTD XUNQIAE LINHAI ZHIJIANG	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/3200	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LETRAX	LEVAMISOLE HYDROCHLORIDE	40MG	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 200.0 TABLET CONTAINER,1.0X 25.0X3.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/3202	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	PRESARTAN-50	LOSARTAN	50MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER

NDA/MAL/HDP/3203	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	TETANUS ANTITOXIN	TETANUS ANTITOXIN	1500 I.U	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X1.0 ML AMPOULE (1 DOSE AMPOULE)
NDA/MAL/HDP/3204	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	RELCEER GEL	ALUMINIUM HYDROXIDE/MAGNESIUM HYDROXIDE/DIMETHICONE/LIQUORICE	6G+80MG+100MG+400MG/5ML	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X180.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3205	EAGLEVET UGANDA LIMITED	MEDVIN PHARMA LIMITED	AZIFAST-250	AZITHROMYCIN	250MG	IPCA LABORATORIES LTD-SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3206	HEALTHCARE LTD.	HEALTHCARE LTD.	POSTINOR 2	LEVONORGESTREL	0.75MG	GEDEON RICHTER PLC-1103 BUDAPEST GYOMROI UT 19-21	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/3207	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	DILCONTIN XL 90	CONTROLLED RELEASE TABLETS OF DILTIAZEM HYDROCHLORIDE	90MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/3208	NIRMA LIMITED.	SUPER MEDIC LTD	NIRFOL 1%	PROPOFOL	1%W/V	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0X20.0 ML VIAL,1.0X10.0X50.0 ML VIAL
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3214	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	INDICONTIN	INDAPAMIDE	1.5MG	MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/3219	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL ORAL SUSPENSION	CHLORAMPHENICOL	125MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3220	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PYLO KIT	LANSOPRAZOLE+TINIDAZOLE+CLARITHROMYCIN	30MG+500MG +250 MG	CIPLA LIMITED PUNE-MIDC, KURKUMBH DISTRICT PUNE 413802	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X1.0X6.0 TABLET BLISTER (BLISTER CONTAINS 2 CAPSULES AND 4 TABLETS)
NDA/MAL/HDP/3221	REMINGTON PHARMACEUTICAL INDUS. PVT LTD PAKISTAN	HEALTHCARE LTD.	OPTADEX-N EYE DROPS	DEXAMETHASONE/NEOMYCIN	1MG/3MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL
NDA/MAL/HDP/3224	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM FLUFED ELIXIR	MULTI-INGREDIENT	MULTI-INGREDIENT	KAMPALA PHARMACEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3225	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DIFLAME	DICLOFENAC DIETHYLAMINE + LINSEED OIL + METHYL SALICYLATE MENTHOL	N/A	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/3226	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	PEDITRAL	ORAL REHYDRATION SALT	N/A	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X29.5 G SACHET
NDA/MAL/HDP/3228	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	ENTOSEC	SECNIDAZOLE	1000MG	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 STRIP
NDA/MAL/HDP/3230	GLAND PHARMA LIMITED	TATA UGANDA LIMITED	METOCLOPRAMIDE INJECTION	METOCLOPRAMIDE HYDROCHLORIDE	5MG/ML	GLAND PHARMA LTD -DOMMARA POCHAMPALLY SURVEY NO. 5	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/3231	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	FLUCOMOL	PARACETAMOL/PHENYLEPHRINE HCL/DEXTROMETHORPHAN HBR/CHLORPHENIRAMINE MALEATE	500MG/10MG /15MG/2MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0X1.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/3232	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM	SULFAMETHOXAZOLE + TRIMETHOPRIM	400MG + 80MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3235	IDA FOUNDATION	KIMSY MEDS LTD	CHLORPROMAZINE INJECTION	CHLORPROMAZINE HYDROCHLORIDE	25MG/ML	GLAND PHARMA LIMITED-D. P PALLY NARSAPUR ROAD, HYDERABAD – 500 043, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/3237	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	KONAZOL CREAM	KETOCONAZOLE	2% W/W	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3239	GLAND PHARMA LIMITED	TATA UGANDA LIMITED	TRAMADOL HYDROCHLORIDE	TRAMADOL HYDROCHLORIDE	50MG/ML	GLAND PHARMA LTD -DOMMARA POCHAMPALLY SURVEY NO. 5	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/3241	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	CLOTRILIN	CLOTRIMAZOLE	1%W/W	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/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

NDA/MAL/HDP/3245	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NYSTATIN ORAL DROPS	NYSTATIN	100,000 I.U/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL TOPICAL DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/3246	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/3249	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LOSACAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIA ZIDE	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
NDA/MAL/HDP/3252	GALENTIC PHARMA(INDIA)PVT LTD	NORVIK ENTERPRISES LIMITED	PYLOOCAIN	BETAMETHASONE + PHENYLEPHRINE + LIDOCAINE	0.5 MG/G + 1 MG/G + 25 MG/G	GALENTIC PHARMA(INDIA) PVT LTD-R-673,MIDC TTC RABALE THANE-BELAPUR ROAD,NAVI	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X30.0 G TUBE
NDA/MAL/HDP/3254	VENUS REMEDIES LIMITED	AARON PHARMACEUTICAL S 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
NDA/MAL/HDP/3255	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/3258	STRIDES ARCOLAB LTD	DELMAR ENTERPRISES LIMITED	LAMIVUDINE/ ZIDOVUDINE & EFAVIRENZ COMBIPACK	LAMIVUDINE/ ZIDOVUDINE + EFAVIRENZ	150MG/300M G + 600MG	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,1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/3259	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	TIGBODERM	BETAMETHASONE + CHLOROCRESOL + GENTAMICIN + CLIOQUINOL + TOLNAFTATE	0.05% W/W + 0.1% W/W + 0.1% W/W + 1% W/W + 1% W/W	NEM LABORATORIES PVT LTD-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

NDA/MAL/HDP/3261	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	TENOFOVIR DF + EMTRICITABINE + EFAVIRENZ	300MG+200MG+600MG	MYLAN LABORATORIES LTD--F-4,F-12 MALEGAON MIDC SINNAR NASHIK 422113 MAHARASHTRA STATE ,MYLAN LABORATORIES LTD -- PLOT NO. H-12 & H-13 MIDCWALUJ INDUSTRIAL AREA AURANGABAD 431136 MAHARASTRA,MYLAN LABORATORIES LIMITED -PLOT NO. 11,12&13 INDORE SPECIAL ECONOMIC ZONE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/3262	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	250MG + 250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3263	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX MUCOLYTIC SYRUP	SALBUTAMOL SULPHATE + BROMHEXINE HYDROCHLORIDE + GUAIFENESIN	2MG/5ML + 4MG/5ML + 100MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3266	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	SALIMIA LINIMENT	METHYL SALICYLATE+TURPENTINE OIL	5ML+25ML	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE
NDA/MAL/HDP/3270	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4000000 IU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/3273	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL CREAM	BETAMETHASONE VALERATE	0.1%W/W	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/3275	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	MEFLIN-500	MEFENAMIC ACID	500MG	LINCOLN PHARMACEUTICALS LIMITED -10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3277	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 500MG	TRANEXAMIC ACID	500MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/3278	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOPIDIC 2% OINTMENT	SODIUM FUSIDATE	20MG/G	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIIHA	JORDAN	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/3279	ROYAL GROUP	ABACUS PHARMA (AFRICA) LIMITED	HAEMOFORTE SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI,INDIA,BAROQUE PHARMACEUTICALS PVT LTD --S.NO.192/2 & S.NO.192/2 &3 SOKHADA-388 620 KHAMBHAT. DIST. ANAND GUJARAT INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/3280	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	TUSPEL PLUS EXPECTORANT	BROMHEXINE HYDROCHLORIDE + TERBUTALINE SULPHATE + AMMONIUM CHLORIDE + MENTHOL	8 MG + 2.5 MG + 100 MG + 1.5 MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3282	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KOFF-GO	PHENYLEPHRINE HCL + CHLORPHENIRAMINE MALEATE + DEXTROMETHORPHAN	5MG/5ML + 2MG/5ML + 10MG/5ML	TORQUE PHARMACEUTICALS (P) LTD-P.O.DAPPAR VILLISS	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3284	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	CHALEATE	CHLORPHENIRAMINE MALEATE	4MG	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/3285	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	AMOXIL	AMOXICILLIN	250MG/5ML	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE DE LA PEYENNIERE 53100 MAYENNE, FRANCE	FRANCE	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3288	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELAED SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE

NDA/MAL/HDP/3289	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID DUSTING POWDER	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL DUSTING POWDERS	1.0X30.0 G BOTTLE,1.0X100.0 G BOTTLE
NDA/MAL/HDP/3291	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FINTOP	BUTENAFINE HCL	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3292	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELADED PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+SODIUM CITRATE+MENTHOL	7MG+28.5MG +0.55MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3294	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	URGENDOL CAPSULES	TRAMADOL HYDROCHLORIDE	50 MG	WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3295	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	GLEVATE	CLOBETASOL	0.05%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3296	MYLAN LABORATORIES LIMITED	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
NDA/MAL/HDP/3297	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	NEPIN-SR-20	NIFEDIPINE	20MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/3299	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	METODINE-DF SUSPENSION	METRONIDAZOLE/DILOXANIDE FUROATE	200MG/250MG	SEARLE PAKISTAN LIMITED-PLOT 35KM, MULTAN ROAD, LAHORE - PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3300	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MUCOSOL PEDIATRIC SYRUP	CARBOCISTEINE	125 MG/5 ML	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/3301	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN CAPSULES 250	TRANEXAMIC ACID	250MG	HILTON PHARMA (PVT) LTD-PLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/3304	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	FELEXIN	CEFALEXIN MONOHYDRATE	250MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3305	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	SPASMOTROY	DROTAVERINE HYDROCHLORIDE	20MG/ML	TROIKAA PHARMACEUTICALS LIMITED - THOL,DIST,MEHSANA PIN:382728 GUJARAT AHMEDABAD INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/3309	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	CLOTRIMAZOLE PESSARIES	CLOTRIMAZOLE	100MG	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP
NDA/MAL/HDP/3310	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	GEMFOS	RISEDRONATE SODIUM	35MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3312	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICAL S LTD.	TIDOMET FORTE	CO-CARELDOPA	25MG/250MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3314	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	SILVEREX	SILVER SULFADIAZINE + CHLORHEXIDINE GLUCONATE	10MG/G+10M G/G	SUN PHARMACEUTICALS IND. LTD-B-2,MADAKAI INDUSTRIAL ESTATE, PONDA,GOA-403404, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X250.0 G TUBE,1.0X25.0 G TUBE,1.0X10.0 G TUBE
NDA/MAL/HDP/3315	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/3316	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX	AMOXYCILLIN TRIHYDRATE	125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3318	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM TABLETS	CO-TRIMOXAZOLE	480MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/3319	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) LIMITED	FERROTONE CAPSULES	FERROUS FUMERATE+FOLIC ACID+VITAMIN B12	162MG +0.75MG +7.5MCG	MEGA LIFESCIENCES LTD.-384 PATTANA 3 ROAD BANGPOO INDUSTRIAL ESTATE SUMUTPRAKAN	THAILAND	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/3321	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DERMOLIN-GM	CLOBETASOL+GENTAMICIN+MICONAZOLE	0.05%W/W+0.1%W/W+2%W/W	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3322	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	NEVIRAPINE	NEVIRAPINE	50MG	AUROBINDO PHARMA LTD-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
NDA/MAL/HDP/3325	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	RAPIDEX	ACETAMINOPHEN+ASPIRIN+CAFFEINE	200MG+400MG+50MG	KAMPALA PHARMACEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3326	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	AMICIP	AMIKACIN	500MG/2ML	CIPLA LTD-M-61, M-62 &M-63 UNIT IX VERNA INDUSTRIAL ESTATE, VERNA, SALTETTE GOA 403 722	INDIA	PARENTERAL ORDINARY DRY VIALS	5.0X2.0 ML VIAL
NDA/MAL/HDP/3328	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZYL PENICILLIN INJECTION	BENZYL PENICILLIN	1 MU	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL, 1.0X10.0X1.0 MU VIAL
NDA/MAL/HDP/3330	SWISS PHARMACEUTICAL PUT LTD	HEALTHCARE LTD.	DEXA-N	DEXAMETHASONE+N EOMYCIN SULPHATE	1%W/W+0.5%W/W	SWISS PHARMACEUTICALS PVT LTD-A159 SINDH INDUSTRIAL AREA KARACHI	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3331	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	BETOPTIC	BETAXOLOL	0.5%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML VIAL
NDA/MAL/HDP/3333	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	NOVACLAV-625	AMOXICILLIN + CLAVULANATE POTASSIUM	500 MG + 125 MG	OKASA PVT LTD-346 KUNDAIM INDUSTRIAL ESTATE GOA, 403115	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3334	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP, 1.0X10.0X 6.0 TABLET STRIP
NDA/MAL/HDP/3340	BLISS GVS PHARMA LIMITED	DELMAR 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

NDA/MAL/HDP/3341	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-250	AZITHROMYCIN	250MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3342	SEARLE PAKISTAN LTD	HEALTHCARE LTD.	METODINE DF TABLETS	METRONIDAZOLE+DILLOXANIDE	400MG+500MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X3.0X5.0 TABLET BLISTER
NDA/MAL/HDP/3343	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDIVEN-CREAM	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3345	ASTRA PHARMACY (U) PVT LTD	ASTRA PHARMA (U) LIMITED	PAINOL-P	PARACETAMOL + 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
NDA/MAL/HDP/3346	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	ZEDEX	BROMHEXINE +AMMONIUM CHLORIDE+ MENTHOL + DEXTROMETHORPHAN	8MG+100MG+5MG+10MG	WOCKHARDT LIMITED --PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3347	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIPEN TABLETS	PHENOXYMETHYLPENICILLIN	250MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3348	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	PIMCEF	CEFEPIME USP	1G	VENUS REMEDIES LTD.-UNIT 11 HOLL TOP INDUSTRIAL ESTATE JHAMAJRI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/3352	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	OMLINK-20	OMEPRAZOLE	20MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3354	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEDIVEN OINTMENT	BETAMETHASONE VALERATE	0.1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE

NDA/MAL/HDP/3356	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL-100 CAPSULES	CELECOXIB	100MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3356	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL-100 CAPSULES	CELECOXIB	100MG	CADILA HEALTHCARE LTD -KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3357	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	ESOREST 20	ESOMEPRAZOLE	20MG	CENTAUR PHARMACEUTICALS PVT L.T.D.- CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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	1.0X7.0X1.0 ML AMPOULE
NDA/MAL/HDP/3360	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORAMPHENICOL EAR DROPS	CHLORAMPHENICAL	5%W/V	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	OTIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/3361	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUCLOX	AMPICILLIN + CLOXACILLIN	250 MG / 5 ML + 250 MG / 5 ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3364	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	ESOREST 40	ESOMEPRAZOLE	40MG	CENTAUR PHARMACEUTICALS PVT L.T.D.- CENTAUR HOUSE NEAR	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3366	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	DIAS	GLIBENCLAMIDE	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
NDA/MAL/HDP/3367	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOMOL SUSPENSION	PARACETAMOL	125 MG/5ML	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3368	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	VIAGRA 50MG	SILDENAFIL	50MG	PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X12.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER,1.0X4.0 TABLET BLISTER

NDA/MAL/HDP/3369	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	AZILIN-500	AZITHROMYCIN	500MG	LINCOLN PHARMACEUTICALS LIMITED-10, 12, 13, TRIMUL ESTATE, AFTER VADSCAR VILLAGE, NEAR KHATRAJ CHOKADI, KHATRAJ-382721, GHANDHINAGAR, GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X3.0 TABLET BLISTER
NDA/MAL/HDP/3370	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DERMOREN 500	GRISEOFULVIN	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3372	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	MUCOLEX	AMBROXOL HYDROCHLORIDE + SALBUTAMOL SULPHATE + GUAIFENESIN	30MG +1MG + 30MG /5ML	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3373	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MYCLAV 625	AMOXICILLIN/CLAVULANATE	500MG/125MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET STRIP, 1.0X10.0X6.0 TABLET STRIP
NDA/MAL/HDP/3374	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	ZITHROX 250MG	AZITHROMYCIN	250MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3376	ASTRAZENECA	MACNAUGHTON LIMITED	TENORMIN	ATENOLOL	50MG	ASTRA ZENECA UK LIMITED-SILK ROAD BUSINESS PARK,MACCLESFIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER, 1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/3377	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AMILINE	AMITRIPTYLINE	25 MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3378	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	CHLOZINE TABLETS	CHLORPROMAZINE	100MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/3379	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFASI	HUMAN CHORIONIC GONADOTROPIN	5000I.U	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X2.0 AMPOULE CARTON
NDA/MAL/HDP/3381	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION	HYDROCORTISONE SODIUM SUCCINATE	100MG	TROIKAA PHARMACEUTICALS LIMITED - THOL,DIST,MEHSANA PIN:382728 GUJARAT AHMEDABAD INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X100.0 MG VIAL
NDA/MAL/HDP/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,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3383	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	ZEPIN	CARBAMAZEPINE	200 MG	AGOG PHARMA LTD-PLOT NO. 33, SECTOR II, VASAI, TALUKA INDL.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3384	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/3385	BLUE CROSS LABORATORIES LTD	STAR PHARMACEUTICALS LTD	MEFTAL-P-SUSPENSION	MEFENAMIC ACID	100MG/5ML	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3386	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	AMBROSE 2	CHLORAMBUCIL	2MG	NAPROD LIFE SCIENCES PVT LTD-G17 MDC TARAPUR IND AREA THONE, MUMBAI INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BOTTLE
NDA/MAL/HDP/3387	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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

NDA/MAL/HDP/3389	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARINASE REPE TABS	LORATADINE + PSEUDOEPHEDRINE	5MG + 120MG	SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	BELGIUM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X10.0X10.0.0 TABLET BLISTER,100.0X10.0.0 TABLET BLISTER
NDA/MAL/HDP/3392	SWISS PHAMACEAUTICAL PUT LTD	HEALTHCARE LTD.	TRAMACIN POWDER	NEOMYCIN + BACITRACIN	0.052G + 0.0432G	SWISS PARENTERALS PVT LTD-809, KERALA INDUSTRIAL ESTATE, G.I.D.C, BAVIA ROAD, DIST, AHMEDABAD, GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X10.0 G CONTAINER
NDA/MAL/HDP/3393	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/3396	CLARIS INJECTABLES LTD	REDDYS PHARMA LIMITED	BUPICAN HEAVY	BUPIVACAINE HYDROCHLORIDE 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
NDA/MAL/HDP/3397	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	TENOFOVIR DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL FUMARATE	300MG	AUROBINDO PHARMA LTD-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
NDA/MAL/HDP/3399	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	LDNIL 10	ROSUVASTATIN	10MG	MSN LABORATORIES LTD-PLOT 42 ANRICH INDUSTRIAL ESTATE BOLLARAM MEDAK DISTRICT 502325 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/3404	GLAXO SMITHLINE LIMITED	ERIS 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
NDA/MAL/HDP/3405	GLAXO SMITH KLINE LTD	ERIS LTD	PANADOL BABY AND INFANT 120MG/5ML	PARACETAMOL	120MG/5ML	FARMACLAIR -440 AVENUE DU GENERAL DE GAULLE 14200 HEROUVILLE SAINT CLAIR FRANCE	FRANCE	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3409	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	CLARITINE	LORATADINE	10MG	SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	BELGIUM	ORAL SOLID ORDINARY TABLETS	3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3410	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	NAPRODOX-50	DOXORUBICIN	50MG	NAPROD LIFE SCIENCES PVT LTD-G17 MDC TARAPUR IND AREA THONE, MUMBAI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 MG VIAL
NDA/MAL/HDP/3411	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABNAL NASAL DROPS	SODIUM CHLORIDE	0.9%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	NASAL SYSTEMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/3412	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	TETRACYCLINE	TETRACYCLINE HYDROCHLORIDE	250 MG	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/3414	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	EXFORGE 10MG/160MG	AMLODIPINE + VALSARTAN	10 MG + 160 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERSTRASSE,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
NDA/MAL/HDP/3415	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID V-1	CLOTRIMAZOLE	500MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	VAGINAL TABLETS	1.0X1.0 PESSARY STRIP
NDA/MAL/HDP/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, BWEOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3422	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	GENTAMICIN EYE/ EAR DROPS	GENTAMYCIN	0.3%W/V	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL

NDA/MAL/HDP/3423	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	AMOXICLAV-DENK 1000/125	AMOXICILLIN TRIHYDTATE + POTASSIUM CLAVULANATE	1000 MG + 125 MG	PENCEF PHARMA GMBH-BRITENBACHSTR ASSE 13 D-13509 BERLIN	GERMANY	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0X3.0 G SACHET,1.0X8.0X3.0 G SACHET
NDA/MAL/HDP/3426	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	RUBEM CREAM	METHYL NICOTINATE + CAPSICUM OLEORESIN+ METHYLSALICYLATE	1%W/W+0.1% W/W+5%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE
NDA/MAL/HDP/3427	UNIVERSAL CORPORATION LTD	HARLEYS UGANDA LIMITED	SULFRAN	COTRIMOXAZOLE	480MG	UNIVERSAL CORPORATION LIMITED -PLOT 13777 KIKUYU ROAD, KIKUYU TOWN, PAST POST OFFICE	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3428	MEDI PHARMA INDUSTRIES 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
NDA/MAL/HDP/3429	XEPA-SOUL PATTINSON	DELMAR 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
NDA/MAL/HDP/3431	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NAZOL-200	KETOCONAZOLE	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
NDA/MAL/HDP/3433	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CO-DIOVAN 80/12.5	VALSARTAN + HYDROCHLOROTHIAZIDE	80 MG +12.5 MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY,NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/3434	PHARMACARE 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,1.0X10.0X10.0 TABLET CARTON,1.0X50.0 TABLET CARTON

NDA/MAL/HDP/3437	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	REMYCIN 100 CAPSULES	DOXYCYCLINE HYDROCHLORIDE	100MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3438	MEDREICH PLC	LABOREX UGANDA LIMITED	PROXACIN	CIPROFLOXACIN	500MG	MEDREICH STERILAB LIMITED-NO. 4/3, AVALAHALI ANJANAPURA POST,OFF KANAKAPWA ROAD, BANGALORE 560062 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER,10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENECHLOR CAPSULE	CHLORAMPHENICOL	250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,10.0 X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3440	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG	INSULIN LISPRO	100IU	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/3441	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LEVOFLOXACIN	LEVOFLOXACIN	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
NDA/MAL/HDP/3443	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	BETASOL OINTMENT	BETAMETHASONE 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
NDA/MAL/HDP/3444	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORVADIL 10	AMLODIPINE BESILATE	10MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/3446	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	CORDARONE	AMIODARONE HYDROCHLORIDE	50MG/ML	SANOFI WINTHROP INDUSTRIE-LAGRAGE 33565 CARBON BLANC CEDEX FRANCE	FRANCE	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE
NDA/MAL/HDP/3449	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	IMMUNOX	CEFTRIAXONE SODIUM	1000MG	VENUS REMEDIES LTD-VNIT-11 HILL TOP INDUSTRIAL ESTATE JHARRUJIRI EPIP INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL
NDA/MAL/HDP/3450	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMADAX 50	TRAMADOL	50MG	AEGIS LIMITED -17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081, LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/3451	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPHENOL CAPSULES (THANEO)	CHLORAMPHENICOL	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/3453	MJ BIOPHARM PVT LTD	TATA UGANDA LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	25MG/ML	M.J BIOPHARM PVT LTD-TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X10.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3458	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL	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 CAPSULE CONTAINER
NDA/MAL/HDP/3459	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ENEMAX	HYPERTONIC SOLUTION OF SODIUM PHOSPHATES	6GM AND 16GM/100ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/3460	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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

NDA/MAL/HDP/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
NDA/MAL/HDP/3462	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PLATOL	CISPLATIN	500MG/100ML	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
NDA/MAL/HDP/3464	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TARTAR CONTROL LISTERINE ANTISEPTIC	ZINC CHLORIDE + DENATURED ALCOHOL MENTHOL 95% + THYMOL	18MG/ 20ML + 0.9ML/20ML + 12.7MG/20ML	JOHNSON&JOHNSON PTY LTD.-241 MAIN ROAD RETREAT 794	SOUTH AFRICA	ORAL LIQUID ORDINARY OTHER LIQUIDS	1.0X500.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/3465	MONDI-MUNDI PHARMA PVT LIMITED	SURGIPHARM (U) LIMITED	FECONTIN-Z	FERROUS GLYCINE SULPHATE+ZINC SULPHATE+FOLIC ACID	100MG+61.8 MG+0.5MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3466	DAWA LIMITED	SUPER MEDIC LTD	DAWASEC	SECNIDAZOLE	1G	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/3467	VENUS REMEDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM TRIHYDRATE	1000MG	VENUS REMEDIES LTD --UNIT II HILL TOP INDUSTRIAL ESTATE JHARMAJRI EPIP PHASE I BHATOLI KALAN BADDI (H.P)	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL
NDA/MAL/HDP/3471	VENUS REMEDIES LTD	AARON PHARMACEUTICALS LTD	PAXOL	PACLITAXEL	100MG/16.7ML	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
NDA/MAL/HDP/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
NDA/MAL/HDP/3474	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	AMCLOREN DRY SYRUP	AMPICILLIN + CLOXACILLIN	125MG+125MG/5ML	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/3475	VENUS REMIDIES LTD	HARLEYS UGANDA LIMITED	RONEM	MEROPENEM	500MG	VENUS REMEDIES LTD, UNIT II,-HILL TOP INDUSTRIAL ESTATE, JHARMAJTI, EPIP, PHASE-1 (EXTENSION), BHATOLI KALAN, BADDI -HP	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/3476	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	PARAFIL	PARACETAMOL	500MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER, 1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3478	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	DICLOREN	DICLOFENAC SODIUM BP	50MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA, KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3483	JOHNSON&JOHNSON PTY LTD. 241	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	SINUTAB 3-WAY	IBUPROFEN + PSEUDOEPHEDRINE HCL	200MG + 30MG	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3485	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ERGOMETRINE	ERGOMETRINE MALEATE	0.5MG/ML	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LTD-N-118 MIDC TARAPUM BOISAR DIST THANE 401506 MAHARASHTRA, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE
NDA/MAL/HDP/3489	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	NEO MEDROL	METHYLPREDNISOLONE ACETATE+ NEOMYCIN SULFATE	2.5MG+2.5MG	PATHEON YM INC. TORONTO- TORONTO, CANADA	CANADA	TOPICAL EXTERNAL LOTIONS	1.0X25.0 ML BOTTLE
NDA/MAL/HDP/3490	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	LAXOLAC SYRUP	LACTULOSE	67G/100ML	MEDICAL UNION PHARMACEUTICALS LTD- ABU SULTAN, ISMAILIA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/3491	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	BENDEX-400	ALBENDAZOLE	400MG	CIPLA LTD-UNIT I & II A-32 & A-42 MIDC PATALGANGA 410220 DIST-RAIGAD, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	10.0X1.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3494	LABORATORIOS NOVAG SA	LABOREX UGANDA LIMITED	GAMALATE B6 SOLUTION	MAGNESIUM GLUTAMATE HYDROBROMIDE + AMINOBUTYRIC ACID + AMINO HYDROXYBUTYRIC 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
NDA/MAL/HDP/3495	BELL SONS & CO.(DRUGGISTS) LTD	ECHO PHARMACY (U) LIMITED	MENTHODEX COUGH MIXTURE	MULTIINGREDIENT	N/A	BELL SONS & CO (DRUGGISTS) LTD- SLAIDBURN CRES CHESHIRE HOUSE/GORSEY LA	UNITED KINGDOM	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/3497	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/3500	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	GIZLAN 300	IRBESARTAN	300MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3502	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	HYDROCORTISONE SODIUM SUCCINATE	HYDROCORTISONE SODIUM SUCCINATE	100MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL + 1*2ML AMPOULE OF WFI
NDA/MAL/HDP/3504	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BIFRIL	ZOFENOPRIL	30MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.I-VIA CAMPO DI PILE 67100 L'AQUILA	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/3505	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASFLIC	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,1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3506	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ULTANE	SEVOFLURANE	100%W/W	AESICA QUEESNBOROUGH LTD- NORTH RD. QUEESNBOROUGH KENT	UNITED KINGDOM	NASAL SYSTEMIC UNIT DOSE LIQUIDS	1.0X250.0 ML BOTTLE
NDA/MAL/HDP/3507	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S 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
NDA/MAL/HDP/3512	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL 250MG	TERBINAFINE	250MG	NORVATIS PHARMA PRODUKTIONS GMBH - 79644 WEHR/BADEN-GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET CARTON
NDA/MAL/HDP/3515	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN 40/240	ARTEMETHER + LUMEFANTRINE	40 MG + 40 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3516	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BENZHEXOL TABLETS BP 5MG	TRIHEXYPHENIDYL HYDROCHLORIDE	5MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 100.0 TABLET BLISTER
NDA/MAL/HDP/3517	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TOTO ZINC	ZINC SULPHATE	20MG	MEDICAMEN BIOTECH LTD-SP-1192, A &B, PHASE –IV, INDUSTRIAL AREA BHIWADI -301019 DIST. ALWAR (RAJASTHAN)	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3518	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASFLOX	CIPROFLOXACIN	500MG	ASTRA LIFE CARE (INDIA) PVT LTD- 57/P,RAJODA 382220, BAVLA AHMEDABAD INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3519	STRIDES ARCOLAB LIMITED	DELMAN 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
NDA/MAL/HDP/3520	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ POWDER	POVIDONE IODINE + METRONIDAZOLE	1%W/W + 5%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X100.0 G BOTTLE,1.0X10.0 G BOTTLE

NDA/MAL/HDP/3522	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY VIALS	1.0X10.0X500.0 MG VIAL
NDA/MAL/HDP/3525	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCILLIN	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 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3526	CYANO PHARMA(P)	RENE PHARMACY LTD	PROMETHAZINE TABLETS	PROMETHAZINE HYDROCHLORIDE	25MG	CYANO PHARMA(P)-115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3527	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-500	LEVOFLOXACIN	500MG	GLENMARK PHARMACEUTICALS LTD (UNIT III)-B-4/5/6 MIDC INDUSTRIAL AREA,CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3528	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART-DISPERSABLE	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER,1.0X2.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3530	GLAXO SMITH KLINE LTD	ERIS LTD	FLIXOTIDE ACCUHALER	FLUTICASONE PROPIONATE	100MCG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 ML CANNISTER
NDA/MAL/HDP/3532	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	SIMEPAR CAPSULES	MULTINGREDIENT	MULTINGREDIENT	ACINO PHARMA AG-DORNACHERSTRASSE 114 P.O.BOX 445 CH4147 AESCH/BL SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X40.0 CAPSULE CONTAINER
NDA/MAL/HDP/3532	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	SIMEPAR CAPSULES	MULTINGREDIENT	MULTINGREDIENT	MEPHA LTD,-DORNACHESTRASSE 114 CH-4147, AESCH, BASEL	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X40.0 CAPSULE CONTAINER
NDA/MAL/HDP/3533	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	LEVOZIN	LEVOCETIRIZINE	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

NDA/MAL/HDP/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
NDA/MAL/HDP/3536	SANOI 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	SANOI PASTEUR CAMPUS MERIEUX--1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/3537	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	NELTOLON GEL	BIFONAZOLE	1%W/W	PHARMATHEN LTD.-6 DERVENAKION STR. 153 51 PALLINI-GREECE	GREECE	TOPICAL EXTERNAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3542	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	MARA MOJA	ASPIRIN + PARACETAMOL + CAFFEINE	400MG + 200MG + 50MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X2.0 TABLET STRIP,1.0X110.0 X2.0 TABLET STRIP
NDA/MAL/HDP/3543	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DROX 250	CEFADROXIL	250 MG	AUROBINDO PHARMA LTD (UNIT VI) ,- SURVEY NOS. 329/39 & 329/47,CHITKUL VILLAGE,PATANCHERU MANDAL, MEDAK DISTRICT PIN CODE 502307, ANDHRA PRADESH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3545	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDID MOUTH PAINT	CLOTRIMAZOLE	1%W/W	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL TOPICAL LIQUIDS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/3546	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENETRIM D.S	SULPHAMETHOXAZOLE + TRIMETHOPRIM	800MG + 160MG	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/3547	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-10	BISOPROLOL	10 MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/3548	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BECLATE 200	BECLOMETASONE	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
NDA/MAL/HDP/3549	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	TRIMEX PAEDIATRIC COUGH EXPECTORANT	CHLORPHENIRAMINE MALEATE+PSEUDO EPHEDRINE HCL+GUAIPHENISIN+ MENTHOL	1.0MG+15.0MG+50.0MG+0.5MG / 5ML	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3551	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZAHA-500MG	AZITHROMYCIN	500MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIAL AREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3553	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 25/67.5 B/L	ARTESUNATE+AMO DIAQUINE	25MG+67.5MG	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/3556	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	GRISACTIN-500 TABLETS	GRISEOFULVIN TABLETS	500MG	REGAL PHARMACEUTICALS LIMITED -PLOT 7879/18 OF BABA DOGO ROAD, RUARAKA, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3558	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	SEROFLO-250	SALMETEROL+ FLUTICASON PROPRIONATE	25MCG + 250MCG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/3560	ASTRA PHARMA UGANDA LIMITED	ASTRA PHARMA (U) LIMITED	DERMIZOL	KETOCONAZOLE	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
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3564	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ATROPINE INJECTION	ATROPINE SULPHATE	1MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD-KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE,1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/3565	PFIZER LABS LIMITED	LABOREX UGANDA LIMITED	UNASYN	SULTAMICILLIN TOSYLATE DIHYDRATE	375MG	HAUPT PHARMA LATINA S.R.L -S.S 156 KM BORGIO SAN MICHELE LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3568	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	MYCOSPOR CREAM	BIFONAZOLE	1%W/W	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	TOPICAL EXTERNAL CREAMS	1.0X50.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/3569	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CARBADAC-200	CARBAMAZEPINE	200MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER

NDA/MAL/HDP/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
NDA/MAL/HDP/3571	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	CADIPHEN EXPECTORANT	CHLORPHENIRAMINE/GUAIFENESIN/AMMONIUM CHLORIDE	2MG//80MG/100MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3574	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METZO 2.5 TABLET	METOLAZONE TABLETS USP	2.5MG	CENTAUR PHARMA PVT.LIMITED-PLANT I-PLOT3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3575	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 400 CAPSULES	CEFIXIME	400MG	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X5.0 CAPSULE BLISTER
NDA/MAL/HDP/3577	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	METOCLOPRAMIDE	METOCLOPRAMIDE	5MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/3578	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	CINNARON 25	CINNARIZINE	25MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3580	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-120	FEXOFENADINE HYDROCHLORIDE	120MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3581	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	METZO 5	METOLAZONE	5MG	CENTAUR PHARMA PVT.LTD-PLANT I-PLOT 3,TIVIM INDUSTRIAL ESTATE,KARASWADA,MAPUSA GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3582	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	SULPHADIMIDINE	SULPHADIMIDINE	500MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/3583	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	SIMVA-DENK 40	SIMVASTATIN	40MG	DENK PHARMA GMBH & CO-G0 11 STR.1 84529 T,HMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3584	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORAMPHENICOL EYE DROPS	CHLORAMPHENICOL	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
NDA/MAL/HDP/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
NDA/MAL/HDP/3588	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	FEXOFEN-180	FEXOFENADINE	180MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X6.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3590	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ALFOXAN 500 FC TABLETS	MEFENAMIC ACID	500MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/3592	FOURRTS (INDIA) LABORATORIES PUT LTD	DELMAW ENTERPRISES LIMITED	MEGATRIM DS	CO-TRIMOXAZOLE TABLETS BP	960MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/3593	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DROX 500	CEFADROXIL	500MG	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 CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3594	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	STERILE QUININE DIHYDROCHLORIDE	QUININE DIHYDROCHLORIDE	300MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LIMITED-N-118, N119, N113, MIDC TARAPUR BOISAR DIST THANE 401506, INIDA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X2.0 ML AMPOULE

NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3596	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	SYNTOCINON	OXYTOCIN	10 I.U/ML	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSRERTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/3597	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	ARTESIAN 20MG/ML	ARTEMETHER	20MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/3598	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	MYOSPAZ	PARACETAMOL + CHLORZOXAZONE	500MG + 250MG	WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3599	ASTRA PHARMA LTD	ASTRA PHARMA (U) LIMITED	CHLORPROMAZINE INJECTION	CHLORPROMAZINE	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE,1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/3600	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	P-ALAXIN TABLETS	DIHYDROARTEMISININ + PIPERAQUINE PHOSPHATE	40MG + 320MG	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X9.0 TABLET BLISTER
NDA/MAL/HDP/3601	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYDROKANT	HYDROCORTISONE ACETATE	1%W/W	SKANT HEALTH CARE LTD -1802-1805 GIDC PHASE III VAPI GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/3606	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	CELLTRIAxon	CEFTRIAXONE	1G	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA. SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/3607	PHARMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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

NDA/MAL/HDP/3608	SHAIGAN PHARMACEUTICALS (PVT) LTD	HEALTHCARE LTD.	MESAN	NICLOSAMIDE	500MG	SHAIGAN PHARMACEUTICALS (PVT) LIMITED- 14 KM ADYALA RD, RAWALPINDI, PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3609	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	ANTINAL	NIFUROXAZIDE	200MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER, 1.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/3610	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PROMETHAZINE TABLETS BP 25MG	PROMETHAZINE HYDROCHLORIDE	25MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER, 1.0X100.0.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/3611	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL SYRUP	PARACETAMOL + CHLORPHENIRAMINE + PSEUDOEPHEDRINE	120MG+1MG+10MG	SHELYS PHARMACEUTICALS LTD,-NEW BAGAMOYO ROAD, MWENGE, PLOT NO 696,BLOCK NO 32, P.O.BOX 3016, DAR ES SALAAM	TANZANIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3612	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOSARTAS-HT	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3613	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/3614	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ERYTHROREN SUSPENSION	ERYTHROMYCIN STEARATE	125MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3615	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	AMPICLOX	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE BLISTER
NDA/MAL/HDP/3616	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZAXTER	MEROPENEM	1G	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/3618	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0 VIAL CARTON

NDA/MAL/HDP/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
NDA/MAL/HDP/3620	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN 10 TABLETS	HALOPERIDOL BP	10MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3622	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	PROXIMEXA	CEFUROXIME AXETIL	125MG/5ML	GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X1.0X50.0 ML BOTTLE
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE
NDA/MAL/HDP/3625	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICAL S LIMITED	AMOXICILLIN	AMOXICILLIN	250MG	SHANDONG XIER KANGTAI PHARMACEUTICAL CO LTD-YANZHOU CITY, CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3626	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX CAPSULES	CEPHALEXIN	250MG	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA.,SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3628	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEMIN 5S	AMINO ACIDS/SORBITOL	5%W/V+5%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION BAGS	1.0X500.0 ML BAG
NDA/MAL/HDP/3630	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 600	THEOPHYLLINE	600MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3631	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ENA-DENK 10	ENALAPRIL MALEATE	10MG	DENK PHARMA GMBH & CO.KG--PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3634	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOPUS	PARACETAMOL/ DEXTROMETHORPHAN HCL/ CHLORPHENIRAMINE	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
NDA/MAL/HDP/3635	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIROGAN	PROMETHAZINE HYDROCHLORIDE	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/3638	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	PETILIN 200	SODIUM VALPROATE	200MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X4.0X10.0 TABLET STRIP
NDA/MAL/HDP/3639	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PANADOL ADVANCE	PARACETAMOL	500MG	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X11.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3640	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	STABILANOL	FLUCONAZOLE	100MG	PHARMATHEN S.A--6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY CAPSULES	1.0X7.0 CAPSULE STRIP
NDA/MAL/HDP/3641	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	TRD-CONTIN 100	TRAMADOL HYDROCHLORIDE	100MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3642	IND-SWIFT	TATA UGANDA LIMITED	CLARIE 250	CLARITHROMYCIN	250MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X2.0X7.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3648	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	UNICONTIN 400	THEOPHYLLINE	400MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3649	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	LAMISIL	TERBINAFINE	125MG	NOVARTIS BARBERA -SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/3650	AMOUN PHARMACEUTICALS COMPANY	BOOTS PHARMACEUTICALS LIMITED	ANTINAL	NIFUROXAZIDE	220MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3651	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ORIPHEX SYRUP	CEPHALEXIN	125MG/5ML	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10-13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD-382213, GUJARAT – INDIA.,SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3652	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	BENDAS-400	ALBENDAZOLE	400MG	ASTRA LIFE CARE (INDIA) PVT.LTD-PLOT 57/P, RAJODA-382220, BAVLA AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER

NDA/MAL/HDP/3653	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN	ARTEMETHER + LUMEFANTRINE	80 MG + 480 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	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)
NDA/MAL/HDP/3654	IVEE AQUA EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYNOZVIN A NASAL DROPS	XYLOMETAZOLINE HYDROCHLORIDE	1MG/ML	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/3655	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAR ENTERPRISES LIMITED	QUADRAJEL GEL	CHLORHEXIDINE+METRONIDAZOLE+LIDOCaine	5%W/W+1.61 %W/W+2.13% W/W	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/3656	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LARITEM	ARTEMETHER / LUMEFANTRINE	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
NDA/MAL/HDP/3657	DAWA LIMITED	SUPER MEDIC LTD	DAWASTIN	NYSTATIN	100000IU/ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/3663	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	AMLODAC 10	AMLODIPINE BESYLATE	10MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET STRIP,1.0X3.0X1 0.0 TABLET BLISTER
NDA/MAL/HDP/3664	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	AZZY	AZITHROMYCIN	500MG	TORQUE PHARMACEUTICALS PVT LTD-ISAAPUR P.O DAPPAR 140056 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER

NDA/MAL/HDP/3666	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM 50	TRAMADOL HYDROCHLORIDE	50MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3668	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE,1.0X140.0 ML BOTTLE
NDA/MAL/HDP/3669	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	CO-TRIMOXAZOLE	SULFAMETHOXAZOLE/TRIMETHOPRIM	200MG/40MG	MEDICAMEN BIOTECH LTD - -SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3670	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	TETRAREN CAPSULES	TETRACYCLINE HYDROCHLORIDE	250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3671	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/3672	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	NITROCONTIN 6.4	NITROGLYCERIN	6.4MG	MODI MUNDIPHARMA (PVT) LTD-MEERUT - MUZAFFARNAGAR ROAD, MODIPURAM, UTTAR PRADESH ESTATE	INDIA	ORAL SOLID ORDINARY SUBLINGUAL TABLETS	1.0X25.0 TABLET CONTAINER
NDA/MAL/HDP/3673	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	PROMETHAZINE	PROMETHAZINE HCL	25MG/ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/3674	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	INTAMINE SYRUP	PROMETHAZINE HYDROCHLORIDE	5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X5.0 L JERRYCAN
NDA/MAL/HDP/3675	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASCOPAN	HYOSCINE BUTYLBROMIDE	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
NDA/MAL/HDP/3676	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	COTRIMOXAZOLE	CO-TRIMOXAZOLE	480MG	MACLEODS PHARMACEUTICALS LTD -.PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER

NDA/MAL/HDP/3677	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	IBUREN	IBUPROFEN	200MG	RENE INDUSTRIES LTD-680,KAMULI,KIREKA,KAMPALA,UGANDA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3678	FOURRTS LABORATORIES LTD	DELMAW ENTERPRISES LIMITED	REDINPLUS	IRON PENTACARBONYL + ZINC SULPHATE MONOHYDRATE + FOLIC ACID + SODIUM SELENITE + LYSINE HYDROCHLORIDE + HISTIDINE HYDROCHLORIDE + CHOLINE BITARTRATE	100MG + 30MG + 7.5MG + 0.11MG + 26MG + 4.4MG + 52MG	FOURRTS (INDIA) LABS PVT LTD.-VANDALUR ROAD. KELAMBAKK AM-603103 TAMIL, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X30.0 CAPSULE BLISTER
NDA/MAL/HDP/3681	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEDOL	PARACETAMOL	500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/3682	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE 10MG/320MG	AMLODIPINE + VALSARTAN	10MG + 320MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/3683	FOURTS(INDIA) LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	COLD TABS FORTINSA	PARACETAMOL + PHENYLEPHRINE +CHLORPHENIRAMINE + CAFFEINE	500MG + 5MG + 2MG + 30MG	FOURTS (INDIA) LABORATORIES PRIVATE LIMITED -VANDALUR ROAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/3684	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	I-PILL	LEVONORGESTREL	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
NDA/MAL/HDP/3685	GALPHAR LABORATORIES LTD	AIVEEN (U) LIMITED	ODICEF	CEFTRIAXONE	1G	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/3686	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBINE	MULTIVITAMIN	MULTINGREDIENT	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

NDA/MAL/HDP/3687	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	5MG/5ML	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3688	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	NEUTRAFLUX MINT FLAVOUR	ALGNIC ACID + MAGNESIUM HYDROXIDE +ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE + SIMETHICONE	200MG +250MG + 250MG + 125MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE,1.0X30.0 ML BOTTLE
NDA/MAL/HDP/3692	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	COTRIM 120	CO-TRIMOXAZOLE	120MG	MACLEODS PHARMACEUTICALS LTD---PLOT NO 25-27 SURVEY PREMEIRE INDUSTRIAL ESTATE KACHIGAM DAMAN (U.T) 396401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3699	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SINOPRIL 5MG TABLETS	LISINOPRIL	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3702	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-20	ATORVASTATIN	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
NDA/MAL/HDP/3703	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	SONATEC	CETYLPIRIDINIUM CHLORIDE	0.05%W/V	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL TOPICAL LIQUIDS	1.0X250.0 ML BOTTLE
NDA/MAL/HDP/3704	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PENEGRA 100	SILDENAFIL	100MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO.203-213, KUNDAIM GOA, 403115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3705	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SORAL 20MG CAPSULES	TENOICAM	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

NDA/MAL/HDP/3707	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	OBETAS-120	ORLISTAT	120MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3708	SANOFI AVENTIS	LABOREX UGANDA LIMITED	AMARYL M	GLIMEPIRIDE+METFORMIN HYDROCHLORIDE	2MG+500MG	HANDOK INC-78, DAEPUNGSANDAN-RO, DAESO-MYEON, EUMSEONG-GUN, CHUNGCHONGBUK-DO, KOREA	NORTH KOREA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3709	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	NIGHT & DAY -N	PARACETAMOL/ DIPHENHYDRAMINE CHLORIDE + PARACETAMOL/ PSEUDOEPHEDRINE	500MG/ 25MG +600MG/ 90MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3710	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	250MG	LABORATORY & ALLIED LTD--PLOT NO. 209/ 10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/3711	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS 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
NDA/MAL/HDP/3712	MICRO LABS LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AMLOZAAR	LOSARTAN POTASSIUM / AMLODIPINE	50MG + 5MG	MICRO LABS LTD-92,SIPCOT INDUSTRIAL COMPLEX,HOSUR-635-126(T.N)INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3714	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	ADALAT LA	NIFEDIPINE	30MG	BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID RETARD FILM-COATED TABLETS	2.0X14.0 TABLET BLISTER,3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3716	I CARE PHARMA LIMITED	VITACARE LTD	CLOXACILLIN SODIUM FOR INJECTION	CLOXACILLIN SODIUM FOR INJECTION	500MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/3717	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CEFTRIAXONE SODIUM	CEFTRIAXONE SODIUM	1G	CSPC ZHONGNUO PHARMACEUTICALS LTD-NO. 88, YANGZI ROAD, SHIJIAZHUANG CITY CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/3718	ALCON PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ISOPTO ATROPINE 1%	ATROPINE SULPHATE	1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE

NDA/MAL/HDP/3720	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	HALDOL DECANOAS	HALOPERIDOL DECANOATE	50MG/ML	JANSSEN PHARMACEUTICAL NV-TURNHOUTSEWEG 30 B-2340 BEERSE BELGIUM	BELGIUM	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/3723	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LACILLIN	AMPICILLIN	125MG/5ML	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3724	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	EPIGAB	PREGABALIN	150MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/3725	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	NEW TUXIRIL	DEXTROMETHOPHAN HBR + PHENYLEPHRINE HCL + MENTHOL	10MG/ML + 5MG/10ML + 5MG/10ML	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3728	ERIS LTD	BENLE CONSULT LIMITED	DICLO-DENK 50	DICLOFENAC SODIUM	50MG	DENK PHARMA GMBH & CO.KG--PRINZREGENTSTR.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
NDA/MAL/HDP/3729	MEDLEY PHARMACEUTICALS	MEDVIN PHARMA LIMITED	DECIFEN-SR	DICLOFENAC SODIUM	100MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID RETARD ENTERIC-COATED TABLETS	1.0X10.0X20.0 TABLET STRIP
NDA/MAL/HDP/3730	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX	MOXIFLOXACIN HYDROCHLORIDE	400MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	2.0X5.0 TABLET BLISTER,1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/3732	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ALBASOL TABLETS 200MG	ALBENDAZOLE	200MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0 TABLET STRIP

NDA/MAL/HDP/3733	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	DOMADOL	TRAMADOL HCL	100MG/2ML	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0X2.0 ML AMPOULE,1.0X5.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/3734	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	ZARICORT CREAM	MICONAZOLE + HYDROCORTISONE	2%W/W + 1%W/W	XEPA SAUL PATTINSON MALAYSIA-1-5 INDUSTRIAL ESTATE 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/3735	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSPRO	ACETYL SALICYLIC ACID	300MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1000.0 TABLET CONTAINER,500.0 TABLET CONTAINER,10.0 TABLET CONTAINER,250.0 TABLET CONTAINER,100.0 TABLET CONTAINER
NDA/MAL/HDP/3736	PHARMAVET LTD	DELMAW ENTERPRISES LIMITED	RECTOL 125 SUPPOSITORY	PARACETAMOL	125MG	BLISS GVS PHARMA LIMITED-PLOT NO. 10/11, SURVEY NO. 38/1, DEWAN UDYOG NAGAR, ALIYALI VILLAGE	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/3737	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	ECOFLOX 500 TABLETS	CIPROFLOXACIN HYDROCHLORIDE	500MG	MEDLEY PHARMACEUTICALS LTD..-PLOT NO. 18 & 19, SURVEY NO.378/7&8, 379/2&3,ZARI CAUSEWAY ROAD, KACHIGAM,DAMAN (U.T) 396210-INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3738	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	AMPICILLIN SODIUM	AMPICILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL,1.0X50.0X500.0 MG VIAL
NDA/MAL/HDP/3739	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	ALDREN	ALENDRONATE	70MG	CADILA HEALTHCARE LTD-KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3741	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ACTIZINE	CETIRIZINE HYDROCHLORIDE	10MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X15.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3743	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CARVIL 3.125	CARVEDILOL	3.125 MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3745	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	WINDERM CREAM	BECLOMETHASONE+ MICONAZOLE+NEO MYCIN	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
NDA/MAL/HDP/3746	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S LIMITED	BENDRO	BENDROFLUMETHIA ZIDE	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
NDA/MAL/HDP/3747	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	ALZOL TABLETS	ALBENDAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	30.0X2.0 TABLET BLISTER
NDA/MAL/HDP/3748	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/3752	COSMOS LTD	ASTRA PHARMA (U) LIMITED	PAINOTAB 200	PARACETAMOL/CAF FEINE	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
NDA/MAL/HDP/3753	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 180	MYCOPHENOLATE SODIUM	180MG	NORVATIS PHARMA STEIN AG-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND,NORVATIS PHARMA PRODUCTIONS GMBH, WEHR-OEFLINGER STR. 4479664 WEHR GERMANY	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X12.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3754	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICAL S LIMITED	SINAREST PD NASAL DROPS	OXYMETAZOLINE HYDROCHLORIDE	0.025%W/V	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/3757	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	UNITRIM SUSPENSION	CO-TRIMOXAZOLE	240MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3760	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	COMPOUND MAGNESIUM TRISILICATE	MAGNESIUM TRISILICATE	370MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/3762	GLAXO WELLCOME (KENYA) LTD	ERIS 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
NDA/MAL/HDP/3763	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	NORVASC	AMLODIPINE	5MG	R-PHARM GERMANY GMBH -HEINRICH-MACH-STRASSE 35,89257,ILLERTISSEN,GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3767	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	AMPOXIN 500	AMPICILLIN + CLOXACILLIN	250 MG + 250 MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3768	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP 30MG	NIMODIPINE	30MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3770	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	500 MG	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/3771	FAES FARMA S.A	LABOREX UGANDA LIMITED	BRONQUIDIAZINA C.R	TRIMETHOPRIM/SULFAMETHOXAZOLE/BROMHEXINE/SODIUM BENZOATE/TOLUBALSAM	80MG/400MG /4MG/250MG /325MG	FAES FARMA, S.A -MAXIMO AGUIRRE, 14, LEJONA 48940 VIZCAYA	SPAIN	ORAL LIQUID ORDINARY LIQUIDS	1.0X150.0 ML BOTTLE
NDA/MAL/HDP/3772	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMULIN N NPH	HUMAN INSULIN ISOPHANE	100IU	LILLY EGYPT S.A.E. & ELI LILLY AND COMPANY LILLY TECHNOLOGY CENTRE INDIANAPOLIS,- INDIANA 46285 USA	EGYPT	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/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,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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 BLISTER
NDA/MAL/HDP/3778	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	XITHRONE	AZITHROMYCIN	200MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE EL OBOUR CITY, CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/3779	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	LOSIMUM 50	LOSARTAN POTASSIUM	50MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X1.0X14.0 TABLET BLISTER

NDA/MAL/HDP/3781	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ALZENTEL	ALBENDAZOLE	20MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE
NDA/MAL/HDP/3782	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LAE-PEN V	PHENOXYMETHYLPE NICILLIN	250MG	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3784	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	CIPUM	CHLORPHENIRAMINE	2MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3787	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPENIV	PHENOXYMETHYLPE NICILLIN	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
NDA/MAL/HDP/3789	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	5MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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, BANGOLORE-560049	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/3794	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMET-200 (THANE)	METRONIDAZOLE	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/3797	CLARIS INJECTABLES LTD	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
NDA/MAL/HDP/3798	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NEUROTON TABLET	MULTI-INGREDIENT	N/A	AMOUN PHARMACETICAL COMPANY-1ST INDUSTRIAL ZONE, EL OBOUR CITY, CAIRO, EGYPT	EGYPT	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3800	CENTAUR PHARMACEUTICALS PRIVATE LIMITED	GITTOES PHARMACEUTICALS LIMITED	COLDAREST	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE + CAFFEINE	500MG+5MG+2MG+30MG	CENTAUR PHARMACEUTICALS PVT LTD -- PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X50.0X4.0 TABLET STRIP
NDA/MAL/HDP/3802	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA 10MG	VARDENAFIL MONOHYDROCHLORIDE TRIHYDRATE	10 MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3803	BLISS GVS PHARMA LIMITED	DELMAR 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
NDA/MAL/HDP/3804	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	NEURORUBINE	VITAMIN B1+VITAMIN B6+VITAMIN B12	100MG+100MG+1MG	ACINO PHARMA AG -DORNACHERSTRASSE, 114, 4147, AESCH, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY I M AMPOULES	1.0X1.0 ML AMPOULE,1.0X3.0 ML AMPOULE
NDA/MAL/HDP/3806	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	NOCID GEL	ALUMINIUM HYDROXIDE + SIMETHICONE + MAGNESIUM	400MG/5ML + 25MG/5ML + 100MG/5ML	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X200.0 ML BOTTLE
NDA/MAL/HDP/3807	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	NINGBO DAHONGYING PHARMACEUTICALS- NO.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE
NDA/MAL/HDP/3808	NORVATIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN SUPPOSITORIES 12.5MG	DICLOFENAC SODIUM	12.5MG	DELPHARM HUNINGUE S.A.S--SITE INDUSTRIAL HUNINGUE26, RUE DE LA CHAPELLE, F-68330, HUNINGUE	FRANCE	RECTAL SYSTEMIC PAEDIATRIC SUPPOSITORIES	1.0X1.0X10.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/3809	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID DAY & NIGHT	PARACETAMOL+CHLORPHENIRAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE + CAFFEINE	500MG+2MG+5MG+15MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET STRIP
NDA/MAL/HDP/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

NDA/MAL/HDP/3812	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	B-TONE	PHENOBARBITONE	30MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3813	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	ACTIPAR	PIPERAZINE CITRATE	500MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/3814	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	50MG/1ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/3815	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	QURE 500	LEVOFLOXACIN HEMIHYDRATE	500MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/3816	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	RAPICLAV-375	AMOXICILLIN + CLAVULANIC ACID	250 MG + 125 MG	IPCA LABORATORIES LTD,.-PLOT 69 TO 72 (B), SECTOR II, KASEZ, GANDHIDHAM - 370230, GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X7.0X3.0 TABLET STRIP,1.0X5.0X2.0 TABLET STRIP
NDA/MAL/HDP/3817	ROYAL PHARMA	ROYAL PHARMA 2011 LIMITED	BENZYPENICILLIN INJECTION	BENZYPENICILLIN SODIUM	1000000 I.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 MU VIAL
NDA/MAL/HDP/3818	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN	RECOMBINANT HUMAN ERYTHROPOIETIN	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
NDA/MAL/HDP/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
NDA/MAL/HDP/3823	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	D-WORM ORAL SUSPENSION	ALBENDAZOLE	200MG/5ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/3826	MACLEODS PHARMACEUTICAL LTD	NORVIK ENTERPRISES LIMITED	KETOMAC	KETOCONAZOLE	200 MG	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,3.0X10.0 TABLET STRIP
NDA/MAL/HDP/3827	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ATORFIT-10	ATORVASTATIN	10MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3828	MEDREICH PLC	LABOREX UGANDA LIMITED	PARAFLAM	IBUPROFEN + PARACETAMOL	400MG + 325MG	MEDREICH STERILAB LTD-UNIT VI 54/2 BOODHIHALLI VI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3829	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	BETACOOOL	DRIED ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE /MAGNESIUM ALUMINUM SILICATE/SIMETHICANE	300MG / 25MG / 50MG / 25MG	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X50.0 TABLET STRIP
NDA/MAL/HDP/3831	ABBVIE (PTY) LTD	MEDICAL ACCESS (UGANDA) LIMITED	ALUVIA	LOPINAVIR+RITONAVIR	200MG+50MG	ABBVIE DEUTSCHLAND GMBH & CO. KG.- KNOLLSTASSE 50, D-67061, LUDWIGSHAFEN, GERMANY.	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X120.0 TABLET CONTAINER
NDA/MAL/HDP/3833	LABORATORY AND 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
NDA/MAL/HDP/3834	ROYAL GROUP	HARLEYS UGANDA LIMITED	TETRACYCLINE	TETRACYCLINE	250MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/3835	GLAXOSMITHKLINE LTD	BETA HEALTHCARE UGANDA LIMITED	HEDEX CAPLETS	PARACETAMOL+ASPIRIN+CAFFEINE ANHYDROUS	200MG+400MG+50MG	SMITHKLINE BEECHAM (NAIROBI)-NAIROBI, KENYA,BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET PACK,1.0X110.0 TABLET PACK,1.0X100.0 TABLET PACK

NDA/MAL/HDP/3837	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NITROFURANTOIN	NITROFURANTOIN	100MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/3839	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLURID	ACETAMINOPHEN + PHENIRAMINE MALEATE	500 MG + 10.5 MG	KAMPALA PHARMACEUTICALS INDUSTIES- PLOT M 444B STRETCHER NTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3840	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TORACTIN TABLETS	CYPROHEPTADINE	4MG	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/3843	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	AZIWOK	AZITHROMYCIN	250MG	WOCKHARDT LIMITED --PLOT 57 VILLAGE KUNJHAL, JHAMAJRI, BAROTIWALA, BADDI, TEHSIL-NALAGARH, DISTRICT SOLAN, 174103 HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/3844	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	VOLTAREN RETARD	DICLOFENAC SODIUM	100MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.,NORVATIS FARMA SPA--VIA PROVINCIALE SCHITO, 131 1-80052, TORRE ANNUNCIATA (NA) ITALY	SWITZERLAND	ORAL SOLID RETARD TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/3845	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CARDIPAC	AMLODIPINE	5MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3846	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	LEVITRA	VARDENAFIL HCL	20 MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3848	WOCKHARDT LTD	STAR PHARMACEUTICAL S 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/SYR UPS/DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/3850	MICRO LABS LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ANGIZAAR-H	LOSARTAN POTASSIUM + HYDROCHLOROTHIA ZIDE	50MG + 12.5MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3869	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	RANTAB INJECTION	RANITIDINE	25MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/3871	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	DOVERIN 40	DROTAVERINE HYDROCHLORIDE	40MG	INTAS PHARMACEUTICALS LIMITED-PLOT NO. 457 / 458 SARKHEJ-BAVLA HIGHWAY, MATODA - 382 210, TALUKA - SANAND, DISTRICT - AHMEDABAD, STATE -	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3872	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	ZYNCET SYRUP	CETIRIZINE HYDROCHLORIDE	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
NDA/MAL/HDP/3873	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CHLORPROMAZINE INJECTION B.P	CHLORPROMAZINE	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
NDA/MAL/HDP/3874	AJANTA PHARMA LTD 310	ABACUS PHARMA (AFRICA) LIMITED	RIDMAL 40/320	DIHYDROARTEMISIN IN + PIPERAQUINE	40MG + 320MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X12.0 TABLET BLISTER,1.0X1.0X3.0 TABLET BLISTER,1.0X1.0X8.0 TABLET BLISTER,1.0X1.0X9.0 TABLET BLISTER,1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3875	PHAMA INTERNATIONAL CO	WIDE SPECTRUM ENTERPRISES (U) 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
NDA/MAL/HDP/3878	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	ASTIDIN 400	CIMETIDINE TABLETS	400 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 TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3879	MEDIPHARM INDUSTRIES LTD	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/SYRUPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE

NDA/MAL/HDP/3881	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MOXACIL	AMOXYCILLIN TRIHYDRATE	125MG/5ML	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3882	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	PEDIVIT FORTE CAPSULES	MULTIINGREDIENT	N/A	J.B. CHEMICALS AND PHARMACEUTICALS LTD-J.B. CHEMICALS & PHARMACEUTICALS LTD, 215/216, GIDC, PANOLI, GUJARAT	INDIA	ORAL SOLID ORDINARY CAPSULES	3.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/3883	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	MYFORTIC 360	MYCOPHENOLATE SODIUM	360MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSRASSE 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
NDA/MAL/HDP/3885	GLAXO WELLCOME(KENYA) LTD	ERIS LTD	ZANTAC	RANITIDINE	150MG	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3886	PHARMA INTERNATIONAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) 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
NDA/MAL/HDP/3887	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 150MG	PREGABALIN	150 MG	PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/3888	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PYRIREN	PYRIDOXINE HYDROCHLORIDE	25MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3889	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 75MG	PREGABALIN	75 MG	PFIZER GMBH ARZEIMITELWORK - MOSWALDA 1144 79090 FREUBURG	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/3890	UNIMED INDIA	METAPLUS (U) LIMITED	PARACETAMOL SYRUP	PARACETAMOL	120MG/5ML	UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3891	PHARMATHEN S.A	GOODMAN INTERNATIONAL LTD	LADININ	CIPROFLOXACIN	500MG	PHARMATHEN S.A--6,DERVENAKION STR .153 51,PALLINI,AHICA GREECE	GREECE	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3892	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TETRAX	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE

NDA/MAL/HDP/3893	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	EPINEPHRINE INJECTION USP	EPINEPHRINE HCL	1MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/3895	ASTRA PHARMA UGANDA LIMITED	ASTRA PHARMA (U) LIMITED	ASNOR	NORFLOXACIN	400MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3896	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN 500	SODIUM VALPROATE (CONTROLLED RELEASE)	500MG	MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3897	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CLAVODAR	AMOXICILLIN/CLAVULANIC ACID	875MG/125MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/3899	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	FEDATE SYRUP	SODIUM FEREDATE + PYRIDOXINE + CYANOCOBALAMIN + FOLIC ACID	216.87MG + 1.5MG + 7.5MCG + 1.5MG	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/3900	ASTRA PHARMA UGANDA LTD	ASTRA PHARMA (U) LIMITED	ASTIBA-500	TINIDAZOLE	500MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET BLISTER
NDA/MAL/HDP/3901	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	MICROGYNON ED FE	LEVONORGESTREL + ETHINYLESTRADIOL	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
NDA/MAL/HDP/3902	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	NODON	NEBIVOLOL	5MG	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3903	PFIZER LABS LTD	ERIS LTD	CELTENTRI 300MG	MARAVIROC	300MG	GODECKE GMBH -MOOSWALDALLEE 179090, FREIBERG GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0X6.0 TABLET BLISTER,
NDA/MAL/HDP/3904	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT PESSARIES	NYSTATIN	100,000 I.U	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	VAGINAL TABLETS	1.0X50.0X14.0 PESSARY STRIP,1.0X14.0 PESSARY STRIP
NDA/MAL/HDP/3906	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	LEROLE	PANTOPRAZOLE	40MG	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL 1*10ML 0.9%NACL AMPOULE

NDA/MAL/HDP/3907	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ANDREWS LIVER SALT REGULAR	MAGNESIUM SULPHATE +SODIUM HYDROGEN CARBONATE +CITRIC ACID	17.4 %W/W+22.6 % W/W+19.5 % W/W	SMITHLINE BEECHAM (NAIROBI)-NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X8.0X5.0 G SACHET,1.0X48.0 X5.0 G SACHET
NDA/MAL/HDP/3908	AUROBINDO PHARMA	GITTOES PHARMACEUTICALS LIMITED	ZIDOVUDINE	ZIDOVUDINE	100MG	AUROBINDO PHARMA LTD --UNIT VII PLOT NO. S1 GREEN INDUSTRIAL PARK POLLEPALLY VILLAGE ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/3911	ASTRA PHARMA UGANDA LTD	ASTRA PHARMA (U) LIMITED	ASID	OMEPRazole	20 MG	ASTRA LIFECARE PVT LTD-57/P RAJODA 382220 BAVLA AHMEDABAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/3912	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
NDA/MAL/HDP/3913	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	VALCONTIN	SODIUM VALPROATE	200 MG	MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3914	GLAXOSMITHKLINE LTD	ERIS 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
NDA/MAL/HDP/3920	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	PHOTERICIN B	AMPHOTERICIN 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
NDA/MAL/HDP/3921	ASTRA PHARMA (U) PVT LTD	ASTRA PHARMA (U) LIMITED	AS-B	PYRIDINE-3-CARBOXAMIDE/ RIBOFLAVIN/ THIAMINE NITRATE	17.25MG/ 1.3MG/ 1.3MG	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,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/3923	ASTRA PHARMA UGANDA LIMITED	ASTRA PHARMA (U) LIMITED	AXASONE	DEXAMETHASONE	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

NDA/MAL/HDP/3924	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED	PARACETAMOL+PSE UDOEPHEDRINE HYDROCHLORIDE+T RIPOLIDINE HYDROCHLORIDE	300MG+36MG +1.5MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 10.0 TABLET BLISTER
NDA/MAL/HDP/3925	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CALCIUM GLUCONATE INJECTION	CALCIUM GLUCONATE	10 %W/V	NINGBO DAHONGYING PHARMACEUTICALS- NO.396 MINZHU RD NINGBO CITY ZHEJIANG, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X50.0X10.0 ML AMPOULE
NDA/MAL/HDP/3927	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL CEPHALEXIN 125	CEPHALEXIN MONOHYDRATE	125MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3928	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	MALAREN	SULPHADOXINE + PYRIMETHAMINE	500MG/25MG	RENE INDUSTRIES LTD .-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X50.0 X3.0 TABLET BLISTER
NDA/MAL/HDP/3931	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COARTEM 80/480	ARTEMETHER + LUMEFANTRINE	80MG +480MG	NORVATIS SAGLIK GIDA VE TARIM URENLERI SAN, VE TIC-AC-YENISEHIR MAHALLESİ IHLA VADISI SOKAK, NO.2, 34912 KURTKOY, INSTANBUL - TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/3932	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIRAX TABLETS	CLIDINIUM BROMIDE + CHLORDIAZEPOXIDE	2.5MG + 5MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/3933	TORRENT PHARAMACEUTICALS LTD	KARURI PHARMACEUTICAL S LTD.	TOZAAR-50	LOSARTAN POTASSIUM	50MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-382721	INDIA	ORAL SOLID ORDINARY TABLETS	5.0X10.0 TABLET BLISTER

NDA/MAL/HDP/3938	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	ADRENALINE INJECTION	ADRENALINE	1MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE
NDA/MAL/HDP/3941	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROZIL 500	CEFPROZIL	500MG	AUROBINDO PHARMA LTD-UNIT VI SY.NO.329/39 & 329/47 CHITKUL VILLAG,PATARICHEM,MANDAT MEDAK DISTRICT,ANDRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3942	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AUROZIL 250	CEFPROZIL	250 MG	AUROBINDO PHARMA LTD-UNIT VI SY.NO.329/39 & 329/47 CHITKUL VILLAG,PATARICHEM,MANDAT MEDAK DISTRICT,ANDRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3943	NVS KENYA LTD	SURGIPHARM (U) LIMITED	SYNTOCINON	OXYTOCIN	5 I.U	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSESTRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/3945	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICALS LIMITED	CEFONE	CEFTRIAZONE	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
NDA/MAL/HDP/3947	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	RABTAS-20	RABEPRAZOLE SODIUM	20 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA,INTAS PHARMACEUTICALS LTD.-PLOT NOS. 457, 458 & 191/218P SARKHEJ-BAVLA HIGHWAY MATODA SANAND AHMEDABAD GUJARAT	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3948	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFIXIME	50MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3949	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MAGNOMINT SUSPENSION	MAGNESIUM TRISILICATE+ALUMINIUM HYDROXIDE	500MG/5ML+250MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3950	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	STROM	TRAMADOL HYDROCHLORIDE	50MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE

NDA/MAL/HDP/3951	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMCLOX	AMPICILLIN + CLOXACILLIN	125MG/5ML + 125MG/5ML	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3954	WOCKHARDT LTD	STAR PHARMACEUTICALS LTD	POWERCEF 1GM INJECTION	CEFTRIAZONE SODIUM	1GM	ZEISS PHARMACEUTICALS PVT. LIMITED-PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/3955	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	NEVIRAPINE	NEVIRAPINE	200 MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAVADI CROSS ANECAL TULK BANGALORE 562 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/3960	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUPAR	PARACETAMOL/IBU PROFEN	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
NDA/MAL/HDP/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
NDA/MAL/HDP/3965	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	OROFER SYRUP	IRON(II) HYDROXIDE POLYMALTOSE COMPLEX	50MG/5ML	EMCURE PHARMACEUTICALS LTD -LANE NO.3 PHASE II,SIDCO INDUSTRIAL COMPLEX,BARI-BRAHMANA JAMMU 181 133, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE
NDA/MAL/HDP/3966	DAWA LIMITED	SUPER MEDIC LTD	ASCORBIC ACID TABLETS	ASCORBIC ACID	100 MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3968	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	NORLUT-N	NORETHISTERONE ACETATE	5MG	CIPLA LTD-VERNA INDIA ESTATES 403722 GOA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3969	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FAWAR FRUIT EFFERVESCENT GRANULES	SODIUM CARBONATE + TARTARIC ACID + CITRIC ACID	2.8G + 1.33G + 0.82G	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X6.5 G SACHET

NDA/MAL/HDP/3970	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	LECOTRIM	CO-TRIMOXAZOLE	480MG	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3974	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMCLOXA	CLOXACILLIN	125MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD-PLOT M 444B STRETCHER ROAD NTINDA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	100.0 ML BOTTLE
NDA/MAL/HDP/3977	CHINOIN PHARMACEUTICALS AND CHEMICAL WORKS, CO. LTD	LABOREX UGANDA LIMITED	NO-SPA 40MG	DROTAVERINE HYDROCHLORIDE	40MG	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PRIVATE CO.LTD-H-2112, VERESEGYHAZ, LEVAI U.5.HUNGARY	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/3980	UNEED GLOBAL GROUP LIMITED	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

NDA/MAL/HDP/3981	GLAXO SMITH KLINE LTD	ERIS 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
NDA/MAL/HDP/3982	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	LONART SUPPOSITORY	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	BLISS GVS PHARMA LIMITED-NO.10 SURVEY NO. 38/1 DEWAN UDYOG NAGAR ALIYALI VILLAGE TAL. PALGHAR DIST. THANE 401404 MAHARASHTRA INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X6.0 SUPPOSITORY STRIP
NDA/MAL/HDP/3983	UNEED GLOBAL GROUP LIMITED	ABACUS PHARMA (AFRICA) LIMITED	EXTRADOL	PARACETAMOL/CAF FEINE 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
NDA/MAL/HDP/3985	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMYCIN SUSPENSION	ERYTHROMYCIN ESTOLATE	125MG/5ML	AGOG PHARMA-PLOT 33 SECTOR THE VASAI-TULUKA CO-OP ESTATE LTD INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/3987	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ROHISOL SYRUP	LEVAMISOLE HYDROCHLORIDE	40MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X500.0 ML BOTTLE,1.0X15.0 ML BOTTLE
NDA/MAL/HDP/3989	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELIB 200MG	CELECOXIB	200MG	UNICHEM LABORATORIES LTD--PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/3995	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	LAMIVUDINE	LAMIVUDINE	150 MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER

NDA/MAL/HDP/3996	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOTOIN TABLETS	NITROFURANTOIN BP	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER,1.0X10.0X10.0.0 TABLET BLISTER
NDA/MAL/HDP/3998	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOKOFF SYRUP	TERBUTALINE SULPHATE +GUAIFENESIN+BROMHEXINE HYDROCHLORIDE +LEVOMENTHOL	1.25MG/5ML+50MG//5ML+4MG/5ML+2.5MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/3999	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	PANSEC DR	PANTOPRAZOLE SODIUM	40MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED,-INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA.	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X4.0X7.0 TABLET STRIP
NDA/MAL/HDP/4000	AMOUN PHARMACEUTICAL COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	APIDONE SYRUP	CHLORPHENARIMINE MALEATE/DEXAMETHASONE	2MG/5ML + 0.5MG/5ML	AMOUN PHARMACEUTICALS COMPANY-1ST INDUSTRIAL ZONE,EL OBOUR CITY, CAIRO, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE
NDA/MAL/HDP/4001	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOCOLD PLUS SYRUP	PARACETAMOL+PHENYLEPHRINE+CHLORPHENIRAMINE+SODIUM CITRATE	125MG/5ML+2.5MG/5ML+1MG/5ML+60MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/4003	TATA UGANDA LIMITED	TATA UGANDA LIMITED	OXYTOCIN INJ	OXYTOCIN	10IU/ML	GLAND PHARMA LIMITED 143-148-D PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0 ML AMPOULE
NDA/MAL/HDP/4004	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	ANTHEL	ALBENDAZOLE	400MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X1.0 TABLET BLISTER

NDA/MAL/HDP/4006	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	RHINATHIOL 5% FOR ADULTS SUGARFREE	CARBOCISTEINE	5G/100ML	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 -,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/4007	SANOFI PASTEUR	LABOREX UGANDA LIMITED	SHANCHOL CHOLERA VACCINE	V.CHOLERA STRAINS-01 INABA FORMALDEHYDE KILLED +01 OGAWA HEAT KILLED + 01 OGAWA FORMALDEHYDE KILLED + 01 INABA HEAT KILLED + 0139 FORMALDEHYDE KILLED	600 + 300 +300 +300 + 600 ELISA UNITS(EU) OF LIPOPOLYSACC HARIDE (LPS)	SHANTHA BIOTECHNICS LTD -SURVEY NO. 274, ATHVELLI VILLAGE, MEDCHAL MANDAL – 501401, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X10.0X1.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/4010	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	PYRI	PYRIDOXINE HYDROCHLORIDE	25MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER,1.0X 250.0 TABLET CONTAINER,1.0X 10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/4015	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	TAMBAC 50	CEFPODOXIME PROXETIL	50MG/5ML	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE

NDA/MAL/HDP/4016	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	COMPOUND SODIUM LACATE INTRAVENOUS INFUSION	MULTI-INGREDIENT	MULTI-INGREDIENT	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/4017	THE ARAB P'CAL MANUFACTURING CO.	GOODMAN INTERNATIONAL LTD	ZOCIN CAPSULES	AZITHROMYCIN	250MG	ARAB PHARMACEUTICAL MANUFACTURING INDUSTRIES --KING ABDULAH 2ND STREET / INDUSTRIAL AREA BUILDING NO. 1 AL-BUHAIRAH / SULT-JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/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,SOMAPURAHOBIL,NELAMANGA LA TALUK,BANGALORE RURAL-562111,INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X20.0 ML BOTTLE
NDA/MAL/HDP/4019	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX 1G	AMOXICILLIN + FLUCLOXACILLIN	500 MG + 500 MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/4022	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASPI-M	CHLORPHENIRAMINE	4MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/4023	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST LINCTUS	CHLORPHENIRAMINE+DEXTROMETHORPHAN+METHANOL	2MG+10MG+1.5MG	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4024	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	SEDALAC SYRUP	LACTULOSE	3.350G/5ML	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/4030	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	XBETA- N	BETAMETHASONE + NEOMYCIN	0.1%W/V +0.5%W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/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

NDA/MAL/HDP/4033	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	BENYLIN PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE	7MG/5ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4035	BAYER SCHERING PHARMA	SURGIPHARM (U) LIMITED	YASMIN	DROSPIRENONE + ETHINYLESTRADIOL	3MG+0.3MG	BAYER WEIMER GMBH UND CO. KG- DOEBEREINERSTRASSE 20 D-99427 WEIMER, GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X21.0 TABLET BLISTER
NDA/MAL/HDP/4038	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	PREDSONE-5	PREDNISOLONE	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
NDA/MAL/HDP/4039	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	EFAVIRENZ	EFAVIRENZ	50MG	AUROBINDO PHARMA LTD UNIT VII---UNIT VII PLOT NO. S1 GREEN INDUSTRIAL PARK POLLEPALLY VILLAGE ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE CONTAINER
NDA/MAL/HDP/4042	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	S-CHLOR	CHLORAMPHENICOL	1G	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/4043	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM AMPI	AMPICILLIN	125MG/ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/4049	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVODAY 500	LEVOFLOXACIN HEMIHYDRATE	500MG	CADILA HEALTH CARE LTD-KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X 5.0 TABLET BLISTER,1.0X20.0 X5.0 TABLET BLISTER,1.0X6.0X 2.0X5.0 TABLET BLISTER
NDA/MAL/HDP/4050	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S LIMITED	CHLORAMPHENICOL EYE DROPS	CHLORAMPHENICOL	0.5%W/V	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL

NDA/MAL/HDP/4052	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/4055	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	BAYER ASPIRIN CARDIO	ACETYLSALICYLIC ACID	100MG	BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/4056	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	FASIGYN	TINIDAZOLE	500MG	PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER,1.0X8.0 TABLET BLISTER
NDA/MAL/HDP/4057	LEBEN LABORATORIES PVT. LTD	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
NDA/MAL/HDP/4060	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	TOBRADEX	TOBRAMYCIN/DEXA METHASONE	0.3%W/V+ 0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/4062	GLAXO SMITH KLEINE LIMITED	ERIS 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,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/4067	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CATENOL-50 TABLETS	ATENOLOL	50MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4068	AUROBINDO PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE/ZIDOVUDINE/EFVIRENZA	LAMIVUDINE+ZIDOVUDINE + EFAVIRENZA	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
NDA/MAL/HDP/4072	SIRMAXO CHEMICALS PVT LTD	SUPER MEDIC LTD	SANQUAD M 20	CHLORHEXIDINE	4%W/V	SIRMAXO CHEMICALS-PLOT NO E 35, TARAPUR, BOISAR DIST, MUMBAI	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X500.0 ML BOTTLE,1.0X5.0 L JERRYCAN
NDA/MAL/HDP/4074	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	UMICORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL
NDA/MAL/HDP/4075	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	CHERICOF COUGH FORMULAR	CHLORPHENIRAMINE/DEXTROMETHORPHAN HBR/PHENYLEPHRINE HCL	2MG/10MG/5MG	RANBAXY LABORATORIES LTD AT: THE MADRAS PHARMACEUTICALS-137-B OLD MAHABALIPURAM ROAD KARAPAKKAM CHENNAI 600 096	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4078	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	EPIGAB	PREGABALIN	75MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/4079	PHARMA INTL CO..	WIDE SPECTRUM ENTERPRISES (U) LIMITED	NERVAMINE	MECOBALAMIN	500MCG	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAHA	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/4082	SANOFI AVENTIS	LABOREX UGANDA LIMITED	NO-SPA FORTE	DROTAVERINE HCL	80MG	CHINOIN PHARMACEUTICALS AND CHEMICAL WORKS CO. LTD-H10-45 BUDAPEST HUNGARY.	HUNGARY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4084	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	WATER FOR INJECTION	STERILIZED WATER FOR INJECTION	N/A	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL
NDA/MAL/HDP/4085	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	ZINACEF	CEFUROXIME SODIUM	750MG	GLAXO WELLCOME -VERONA ITALY	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL
NDA/MAL/HDP/4086	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	KELVIN SUSPENSION	PARACETAMOL	120MG/5ML	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4091	HILTON PHARMA PVT LTD	HEALTHCARE LTD.	MYTEKA TABLETS	MONTELUKAST 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

NDA/MAL/HDP/4092	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	FLORANORM	SACCHAROMYCES 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
NDA/MAL/HDP/4093	LEBEN LABORATORIES LTD	ANDYCO PHARMACY (UGANDA) LTD	BECLOMIN OINTMENT	BECLOMETHASONE+ MICONAZOLE+NEO MYCIN	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
NDA/MAL/HDP/4094	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	EFAVIRENZ	EFAVIRENZ	200MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAVADI CROSS ANECAL TULK BANGALORE 562 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X90.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/4097	GLAXOSMITHKLINE LTD UK	ERIS 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
NDA/MAL/HDP/4098	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	EFAVIRENZ TABLETS	EFAVIRENZ	600MG	STRIDES ARCOLAB LTD-36/7 SURAGAJAKKANAHALI INDLAVADI CROSS ANECAL TULK BANGALORE 562 INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/4099	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	GLEVO I.V	LEVOFLOXAXIN	500MG/100M L	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
NDA/MAL/HDP/4100	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	NORETHISTERONE	NORETHISTERONE	5MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4101	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICAL S 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

NDA/MAL/HDP/4103	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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	PARENTERAL ORDINARY I M VIALS	1.0X100.0X2.0 ML VIAL (20 DOSES)
NDA/MAL/HDP/4104	DAWA LIMITED	SUPER MEDIC LTD	DAWA-PROM	PROMETHAZINE HCL	25MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4107	ABBOTT HEALTHCARE , SAS	PHILLIPS PHARMACEUTICALS (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
NDA/MAL/HDP/4112	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	ERYTHRONE TABLETS 250MG	ERYTHROMYCIN	250MG	STRIDES ARCOLAB LIMITED-DEWAN & SONS IND. AREA,VEOOR, PALGHAR, MAHARASTRA,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
NDA/MAL/HDP/4113	MICRO LABS LTD	LABOREX UGANDA LIMITED	EROSTIN 10	EBASTINE	10 MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4114	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	RINALIN SYRUP	CHLORPHENIRAMINE MALEATE	2MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4115	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	PREDILONE	PREDNISOLONE	5.0 MG	REGAL PHARMACEUTICALS LTD-PLOT NO 7879 OFF BABA DOGO ROAD KUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4118	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	OCUREST-AH	PHENYLEPHRINE HYDROCHLORIDE+NAPHAZOLINE HYDROCHLORIDE+CHLORPHENIRAMINE MALEATE+MENTHOL+CAMPBOR	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

NDA/MAL/HDP/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
NDA/MAL/HDP/4123	HETERO LABS LTD UNIT VI	ABACUS PHARMA (AFRICA) LIMITED	NEVIRAPINE	NEVIRAPINE	200MG	HETERO LABS LTD (UNIT-V)-SEZ JADCHERIA HYDRABAD,HETERO LABS LIMITED .-UNIT 111, H22-110, I.D.A, JEEDIMETLA, HYDERABAD, 500055	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/4125	MEDIPHARM INDUSTRIES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PARACETAMOL SUSPENSION	PARACETAMOL	120MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4126	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELIB 100MG	CELECOXIB	100MG	UNICHEM LABORATORIES LTD--PLOT 17 & 18, PILERNE IND. ESTATE, PILERNE, BARDEZ GOA-403511	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4127	SANOFI AVENTIS 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
NDA/MAL/HDP/4128	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	VITAREN SYRUP	VITAMIN A + VITAMIN B2 + VITAMIN B1 + VITAMIN B6 + VITAMIN C + VITAMIN E + VITAMIN B3	1500IU/5ML + 1MG/5ML + 1MG/5ML + 0.5MG/5ML + 20MG/5ML + 100 IU/5ML + 10MG/5ML	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X60.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4129	IDA FOUNDATION	KIMSY MEDS LTD	PRAZQUANTEL	PRAZQUANTEL	600MG	MICRO LABS LTD --PLOT NO. S-155 TO S-159 VERNA INDUSTRIAL ESTATE III VERNA GOA 403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/4132	CADILA HEALTH CARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ZYCEL	CELECOXIB	200MG	CADILA HEALTHCARE LTD -KUNDAIM INDUSTRIAL ESTATE PONDA GOA 403 401	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/4134	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	CITAL	DISODIUM HYDROGEN CITRATE	1.37G/5ML	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4140	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICAL S LIMITED	DIAZEPAM INJECTION	DIAZEPAM INJECTION	10MG/2ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/4142	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	CO-ARTESAIN	ARTEMETHER + LUMEFANTRINE	360MG + 2160MG	MPF BV-APPLEHOF 13; NI 8465 RX OUDEHASKE NETHERLANDS	NETHERLANDS	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/4143	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	TAM CONTIN 0.4	TAMSULOSIN HYDROCHLORIDE	0.4MG	MODI MUNDIPHARMA PVT. LTD-MEERUT-MUZAFFARNAGAR ROAD, MODIPURAM – 250110 UTTAR PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/4144	COSMOS LTD	ASTRA PHARMA (U) LIMITED	NYCOSTAT OINTMENT	NYSTATIN	100.000 I.U	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE
NDA/MAL/HDP/4146	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/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
NDA/MAL/HDP/4148	COSMOS LIMITED	ASTRA PHARMA (U) LIMITED	AMITRIPTYLINE TABLETS	AMITRIPTYLINE	25MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/4149	GLAXOSMITH KLINE LTD	ERIS LTD	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,1.0X10.0 ML AMPOULE
NDA/MAL/HDP/4150	TORRENT PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	ANGIOPRIL-25	CAPTOPRIL	25MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,TEH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4151	IDA	KIMSY MEDS LTD	AMITRIPTYLINE	AMITRIPYLINE	25MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/4165	CADILA HEALTH CARE LIMITED	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	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/4169	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZYD-200	FLUCONAZOLE	200MG	CADILA HEALTH CARE LTD-SARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDAD 382210, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/4170	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	TRAMAZAC	TRAMADOL HYDROCHLORIDE	50MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4171	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	TOREX	MULTIINGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4172	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	KOF OFF EXPECTORANT	MULTI-INGREDIENT	MULTI-INGREDIENT	RENE INDUSTRIES-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X110.0 ML BOTTLE
NDA/MAL/HDP/4173	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NASONEX	MOMETASONE FUROATE MONOHYDRATE	0.05%W/V	MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685,SCHERING PLOUGH LABO N.V,- INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIUM	BELGIUM	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/4175	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KOACT 156.25	AMOXYCILLIN TRIHYDRATE+POTASSIUM CLAVUNALATE	156.25MG/5ML	AUROBINDO PHARMA LTD, UNIT XII,- SURVEY NO 314, BACHUPALLY VILLAGE, QUTHUBULLAPAR, R.R DISTRICT .A. PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4180	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	OSMOWIN	LACTULOSE	10G/15ML	G.S PHAMBUTOR PVT LTD-G.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/4181	UMEDICA LABS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	USTREP	STREPTOMYCIN SULPHATE	1G	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/4182	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST- FORTE	MULTI INGREDIENT	MULTI INGREDIENT	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X50.0 X4.0 TABLET STRIP
NDA/MAL/HDP/4183	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	CHLORPROMAZINE	CHLORPROMAZINE	25MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD-NO 396, MINGZHU ROAD NINGBO CITY CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4187	BAYER PHARMA AG	STAR PHARMACEUTICALS LTD	NORIGYNON	ESTRADIOL VALERATE +NORETHINDRONE ENANTHATE	5 MG+50 MG / ML	HOSPIRA INC-D - 51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/4188	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOPRAZ	PRAZIQUANTEL	600MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X4.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER

NDA/MAL/HDP/4190	ASTRAZENECA	MACNAUGHTON LIMITED	NOLVADEX	TAMOXIFEN	10MG	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,1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4241	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AMPICILLIN SODIUM FOR INJECTION BP	AMPICILLIN SODIUM	500MG	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL
NDA/MAL/HDP/4273	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	SOLUDINE 10%	POVIDINE IODINE	10 %W/V	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE
NDA/MAL/HDP/4275	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 100MG/4ML	BEVACIZUMAB	100 MG/ 4ML	F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL,ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/4277	NABIQASIM INDUSTRIES (PVT) LIMITED	JEET PHARMACEUTICALS LIMITED	VIVIRON PLUS SYRUP	FERRIC AMMONIUM CITRATE +FOLIC ACID + PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE	50MG + 0.5MG + 2.2MG + 1.3MG +11MG	NABIQASIM INDUSTRIES (PVT) LTD--17/24,KORANGI INDUSTRIAL AREA, KORANGI, KARACHI- PAKISTAN.	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X250.0 ML BOTTLE
NDA/MAL/HDP/4279	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROTIM	TIMOLOL MALEATE	0.5% W/V	AUROLAB-NO. 1, SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/4280	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULFATE+LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 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

NDA/MAL/HDP/4284	F. HOFFMANN LA-ROCHE	LABOREX UGANDA LIMITED	AVASTIN 400MG/4ML	BEVACIZUMAB	400MG/4ML	F.HOFFMANN-LA ROCHE LTD-GRENZACHERSTRASSE 124,CH- 4070 BASEL,ROCHE DIAGNOSTICS GMBH-SANDHOFER STRASSE 116 D-68305 MANNHEIM GERMANY	SWITZERLAND	PARENTERAL ORDINARY VIALS	1.0X16.0 ML VIAL
NDA/MAL/HDP/4286	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEGRA-50	SILDENAFIL CITRATE	50MG	THE MADRAS PHARMACEUTICALS-137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/4287	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANAXONE 1000	CEFTRIAZONE	1000MG	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL,1.0X50.0X10.0 ML VIAL
NDA/MAL/HDP/4288	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COLESTOP	ATORVASTATIN	10MG	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4289	GLAXOSMITHKLINE LTD	ERIS LTD	TWINRIX ADULT	INACTIVATED HEPATITIS A ANTIGEN + HEPATITIS B SURFACE ANTIGEN	720 ELISA UNITS + 20MCG	GLAXOSMITHKLINE BIOLOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL (1 DOSE)
NDA/MAL/HDP/4291	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	VITAMIN B COMPLEX INJECTION	VITAMIN B COMPLEX	10MG/2ML	NINGBO DAHONGYING PHARMACEUTICALS LTD- NO. 396 MIN	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4294	GLAXO SMITHLINE LIMITED	ERIS LTD	FLIXOTIDE ACCUHALER 250	FLUTICASONE PROPIONATE	250MCG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISIER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 METERED DOSE CANNISTER
NDA/MAL/HDP/4295	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASTRAFLAM TABLETS	PARACETAMOL + 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
NDA/MAL/HDP/4297	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	CLOBEN-G	CLOTRIMAZOLE/BECLOMETHASONE/GENTAMYCIN	1%W/W+0.025%W/W+0.1%W/W	INDOCO REMEDIES LIMITED-L-14 VERNA INDUSTRIAL AREA VERNA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4298	SANDOZ GMBH, KENYA C/O NORVATIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COLESTOP	ATORVASTATIN	40MG	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4302	GLAXO SMITH KLINE LTD	ERIS LTD	FLIXOTIDE ACCUHALER 500	FLUTICASONE PROPIONATE	500MCG	GLAXO WELLCOME PRODUCTION-ZONE INDUSTRIELLE NO.2 23 RUE LAVOISER 27000 EVREUX	FRANCE	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X60.0 METERED DOSE CANNISTER
NDA/MAL/HDP/4303	PFIZER LABORATORIES (PTY)	LABOREX UGANDA LIMITED	SAYANA PRESS	MEDROXYPROGESTERONE ACETATE	104MG/0.65ML	PFIZER MANUFACTURING -NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X200.0X0.65 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/4309	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) LIMITED	LAMIVUDINE + ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG + 300MG	HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGAR DISTRICT, ANDHRA PRADESH - INDIA,HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/4310	GLAXOSMITHLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED SYRUP	TRIPLORIDINE HCL/PSEUDOEPHEDRINE	1.25MG/30MG	GLAXO WELLCOME EGYPT SAE.-EL SALAM CITY 11491, CAIRO	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X2.0 L JERRYCAN
NDA/MAL/HDP/4312	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F	FOLLITROPIN ALFA	75IU/IE	MERCK SERONO S.P.A-VIA DELLE MAGNOLIE,15.70026 MODUGNO (BA).ITALY,MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1 PRE FILLED SYRINGE OF WFI
NDA/MAL/HDP/4315	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DESLORA-DENK 5	DESLORATIDINE	5MG	DENK PHARMA GMBH & CO.KG -GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4317	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 50/12.5	LOSARTAN + HYDROCHLOROTHIAZIDE	50MG + 12.5MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4318	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	AKUGABALIN	PREGABALIN	75 MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4321	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	CUSIMOLOL 0.5%	TIMOLOL MALEATE	0.5% W/V	ALCON CUSI S.A. -CAMIL FABRA,58 08320 EL MASNOU BARCELONA SPAIN	SPAIN	OPHTHALMIC DROPS	1.0X5.0 ML VIAL

NDA/MAL/HDP/4322	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	VALSAR-DENK 160	VALSARTAN	160MG	DENK PHARMA GMBH & CO.KG -GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/4324	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/4325	AJANTA PHARMA LTD 310	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC 100	ACECLOFENAC	100MG	GLENMARK PHARMACEUTICALS LTD (UNIT III)-B-4/5/6 MIDC INDUSTRIAL AREA,CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4326	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	CUSICROM 4% EYE DROPS	SODIUM CROMOGLYCAT	4 %W/V	ALCON CUSI S.A .-CAMIL FABRA,58 08320 EL MASNOU BARCELONA SPAIN	SPAIN	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/4329	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMINE MALEATE	2MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4330	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN CAPSULES	FLUCLOXACILLIN	250MG	SPARSH BIO-TECH PVT. LTD.--PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/4331	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC	ACECLOFENAC	100MG	STEDMAN PHARMACEUTICALS PVT LIMITED-NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4332	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	VALSAR-DENK 320	VALSARTAN	320MG	DENK PHARMA GMBH & CO.KG -GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/4333	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	CARVIBERG	CARVEDILOL USP	6.25MG	THE MADRAS PHARMACEUTICALS-137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4334	DENK PHARM GMBH&CO.KG	BENLE CONSULT LIMITED	LOSAR-DENK 50	LOSARTAN	50MG	DENK PHARMA GMBH &CO.KG-PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4335	DAWA LIMITED	SUPER MEDIC LTD	CURAMOL SUSPENSION	PARACETAMOL	120MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4336	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	NEOGAB	GABAPENTIN	400MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4337	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	VALSAR-DENK 80	VALSARTAN	80MG	DENK PHARMA GMBH & CO.KG -GOLLSTR 1,84529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/4339	GLAXOSMITHKLINE LIMITED	ERIS 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
NDA/MAL/HDP/4340	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	VITAMIN B COMPLEX	VITAMIN B1 + VITAMIN B2 + SODIUM NICOTINAMIDE + VITAMIN B6 + D-PANTHENOL SODIUM	10MG + 1.37MG + 15MG + 1MG + 0.5MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD--KAITEE ROAD, TIANNING INDUSTRIAL ZONE, LISHUI, ZHEJIANG, P.R.CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4343	PASTEUR MERIEUX CONNANGHT	LABOREX UGANDA LIMITED	EUVAX B (PAEDIATRIC)	HEPATITIS B VACCINE, RECOMBINANT	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)
NDA/MAL/HDP/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
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4350	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	OLFEN-75	DICLOFENAC SODIUM	75MG/2ML	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE

NDA/MAL/HDP/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
NDA/MAL/HDP/4352	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN SYRUP	QUININE HYDROCHLORIDE	100MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4354	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RUXID 300	ROXITHROMYCIN	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/4358	A.MENARINI INDUSTRIE FARMACEUTICHE S.R.I	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	LIOTON	HEPARIN SODIUM	1000I.U/G	A. MENARINI MANUFACTURING LOGICTICS AND SERVICES-VIA 3 SETTE SANTI FLORENCE 50131 ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/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,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4361	: ALKEM LABORATORIES LIMITEDV	ABACUS PHARMA (AFRICA) LIMITED	TAXIM-O	CEFEXIME	200MG	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4363	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICAL S LIMITED	ZEPTRIN	CO-TRIMOXAZOLE	480MG	THE MADRAS PHARMACEUTICALS-137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4364	CADILA HEALTHCARE LIMITED	ABACUS PHARMA (AFRICA) LIMITED	VOMIZ OD 8	ONDANSETRON HYDROCHLORIDE 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
NDA/MAL/HDP/4365	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ACTINAC PLUS	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	AJANTA PHARMA LIMITED-B-4/5/6,MIDC AREA, PAITHAN,431 148 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4366	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CLOXISPA	CLOXACILLIN	250MG	SPARSH BIO-TECH LTD-PLOT NO.1 SURVEY NO.242/234/244, VILLAGE LAKHABARAD, JAMNAGAR-361006	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER,1.0X 100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4367	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 8MG	CANDESARTAN	8MG	ASTRA ZENECA AB, SODERTALJE-GARTUNAYEGEN, SODERTALJE	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4369	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUCAP	CHLORPHENAMINE MALEATE+PSEUDOE PHEDRINE HYDROCHLORIDE+P ARACETAMOL	1.25MG+10MG+120MG	TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4371	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	NEVIHOPE 200	NEVIRAPINE	200MG	MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/4373	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICAL S 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
NDA/MAL/HDP/4375	PFIZER LAB LTD	LABOREX UGANDA LIMITED	ZITHROMAX	AZITHROMYCIN DIHYDRATE	200MG/5ML	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE,1.0X15.0 ML BOTTLE
NDA/MAL/HDP/4376	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	EFAVIRENZ+LAMIVUDINE & TENOFOVIR TABLETS	EFAVIRENZ + LAMIVUDINE + TENOFOVIR	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

NDA/MAL/HDP/4377	MEDIPHARM INDUSTRIES LTD	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
NDA/MAL/HDP/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,1.0X1.0X6.0X20.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/4380	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	ZINNAT SUSPENSION	CEFUROXIME AXETIL-	125MG/5ML	GLAXOSMITHKLINE UK LTD-HARMIRE RD BARNARD CASTLE DURHAM, DL12DT UNITED	UNITED KINGDOM	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE,1.0X50.0 ML BOTTLE
NDA/MAL/HDP/4381	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	50MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4383	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEEMYCIN - 150	CLINDAMYCIN HYDROCHLORIDE BP	150MG	THE MADRAS PHARMACEUTICALS-137-B,OLD MAHABALI PURAM ROAD,KARAPAKKAM,CHENNAI INDIA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/4389	PHARMACARE LTD	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	600MG	JANSSEN ORTHO LLC.--STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/4390	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROCOL	CHLORAMPHENICOL	0.5%W/V	AUROLAB-NO 1 SIVAGANGAI MAIN ROAD, VEERAPANJAN MADURAI - 625 020 TAMIL NADU, INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/4391	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	MOBYLE-A	ACECLOFENAC + PARACETAMOL	100 MG + 325 MG	LINCOLN PHARMACEUTICALS LTD-TRIMUL ESTATE AT & POST KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4392	IND SWIFT LTD	TATA UGANDA LIMITED	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
NDA/MAL/HDP/4394	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NS	SODIUM CHLORIDE	0.9% W/V	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/4396	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ABACAVIR SULPHATE	ABACAVIR SULFATE	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
NDA/MAL/HDP/4397	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BISODAC-HF 2.5	BISOPROLOL FUMARATE	2.5MG	AUROBINDO PHARMA LTD UNIT III.-SURVEY NO.313 BACHUPALL VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4398	NIRMA LIMITED (HEALTHCARE DIVISION) NIRLIFE HEALTHCARE	SUPER MEDIC LTD	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
NDA/MAL/HDP/4400	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ORAL REHYDRATION SALT (DTS)	ORAL REHYDRATION SALT	N/A	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X100.0X20.6 G SACHET,1.0X100.0X10.3 G SACHET
NDA/MAL/HDP/4401	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAZONE 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
NDA/MAL/HDP/4402	VIRBAC RSA (PTY) LTD	METRO PHARMACEUTICALS LIMITED	CLOTRILIN	CLOTRIMAZOLE	100MG	LINCOLN PHARMACEUTICALS LTD-10, 11, 13, TRIMUL ESTATE KHATRAJ, NEAR KHATRAJ, CHOKADI , KHATRAJ-382721, GHANDINAGAR GUJARAT, INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 TABLET STRIP
NDA/MAL/HDP/4404	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LIMITED	FOLIGRAF	RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE	75I.U/ VIAL	BHARAT SERUMS AND VACCINES LIMITED,- PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (EAST), INDIA	INDIA	PARENTERAL RETARD OTHER VIALS	1.0X1.0 VIAL CARTON

NDA/MAL/HDP/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
NDA/MAL/HDP/4407	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	SUXAMETHONIUM CHLORIDE- FRESENIUS	SUXAMETHONIUM CHLORIDE	100MG/2ML	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD V-6 GIBAUD...ROAD KORSTEN, PORT ELIZABETH, SOUTH AFRICA.	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4408	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNISTEN CREAM	CLOTRIMAZOLE	1%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/4409	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ROBESTAR 10MG	ROSUVASTATIN CALCIUM	10MG	LEK PHARMACEUTICALS .D.D -VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4410	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 4	MONTELUKAST 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
NDA/MAL/HDP/4411	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND PLUS	CANDESARTAN + HYDROCHLOROTHIAZIDE	16 MG + 12.5 MG	ASTRA ZENECA AB, SODERTALJE-GARTUNAYEGEN, SODERTALJE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4412	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-KAST 5	MONTELUKAST 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
NDA/MAL/HDP/4413	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE	1G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 2 PLASTIC AMPOULES OF WFI
NDA/MAL/HDP/4414	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ROBESTAR 20MG	ROSUVASTATIN CALCIUM	20MG	LEK PHARMACEUTICALS LTD-LEK PHARMACEUTICALS VEROVSKOVA 57 SI 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4415	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	CATAFLAM 50MG TABLETS	DICLOFENAC POTASSIUM	50MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY,NOVARTIS--URUNLERI INSTABUL TURKEY	ITALY	ORAL SOLID ORDINARY COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4417	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPICEPHIN	CEFTRIAXONE SODIUM	500MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X0.5 G VIAL + 1*5 ML OF WFI GLASS AMPOULES
NDA/MAL/HDP/4418	MEDOCHIE LTD	BOOTS PHARMACEUTICALS LIMITED	VALORAN	CEFOTAXIME	1000MG	MEDOCHIE LTD-1-10 ASTRONAFTON & CONSTANTINOPOLEOS 3505 LIMASSOL	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/4419	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIGONAL 75	HUMAN MENOPAUSAL GONADOTROPHIN	75IU/5ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X5.0 ML VIAL + 1 ML AMPOULE 0.9%W/V NACL
NDA/MAL/HDP/4425	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REQUIN FC	QUININE	300MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4446	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	HI-ALFA 2.5	ALFUZOSIN HYDROCHLORIDE	2.5MG	AUROBINDO PHARMA LTD UNIT III.-SURVEY NO.313 BACHUPALL VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4468	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 40	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40MG	AUROBINDOPHARMA LIMITED,-UNIT VII, SEZ APIIC, PLOT NO.SI SURVEY NO'S 425, 434,435 & 458 GREEN INDUSTRIAL PARK, POLEPALLY VILLAGEJEDCHERTA MANDAL, MAHABOBNAGAR DISTRICT, ANDRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4480	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	KIPEL 5	MONTELUKAST	5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4519	ARISTO PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 5	AMLODIPINE BESILATE	5MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4522	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	S-AMLOSAFE 2.5	AMLODIPINE BESILATE	2.5 MG	ARISTO PHARMACEUTICALS PVT LTD-PLOT NO 208 NEW INDUSTRIAL AREA NO 11 MANDIDEEP	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4523	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	BIGOMET SR 500	METFORMIN HYDROCHLORIDE	500MG	ARISTO PHARMACEUTICALS PVT. LIMITED-PLOT NO. 208, NEW INDUSTRIAL AREA NO.II,MANDIDEEP PRADESH	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4524	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL 150	FLUCONAZOLE	150MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X1.0 CAPSULE BLISTER
NDA/MAL/HDP/4526	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AZ-500	AZITHROMYCIN	500MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/4528	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE MF 15/500	PIOGLITAZONE + METFORMIN	15 MG + 500 MG	ARISTO PHARMACEUTICALS PVT LIMITED-PLOT 208, NEW INDUSTRIAL AREA NO II, MANDIDEEP-462 046 (DISTRICT) RAISEN, MADHYA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4530	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TREDOL 100	ATENOLOL	100MG	AEGIS LIMITED -17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081, LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4531	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TREDOL 50	ATENOLOL	50MG	AEGIS LIMITED -17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081, LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4532	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIRUCID 400	ACICLOVIR	400 MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY OTHER TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4534	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	LORYTEC 10	LORATADINE	10MG	DELORBIS PHARMACEUTICALS LTD-17 ATHINON STR., ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081 LEFKOSIA, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4535	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CLERON 250	CLARITHROMYCIN	250MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/4536	SEDICO PHARMACEUTICAL CO.	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FLUCAMOX	FLUCLOXACILLIN + AMOXICILLIN	250MG+250MG	SEDICO PHARMACEUTICAL CO.-1ST INDUSTRIAL ZONE 6 TH OCTOBER CITY GIZA,EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X4.0 CAPSULE STRIP

NDA/MAL/HDP/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
NDA/MAL/HDP/4540	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIPROLOX500	CIPROFLOXACIN	500MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4541	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	AMOXIL	AMOXYCILLIN	500MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4542	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	CLERON 500	CLARITHROMYCIN	500MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4543	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	RHINATHIOL 5%	CARBOCISTEINE	5%W/V	NATTERMAN & CIE , GMBH NATTERMANNALLEE 1 -,50829 COLOGNE , GERMANY	GERMANY	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE
NDA/MAL/HDP/4544	COSMOS LTD	ASTRA PHARMA (U) LIMITED	SALBUT TABLET 4MG	SALBUTAMOL	4MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/4545	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-ART 20/120	ARTEMETHER + LUMEFANTRINE	20 MG + 120 MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X8.0 TABLET BLISTER
NDA/MAL/HDP/4546	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CHLORAMPHENICOL INJECTION IG	CHLORAMPHENICOL SODIUM SUCCINATE	1G	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0X1.0 G VIAL,1.0X50.0X1.0 G VIAL
NDA/MAL/HDP/4549	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	UNIXIL 500MG	AMOXYCILLIN TRIHYDRATE	500MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/4550	SANOFI AVENTIS FRANCE	LABOREX UGANDA LIMITED	RHINATHIOL 2%	CARBOCISTEINE	20MG/ML	UNITHER LIQUID MANUFACTURING INDUSTRIE -COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770,A. NATTERMANN & CIE GMBH.-NATTERMANNALLEE 1 ,50829 COLOGNE, GERMANY	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE

NDA/MAL/HDP/4553	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ARTESUN	ARTESUNATE	30MG	GUILIN PHARMACEUTICAL CO.,LTD-NO 43 QILIDIAN ROAD GUILIN 541002, GUANGXI	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 MG VIAL + 1*0.5 ML SODIUM BICARBONATE
NDA/MAL/HDP/4556	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250MG + 125MG	ALKEM LABORATORIES LTD--167/1, VILLAGE DABHEL, AMALIYA DAMAN-396210, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/4557	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	HETERO LABS LTD-HETERO LABS LTD, UNIT 111, H22-110, I.D.A, JEEDIMETLA, HYDERABAD, 500055,HETERO LABS LTD (UNIT-V)-SEZ JADCHERIA HYDRABAD	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/4558	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	IFICIPRO 500	CIPROFLOXACIN	500MG	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4559	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/4562	F. HOFFMANN- LA ROCHE LTD	LABOREX UGANDA LIMITED	PEGASYS	PEGINTERFERON ALPHA 2A	180MCG/2ML	F.HOFFMANN- LA ROCHE LTD-CH-4070 BASEL SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X2.0 ML PRE FILLED SYRINGE
NDA/MAL/HDP/4563	TATA UGANDA LIMITED	TATA UGANDA LIMITED	QUININE DIHYDROCHLORIDE INJECTION	QUININE DIHYDROCHLORIDE	300MG/ML	GLAND PHARMA LTD .-D.P. PALLY, SURVEY 143-148, 150&	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4566	TATA UGANDA LIMITED	TATA UGANDA LIMITED	FUROSEMIDE INJECTION BP	FUROSEMIDE	10MG/ML	GLAND PHARMA LTD .-D.P. PALLY, SURVEY 143-148, 150&	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4568	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500MG + 125MG	ALKEM LABORATORIES LTD--167/1, VILLAGE DABHEL, AMALIYA DAMAN-396210, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/4569	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMADOL SYRUP	PARACETAMOL	120MG/5ML	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/4573	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM DT 228.5MG	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	200MG + 28.5MG	ALKEM LABORATORIES LTD--167/1, VILLAGE DABHEL, AMALIYA DAMAN-396210, INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP
NDA/MAL/HDP/4575	FDC LTD	AIVEEN (U) LIMITED	PYRICORT EYE/EAR DROPS	DEXAMETHASONE+ GENTAMICIN	0.1%+0.3%W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/4577	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MAGTAM	CEFOPERAZONE + SULBACTAM	500 MG + 500 MG	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/4579	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 500 IV VIALS	CEFTRIAXONE	500MG	LABESFAL LABORATORIOS ALMIRO, S.A ,.- ZONA INDUSTRIAL DO LABENGO, 3465-157 SANTIAGO DE BESTEIROS	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL + 1*5 ML WFI AMPOULE
NDA/MAL/HDP/4581	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	CLAVAM 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	ALKEM LABORATORIES LTD--167/1, VILLAGE DABHEL, AMALIYA DAMAN-396210, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/4588	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	FLUCAN 200	FLUCONAZOLE	200MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0 TABLET BLISTER
NDA/MAL/HDP/4589	FEROZSONS LABORATORIES LTD	TOP UNIVERSAL MEDICARE LIMITED	LEFOXICIN-500	LEVOFLOXACIN HEMIHYDRATE	500MG	FEROZSONS LABORATORIES LTD-AMANGARH-NOWSHERA, (KHYBER PAKHTOONKHWHA), PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4591	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	SILVER KANT	SILVER SULPHADIAZINE USP	1%W/W	S.KANT HEALTHCARE LTD-1802-18-5 GIDC PHASE III, VAPI-396195,GUJARAT INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4592	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	PENTALINK 40	PANTOPRAZOLE	40MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4594	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	TINIBA-500 TABLETS	TINIDAZOLE	500MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0X4.0 TABLET BLISTER,1.0X25.0X4.0 TABLET BLISTER
NDA/MAL/HDP/4595	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	VAST-20	ATORVASTATIN	20MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4596	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	TRIZ TABLETS	CETIRIZINE	10MG	INDOCO REMEDIES LTD, B-20,-B-20 MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X5.0X10.0 BLISTER BLISTER,1.0X5.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4598	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AZ-250	AZITHROMYCIN	250MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/4601	SANOFI PASTEUR	LABOREX UGANDA LIMITED	PENTAXIM VACCINE	MULTI-INGREDIENT	MULTI-INGREDIENT	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE,1.0X0.5 ML VIAL
NDA/MAL/HDP/4602	ELI-LILLY (SUISSE) SA	LABOREX UGANDA LIMITED	HUMALOG MIX 50	INSULIN LISPRO	100 .IU(50 I.U+50 I.U)	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X3.0 ML VIAL,1.0X5.0 ML VIAL
NDA/MAL/HDP/4603	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	HALOXEN - 5	HALOPERIDOL	5MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4605	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGODRYL SYRUP	BROMHEXINE HCL+DEXTROMETHORPHAN HBR+AMMONIUM CHLORIDE+MENTHOL	4MG/5ML+5MG/5ML+50MG/5ML+2.5MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE,1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4606	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	ROVAS 10	ROSUVASTATIN	10MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4611	DAFRA PHARMA LTD	LABOREX UGANDA LIMITED	DAFRACLAV	AMOXICILLIN + POTASSIUM CLAVULANATE	200MG + 28MG	BILIM PHARMACEUTICALS-ISLETMESI 59501 CERKEZKOY TEKIRDAG	TURKEY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/4615	NVS KENYA LTD	SURGIPHARM (U) LIMITED	TASIGNA 150	NILOTONIB HYDROCHLORIDE MONOHYDRATE	150MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSETRASSE CH-4332 STEIN SWITZERLAND.	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X7.0X4.0 CAPSULE BLISTER
NDA/MAL/HDP/4617	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN	10MG	IPR PHARMACEUTICALS INC,-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4620	GLAXO SMITH KLINE LTD	ERIS 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
NDA/MAL/HDP/4621	CADILA HEALTH CARE LIMITED	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
NDA/MAL/HDP/4622	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	CLOXAREN	CLOXACILLIN	250MG	RENE INDUSTRIES-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4623	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	LOPERAREN	LOPERAMIDE HYDROCHLORIDE	2MG	RENE INDUSTRIAL LTD-RENE INDUSTRIES LTD, PLOT 680, KAMULI-KIREKA KAMPALA UGANDA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4626	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	GASEC-20	OMEPRAZOLE	20MG	ACINO PHARMA AG -DORNACHERSTRASSE, 114, 4147, AESCH, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X14.0 CAPSULE BOTTLE
NDA/MAL/HDP/4627	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM CREAM	HYDROCORTISONE	1%W/W	LABORATORY AND ALLIED LTD-PLOT 209/10349-MOMBASA ROAD NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4629	DAWA LIMITED	SUPER MEDIC LTD	ORACEF	CEFALEXIN MONOHYDRATE	125MG/5ML	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4634	DENK PHARMA GMBH &CO. KG	BENLE CONSULT LIMITED	LOSAR-DENK 100	LOSARTAN	100MG	DENK PHARMA GMBH &CO.KG--PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4635	SANOFI-AVENTIS	LABOREX UGANDA LIMITED	RHINATHIOL 5%	CARBOCISTEINE	5%W/V	UNITHER LIQUID MANUFACTURING INDUSTRIE -COLOMIERS 1-3 ALLE DE LA NESTE L DEN SIGAL 31770	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X125.0 ML BOTTLE

NDA/MAL/HDP/4636	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLARAM 0.5	ALPRAZOLAM	0.5MG	AEGIS LIMITED -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
NDA/MAL/HDP/4637	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	PARACETAMOL	PARACETAMOL	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
NDA/MAL/HDP/4640	GLAXOSMITHLINE LTD	ERIS LTD	REQUIP PD 24 HOUR 8 MG	ROPINIROLE	8MG	GLAXO WELLCOME S.A.-AVENIDA DE EXTREMADURA 309400 ARANDA DE DUERO BURGOS SPAIN	SPAIN	ORAL SOLID ORDINARY TABLETS	1.0X28.0 TABLET BLISTER
NDA/MAL/HDP/4641	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	RHEOSORBILACT	SORBITOL + SODIUM LACTATE + NA CL + CALCIUM CHLORIDE + MAGNESIUM CHLORIDE	6G +1.9G +0.6G + 0.01G +0.03G +0.02	YURIA-PHARM, LTD.-18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE.	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X400. 0 ML BOTTLE
NDA/MAL/HDP/4645	ASTRA ZENECA	MACNAUGHTON LIMITED	CRESTOR	ROSUVASTATIN CALCIUM	20MG	IPR PHARMACEUTICALS INC,-LOT 17 INDUSTRIAL PARK PUERTO RICO, SAN ISIDRO, PUERTO RICO	PUERTO RICO	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/4646	YURIA PHARM LTD	YURIA PHARM EAST AFRICA LIMITED	LEFLOCIN	LEVOFLOXACIN	5MG/ML	YURIA-PHARM, LTD.-18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE.	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X150.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE
NDA/MAL/HDP/4647	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	LEVOLIN	LEVOSALBUTAMOL	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
NDA/MAL/HDP/4650	NORVATIS PHARMA AG- SWITZERLAND	KARURI PHARMACEUTICAL S LTD.	DUOTRAV	TRAVOPROST + TIMOLOL MALEATE	40MG/ML + 5MG/ML	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X1.0X2.5 ML VIAL
NDA/MAL/HDP/4652	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	SII TETANUS TOXOID VACCINE	TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE	≥ 5 LF (≥ 40 IU) ON ≤ 1.25 MG OF ALUMINIUM PHOSPHATE	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE (1 DOSE AMPOULE),1.0X1 0.0 ML VIAL (20 DOSE VIAL)

NDA/MAL/HDP/4655	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	DECASAN	DECAMETHOXIN	0.2MG/1ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X400.0 ML BOTTLE,1.0X1000.0 ML CONTAINER,1.0X2.0 ML CONTAINER
NDA/MAL/HDP/4656	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASCET	CETIRIZINE	10MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDOBAD, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0TABLET BLISTER,
NDA/MAL/HDP/4657	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4660	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4661	YURIA PHARM EAST AFRICA LIMITED	YURIA PHARM EAST AFRICA LIMITED	FLUCONAZOLE-UF	FLUCONAZOLE	2MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/4663	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4665	YURIA PHARM LTD	YURIA PHARM EAST AFRICA LIMITED	ORNIGIL	ORNIDAZOLE	5MG/ML	YURIA-PHARM, LTD. -18030 VERBOVETSKOGO STR. 108 CHERKASSY, UKRAINE..	UKRAINE	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4666	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	ANTIPLEX	CLOPIDOGREL BISULFATE	30MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4669	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	DICLOGESIC 100MG SUPPOSITORIES	DICLOFENAC SODIUM.	100MG	DAR AL DAWA-DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD. NA'UR PRINCE HASHEM BIN AL-HUSSEIN STREET. AMMAN, JORDAN	JORDAN	TOPICAL EXTERNAL ADULT SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/4670	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICALS UGANDA LTD	MEDOMOX 500	AMOXICILLIN	500MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4675	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4677	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF	CEFUROXIME	125MG/5ML	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X30.0 ML BOTTLE,1.0X70.0 ML BOTTLE
NDA/MAL/HDP/4678	: ALKEM LABORATORIES LIMITEDv	ABACUS PHARMA (AFRICA) LIMITED	ZOCEF-500	CEFUROXIME AXETIL	500MG	ALKEM LABORATORIES LIMITED.-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4680	SANCE LABORATORIES PVT LTD	DELMAW ENTERPRISES LIMITED	SANCEPH DS	CEPHALEXIN	125MG/5ML	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4681	SANOFI AVENTIS	LABOREX UGANDA LIMITED	INSUMAN COMB 30	DISSOLVED INSULIN+CRYSTALLINE PROTAMINE INSULIN	30%+70%	SANOFI-AVENTIS DEUTSCHLAND GMBH - INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING H650 65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/4700	MEDIPHARM SALES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIZOLE	METRONIDAZOLE	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4701	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	MEBRONE 100 TABLETS	MEBENDAZOLE	100MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/4702	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABTOL 20%W/V	MANNITOL	200MG/ML	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4703	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABGYL	METRONIDAZOLE	500MG	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4704	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4705	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4706	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL GEL	DICLOFENAC DIETHYLAMINE	1.16%W/W	G,S PHARMBUTOR PVT LTD -B-172 INDUSTRIAL AREA BEHROR 301701 RAJASTHAN	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G CONTAINER
NDA/MAL/HDP/4707	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL INJECTION	DICLOFENAC SODIUM	25MG/ML	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH - INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0 ML AMPOULE
NDA/MAL/HDP/4708	MEDIPHARM SALES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIFEN	IBUPROFEN	100MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE

NDA/MAL/HDP/4710	COSMOS LTD	ASTRA PHARMA (U) LIMITED	MEDOPRESS TABLETS 250MG	METHYLDOPA	250MG	COSMOS LIMITED..-RANGWE ROAD, OFF LUNGA LUNGA ROAD, INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4715	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL FORTE	MEFENAMIC ACID + PARACETAMOL	500MG + 450MG	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4717	BLUE CROSS LABARATORIES LIMITED	STAR PHARMACEUTICALS LTD	MEFTAL-SPAS	MEFENAMIC ACID + DICYCLOMINE HYDROCHLORIDE	250MG + 10MG	BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X20.0 TABLET BLISTER
NDA/MAL/HDP/4718	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/4719	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/4720	SQUARE CEPHALOSPORINS LTD	GAMA PHARMACEUTICALS (U) LIMITED	CEFTRON	CEFTRIAXONE	1G	SQUARE PHARMACEUTICALS LIMITED--DHAKA UNIT KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10 ML AMPOULE WATER FOR INJECTION

NDA/MAL/HDP/4722	GLAXO SMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED COLD TABLETS	TRIPROLIDINE HYDROCHLORIDE+PS EUDOPHEDRINE HYDROCHLORIDE	2.5MG+60MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET BLISTER,1.0X12.0 TABLET BLISTER,1.0X96.0 TABLET BLISTER,1.0X480.0 TABLET BLISTER
NDA/MAL/HDP/4723	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEGYL SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4724	GLAXOSMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ACTIFED DRY COUGH & COLD	TRIPROLIDINE HYDROCHLORIDE+PS EUDOPHEDRINE HYDROCHLORIDE+D EXTROMETHORPHAN	1.25MG+30MG+10MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE,1.0X2.0 L BOTTLE
NDA/MAL/HDP/4725	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEGYL TABLET	METRONIDAZOLE	200MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4726	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	ADB MIN MULTIPOWER	MULTI-INGREDIENT	MULTI-INGREDIENT	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X300.0 ML BOTTLE
NDA/MAL/HDP/4727	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	MELONAX	MELOXICAM	15MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4728	M.J.BIOPHARM PVT LTD	TATA UGANDA LIMITED	ADRENALINE	ADRENALINE	1MG/ML	M.J BIOPHARM PVT LTD-TALOJA DISTRICT RAIGAD 410208 NAVI MUMBAI	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE
NDA/MAL/HDP/4729	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	MELONAX	MELOXICAM	7.5MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4730	SANOFI PASTEUR	LABOREX UGANDA LIMITED	MENACTRA	MENINGOCOCCAL GROUPS (A + C +Y + W-135) + POLYSACCHARIDE DIPHTHERIA 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)
NDA/MAL/HDP/4731	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	MENAFRIVAC	MENINGOCOCCAL A CONJUGATE VACCINE	10MCG/ 0.5ML + 10-33MCG/0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X10.0 DOSE VIAL + 1*5ML AMPOULE OF DILUENT
NDA/MAL/HDP/4734	SANOFI PASTEUR	LABOREX UGANDA LIMITED	MENINGOCOCCAL VACCINE A+C	MENINGOCOCCAL A+C VACCINE	50MCG/0.5ML + 50MCG/0.5ML	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M VIALS	1.0X10.0 DOSE VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/4736	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MEPHAQUIN LACTAB	MEFLOQUINE	250MG	ACINO PHARMA AG (FORMER MEPHA LLC)-DORNACHERSTRASSE 114 P.O BOX 445 CH4147, AESCH/BL	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/4738	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICAL S LTD.	CILOXAN	CIPROFLOXACIN	0.3%W/V	ALCON -ALCON COUVREUR NV B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/4739	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICAL S 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
NDA/MAL/HDP/4740	ASTRA ZENECA	MACNAUGHTON LIMITED	MERONEM	MEROPENEM	500MG	SUMITOMO PHARMACEUTICALS CO. LTD-JAPAN,ACS-DOBFAR ITALIA	JAPAN	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/4742	ASTRA ZENECA	MACNAUGHTON LIMITED	MERONEM	MEROPENEM	1G	SUMITOMO PHARMACEUTICALS CO. LTD-JAPAN,ACS-DOBFAR ITALIA	JAPAN	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/4743	DAFRA PHARMA N.V/S.A	LABOREX UGANDA LIMITED	MERONIA 1000	MEROPENEM	1000MG	PHARMATHEN S.A-6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	PARENTERAL ORDINARY VIALS	1.0X1000.0 MG VIAL

NDA/MAL/HDP/4744	DAFRA PHARMA N.V/S.A	LABOREX UGANDA LIMITED	MERONIA 500	MEROPENEM	500MG	PHARMATHEN S.A-6,DERVENAKION STR,PALLINI,AHICA GREECE	GREECE	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/4745	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	PIPZO	PIPERACILLIN + TAZOBACTAM	4.5G	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X4.5 G VIAL
NDA/MAL/HDP/4746	MIRACALUS PHARMA PVT.LTD	AIVEEN (U) LIMITED	ABINGEM-200	GEMCITABINE	200MG	NAPROD LIFE SCIENCES PVT LTD-G-17, MIDC, TARAPUR INDUSTRIAL AREA, BIOSAR THANE, MUMBAI	INDIA	PARENTERAL ORDINARY VIALS	1.0X200.0 MG VIAL
NDA/MAL/HDP/4747	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ZITHRORIV	AZITHROMYCIN	200MG/5ML	RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X22.5 ML BOTTLE
NDA/MAL/HDP/4748	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICAL S LTD.	ACICONE-S CHEWABLE TABLET	MAGALDRATE+SIME THICONE	720MG+25MG	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X5.0X4.0 TABLET BLISTER
NDA/MAL/HDP/4750	BAYER AG	SURGIPHARM (U) LIMITED	CIPROBAY I.V	CIPROFLOXACIN	2MG/ML	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4751	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	FEROL	FERROUS SULPHATE	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4752	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	ADRIBLASTINA RD	DOXORUBICIN HYDROCHLORIDE	10MG	PHARMACIA AND UPJOHN S.P.A ITALY-VIA COMMESCION MARINO DEL TRONTO(ASCOLI PICENE)ITALY	ITALY	PARENTERAL ORDINARY OTHER VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/4753	BAYER AG	SURGIPHARM (U) LIMITED	CIPROBAY 750	CIPROFLOXACIN	750MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4754	BAYER PHARMA	SURGIPHARM (U) LIMITED	CIPROBAY XR	CIPROFLOXACIN	500MG	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	ORAL SOLID RETARD TABLETS	1.0X1.0X3.0 TABLET BLISTER

NDA/MAL/HDP/4755	BAYER SCHERING AG	SURGIPHARM (U) LIMITED	ADVANTAN CREAM	METHYL PREDNISOLONE ACEPONATE	0.1%W/W	BAYER HEALTH CARE MANUFACTURING S.R.L S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4757	ERIS LTD	BENLE CONSULT LIMITED	METFORMIN-DENK 500	METFORMIN	500MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X1.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4758	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	METFORMIN DENK 1000	METFORMIN	1000MG	DENK PHARMA GMBH &CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER
NDA/MAL/HDP/4759	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/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
NDA/MAL/HDP/4763	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	FEROSOFT	IRON(III) HYDROXIDE POLYMALTOSE COMPLEX	100MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4765	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	FEROSOFT-FA	IRON(III)HYDROXIDE POLYMALTOSE COMPLEX/FOLIC ACID	100MG/0.35MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4766	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGOBEN SUSPENSION	MEBENDAZOLE	100MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/4768	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	METHACHLOR EYE DROPS	DEXAMETHASONE/C FLORAMPHENICOL	1MG/2MG	REMINGTON PHARMACEUTICAL INDUS. PVT LTD-, 117 ALLAM	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE

NDA/MAL/HDP/4769	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOBEX	MEBENDAZOLE	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4771	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	METHYLERGOMETRINE	METHYLERGOMETRINE MALEATE	20MCG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/4773	IDA FOUNDATION	KIMSY MEDS LTD	METHYLERGOMETRINE	METHYLERGOMETRINE	0.2MG/ML	GLAND PHARMA LTD -D.P.PALLY, DUNDIGAU POST NEAR GANDIMAISAMMA CROSS ROAD, QUTHBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD - 500043, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/4774	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FERROFOL VIT-Z	FERROUS SULPHATE+FOLIC ACID+ASCORBIC ACID+THIAMINE MONONITRATE+RIBOTLAVINE+PYRIDOXINE HCL+NICOTINAMIDE +ZINC	150MG+0.5MG+50MG+2MG+2MG+1MG+10MG+25MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY-10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X6.0 CAPSULE BLISTER
NDA/MAL/HDP/4777	MERCK SHARP & DOHME BV	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CRIXIVAN	INDINAVIR SULPHATE	400MG	MERCK SHARP & DOHME B.V-WAARDENWEG 392031 BN, HAARLEM	NETHERLANDS	ORAL SOLID ORDINARY CAPSULES	1.0X180.0 CAPSULE BOTTLE
NDA/MAL/HDP/4778	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CURISAFE	CEFADROXIL MONOHYDRATE	125MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4779	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	CUTIVATE	FLUTICASONE PROPIONATE	0.05%W/W	GLAXO WELLCOME (UK)-UK	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE
NDA/MAL/HDP/4780	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	CUTIVATE	FLUTICASONE PROPIONATE	0.005%W/W	GLAXO WELLCOME (UK)-UK	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE

NDA/MAL/HDP/4781	CYANO PHARMA(P)	RENE PHARMACY LTD	CYANO IRON TABLETS	FERROUS SULPHATE	200MG	CYANO PHARMA(P)-115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4782	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/4783	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CYPOTIN	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4784	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	D50	GLUCOSE INTRAVENOUS INFUSION	50%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4785	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	DAKTACORT	MICONAZOLE NITRATE+HYDROCO RTISONE	2%W/W+1%W /W	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4786	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	COTRIMOXAZOLE 960MG	SULPHAMETHOXAZ OLE + TRIMETHOPRIM	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/4789	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	300MG	FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CARTON,1.0X2.0 X8.0 CAPSULE STRIP
NDA/MAL/HDP/4790	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN HYDROCHLORIDE	150MG	FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	BELGIUM	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE STRIP,1.0X100.0 CAPSULE CARTON

NDA/MAL/HDP/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/GRANULES	1.0X80.0 ML BOTTLE
NDA/MAL/HDP/4792	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DALACIN C	CLINDAMYCIN PHOSPHATE	150MG/ML	PFIZER MANUFACTURING -NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X4.0 ML VIAL, 1.0X2.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/4794	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	DALADOL	DICLOFENAC SODIUM + PARACETAMOL	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
NDA/MAL/HDP/4795	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4796	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	DARROWS SOLUTION (HALF STRENGTH)	POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE	0.13%+0.20%+0.30%	ABACUS PARENTERAL DRUGS LTD-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/4799	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CITROLIN SOLUTION	CETRIMIDE+LIDOCAINE	25MG+3MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL TOPICAL LIQUIDS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/4800	DAWA LIMITED	SUPER MEDIC LTD	DAWAVITE SYRUP	MULTI-INGREDIENT	MULTI-INGREDIENT	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4801	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	DAZEL KIT	FLUCONAZOLE + AZITHROMYCIN + SECNIDAZOLE	150MG + 1G + 1G	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/4804	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CLAVODAR	AMOXICILLIN + CLAVULANIC	200MG + 28MG /5ML	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X70.0 ML BOTTLE

NDA/MAL/HDP/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,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4806	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOFER	FERROUS SULPHATE+FOLIC ACID	200MG + 0.25MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4809	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCORT	HYDROCORTISONE	0.1%W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4810	TATA UGANDA LIMITED	TATA UGANDA LIMITED	METHYLERGONOVINE	METHYLERGONOVINE MALEATE	0.2MG/ML	GLAND PHARMA LTD -D.P.PALLY, DUNDIGAU POST NEAR GANDIMASAMMA CROSS ROAD, QUTHBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD - 500043, ANDHRA PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/4811	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOGYL	METRONIDAZOLE	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4812	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL SUSPENSION	METRONIDAZOLE BENZOATE	125MG/5ML	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/4813	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOMETROL TABLETS (THANE)	METRONIDAZOLE	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4814	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	METLIFE	METRONIDAZOLE	500MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4815	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROLIC-LF	FERROUS SULPHATE +FOLIC ACID	200MG+0.4MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4818	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	FERROUS SULPHATE	FERROUS SULPHATE	200MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4819	FDC LTD	AIVEEN (U) LIMITED	ORAL REHYDRATION SALT	ORAL REHYDRATION SALT	27.9GM	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X27.9 G SACHET
NDA/MAL/HDP/4820	IDA	KIMSY MEDS LTD	FERROUS SULPHATE+FOLIC ACID	FERROUS SULPHATE+FOLIC ACID	200MG+0.4MG	BIO NOVA PHARM LTD.-C-66/1 OKHLA INDUSTRIAL AREA PHASE II NEW DEHLI	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4821	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	METPURE-XL 50	METOPROLOL	50MG	EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI-BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4823	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	METRIS INFUSION	METRONIDAZOLE	5MG/ML	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4824	MISSION PHARMA A/S	JOINT MEDICAL STORE (UPMB - UCMB)	FERROUS SULPHATE+FOLIC ACID	FERROUS SULPHATE+FOLIC ACID	200MG+0.25 MG	BIO NOVA PHARM LTD.-C-66/1 OKHLA INDUSTRIAL AREA PHASE II NEW DEHLI	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4825	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	ALOHA LIQUID	MULTI-INGREDIENT	N/A	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/4826	UNIQUE PHARMACEUTICALS LTD	TATA UGANDA LIMITED	METROGYL DENTA GEL	METRONIDAZOLE + CHLORHEXIDINE	1%W/W + 0.25%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/4828	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	METROGYL GEL	METRONIDAZOLE	1%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	TOPICAL EXTERNAL EMULSION GELS	1.0X30.0 G TUBE
NDA/MAL/HDP/4830	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	METROGYL INJECTION	METRONIDAZOLE	5MG/ML	UNIQUE PHARMACEUTICAL LABORATORIES, (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD-PLOT NO 4, PHASE IV, GIDC INDUSTRIAL AREA, PANOLI 394 116,UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)--304-308 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4832	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	METROGYL SUSPENSION	METRONIDAZOLE	200MG/5ML	UNIQUE PHARMACEUTICAL LABORATORIES-PLOT NO. 215-219, G.I.D.C. INDUSTRIAL AREA,PANOLI — 394 116, GUJARAT, INDIA. ,J.B. CHEMICALS AND PHARMACEUTICALS LTD -128/1, GIDC, ANKLESHWAR 393 002, GUJARAT	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/4836	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	METRON	METRONIDAZOLE	200MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/4839	PHARMAVET LTD	DELMAW ENTERPRISES LIMITED	ANOMEX	ZINC OXIDE+LIDOCAINE+HYDROCORTISONE+ALLANTOIN	5%W/W+3%W/W+0.25%W/W+0.5%W/W	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER,1.0X2.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/4840	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	METRONIDAZOLE	METRONIDAZOLE	200MG	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/4845	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ANTIDEP	IMIPRAMINE	25MG	TORRENT PHARMACEUTICALS LTD-INDRAD-382 721, DIST.MEHSANA,INDIA.AT:VILL.MANAKPUR,T EH.NALAGARH,DIST.SOLAN(H.P.)	INDIA	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/4849	SCIENTIFIC LABORATORY SUPPLIES LIMITED	METAPLUS (U) LIMITED	METRONIDAZOLE ORAL SUSPENSION	METRONIDAZOLE BENZOATE	125MG/5ML	UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4854	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN FC	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4855	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	ASCORIL EXPECTORANT	BROMHEXINE+MENTHOL+TERBUTALINE+GUAIFENESIN	2MG+0.5MG+1.25MG+50MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE,1.0X100.0 ML BOTTLE

NDA/MAL/HDP/4856	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	METROREN	METRONIDAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X20.0 X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/4858	RENE INDUSTRIES	RENE INDUSTRIES LIMITED	METROREN SUSPENSION	METRONIDAZOLE BENZOATE	200MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4859	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	FLOXAPEN	FLUCLOXACILLIN	250MG	SMITHLINE BEECHAM CLARENDON RD WORTHIN-CLARENDON RD WORTHING WEST SUSSEX	UNITED KINGDOM	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CARTON
NDA/MAL/HDP/4860	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LIMITED	K-FEN SUSPENSION	IBUPROFEN	100MG/5ML	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/4862	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	FLOXAPEN SYRUP	FLUCLOXACILLIN	125MG/5ML	MEDREICH LIMITED-12TH MIL,OLD MADRAS ROAD,VIRGONAGAR,BANGALORE-560 049,INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4863	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S 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
NDA/MAL/HDP/4865	MEDICAL UNION PHARMACUITICALS	KARURI PHARMACEUTICAL S LTD.	MICONAZ CREAM	MICONAZOLE NITRATE	2%W/W	MEDICAL UNION PHARMA .CO-ABU-SULTAN ISMAILIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/4866	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICAL S LIMITED	FLUCAN	FLUCONAZOLE	150MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0 TABLET BLISTER
NDA/MAL/HDP/4867	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/4868	NIRMA LIMITED (HEALTHCARE DI VISION) NIRLIFE HEALTHCARE	SUPER MEDIC LTD	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

NDA/MAL/HDP/4869	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	MICOGEL CREAM	MICONAZOLE NITRATE	2%W/W	CIPLA LTD--PLOT NO L-139,VERNA IND ESTATE, VERNA GOA-403 INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/4870	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	FLUCAS	FLUCONAZOLE	150MG	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	1.0X1.0 CAPSULE BLISTER
NDA/MAL/HDP/4871	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	MICOBACT POWDER	MICONAZOLE + CHLOROHEXIDINE	2%W/W + 0.05%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL POWDERS	1.0X30.0 G CONTAINER,1.0X 50.0 G CONTAINER,1.0X 75.0 G CONTAINER,1.0X 100.0 G CONTAINER
NDA/MAL/HDP/4872	DAWA LIMITED	SUPER MEDIC LTD	MICLOCIN CREAM	MICONAZOLE NITRATE + CLOBETASOL PROPRIONATE + GENTAMICIN	2%W/W+0.5% W/W+0.1W/W	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/4874	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	1.0X2.0X0.6 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/4875	PHARM ACCESS AFRICA LTD	MARIE STOPES UGANDA LIMITED	MISOCLEAR	MISOPROSTOL	200MCG	ACME FORMULATION PVT LTD,-ACME FORMULATION PVT LTD ROPAR ROAD NALAGARH DIST SOLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4876	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	1.0X2.0X0.8 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/4877	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	1.0X2.0X0.4 ML PRE- FILLED SYRINGE

NDA/MAL/HDP/4878	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	FLUCOLIFE	FLUCONAZOLE	200MG/100ML	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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,1.0X7.0X4.0 TABLET BLISTER,1.0X15.0X4.0 TABLET BLISTER
NDA/MAL/HDP/4881	ASTRA LIFE CARE (INDIA) PVT LTD	ASTRA PHARMA (U) LIMITED	ASDOXIN	DOXYCYCLINE	100MG	ASTRA LIFE CARE(INDIA) PVT LTD-57/P, POJODA, 382220, BOVIA, AHMEDABAD, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4883	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASFEN-FC	IBUPROFEN	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 TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/4887	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	200MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4888	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASOMYCIN	ERYTHROMYCIN	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	1.0X1000.0 TABLET CONTAINER,10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4889	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	50MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BLISTER

NDA/MAL/HDP/4890	DELORBIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCOZAL	FLUCONAZOLE	100MG	AEGIS LTD-17 ATHINON STREET, ERGATON INDUSTRIAL AREA, NICOSIA CYPRUS	CYPRUS	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/4891	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ASPEC TABLET	ASPIRIN+PARACETA MOL+CAFFEINE ANHYDROUS	150MG+250M G+300MG	REGAL PHARMACEUTICALS LTD-OFF BABA DOGO RD, RUARAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X500. 0 TABLET CONTAINER,1.0X 100.0 TABLET CONTAINER
NDA/MAL/HDP/4892	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	FLUFED COUGH FORMULA	MULTI-INGREDIENT	MULTI- INGREDIENT	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4895	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4899	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	CLOSERINE	CYCLOSERINE	250MG	CIPLA LTD -CIPLA LTD VERNA IND BT GOA 403722	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X40.0 CAPSULE CONTAINER
NDA/MAL/HDP/4901	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	AVELOX IV	MOXIFLOXACIN HCL	400MG/250M L	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE
NDA/MAL/HDP/4903	AGOG PHARMA LTD.	GITTOES PHARMACEUTICAL S LIMITED	CMT-TABLETS	MAGNESIUM TRISILICATE+DRIED ALUMINIUM HYDROXIDE+PEPPER MINT 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
NDA/MAL/HDP/4904	NOVO NORDISK	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/4905	XEPA-SOUL PATTINSON	DELMAW ENTERPRISES LIMITED	AVORAX CREAM	ACYCLOVIR	5%W/W	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE

NDA/MAL/HDP/4906	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	AVORAX TABLETS	ACYCLOVIR	200MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X5.0 TABLET STRIP
NDA/MAL/HDP/4908	NOVO NORDISK	STAR PHARMACEUTICALS LTD	MIXTARD 30 PENFILL	BIPHASIC ISOPHANE INSULIN (HUMAN)	100 I.U./ML	NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD	DENMARK	PARENTERAL ORDINARY CARTRIDGES	1.0X3.0 ML CARTRIDGE, 1.0X1.5 ML CARTRIDGE
NDA/MAL/HDP/4909	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXAGYL	METRONIDAZOLE	0.5%W/V	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4910	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	FLUZOL	FLUCONAZOLE	200MG	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4911	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	MOFILET-500	MYCOPHENOLATE MOFETIL	500MG	EMCURE PHARMACEUTICALS LIMITED -LANE NO.3 PHASE II SIDCO INDUSTRIAL COMPLEX BARI-BRAHMANA JAMMU ,181133	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4917	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL EVILINE FORTE SUSPENSION	MAGNESSIUM HYDROXIDE +ALUMINIUM HYDROXIDE+SIMETHICONE	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
NDA/MAL/HDP/4919	KOTRA PHARMA (M) SDN BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL FUSIDIC ACID- B CREAM	FUSIDIC ACID+BETAMETHASONE 17 VALERATE	2%,W/W,+0.1 % W/W	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/4922	KOPRAN LIMITED	TATA UGANDA LIMITED	CIPROQUIN-500	CIPROFLOXACIN	500MG	KOPRAN LIMITED-VILLAGE- SAVROLI (KHOPOLI), TALUKA- KHALAPUR, DIST. RAIGAD, MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4924	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	MULTIVIT TABLET	MULTIVITAMIN	MULTI-INGREDIENT	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER

NDA/MAL/HDP/4926	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	FOLIC ACID	FOLIC ACID	5MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4927	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	AZOPT	BRINZOLAMIDE	10MG/ML	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/4928	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	FOLIC ACID TABLETS	FOLIC ACID	5MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4929	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	15MG/ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/4931	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	FOLIC ACID TABLET	FOLIC ACID	5MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER
NDA/MAL/HDP/4932	MARTINDALE AND AURUM PHARMACEUTICAL	LABOREX UGANDA LIMITED	MORPHINE INJECTION	MORPHINE	10MG/ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X1.0 ML AMPOULE
NDA/MAL/HDP/4933	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	AZUDOX	DOXYCYCLINE HYDROCHLORIDE	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD -PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X100.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE BLISTER,1.0X500.0 CAPSULE CONTAINER,1.0X250.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER
NDA/MAL/HDP/4935	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	BACTROBAN OINTMENT	MUPIROCIIN	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

NDA/MAL/HDP/4936	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	COMBIFEN	IBUPROFEN + PARACETAMOL	400MG + 500MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4937	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	MOTILIUM	DOMPERIDONE	10MG	JANSSEN-CILAG-27 100 VAL DE REUIL, FRANCE	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0 TABLET CARTON,1.0X30.0 TABLET CARTON
NDA/MAL/HDP/4938	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/4939	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	FOLIREN	FOLIC ACID	5MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4941	GLAXO SMITH KLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	BEECHAMS POWDERS HOT LEMON	PARACETAMOL+PHENYLEPHEDRINE	600MG+10MG	SMITHLINE BEECHAM (NAIROBI)-NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X48.0X5.6 G SACHET,1.0X5.0X5.6 G SACHET
NDA/MAL/HDP/4943	ASTRAZENECA	MACNAUGHTON LIMITED	NOLVADEX	TAMOXIFEN	20MG	ASTRAZENECA UK LIMITED -ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4944	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	BENA EXPECTORANT	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + SODIUM CITRATE	14MG + 135MG + 57.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD-1-5 CHENG INDUSTRIAL ESTATE, 75250 MALEKA, MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/4945	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	FORMIT	METFORMIN	850MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4946	ESAPHARMA S.R.L..	BYAMAKA PHARMACEUTICAL COMPANY LTD	MOVATE	CLOBETASOL	0.05%W/W	ESAPHARMA S.R.L.VIA-VIA ALCIDE DE GASPERI, 23, MELZO MI, ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE

NDA/MAL/HDP/4948	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	FORMIT 1000	METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/4949	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN DRY COUGH DM	DEXTROMETHORPHAN HYDROBROMIDE	15MG/ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4950	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	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
NDA/MAL/HDP/4951	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN ORIGINAL	DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE	12.5 MG/5ML + 125 MG/5ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE,1.0X2.5 L BOTTLE
NDA/MAL/HDP/4952	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN WITH CODEINE	DIPHENHYDRAMINE HCL + AMMONIUM CHLORIDE + CODEINE PHOSPHATE	12.5MG/5ML +125MG/5ML +10MG/5ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/4953	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/4955	NIRMA LIMITED.	SUPER MEDIC LTD	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
NDA/MAL/HDP/4956	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	CONTRAPAQUE 30	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
NDA/MAL/HDP/4957	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MUMFER	IRON (111) POLYMALTOSE COMPLEX + FOLIC ACID	100MG + 500MCG	GLENMARK PHARMACEUTICALS LTD PLOT E-PLOT NO. E-37, 39, MIDC AREA, SATPUR, NASIK - 422 007, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY CHEWABLE COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4958	TROIKA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	BENZOSED	MIDAZOLAM	1MG/ML	TROIKA PHARMACEUTICALS LTD .SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/4959	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PAEDIATRIC LINCTUS	CHLORPHENIRAMINE / PHENYLEPHRINE / DEXTROMETHORPHAN	1MG/ 5MG/ 10MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/4962	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	BETAD	BETAMETHASONE DIPROPIONATE	0.05%W/W	S.KANT HEALTHCARE LTD-PLOT 1802, 1805, GIDC PHASE III VAPI 39179, GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X1.0X30.0 G TUBE, 1.0X1.0X15.0 G TUBE
NDA/MAL/HDP/4964	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS PLUS PAEDIATRIC SUSPENSION	CHLORPHENAMINE+ PHENYLEPHRINE+PARACETAMOL	IMG+5MG+16 0MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/4965	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	BETAFEN SYRUP	IBUPROFEN	100MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4966	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	CONTUS-650	CHLORPHENIRAMINE + PHENYLEPHRINE + PARACETAMOL	2MG + 5MG + 650MG	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X50.0 X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/4967	MEDIPHARM SALES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX JUNIOR	MULTI-INGREDIENT	MULTI-INGREDIENT	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEOGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE, 1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4968	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FRUSEMIDE INJECTION	FUROSEMIDE	10MG/ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE

NDA/MAL/HDP/4969	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	BENZATHINE PENICILLIN	BENZATHINE PENICILLIN	2.4 M.U	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X2.4 MU VIAL
NDA/MAL/HDP/4970	MEDIPHARM SALES (E.A) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	PIRITEX DRY COUGH SYRUP	DIPHENHYDRAMINE HCL/ DEXTROMETHORPHAN HBR/ PSEUDOEPHEDRINE HCL	14MG+15MG+30MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD, BWEYOGGERERE	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/4971	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	FRUSEMIDE TABLETS	FUROSEMIDE	40MG	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED-PLOT 9-12,DEWAN & SONS INDL. AREA, VEOOR,PALGHAR-401404. INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET STRIP,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4972	JOHNSON &JOHNSON (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	COOLMINT LISTERINE	MENTHOL + ALCOHOL 95%	0.02% + 4.58ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X250.0 ML CONTAINER,1.0X 500.0 ML CONTAINER
NDA/MAL/HDP/4973	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	PERGOVERIS	FOLLITROPIN ALFA/LUTROPIN ALFA	150 I.U/75 I.U	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 ML VIAL + 1*1ML VIAL OF WFI
NDA/MAL/HDP/4974	COSMOS LTD	ASTRA PHARMA (U) LIMITED	FRUSEMIDE TABLETS BP 40MG	FUROSEMIDE	40MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER
NDA/MAL/HDP/4975	FREDUN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	FRUSINA TABLETS	FUROSEMIDE	40MG	FREDUN PHARMACEUTICALS LTD-14,15,16 ZORBIA INDUSTRIAL COMPLEX VEOOR PALGHAR EAST INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X 1000.0 TABLET CONTAINER,1.0X 10.0 TABLET BLISTER
NDA/MAL/HDP/4976	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	PERGLIM 2	GLIMEPIRIDE	2MG	INVENTIA HEALTHCARE PVT. LTD.-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/4978	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	PERAZONE	DEXAMETHASONE	0.5MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/4979	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	FUROSEMIDE	FUROSEMIDE	10MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT LTD-N-118 M.I.D.C, TAAPUR,BOISAR,DIST.THANE MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/4982	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMAG TABLETS	MAGNESIUM TRISILICATE	370MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/4986	IDA FOUNDATION	KIMSY MEDS LTD	CO-TRIMOXAZOLE	CO-TRIMOXAZOLE	960MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/4990	IDA FOUNDATION	KIMSY MEDS LTD	COTRIMOXAZOLE	SULFAMETHOXAZOLE + TRIMETHOPRIM	800MG +160MG	MEDOPHARM -34B INDUSTRIAL AREA MALUR 563130	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/4995	ROYAL GROUP	HARLEYS UGANDA LIMITED	GENTABACT EYE/EAR DROPS	GENTAMYCIN SULPHATE	0.3%W/V	AHLCON PARENTERALS (I) LIMITED-SP-918,INDUSTRIAL AREA,PHASE III BHIWADI DIST, ALWAR (RAJASTHAN) INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/4998	MYLAN LABORATORIES LIMITED.	NORVIK ENTERPRISES LIMITED	HYAN	LEVONORGESTREL	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

NDA/MAL/HDP/4999	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	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 ML VIAL
NDA/MAL/HDP/5001	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	GENTAMICIN INJECTION	GENTAMYCIN	80MG/2ML	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/5002	ELI-LILLY EXPORT SA	LABOREX UGANDA LIMITED	HUMALOG MIX 25	INSULIN LISPRO + INSULIN LISPRO PROTAMINE	25I.U+75I.U	LILLY FRANCE SA-FRANCE	FRANCE	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL,1.0X5.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/5004	GLAXOSMITHKLINE LIMITED LIKONI	BETA HEALTHCARE UGANDA LIMITED	COFTA TABLETS	MULTI-INGREDIENT	N/A	GLAXOSMITHKLINE LIMITED - -78392-00507, VIWANDANI LIKONI ROAD NAIROBI KENYA,BETA HEALTHCARE INTERNATIONAL LTD - -PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY LOZENGES	1.0X100.0 TABLET CARTON,1.0X50.0 TABLET CARTON,1.0X150.0 TABLET CARTON
NDA/MAL/HDP/5005	MACK BROWN PHARMACEUTICALS PVT LTD	SHURIK LTD	COLD GO	PARACETAMOL+PHE NYLEPHRINE HYDROCHLORIDE+CHLORPHENIRAMINE MALEATE+CAFFEINE	325MG+10MG +2MG+30MG	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/5007	DELOBORIS PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	VIRUCID	ACYCLOVIR	200MG	AEGIS LIMITED -17, ATHINON STREET, ERGATES INDUSTRIAL AREA, 2643 ERGATES, P.O. BOX 28629, 2081, LEFKOSIA	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X25.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/5010	XEPA SOUL PATTISON (M) SDN BHD	DELMAW ENTERPRISES LIMITED	ZARIN CREAM	CLOTRIMAZOLE	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

NDA/MAL/HDP/5011	UNIMED	METAPLUS (U) LIMITED	COLDAFEX TABLETS	MULTI-INGREDIENT	MULTI-INGREDIENT	UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X50.0X4.0 TABLET STRIP,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5014	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	VERMOREX SUSPENSION	MEBENDAZOLE	100MG/5ML	J.B CHEMICALS & PHARMACEUTICALS LTD-128/1 GIDC ANKLESHWAR 393 022 GUJARAT INDIA,UNIQUE PHARMACEUTICAL LABORATORIES (A DIV. OF J.B CHEMICALS & PHARMACEUTICALS LTD)-216-219 GIDC INDUSTRIAL AREA PANOLI 394 116 DIST BHARUCH	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/5015	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP CAPSULES	PHENYLEPHRINE HYDROCHLORIDE+C HLORPHENIRAMINE	5MG+4MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X500.0 CAPSULE CONTAINER,1.0X1000.0 CAPSULE CONTAINER,1.0X8.0X12.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER,1.0X12.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5016	IDA FOUNDATION	KIMSY MEDS LTD	GENTAMYCIN INJECTION	GENTAMYCIN SULPHATE	40MG/ML	GLAND PHARMA LTD -D.P PALLY DUNDIGAL POST QUTBULLAPUR MANDAL RANGA REDDY DISTRICT HYDERABAD 500043	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE

NDA/MAL/HDP/5017	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP SYRUP	PARACETAMOL+PRO METHAZINE HYDROCHLORIDE+C ODEINE PHOSPHATE+PSEUDO EPHEDRINE HYDROCHLORIDE	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
NDA/MAL/HDP/5018	GLAXO WELLCOME (KENYA) LTD	ERIS LTD	VENTOLIN	SALBUTAMOL	100MCG	GLAXO WELLCOME PRODUCTION.-ZONE INDUSTRIELLE NO.2 23, RUE LAVOISIER 27000 EVREUX, FRANCE.	FRANCE	RECTAL SYSTEMIC METERED-DOSE PRESSURISED AEROSOLS	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/5019	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	COLOSPASMIN FORTE	MEBEVERINE	135MG	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)-EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO (E.I.P.C.O)	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X20.0 TABLET BLISTER
NDA/MAL/HDP/5020	GLAXO WELLCOME (KENYA) LTD	ERIS 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
NDA/MAL/HDP/5021	BAYER SCHERING PHARMA FRANCE	SURGIPHARM (U) LIMITED	COMBINATION 3	ETHINYL ESTRADIOL+ LEVONORGESTREL+F ERROUS 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
NDA/MAL/HDP/5023	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	COTREICH	CO-TRIMOXAZOLE	240MG/5ML	MEDRIECH STERILAB LTD.--ANALGHALLI, BANGLORE - 560062	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE, 1.0X60.0 ML BOTTLE
NDA/MAL/HDP/5025	THE MENTHOLATUM COMPANY LTD	HARLEYS UGANDA LIMITED	DEEP FREEZE COLD GEL	MENTHOL	2%W/W	THE MENTHOLATUM COMPANY LTD, TWYFORD,-TWYFORD, BENKSHIRE, E	UNITED KINGDOM	TOPICAL EXTERNAL GELS AND SOLS	1.0X35.0 G TUBE, 1.0X50.0 G TUBE, 1.0X100.0 G TUBE
NDA/MAL/HDP/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

NDA/MAL/HDP/5028	THE MENTHOLATUM COMPANY LTD TWY	HARLEYS UGANDA LIMITED	DEEP HEAT SPRAY	MULTI-INGREDIENT	MULTI-INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,-1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL PRESSURISED AEROSOLS	1.0X150.0 ML CANNISTER
NDA/MAL/HDP/5030	PFIZER LAB LTD	LABOREX UGANDA LIMITED	SOLU-MEDROL	METHYLPREDNISOLONE HEMISUCCINATE	125MG/2ML	PFIZER MANUFACTURING -NV/NA, RIJKSWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 ML VIAL,1.0X8.0 ML VIAL
NDA/MAL/HDP/5031	THE MENTHOLATUM COMPANY LTD	HARLEYS UGANDA LIMITED	DEEP HEAT RUB	MULTI-INGREDIENT	MULTI-INGREDIENT	THE MENTHOLATUM COMPANY LTD, TWYFORD,-1 REDWOOD AVENUE, PEEL PARK CAMPUS EAST KILBRIDE, G74 SCOTLAND	UNITED KINGDOM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X35.0 G TUBE,1.0X67.0 G TUBE,1.0X100.0 G TUBE
NDA/MAL/HDP/5032	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	DELATED DRY COUGH SYRUP (NON DROWSY)	DEXTROMETHORPHAN	7.5MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5033	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAR ENTERPRISES LIMITED	MEBFIL TABLETS	MEBENDAZOLE	100MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/5034	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	MEBENDAZOLE TABLET	MEBENDAZOLE	100MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5035	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	MEBENDAZOLE	MEBENDAZOLE	100MG/5ML	MEDICAMEN BIOTECH LTD - -SP-1192 A&B PHASE IV INDUSTRIAL AREA BHIWADI 301019 DIST. ALWAR (RAJASTHAN) - INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/5038	UNICHEM LABORATORIES LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	M-CAM TABLETS	MELOXICAM	15MG	UNICHEM LABORATORIES LIMITED-UNICHEM LABORATORIES LIMITED. UNIT II, VILLAGE BHATAULI KALAN, BADDI, DIST. SOLAN PIN CODE 173 205, HIMACHAL PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5039	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	SURGIPHARM (U) LIMITED	GILOBA	GINKGO 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

NDA/MAL/HDP/5040	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-MEDROL	METHYLPREDNISOLONE ACETATE	40MG/ML	PFIZER MANUFACTURING -NV/NA, RIJKSWEWEG 12 2870, PUURS	BELGIUM	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL, 1.0X2.0 ML VIAL, 1.0X5.0 ML VIAL
NDA/MAL/HDP/5041	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	MAXITROL	DEXAMETHASONE/NEOMYCIN/POLYMYXIN B	0.1%W/W +0.1%W/W+6000 I.U	ALCON COUVREUR NV-RIJKSWEWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC OINTMENTS	1.0X3.5 G TUBE
NDA/MAL/HDP/5042	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSATRIM DS TABLETS	CO-TRIMOXAZOLE	960MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X500.0 TABLET CONTAINER, 1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5043	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	MAXITROL	DEXAMETHASONE/NEOMYCIN/POLYMYXIN B	0.1%W/W+3500I.U/ML+6000I.U/ML	ALCON COUVREUR NV-RIJKSWEWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5044	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	DEPO-PROVERA	MEDROXYPROGESTERONE ACETATE	150MG/ML	PHARMACIA AND UPJOHN S.P.A-RIJKSWEWEG 12, B-2870 PUURS	BELGIUM	PARENTERAL ORDINARY I M VIALS	1.0X3.5 ML VIAL, 1.0X1.0 ML VIAL
NDA/MAL/HDP/5045	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	MAXIT TABLETS	DICLOFENAC	50MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5046	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	GIZLAN PLUS 150/12.5	IRBESARTAN+HYDROCHLOROTHIAZIDE	150MG+12.5 MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/5047	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/5048	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/5049	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	GIZLAN PLUS 300/12.5	IRBESARTAN/HYDROCHLOROTHIAZIDE	300MG/12.5MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP

NDA/MAL/HDP/5050	NORVATIS PHARMA AG-SWITZERLAND	KARURI PHARMACEUTICALS LTD.	MAXIDEX	DEXAMETHASONE	0.1%W/V	ALCON COUVREUR NV-RIJKSWEG 14, B-2870 PUURS BELGIUM	BELGIUM	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5051	CADILA HEALTHCARE LIMITED SARKHEJ	ABACUS PHARMA (AFRICA) LIMITED	DERIHALER	SALBUTAMOL	100CMG/DOSE	CADILA HEALTHCARE LTD---SARKHEJ-PLOT 417,419,420, SARKHEJ-BAVLA NH NO.8A,VILLAGE: MORAIYA TAL: SANAND DISTRICT AHMEDABAD 382210	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/5052	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	GLAMIDE TABLETS	GLIBENCLAMIDE	5 MG	LA-MED HEALTHCARE PVT LTD-1389 TRASAD ROAD, DHOLKA, AHMEDABAD, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	2.0X50.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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,0186PRETORIA-PRIVATE BAG X516,SILVERTON,0127,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0 TABLET BLISTER,1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5055	GLAXOSMITHKLINE LTD UK	ERIS 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
NDA/MAL/HDP/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,0186PRETORIA-PRIVATE BAG X516,SILVERTON,0127,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X350.0 ML BOTTLE,1.0X150.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE
NDA/MAL/HDP/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,0186PRETORIA-PRIVATE BAG X516,SILVERTON,0127,SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X4.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5059	AVENTIS PHARMA (PTY) LTD SOUTH AFRICA	LABOREX UGANDA LIMITED	MAALOX PLUS SUSPENSION	MAGNESIUM HYDROXIDE + ALUMINIUM HYDROXIDE	665MG/5ML + 200MG/5ML	WINTHROP PHARMACEUTICALS (PTY) LTD.- PLOT NO.315 WALTLOO ROAD,PRETORIA,0186PRETORIA-PRIVATE BAG X516,SILVERTON,0127,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X350.0 ML BOTTLE,1.0X150.0 ML BOTTLE,1.0X100.0 ML BOTTLE,1.0X500.0 ML BOTTLE
NDA/MAL/HDP/5061	TATA UGANDA LIMITED	TATA UGANDA LIMITED	MAGNESIUM SULPHATE	MAGNESIUM SULPHATE	50MG/ML	GLAND PHARMA LIMITED 143-148-SURVEY NOS. 143-148, 150&151, NEAR GANDIMAISAMMA CROSS ROADS. RANGA REDDY DISTRICT HYDERABAD 500043	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/5066	M.J.BIOPHARM PVT LTD	TATA UGANDA LIMITED	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE SODIUM PHOSPHATE	4MG/ML	M.J. BIOPHARM PVT. LTD-L-7, M.I.D.C. , TALOJA, DISTRICT RAIGAD - 410 208 NAVI MUMBAI, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X100.0X1.0 ML AMPOULE
NDA/MAL/HDP/5067	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	LUFENAC	DICLOFENAC	25MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/5068	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE SODIUM PHOSPHATE	8MG/2ML	NINGBO DAHONGYING PHARMACEUTICAL CO LTD.-NO. 3986, HI-TECH PARK MINZHU ROAD, NINGBO CITY, ZHEJIANG	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/5070	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-60	ENOXAPARIN SODIUM	60MG/0.6ML	EMCURE PHARMACEUTICALS LTD -PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/5071	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	LOMOH-40	ENOXAPARIN SODIUM	40MG/0.4ML	EMCURE PHARMACEUTICALS LTD -PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/5072	CYANO PHARMA(P)	RENE PHARMACY LTD	DEXAMETHASONE TABLETS	DEXAMETHASONE	0.5MG	CYANO PHARMA(P)-115-C IND ESTATE POLO GROUND INDORE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/5073	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA EYE/EAR DROP	DEXAMATHASONE SODIUM PHOSPHATE+NEOM YCIN 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

NDA/MAL/HDP/5074	CADILA HEALTH CARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA INJECTION	DEXAMETHASONE DISODIUM PHOSPHATE	4MG/ML	CADILA HEALTH CARE LTD-SARKHEJ BAVLA N.H NO. 8A MORAIJA, TAL, SANARD, AHMEDAD 382210, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL
NDA/MAL/HDP/5075	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	DEXONA TABLETS	DEXAMETHASONE	0.5MG	CADILA HEALTHCARE LIMITED SARKHEJ-SARKHEJ-BAVLA N.H NO.8A, N.H NO.8A,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET STRIP
NDA/MAL/HDP/5076	XEPA SOUL PATTISON (M) SDN BHD	DELMAR ENTERPRISES LIMITED	DEXTRACIN EYE DROPS	DEXAMETHASONE + NEOMYCIN	0.1MG + 0.5MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5078	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	GLANDIN E2 VAGINAL	DINOPROSTONE	3MG	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	VAGINAL TABLETS	1.0X1.0 TABLET STRIP
NDA/MAL/HDP/5079	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	GLEMONT CT 5	MONTELUKAST	5MG	GLENMARK PHARMACEUTICALS LTD-VILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5080	GENO PHARMACEUTICALS PVT LTD	HARLEYS UGANDA LIMITED	LOBAK	DICLOFENAC/PARACETAMOL/CHLORZOXAZONE	50MG/325MG /250MG	GENO PHARMACEUTICALS LTD--PHARMACEUTICAL COMPLEX, TIVIM INDUSTRIAL ESTATE, P.O. KARASWADA, MAPUSA, GOA 403526	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5086	FOURRTS (INDIA) LABORATORIES PVT LTD	DELMAR ENTERPRISES LIMITED	GLIFIL M FORT	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG+500MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5087	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIABEN TABLETS	GLIBENCLAMIDE	5MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5092	MICRO LABS LTD 92 SIPCOT	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIAPRIDE	GLIMEPIRIDE	2MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSUR R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5093	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	LIPODAR 10	ATORVASTATIN	10MG	DAR AL DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5095	MICRO LABS LTD	LABOREX UGANDA LIMITED	DIAPRIDE PLUS	GLIMEPIRIDE + METFORMIN	1MG + 500MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5097	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	GLUCOLIFE	GLUCOSE	5%W/V	EUROLIFE HEALTHCARE PVT LTD-BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5098	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DIARIV	DI-iodo HYDROXYQUINOLIN E/ PHTHALYL SULPHATHIAZOLE/ HOMATROPINE / STREPTOMYCIN	125MG/ 150MG/ 1MG/ 100MG	RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/5099	COSMOS LTD	ASTRA PHARMA (U) LIMITED	GLUCOMET	METFORMIN	500MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5100	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	L-GENTA	GENTAMICIN	0.3%W/V	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/5101	F. HOFFMANN- LA ROCHE LTD	LABOREX UGANDA LIMITED	LEXOTANIL	BROMAZEPAM	1.5MG	F. HOFFMANNLA ROCHE LTD BASEL, SWITZERLAND-GRENZACHERSTRASSE 124 4070, BASEL	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5102	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 500MG	METFORMIN	500MG	MERCK SANTÉ-2, RUE DU PRESOIR VERT F 45400, SEMOY,NKUNZI PHARMACEUTICALS (PTY) LTD.-259 DAVIDSON ROAD CNR PEDDIE STREET, WADEVILLE EST. 1 GERMISTON 1422	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X500.0 TABLET CONTAINER,1.0X 6.0X15.0 TABLET BLISTER,1.0X30.0 TABLET BLISTER
NDA/MAL/HDP/5103	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 1000MG	METFORMIN	1000MG	MERCK SANTE S A S,2RUE DU PRESOIR VERT,SEMOY & MERCK PHARMACEUTICAL MANUFACTURING PVT LTD-259 DAVIDSON ROAD,WADEVILLE,GERMISTON	FRANCE	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER
NDA/MAL/HDP/5104	NOVO NORDISK PHARMA GULF FZ-LC	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	LEVEMIR FLEXPEN	INSULIN DETEMIR	100 I.U/ML	NOVO NORDISK A/S - NOVO ALLE DK-2880 BAGSVAERD	DENMARK	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN

NDA/MAL/HDP/5106	ESAPHARMA S.R.L..	BYAMAKA PHARMACEUTICAL COMPANY LTD	LEMONVATE CREAM	CLOBETASOL PROPIONATE	0.05%W/W	ESAPHARMA S.R.L.VIA-VIA ALCIDE DE GASPERI, 23, MELZO MI, ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE
NDA/MAL/HDP/5107	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	INDOREN CAPSULES	INDOMETHACIN	25MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/5110	NIRMA LIMITED.	SUPER MEDIC LTD	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
NDA/MAL/HDP/5112	WIN-MEDICARE PVT LTD	SURGIPHARM (U) LIMITED	DICLOMOL SR TABLETS	DICLOFENAC SODIUM	100MG	WIN MEDICARE PVT LIMITED-MEERUT, MUZAFFARNAGER ROAD, MODIPURAM – 250110, UTTAR PRADESH -INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5114	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	LATONE MULTIVITAMIN	MULTIVITAMIN	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
NDA/MAL/HDP/5115	AGOG PHARMA LTD.	GITTOES PHARMACEUTICAL S LIMITED	INDOS-25(THANE)	INDOMETHACIN	25MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,20.0 X5.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5117	VENUS REMEDIES LIMITED	HARLEYS UGANDA LIMITED	LASTINEM	IMIPENEM + CILASTATIN	500MG + 500MG	VENUS REMEDIES-UNIT II HILLTOP INDUSTRIAL ESTATES JHARMAJRI EPIP PHASE 1 BHOTOLI KALA BADDI INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/5119	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	KONTRAC 200	MISOPROSTOL	200MCG	FOURRTS INDIA LABORATORIES PVT. LIMITED VANDALUR ROAD, KELAMBAKKAM 603103, CHENNAI, TAMIL NADU, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X2.0 TABLET STRIP,1.0X10.0X 10.0 TABLET BLISTER

NDA/MAL/HDP/5120	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 500 TABLETS	METFORMIN	500MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/5121	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	DICLORAN GEL	DICLOFENAC DIETHYLAMMONIUM	1%W/W	UNIQUE PHARMACEUTICALS LABS (A DIV OF J.B CHEMICALS & PHARMACEUTICAL LTD)--304-308 ,GIDC , PANOLI 394116	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X50.0 G TUBE,1.0X20.0 G TUBE
NDA/MAL/HDP/5122	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	KOFAREST SYRUP	SALBUTAMOL SULPHATE/AMBROXOL SULPHATE/GUAFENESIN/MENTHOL	2MG+30MG+100MG+5MG/10ML	CENTAUR PHARMACEUTICALS LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/5123	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GLYFORMIN 850 TABLETS	METFORMIN	850MG	REMEDICA LIMITED -AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE. LIMASSOL, CYPRUS 3056, CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5124	GLAXOSMITHKLINE LTD BELGIUM	ERIS LTD	INFANRIX-HEXA	DIPHTHERIA + PERTUSSIS + BORDETELLA/PERTUSSIS + PERTUSSIS + HAEMAGGLUTININ + PERTACTIN + (HEPATITIS B/POLIOVIRUS TYPE 1 +2 +3)	NLT 30 IU + NLT 40IU + 25MCG + 25MCG + 8MCG + 10MCG + (TYPE 1 40D +TYPE 2 + TYPE 3)	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X0.5 ML VIAL (1 DOSE)
NDA/MAL/HDP/5125	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	GLYGESIC FORTE RHUMETIC CREAM	MULTI INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/5127	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	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
NDA/MAL/HDP/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
NDA/MAL/HDP/5129	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	KLEEN ENEMA	DISODIUM BISPHOSPHATE/ SODIUM PHOSPHATE	19.2G+7.2G/120ML	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	RECTAL SYSTEMIC ENEMA LIQUIDS	1.0X135.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/5132	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	KETROZOL 200 TABLETS	KETOCONAZOLE	200MG	REMEDICA LIMITED,-LIMASSOL INDUSTRIAL ESTATE, AHARNON ST, P.O. BOX 51706,3508 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5133	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GONAL-F PEN 900IU/1.5ML(66MCG/1.5ML)	FOLLITROPIN ALFA	66MCG/1.5ML	MERCK SERONO S.A. (MSA) -1170 SUCCURSALE D'AUBONNE ZONE INDUSTRIELLE DE L'OURIETTAZ, SWITZERLAND	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.
NDA/MAL/HDP/5134	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING COUGH TABLETS	MULTIINGREDIENT	N/A	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON
NDA/MAL/HDP/5135	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	KETOZ	KETOCONAZOLE	2%W/W	SK ANT HEALTHCARE LTD-1802-1805 GIDC PHASE III, VAPI-396195 GUJARAT, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/5136	BETA HEALTHCARE INTERNATIONAL LTD	BETA HEALTHCARE UGANDA LIMITED	GOODMORNING LUNG TONIC	MULTIINGREDIENT	N/A	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X50.0 ML BOTTLE
NDA/MAL/HDP/5137	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	KETOREN	KETOCONAZOLE	200MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5139	NOVO NORDISK	STAR PHARMACEUTICALS LTD	INSULATARD HM PENFILL	ISOPHANE INSULIN (HUMAN)	100I.U/ML	NOVO NORDISK PHARMA-NOVO ALLE	DENMARK	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X1.5 ML CARTRIDGE,1.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/5140	PFIZER LABORATORIES PTY LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	200MG	FAREVA AMBOISE - -ZONE INDUSTRIELLE, 29 ROUTE DES INDUSTRIES, 37530 POCE SUR CISSE, FRANCE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/5141	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	KETOMAC SHAMPOO	KETOCONAZOLE	2%W/V	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	75.0 ML BOTTLE
NDA/MAL/HDP/5142	REGAL PHARMACEUICALS LTD	REGAL PHARMA (U) LTD	INTAMINE CREAM	MEPYRAMINE MALEATE	2%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X25.0 G TUBE,1.0X400.0 G TUBE
NDA/MAL/HDP/5143	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 25MG	METOPROLOL	25MG	ASTRA ZENECA AB-GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/5144	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOCONAZOLE 200MG	KETOCONAZOLE	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
NDA/MAL/HDP/5146	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 100MG	METOPROLOL	100MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5147	ASTRA ZENECA	MACNAUGHTON LIMITED	BETALOC ZOK - 50MG	METOPROLOL	50MG	ASTRA ZENECA AB-GARTUNAVGEN SE 151 58 SODAERTAJJE SWEDEN	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5148	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	BETANASE TABLETS	GLIBENCLAMIDE	5MG	CADILA HEALTHCARE LIMITED--KUNDAIM INDUSTRIAL ESTATE, PLOT NO. 203-213, KUNDAIM,GOA-403 115, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X5.0X3.0X10.0 TABLET BLISTER,1.0X100.0.0 TABLET CONTAINER,1.0X2.0X50.0 TABLET BLISTER
NDA/MAL/HDP/5149	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE SYRUP	DIMENHYDRINATE	12.5MG/4ML	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE

NDA/MAL/HDP/5150	GLENMARK PHARMACUTICALS LTD	STAR PHARMACEUTICALS LTD	KETO PLUS SHAMPOO	KETOCONAZOLE/ZINC PYRITHIONE	1%W/V+2%W/V	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	60.0 ML BOTTLE
NDA/MAL/HDP/5151	SOLVAY PHARMACEUTICALS BV	STAR PHARMACEUTICALS LTD	BETASERC	BETAHISTINE	8MG	SOLVAY PHARMACEUTICALS -VEERWENG 12,8121AA,DIST. THE NETHERLANDS	NETHERLANDS	ORAL SOLID ORDINARY TABLETS	4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/5153	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	GRAVINATE TABLETS	DIMENHYDRINATE	50MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5154	BETA HEALTHCARE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/5156	PHARMATHEN LTD	GOODMAN INTERNATIONAL LTD	IRIFONE GEL	ETOFENAMATE	5%W/W	PHARMATHEN LTD.-6 DERVENAKION STR. 153 51 PALLINI-GREECE	GREECE	TOPICAL EXTERNAL OTHER GELS/SOLS	50.0 G CONTAINER,100.0 G CONTAINER
NDA/MAL/HDP/5157	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	BETAVEL N	BETAMETHASONE+N EOMYCIN 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
NDA/MAL/HDP/5158	NIRMA LIMITED.	SUPER MEDIC LTD	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
NDA/MAL/HDP/5162	VENUS REMIDIES LTD	AARON PHARMACEUTICALS LTD	IRINOL	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	20MG/ML	VENUS REMIDIES 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
NDA/MAL/HDP/5163	ROTEX MEDICA GBH ARZNEIMITTELI	GITTOES PHARMACEUTICALS LIMITED	KETAMINE HYDROCHLORIDE INJECTION	KETAMINE HYDROCHLORIDE	50MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY VIALS	10.0 ML VIAL
NDA/MAL/HDP/5164	COSMOS LTD	ASTRA PHARMA (U) LIMITED	BROMSAL EXPECTORANT	SALBUTAMOL SULPHATE+BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+MENTHOL	1MG+2MG+50MG+0.5MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/5165	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	GRISEOFULVIN 500 TABLETS	GRISEOFULVIN	500MG	REMEDICA LIMITED-LIMASSOL INDUSTRIAL ESTATE, AHAR	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5166	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICALS LIMITED	KETAMINE HYDROCHLORIDE	KETAMINE HYDROCHLORIDE	50MG/ML	UMEDICA LABORATORIES PVT LTD-PLOT NO. 221, 2ND PHASE, GIDC, VAPI 396195, GUJARAT. INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/5167	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	BRUSTAN TABLETS	IBUPROFEN + PARACETAMOL	400MG + 300MG	SUN PHARMACEUTICALS IND. LTD-B-2, MADAKAI INDUSTRIAL ESTATE, PONDA, GOA-403404, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5169	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GVGYL SUPPOSITORY	METRONIDAZOLE BP	500MG	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/5170	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	CANDITRAL CAPSULE	ITRACONAZOLE	100MG	GLENMARK PHARMACEUTICALS LTD-PLOT NO E -37, 39 ,D	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0 CAPSULE STRIP
NDA/MAL/HDP/5171	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	KETAMAX-50	KETAMINE	50MG/ML	TROIKAA PHARMACEUTICALS LIMITED-C-1 SARA INDUSTRIAL ESTATE, SELAQUI, DEHRADUN- 248197, UTTARAKHAND, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/5177	YURIA PHARM LTD	YURIA PHARM EAST AFRICA LIMITED	ISONIAZID	ISONIAZID	100MG/5ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/5178	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	CARBOTEEN	CARBOPLATIN	450MG/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
NDA/MAL/HDP/5179	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 200MG CAPSULES	CEFIXIME TRIHYDRATE	200MG	PHARMA INTERNATIONAL CO.,-AL-QASTAL AREA, AIRPORT ROAD, 11941, AMMAN	JORDAN	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X8.0 CAPSULE BLISTER
NDA/MAL/HDP/5180	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (PAEDIATRIC)	EPHEDRINE HYDROCHLORIDE	5MG/ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/5181	JASSEN-CILAG (PTY) LTD	LABOREX UGANDA LIMITED	GYNO-DAKTARIN OVULES	MICONAZOLE NITRATE	400MG	JANSSEN PHARMACEUTICAL PTY LTD-15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	VAGINAL SUPPOSITORIES	1.0X3.0 OVULE BLISTER

NDA/MAL/HDP/5182	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	ISORYN DROPS (ADULT)	EPHEDRINE HYDROCHLORIDE	10MG/ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/5183	PHARCO B PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CAPSULES	MICONAZOLE NITRATE	400MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL SUPPOSITORIES	1.0X3.0 CAPSULE BLISTER
NDA/MAL/HDP/5184	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	GYNOZOL VAGINAL CREAM	MICONAZOLE NITRATE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	VAGINAL CREAMS	1.0X40.0 G TUBE
NDA/MAL/HDP/5185	CENTAUR PHARMACEUTICALS LTD	GITTOES PHARMACEUTICALS LIMITED	HB FORTE	MULTI INGREDIENT	N/A	CENTAUR PHARMACEUTICALS PVT LTD-PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE, 1.0X250.0 ML BOTTLE
NDA/MAL/HDP/5186	TROIKAA PHARMACEUTICALS LTD	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
NDA/MAL/HDP/5188	AGOG PHARMA LTD.	GITTOES PHARMACEUTICALS LIMITED	ITRAZ CAPSULES	ITRACONAZOLE	100MG	AGOG PHARMA LTD-PLOT NO.33, SECTOR II, VASAI, TALUKA INDL CO-OP ESTATE LTD, GAURAI PADA, VASAI(E) DIST. THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X5.0 CAPSULE BLISTER, 1.0X6.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5190	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	HICLOR	CEFACLOX	250MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/5191	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYBETASONE EYE DROPS	BETAMETHASONE	1MG/ML	IVEE INFUSIONS EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE, LR NO.18474/84, ATHI RIVER, KENYA	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5192	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYDEXGENT EYE/EAR DROPS	DEXAMETHASONE/G ENTAMICIN	0.1% & 0.3%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84, ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER, KENYA	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5193	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYDEXNEOCIN EYE DROPS	DEXAMETHASONE/N EOMYCIN	0.1% & 0.35%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84, ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER, KENYA	KENYA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE, 1.0X5.0 ML BOTTLE

NDA/MAL/HDP/5194	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYDEXONE EYE DROPS	DEXAMETHASONE	0.1%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	5.0 ML BOTTLE
NDA/MAL/HDP/5195	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYFRIN P NASAL DROPS	EPHEDRINE HYDROCHLORIDE	0.5%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE,1.0X10.0 ML BOTTLE
NDA/MAL/HDP/5196	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYFRIN NASAL DROPS	EPHEDRINE HYDROCHLORIDE	1%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	NASAL TOPICAL DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/5197	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYGENTACIN EYE/EAR DROP	GENTAMICIN SULPHATE	0.3%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	5.0 ML BOTTLE,10.0 ML BOTTLE,7.5 ML BOTTLE
NDA/MAL/HDP/5198	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	HICLOR	CEFACLOR	500MG	HILTON PHARMA (PVT) LTD-PLOT 13 SECTOR 15 KORANGI INDUSTRIAL AREA KARACHI	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/5199	LABORATORY AND ALLIED LTD	HARLEYS UGANDA LIMITED	HYCORUM OINTMENT	HYDROCORTISONE	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
NDA/MAL/HDP/5200	COSMOS LTD	ASTRA PHARMA (U) LIMITED	HYDRALAZINE TABLETS B.P 25MG.	HYDRALAZINE HYDROCHLORIDE	25MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5201	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM BENDAZOLE	MEBENDAZOLE	100MG	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X100.0X10.0 TABLET BLISTER,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5202	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	HYDROCORT INJECTION	HYDROCORTISONE 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
NDA/MAL/HDP/5203	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM METRO	METRONIDAZOLE	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,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5204	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM METRO	METRONIDAZOLE BENZOATE	200MG/5ML	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/5205	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-VENT	SALBUTAMOL	4MG	KAMPALA PHARMACEUTICALS INDUSTRIES- PLOT NO M44B STRETCHER ROAD INTINDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET JAR,1.0X500.0 TABLET JAR,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/5206	TATA UGANDA LIMITED	TATA UGANDA LIMITED	DIGOXIN INJECTION BP	DIGOXIN	0.25MG/ML	GLAND PHARMA LTD .-D.P. PALLY, SURVEY 143-148, 150&	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/5211	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DINAC GEL	DICLOFENAC	1%W/W	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/5214	NIRMA LIMITED.	SUPER MEDIC LTD	NIRMET	METRONIDAZOLE	500MG/100ML	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5215	J.B CHEMICALS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	METROGYL TABLETS	METRONIDAZOLE	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
NDA/MAL/HDP/5221	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	75MG/3ML	NINGBO DAHONGYING PHARMACEUTICAL CO.LTD-NO. 396 MINGZHU ROAD, HI-TECH PARK, NINGBO CITY ZHEJIANG PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X3.0 ML AMPOULE

NDA/MAL/HDP/5222	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	EMTRICITABINE+TENOF OVIR DF	EMTRICITABINE/TEN OFOVIR	200MG/300MG	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
NDA/MAL/HDP/5224	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EMTRICITABINE+TENOF OVIR DISOPROXIL FUMERATE	EMTRICITABINE/TEN OFOVIR DISOPROXIL FUMERATE	200MG/300MG	AUROBINDO PHARMA LTD UNIT III- AUROBINDO PHARMA LTD UNIT III SURVEY NO. 313 BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT (A.P)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5226	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) LIMITED	EMTRICITABINE+TENOF OVIR DISOPROXIL FUMERATE	EMTRICITABINE+TEN OFOVIR DISOPROXIL FUMERATE	200MG/300MG	HETERO DRUGS LTD-UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055,HETERO LABS LTD (UNIT-V)- SY.NO.438,439,440 & 458 APIIC FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOONNAGAR DISTRICT, ANDHRA PRADESH - INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5228	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	DICLOGENTA	DICLOFENAC SODIUM+GENTAMICIN SULPHATE	1MG/ML+3MG/ML	CENTAUR PHARMACEUTICALS PVT LTD -- PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/5231	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL 10	ENALAPRIL MALEATE	10MG	INTAS PHARMACEUTICALS LTD-PLOT 457/458, SARKHEJ BAVLA HIGHWAY MATODA 382 210 TAL: SANAND, AHMEDABAD, INDIA ,INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5232	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ENAPRIL-5	ENALAPRIL MALEATE	5MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5233	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ENVAS 10 MG TABLETS	ENALAPRIL	10MG	CADILA PHARMACEUTICALS LTD DHOLKA ...- SURVEY NO. 1389, DHOLKA – 387 810, AHMEDABAD, GUJARAT STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5234	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ENVAS 5MG TABLETS	ENALAPRIL MALEATE	5MG	CADILA PHARMACEUTICALS LTD DHOLKA ...- SURVEY NO. 1389, DHOLKA – 387 810, AHMEDABAD, GUJARAT STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5235	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	DICLORAN DELAYED-RELEASE TABLETS	DICLOFENAC SODIUM	50MG	UNIQUE PHARMACEUTICALS LABORATORIES-- SURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN –PLOT NO. 215-219, 396 210 INDIA	INDIA	ORAL SOLID RETARD ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/5236	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ETHIONAMIDE TABLETS USP	ETHIONAMIDE	250MG	CIPLA LTD-UNIT I & II A-32 & A-42 MIDC PATALGANGA 410220 DIST-RAIGAD, MAHARASHTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100. 0 TABLET CONTAINER
NDA/MAL/HDP/5237	EUROLIFE HEALTHCARE PVT LIMITED	AIVEEN (U) LIMITED	EUROCIP	CIPROFLOXACIN	200MG/100ML	EUROLIFE HEALTHCARE PVT LTD- BHAGWANPUR ROAD, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5242	SHAIGAN PHARMACEUTICALS LTD	HEALTHCARE LTD.	ERGOMIN	METHYLERGOMETRINE MALEATE	0.125MG	SHAIGAN PHARMACEUTICALS (PVT) LTD- 14TH KM, ADYALA ROAD, RAWALPINDI- PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X150.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER
NDA/MAL/HDP/5243	IND SWIFT LTD	TATA UGANDA LIMITED	EZO 20	ESOMEPRAZOLE MAGNESIUM	20MG	IND-SWIFT-LTD,-GLOBAL BUSINESS UNIT, JAWAHARPUR, OFF NH-21 DERABASSI	INDIA	ORAL SOLID RETARD TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5245	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	FABUTAS-40	FEBUXOSTAT	40MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5248	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMPI	AMPICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,500.0 CAPSULE CONTAINER,250.0 CAPSULE CONTAINER,1.0X10.0 CAPSULE CONTAINER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/5249	EMCURE PHARMACEUTICALS LTD	HARLEYS UGANDA LIMITED	ENCIFER	IRON SUCROSE	100MG/5ML	EMCURE PHARMACEUTICALS LTD -PLOT NO. P-1 ITBT PARK PHASE II MIDC HINJWADI PUNE 411057	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE
NDA/MAL/HDP/5250	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOLIN SYRUP	SALBUTAMOL + AMMONIUM CHLORIDE	2MG/5ML +100MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/5251	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	DIFLUCAN	FLUCONAZOLE	150MG	PFIZER PGM -AMBROISE ZONE INDUSTRIELLE 29 ROUTE DES INDUSTRIES 37530 POCE SUR CISSE	FRANCE	ORAL SOLID ORDINARY CAPSULES	1.0X1.0 CAPSULE BLISTER
NDA/MAL/HDP/5252	CIPLA LIMITED.	QUALITY CHEMICALS LTD - HUMAN	ENCLEX-40	ENOXAPARIN SODIUM	40MG/0.4ML	CIPLA LTD.-VERNA IND. ESTATE GOA 403 722 INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X2.0X0.4 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/5253	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCOZOL SUSPENSION	BENZOYL METRONIDAZOLE	200MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/5254	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	FARMORUBICIN RD	EPIRUBICIN HYDROCHLORIDE	10MG	PHARMACIA AND UPJOHN S.P.A.-EUROPE	EUROPE	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X10.0 ML VIAL
NDA/MAL/HDP/5255	GLAXOSMITHKLINE LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO LEMONFRUIT SALT	MULTI-INGREDIENT	MULTI-INGREDIENT	GLAXO SMITH KLINE LTD-LIKONI RD, INDUSTRIAL AREA,NAIROBI KENYA,GLAXOSMITHKLINE-CAPE TOWN, S.A	SOUTH AFRICA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X8.0X4.5 G SACHET,1.0X10.0 X4.5 G SACHET,1.0X48.0 X4.5 G SACHET

NDA/MAL/HDP/5256	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROFOS INJECTION	BETAMETHASONE DISODIUM PHOSPHATE + BETAMETHASONE DIPROPIONATE	2MG + 5MG/ML	MSD (PTY) LTD- LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA,SCHERING-PLOUGH LABO N.V-- INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	BELGIUM	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/5258	MEDIPHARM INDUSTRIES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ERYMED ORAL SUSPENSION	ERYTHROMYCIN	125MG/5ML	MEDIPHARM INDUSTRIES (E.A) LTD-PLOT 65, KAKAJJO ROAD (BWEYOGGERERE)	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5259	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CARDINOL TABLET	ATENOLOL	100MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X14.0 TABLET STRIP
NDA/MAL/HDP/5260	KAMPALA PHARMACEUTICAL INDUSTRIES LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	ERYMYCIN	ERYTHROMYCIN ESTOLATE	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/5263	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROSALIC OINTMENT	BETAMETHASONE + SALICYLIC ACID	0.5 %W/W + 0.3 %W/W	SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30, ZONE A 2220 HEIST-OP-DEN-BERG	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 MG TUBE
NDA/MAL/HDP/5265	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIPROSONE OINTMENT	BETAMETHASONE DIPROPIONATE	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
NDA/MAL/HDP/5267	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	ERYTHROMYCIN STEARATE	ERYTHROMYCIN 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
NDA/MAL/HDP/5268	MISSION PHARMA A/S INDIA	JOINT MEDICAL STORE (UPMB - UCMB)	ERYTHROMYCIN STEARATE TABLETS	ERYTHROMYCIN	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
NDA/MAL/HDP/5269	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	DIVAA OD 500	DIVALPROEX	500MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/5274	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	ECOZOLE	ECONAZOLE	150MG	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	VAGINAL TABLETS	1.0X3.0 PESSARY STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/5276	F.HOFFMANN-LA ROCHE LTD	LABOREX UGANDA LIMITED	DORMICUM INJECTION	MIDAZOLAM	5MG/5ML	F. HOFFMAN LA ROCHE LTD-CH-4070 BASEL GRENZACHERSTRASSE 124, 4058 BASEL	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE
NDA/MAL/HDP/5277	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	EFAVIRENZ	EFAVIRENZ	600MG	MACLEODS PHARMACEUTICALS LTD .-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5278	ROCHE	LABOREX UGANDA LIMITED	DORMICUM	MIDAZOLAM	7.5MG	F. HOFFMAN LA ROCHE LTD-CH-4070 BASEL GRENZACHERSTRASSE 124, 4058 BASEL	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5279	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DOSIN	DOXAZOCIN	2MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5281	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ+EMTRICITABINE+TENOFVIR DISOPROXIL	EFAVIRENZ + EMTRICITABINE + TENOFVIR DISOPROXIL FUMARATE	600MG +200MG + 300MG	AUROBINDO PHARMA LTD UNIT VII-SEZ SURVEY NO. 411/P,425/P, 434/P, 435/P AND 458/P PLOT NO S1 (PART) SPECIAL ECONOMIC ZONE GREEN INDUSTRIAL PARK POLEPALLY VILLAGRE ANDHRA PRADESH 509302	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5283	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	IBUMEX GEL	IBUPROFEN	5%W/W	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	TOPICAL EXTERNAL EMULSION GELS	1.0X25.0 G TUBE
NDA/MAL/HDP/5284	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	EFAVIRENZ+EMTRICITABINE+TENOFVIR	EFAVIRENZ + EMTRICITABINE + TENOFVIR	600MG + 200MG + 300MG	HETERO LABS LTD(UNIT V).-JADCHERLA (M),MAHABOONNAGAR DIST, ANDHRA PRADESH,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER

NDA/MAL/HDP/5287	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMERATE	EFAVIRENZ + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMERATE	600MG + 300MG + 300MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), -SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5288	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	IBUMEX SUSPENSION	IBUPROFEN	100MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SUSPENSIONS	100.0 ML BOTTLE, 60.0 ML BOTTLE
NDA/MAL/HDP/5290	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ELOCOM CREAM	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM	BELGIUM	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/5291	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	IBUMEX TABLET	IBUPROFEN	200MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER, 1.0X20.0 TABLET BLISTER, 1.0X500.0 TABLET CONTAINER
NDA/MAL/HDP/5292	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	DOMI 10	DOMPERIDONE	10MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL, GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5294	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ELOCOM OINTMENT	MOMETASONE FUROATE	0.1%W/W	SCHERING-PLOUGH LABO N.V--INDUSTRIE PARK 30,B-2220 HEIST-OP-DEN-BERG,BELGIUM	BELGIUM	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/5295	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	DOXY	DOXYCYCLINE	100MG	LABORATORY & ALLIED LTD--PLOT NO. 209/10349, OPP. SAMEER BUSINESS PARK, MOMBASA ROAD P.O. BOX 42875, GPO 00100, NAIROBI, KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X280.0 CAPSULE CONTAINER, 1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5296	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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

NDA/MAL/HDP/5300	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DOLAC	KETOROLAC TROMETHAMINE	30MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/5301	SANOFI PASTEUR	LABOREX UGANDA LIMITED	DULTAVAX	DIPHTERIA/ TETANUS/ AND (INACTIVATED) POLIOMYELITIS VACCINE (ADSORBED)	2 IU/ 20IU/ POLIOMYELITIS (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
NDA/MAL/HDP/5302	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	IBUGO-COMBI	IBUPROFEN + PARACETAMOL + CAFFEINE	200MG + 325MG + 30MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER,1.0X100.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5307	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DUOTROL	GLIBENCLAMIDE + METFORMIN HYDROCHLORIDE	5MG + 500MG	FREDUN PHARMACEUTICALS LIMITED---14,15,16 ZORABIAN INDUSTRIAL COMPLEX PALAGHAR (EAST), DIST THANE 401 404 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5311	ABBOTT HEALTHCARE PRODUCTS B.V.	STAR PHARMACEUTICALS LTD	DUPHASTON TABLETS	DYDROGESTERONE	10MG	ABBOTT BIOLOGICALS B.V -ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X20.0 TABLET BLISTER
NDA/MAL/HDP/5316	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR	DICLOFENAC SODIUM + PARACETAMOL	50MG + 500MG	TROIKAA PHARMACEUTICALS LTD .-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5317	MACK BROWN	SHURIK LTD	DR MAC'S COUGH FROMULA	GUAIFENESIN+BRO MHEXINE	100MG + 8MG/5ML	TORQUE PHARMACEUTICALS LTD-ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5318	TROIKAA PHARMACEUTICALS LTD	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
NDA/MAL/HDP/5319	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	DYNAPAR SR	DICLOFENAC SODIUM	100MG	TROIKAA PHARMACEUTICALS LTD.-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD ENTERIC- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5321	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	IBUGESIC COLD & SINUS	IBUPROFEN/PSEUDO EPHEDRINE	200MG/30MG	DAR AL DAWA-NA'UR PLANT AMMAN	JORDAN	ORAL SOLID ORDINARY GELATIN-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5323	STEDMAN PHARMACEUTICALS LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	IODINATED POVIDONE + METRONIDAZOLE	1.0% W/V + 5.0% W/V	STEDMAN PHARMACEUTICALS PVT LTD...-C- 4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X60.0 ML CONTAINER,1.0X 30.0 ML CONTAINER,1.0X 100.0 ML CONTAINER,1.0X 500.0 ML CONTAINER
NDA/MAL/HDP/5324	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 400	IBUPROFEN	400MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER

NDA/MAL/HDP/5325	BEIJING HOLLEY-COTEC PHARMACEUTICALS CO.,LTD	SUPER PHARMACEUTICALS LIMITED	INDOMETACIN	INDOMETHACIN	25MG	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5327	FOURRTS(INDIA) LABORATORIES PVT.LIMITED	DELMAW ENTERPRISES LIMITED	IBUFIL 200	IBUPROFEN	200MG	FOURRTS(INDIA) LABORATORIES PVT.LIMITED-VANDALUR ROAD,KELAMBAKKAM-603 103, TAMIL NADU,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5328	ASTRA PHARMA (UK) LTD	ASTRA PHARMA (U) LIMITED	INDOMETACIN 25MG CAPSULES BP	INDOMETHACIN	25MG	ZHEJIANG RUIXIN PHARMACEUTICAL CO. LTD- KAIFA ROAD, LISHUI, ZHEJIANG P.R OF CHINA	CHINA	ORAL SOLID ORDINARY CAPSULES	1000.0 CAPSULE CONTAINER,1.0X100.0X10.0 CAPSULE BLISTER,1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5330	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ-V	MICONAZOLE + METRONIDAZOLE	2.0%W/W + 1.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE

NDA/MAL/HDP/5333	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	IBUFEN	IBUPROFEN	200MG	KPI (KAMPALA PHARMACEUTICAL INDUSTRIES LTD-PLOT M444 B STRETCHER ROAD NTINDA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X100.0X10.0 TABLET BLISTER,500.0 TABLET CONTAINER,100 0.0 TABLET CONTAINER,250. 0 TABLET CONTAINER,1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5336	SANOFI PASTEUR	LABOREX UGANDA LIMITED	AVAXIM 160U	INACTIVATED HEPATITIS A VACCINE ADSORBED	160 ANTIGEN UNITS	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/5337	SANOFI PASTEUR	LABOREX UGANDA LIMITED	AVAXIM 80IU PAEDIATRIC	INACTIVATED HEPATITIS A VACCINE ADSORBED	80 ANTIGEN UNITS	SANOFI PASTEUR-1541 AVENUE MARCEL MERIEUX, 69280 MARCY, LETOILE	FRANCE	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/5338	XEPA SOUL PATTISON (M) SDN BHD	DELMAR ENTERPRISES LIMITED	HYDROSIL TABLETS	ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE+SIMETHICONE	200MG+200MG+20MG	XEPA-SOUL PATTINSON (MALAYSIA) SDA BHD-1-5, CHENG INDUSTRIAL ESTATE, 75250, MELAKA, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X20.0 TABLET BLISTER
NDA/MAL/HDP/5340	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLIN SYRUP	DIPHENHYDRAMINE HCL/DEXTROMETHORPHAN HBR	5MG/6.25MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/5341	LABORATORY&ALLIED LTD	HARLEYS UGANDA LIMITED	HYDOPA	METHYLDOPA	250MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/5342	BELL SONS & CO.(DRUGGISTS) LTD	ECHO PHARMACY (U) LIMITED	BELL'S MUSCLE RUB	MULTI-INGREDIENT	N/A	BELL SONS & CO (DRUGGISTS) LTD-SLAIDBURN CRES CHESHIRE HOUSE/GORSEY LA	UNITED KINGDOM	TOPICAL EXTERNAL OINTMENTS	1.0X40.0 G TUBE

NDA/MAL/HDP/5343	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CEFORAN 1GM	CEFOTAXIME SODIUM	1GM	PHARCO PHARMACEUTICALS LTD-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
NDA/MAL/HDP/5344	IDA FOUNDATION	KIMSY MEDS LTD	CEFTRIAXONE	CEFTRIAXONE	1G	OKASA PHARMA PVT LTD-L-2, ADDITIONAL M.I.D.C. AREA, SATARA SATARA-415004, MAHARASHTRA, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 G VIAL
NDA/MAL/HDP/5345	VHB MEDI SCIENCES LTD	LLOYDS PHARMACY UGANDA LTD	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
NDA/MAL/HDP/5346	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFUTIL 500	CEFUROXIME AXETIL	500MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET CONTAINER
NDA/MAL/HDP/5347	PHARMA INTERNATIONAL COMPANY	OMAB UGANDA LIMITED	CEFUTIL 250	CEFUROXIME AXETIL	250MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5348	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CELEPID 20	INTRAVENOUS FAT EMULSION	20%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X250.0 ML BOTTLE,1.0X500.0 ML BOTTLE
NDA/MAL/HDP/5349	MSD (PTY) LIMITED SA	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	CELESTAMINE TABLETS	BETAMETHASONE + DEXCHLORPHENIRAMINE	0.25MG + 2MG	SCHERING PLOUGH LABO N.V,-INDUSTRY PARK 30, 2220 HEIST OPDENBERG BELGIAM, MSD (PTY) LTD- LOCATED AT 117 16TH ROAD HALFWAY HOUSE SOUTH AFRICA	BELGIUM	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/5350	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CEPHADAR FORTE	CEPHALEXIN	250MG/5ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5351	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	CEPHADAR	CEPHALEXIN MONOHYDRATE	125MG/5ML	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5352	GLENMARK PHARMACEUTICALS 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

NDA/MAL/HDP/5355	H.HOFFMAN ROCHE	LABOREX UGANDA LIMITED	BONVIVA	IBANDRONIC ACID	150MG	H. HOFFMAN ROCHE-GRENZACHERSTRASE 124, EXT 4070, BASEL SWITZERLAND & CH-4303 KAISERANGST SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5357	GLAXOSMITHKLINE LIMITED-	UNITED HEALTHCARE DISTRIBUTORS LTD	CA-C 1000	CALCIUM CARBONATE+ASCORBIC ACID	327MG+1000MG	NOVARTIS CONSUMER HEALTH-SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET CONTAINER
NDA/MAL/HDP/5358	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	CADISTIN EXPECTORANT	GUAIFENESIN+AMMONIUM CHLORIDE+CHLORPHENIRAMINE+SODIUM CITRATE	80MG+100MG+2MG+44MG	SAKAR HEALTHCARE PVT LTD-SAKAR HEALTHCARE PVT LTD, BLOCK NO 10-13, M.N. DESA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/5360	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	MOXICIP 400	MOXIFLOXACIN	400MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/5361	MACK BROWN PHARMECEUTICALS PVT LTD	SHURIK LTD	CALFIC	MULTI-INGREDIENT	N/A	TORQUE PHARMACEUTICALS LTD -ISSAPUR P.O DAPPAR 140506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5362	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 150MG	BICALUTAMIDE	150MG	ASTRAZENECA MACCLESFIELD-CHESHIRE	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	2.0X14.0 TABLET STRIP
NDA/MAL/HDP/5363	ASTRA ZENECA	MACNAUGHTON LIMITED	CASODEX 50MG	BICALUTAMIDE	50MG	ASTRA ZENECA UK LIMITED-ASTRAZENECA UK LIMITED SILK ROAD BUSINESS PARK, MACCLES FIELD,CHESHIRE SK 10 2NA,,BULK CORDEN PHARMA GMBH-OTT HAHN STRASSE ,68723 GERMANY	UNITED KINGDOM	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/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,1.0X20.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/5368	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFIX 100MG/5ML DRY SUSPENSION	CEFIXIME	100MG/5ML	PHARMA INTERNATIONAL CO.-AMMAN JORDAN PLANT AL-QARTAL MARKETING DEPARTMENT ALBUJAH COMPLEX, ALJUBAIHA	JORDAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/5369	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	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	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/5372	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	DUOMUNE	LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	300MG+300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED - -PLOT 1-7 1ST RING ROAD, LUZIRA, KAMPALA,CIPLA LTD ----D-7 MIDC INDUSTRIAL AREA, KURKUMBH, TAL	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/5376	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	LAMIVUDINE & ZIDOVUDINE	LAMIVUDINE + ZIDOVUDINE	150MG+300MG	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
NDA/MAL/HDP/5377	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	BENYLIN FOUR FLU LIQUID	DIPHENHYDRAMINE + PARACETAMOL + PSEUDOEPHEDRINE	25MG/20ML + 1G/20ML + 45MG/20ML	JOHNSON&JOHNSON PTY LTD.-EDMS BPK241 MAIN ROAD /HOOFWEG 241,RETREAT 7945,SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE

NDA/MAL/HDP/5378	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	X-VITA	MULTIINGREDIENT	N/A	MAXHEAL PHARMACEUTICALS INDIA LTD-J-7 MIDC, TARAPUR INDUSTRIAL AREA, BOISAR-401506, DIST.THANE, MARAHASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X15.0 CAPSULE BLISTER
NDA/MAL/HDP/5379	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLANAS-30	LANSOPRAZOLE	30MG	AJANTA PHARMA LTD--B-4/5/6 MIDC INDUSTRIAL AREA PAITHAN 431 128 AURANGABAD	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0 X10.0 CAPSULE BLISTER
NDA/MAL/HDP/5380	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CIROZEP	DIAZEPAM	5MG/ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD .-N-118,M.I.D.C, TARAPUR,BOISAR, DIST.THANE-401506, MAHARASHTRA,INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/5381	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	ADIFLAM GEL	DICLOFENAC DIETHYLAMINE	1.16%W/W	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA-- 444 104 (MS).	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/5382	HEBEI NOVASCON TRADING CO. LTD	RENE PHARMACY LTD	DICLOFENAC SODIUM	DICLOFENAC	75MG/3ML	ANHUI CHENGSHI MEDICINE MANUFACTURE CO. LTD-INDUSTRIAL AREA, BENGBU CITY, ANHUI PROVINCE, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/5385	NAPROD LIFE SCIENCES PVT LTD	AIVEEN (U) LIMITED	VINROS A-1	VINCRISTINE SULPHATE	1MG	NAPROD LIFE SCIENCES PVT LTD-G-17, MIDC, TARAPUR INDUSTRIAL AREA, BIOSAR THANE, MUMBAI	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/5386	WIN-MEDICARE LTD	SURGIPHARM (U) LIMITED	UDIHEP TABLETS	URSODEOXYCHOLIC ACID	150MG	WIN- MEDICARE LTD-MODIPURAM -250 110,UTTAR PRAADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5387	HILTON PHARMA (PVT) LTD	HEALTHCARE LTD.	TRANSAMIN INJECTION 250MG	TRANEXAMIC ACID	250MG/5ML	HILTON PHARMA (PVT) LTD-PLOT 13, SECTOR 15, KORANGI INDUSTRIAL AREA,KARACHI, PAKISTAN.	PAKISTAN	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE
NDA/MAL/HDP/5388	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	LARINATE	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

NDA/MAL/HDP/5389	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LUMARTEM	ARTEMETHER + LUMEFANTRINE	20MG + 120 MG	CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775	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
NDA/MAL/HDP/5390	ROYAL GROUP	HARLEYS UGANDA LIMITED	ARTEMETHER INJECTION	ARTEMETHER	80MG/ML	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	CHINA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE
NDA/MAL/HDP/5391	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	NITROFURANTOIN	NITROFURANTOIN	100MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/5392	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 10	AMLODIPINE MESILATE MONOHYDRATE	10MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5393	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMLO-DENK 5	AMLODIPINE MESILATE MONOHYDRATE	5MG	DENK PHARMA GMBH &CO.KG- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5395	MICRO LABS LTD	LABOREX UGANDA LIMITED	OFLOX	OFLOXACIN	200MG	MICRO LABS LTD-92, SIPCOT INDUSTRIAL COMPLEX HOSU R-635126 (T.N) INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/5397	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-100	BECLOMETHASONE	100MCG PER ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/5400	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS 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
NDA/MAL/HDP/5401	PIRAMAL HEALTHCARE LTD	TATA UGANDA LIMITED	HALOTHANE	HALOTHANE	250ML	PIRAMAL ENTERPRISES LTD --DIGWAL VILLAGE KOHIR MENDAL MEDAK DISTRICT,ANDHRA PRADESH	INDIA	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE
NDA/MAL/HDP/5404	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC P	ACECLOFENAC + PARACETAMOL	100 MG + 500 MG	INTAS PHARMACEUTICALS LTD-SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5405	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	OLANDUS	OLANZAPINE	10MG	CADILA HEALTH CARE LIMITED-KUNDAIM INDUSTRIAL ESTATE, PONDA, GOA-403401, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5406	INTAS, PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	HIFENAC SR	ACECLOFENAC	200 MG	INTAS PHARMACEUTICALS LIMITED(BIOPHARMA DIVISION)-CAMP ROAD SELAQUI-248197, DEHRADUN (UTTARAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5409	LINCON PHARMCEUTICALS 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
NDA/MAL/HDP/5410	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	UNICTAM 1500	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	MEDICAL UNION PHARMACEUTICALS LTD - - ABU SULTAN, CR 13363 ISMAILIA, EGYPT	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/5412	UNIQUE PHARMACEUTICAL LABORATORIES	TATA UGANDA LIMITED	IFICIPRO 250	CIPROFLOXACIN	250MG	JB CHEMICALS AND PHARMACEUTICALS-128/1,CIIDC ANKLESHWER 393 002GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5413	PASTEUR MERIEUX CONNANGHT	LABOREX UGANDA LIMITED	EUVAX B (ADULT)	HEPATITIS B VACCINE	1ML	PASTEUR MERIEUX CONNANGHT-SOUTH KOREA,LG LIFE SCIENCES LTD- 601, YONGJEE-DONG, IKSAN, JE	SOUTH KOREA	PARENTERAL ORDINARY I M VIALS	1.0X10.0 ML VIAL,1.0X1.0 ML VIAL
NDA/MAL/HDP/5414	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	XYLO-ACINO 0.1%	XYLOMETAZOLINE	0.1 % W/V	MERCKLE GMBH,-LUDWIG MERCKLE STRASSE3 D-89143 BLAUBEUREN	GERMANY	NASAL TOPICAL DROPS	1.0X1.0X10.0 ML BOTTLE

NDA/MAL/HDP/5415	CENTAUR PHARMACEUTICALS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	SINAREST	OXYMETAZOLINE	0.05%W/V	CENTAUR PHARMACEUTICALS PVT LTD -- PLOT NO.3 TIVIN INDUSTRIAL ESTATE KARASWADA 403526 INDIA	INDIA	NASAL TOPICAL DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/5416	OTSUKA PHARMACEUTICAL INDIA PRIVATE LIMITED	REDDYS PHARMA LIMITED	CIPROX	CIPROFLOXACIN	0.2%W/V	OTSUKA PHARMACEUTICAL INDIA PRIVATE LTD-VILLAGE – VASANA – CHACHARWADIP, TAL: SANAND, AHMADABAD	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5417	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CIPROPHARM	CIPROFLOXACIN	500MG	PHARMA INTERNATIONAL COMPANY-MAIN STREET, AL QASTAL INDUSTRIAL AREA AMMAN- JORDAN JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5419	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	AGO-CPM	CHLORPHENIRAMINE	4MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5422	KOTRAPHARMA (M) SDN.BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/5423	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	EFAVIRENZ+LAMIVUDINE+TENOFIVIR	600MG/300MG/300MG	HETERO DRUGS LTD-UNIT-111 NO 22-110 I.D.A JEEDIMETTA HYDRABAD 500055,HETERO LABS LTD. UNIT (V) .- S.NO.439, 440, 441& 458, APIIC, PHARMA SEZ, POLLEPALLY (VILLAGE), JADCHERLA (MANDAL) MAHABOOB NAGAR (DIST)-509301 INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET CONTAINER
NDA/MAL/HDP/5425	ROYAL GROUP	HARLEYS UGANDA LIMITED	PARACETAMOL	PARACETAMOL	500MG	HEBEI (JIHENG GRP) PHARMACEUTICALS CO.LTD-INDIA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5426	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	CEPROLEN	CIPROFLOXACIN	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
NDA/MAL/HDP/5427	NIRMA LIMITED.	SUPER MEDIC LTD	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

NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER,1.0X100.0 TABLET CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/5432	HETERO DRUGS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZIDOVUDINE	ZIDOVUDINE	300MG	HETERO LABS LTD UNIT III-22-110 IDA JEEDIMETIA HYDERABAD ANDHRA PRADESH ,	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/5433	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	COLD CAP NIGHT TIME	PARACETAMOL+CHLORPHENIRAMINE	500MG+2MG	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA,NAIROBI,KENYA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/5434	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE CO-PACK	DT ZINC-20 + ORAL REHYDRATION SALTS (ORS)	20G	AGOG PHARMA 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
NDA/MAL/HDP/5435	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	PIC	PARACETAMOL+IBUPROFEN+CAFFEINE	500MG+200MG+30MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET STRIP
NDA/MAL/HDP/5436	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	CEFICAD 1000	CEFEPIME HCL	1000MG	LA-MED HEALTHCARE PVT LTD-1389 TRASAD ROAD, DHOLKA, AHMEDABAD, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1000.0 MG VIAL
NDA/MAL/HDP/5437	MEDIPHARM (EA) LTD	MEDIPHARM INDUSTRIES (E.A) LTD	ORALYTE ORANGE	GLUCOSE/NACL/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
NDA/MAL/HDP/5438	CLARIS INJECTABLES LTD	REDDYS PHARMA LIMITED	TAMIN	PARACETAMOL	10MG/ML	CLARIS INJECTABLES LIMITED---CHACHARWADI VASANA 382 213 AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE,1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML VIAL

NDA/MAL/HDP/5439	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENIRON SYRUP	VITAMIN B6 + FERROUS GLUCONATE + VITAMIN B1 + VITAMIN C + VITAMIN B2	2MG/5ML + 200MG/5ML + 2MG/5ML + 20MG/5ML + 2MG/5ML	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5441	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL NASATAB TABLETS	PARACETAMOL+CHL ORPHENIRAMINE+PS EUDOEPHEDRINE	500MG+4MG+60MG	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5442	NEM LABORATORIES PRIVATE LIMITED	RENE PHARMACY LTD	CHLORAMPHENICOL OPHTHALMIC OINTMENT USP 1%	CHLORAMPHENICOL	1%W/W	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	OPHTHALMIC OINTMENTS	1.0X20.0X3.5 G TUBE
NDA/MAL/HDP/5445	ESKAYEF BANGLADESH LTD	MEDVIN PHARMA LIMITED	AZITHRAX 500	AZITHROMYCIN 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,1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/5446	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	PHENICOL- 250	CHLORAMPHENICOL	250MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5449	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	CLOFENAC 50	DICLOFENAC SODIUM	50MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5453	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 250MG/5ML	AMOXICILLIN	250MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X10.0 ML BOTTLE

NDA/MAL/HDP/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
NDA/MAL/HDP/5456	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	FARCONCIL 125MG/5ML	AMOXICILLIN	125MG/5ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/5457	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 100/270 B/L	ARTESUNATE+AMODIAQUINE	100MG+270MG	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER, 1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/5458	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	FALCIMON 50/135 B/L	ARTESUNATE+AMODIAQUINE	50MG+135MG	CIPLA LTD UNIT II-A-42 MIDC PATALGANGA DISTRICT RAIGAD MAHARASHTRA STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/5460	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ASAQ GPSC	ARTESUNATE+AMODIAQUINE	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
NDA/MAL/HDP/5461	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE	ARTESUNATE+AMODIAQUINE	25MG+67.5MG	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
NDA/MAL/HDP/5462	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE WINTHROP	ARTESUNATE+AMODIAQUINE	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
NDA/MAL/HDP/5463	SANOFI AVENTIS	LABOREX UGANDA LIMITED	ARTESUNATE AMODIAQUINE WINTHROP	ARTESUNATE+AMODIAQUINE	100MG+270MG	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, 1.0X25.0X6.0 TABLET BLISTER, 1.0X6.0 TABLET BLISTER

NDA/MAL/HDP/5464	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICALS LIMITED	CO-METHER	ARTEMETHER + LUMEFANTRINE	20MG + 120MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER,1.0X3.0X8.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,2.0X6.0 TABLET BLISTER,4.0X6.0 TABLET BLISTER,1.0X1.0X24.0 TABLET BLISTER
NDA/MAL/HDP/5467	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAMSIDAR	SULFADOXINE/PYRIMETHAMINE	525MG	KAMPALA PHARMACEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100.0 TABLET CARTON,1.0X250.0 TABLET CONTAINER,1.0X500.0 TABLET CONTAINER,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/5469	BAYER PHARMA AG	SURGIPHARM (U) LIMITED	NIMOTOP	NIMODIPINE	0.2MG/ML	BAYER PHARMA AG -51368 LEVERKUSEN GERMANY	GERMANY	PARENTERAL ORDINARY I V VIALS	1.0X50.0 ML VIAL
NDA/MAL/HDP/5470	ANKUR DRUGS AND PHARMA LTD	JOINT MEDICAL STORE (UPMB - UCMB)	VERIUN CP-325	CEFEXIME + CLAVULANATE POTASSIUM	200 MG + 125 MG	ANKUR DRUGS AND PHARMA LTD- UNIT I-VILLAGE – MANAKPUR, PO – LODHIMAJRA, NALAGARH DIST. SOLAN (HP) – 174 101(INDIA)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5472	OTSUKA PHARMACEUTICAL INDIA PRIVATE 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

NDA/MAL/HDP/5473	TROIKA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	TROYPOFOL	PROPOFOL	1%W/V	TROIKA PHARMACEUTICALS LTD .-C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0 ML VIAL,1.0X20.0 ML VIAL
NDA/MAL/HDP/5474	PHARMA INTERNATIONAL CO	OMAB UGANDA LIMITED	CEFODOX	CEFPODOXIME	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
NDA/MAL/HDP/5475	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/5476	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	MESPORIN 1000MG I.V	CEFTRIAZONE	1000MG	LABESFAL LABORATORIES-ALMIRO S.A ZONA INDUSTRIAL DO LAGEDO, 3465-157, SANTIAGO DE BESTEIRO PORTUGAL	PORTUGAL	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 10 ML WFI
NDA/MAL/HDP/5478	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BECLATE-50	BECLOMETHASONE DIPROPIONATE	50MCG/ACTUATION	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/5479	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	RANFERON 12 CAPSULES	MULTI-INGREDIENT	MULTI-INGREDIENT	SUN PHARMACEUTICAL INDUSTRIES LIMITED,-INDUSTRIAL AREA NO.3, A.B.ROAD DEWAS,455001 MADHYA PRADESH INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X30.0 CAPSULE BLISTER
NDA/MAL/HDP/5480	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	BECLATE NASAL SPRAY	BECLOMETHASONE DIPROPIONATE	50MCG	CIPLA LTD.- -PLOT NO L/139 TO L/146, VERNA INDUSTRIAL ESTATE, VERNA, SOUTH GOA DISTRICT, 403722 GOA	INDIA	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5483	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICALS LTD	ASAQ GPSC	ARTESUNATE + AMODIAQUINE	25 MG + 67.5 MG	GUILIN PHARMACEUTICALS CO. LTD-NO 43 SHANGHAI ROAD GUILIN GUANGXI CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0X20.0 TABLET BLISTER
NDA/MAL/HDP/5485	BEXIMCO PHARMACEUTICALS LIMITED	KIMSY MEDS LTD	AZMASOL HFA	SALBUTAMOL	100MCG/ACTUATION	BEXIMCO PHARMACEUTICALS LTD-TONGI-1711, GAZIPUR, BANGLADESH	BANGLADESH	TOPICAL EXTERNAL METERED-DOSE PRESSURISED AEROSOLS	1.0X200.0 METERED DOSE CANNISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/5487	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	IBICAR-S	SALBUTAMOL + BECLOMETASONE	100MCG/ACTUATION + 50MCG/ACTUATION	GLENMARK PHARMACEUTICALS LTD (UNIT III).-UNIT III VILLAGE KISHANPURA,BADDI-NALAGARH ROAD TEHSIL BADDI,DISTT. SOLAN, HIMACHAL PRADESH -173 205 INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/5489	UNICHEM LABORATORIES LTD	EUROPA HEALTHCARE (U) LTD	CORBIS-5	BISOPROLOL	5MG	UNICHEM LABORATORIES LIMITED UNIT II-VILLAGE BHATAULI KALAN BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/5492	STRIDES ARCOLAB LTD	DELMAW ENTERPRISES LIMITED	RIFAMPICIN + ISONIAZID	RIFAMPICIN + ISONIAZID	150MG + 75MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER,1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/5494	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	ASMOX	AMOXYCILLIN	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	10.0X10.0 CAPSULE BLISTER,1.0X100.0 CAPSULE CONTAINER
NDA/MAL/HDP/5495	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOCAL TABLETS	CALCIUM LACTATE	300MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5496	ASTRA ZENECA	MACNAUGHTON LIMITED	ATACAND 16MG	CANDESARTAN CILEXETIL	16MG	ASTRA ZENECA AB-SE-151 85 SODERTALJE, SWEDEN (GARTUNAVAGEN & SNACKVIKEN)	SWEDEN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/5497	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	EXPEN	BENZYL PENICILLIN	1MU	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X1.0 MU VIAL
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/5566	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	HYCORT OINTMENT	HYDROCORTISONE	1%W/W	KAMPALA PHARMECEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X30.0 G TUBE
NDA/MAL/HDP/5575	SK AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	HYOSCINE BUTYL BROMIDE	HYOSCINE BUTYL BROMIDE	10MG	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,1.0X100.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/5596	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LIMITED	GERMILON	CHLORHEXIDINE GLUCONATE + CETRIMIDE	0.3%W/V + 3%W/V	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X200.0 ML BOTTLE,1.0X1.0 L BOTTLE,1.0X5.0 L BOTTLE
NDA/MAL/HDP/5619	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	RABELOC 20	RABEPRAZOLE SODIUM	20MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X1.0X10.0 TABLET STRIP
NDA/MAL/HDP/5634	BAYER AG	SURGIPHARM (U) LIMITED	CIPROBAY	CIPROFLOXACIN	500MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/5639	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICALS (U) LIMITED	FEROMAX	IRON SUCROSE	20MG/ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA, P.O.BOX: 997, RAS AL KHAIMAH, U.A.E.	UNITED ARAB EMIRATES	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE
NDA/MAL/HDP/5644	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICALS LIMITED	FORTIFIED PROCAINE PENICILLIN	FORTIFIED PROCAINE PENICILLIN	4 MEGA UNITS	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO, LTD.-NO.47 FENGSHOU ROAD, SHIJIAZHUANG CITY, CHINA.	CHINA	PARENTERAL ORDINARY VIALS	1.0X4.0 MU VIAL
NDA/MAL/HDP/5648	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD	TATA UGANDA LIMITED	CLOXACILLIN SODIUM	CLOXACILLIN SODIUM	500MG	KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD- #14, II PHASE PIA, BANGALORE 560058	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL

NDA/MAL/HDP/5685	JOHNSON&JOHNSON PTY LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	VERMOX	MEBENDAZOLE	20MG/5ML	SPECPHARM HOLDINGS- 15TH ROAD HALFWAY HOUSE	SOUTH AFRICA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/6031	NORVATIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG + 160MG +25MG	GLIBENCLAMIDE,AM LODIPINE + VALSARTAN + HYDROCHLOROTHIA ZIDE	5MG,10MG + 160MG +25MG	NORVATIS PHARMA STEIN- SCHAFFHAUSERSTRASSE 4332 STEIN	SWITZERLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6034	AGOG PHARMA LIMITED	GITTOES PHARMACEUTICAL S LTD - WILLIAM STREET	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
NDA/MAL/HDP/6037	GITTOES PHARMACEUTICALS LIMITED	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/6038	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S LIMITED	FIXDEP-180	FEXOFENADINE HYDROCHLORIDE	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
NDA/MAL/HDP/6039	GLENMARK PHARMACEUTICAL LTD	STAR PHARMACEUTICAL S LTD	COMBIWAVE SF 250	SALMETEROL XINAFOATE/FLUTICA SONE PROPIONATE	25MCG+250M CG/ACTUATIO N	GLENMARK PHARMACEUTICALS LIMITED- UNIT-I, VILLAGE KISHANPURA, BADDI, NALAGARH ROAD, TEHSIL NALAGARH,HIMACHAL PRADESH 174 101, MAHARASHTRA STATE, INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/6040	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/6041	AGOG PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	CANDIZOL	CLOTRIMAZOLE	100MG	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	VAGINAL TABLETS	1.0X6.0 PESSARY STRIP

NDA/MAL/HDP/6042	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	COMBIWAVE SF 125	SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE	25MCG+125MCG/ACTUATION	GLENMARK PHARMACEUTICALS LIMITED-UNIT-I, VILLAGE KISHANPURA, BADDI, NALAGARH ROAD, TEHSIL NALAGARH,HIMACHAL PRADESH 174 101, MAHARASHTRA STATE, INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/6043	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LIMITED	ZEMILAST	IMIPENEM + CILASTATIN	500MG+500MG	ZEISS PHARMACEUTICALS PVT. LIMITED-PLOT NO. 72, EPIP I, JHARMAJIRI, BADDI (HP), INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/6044	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	COMBIWAVE SF 50	SALMETEROL XINAFOATE + FLUTICASONE PROPIONATE	25MCG+50MCG/ACTUATION	GLENMARK PHARMACEUTICALS LIMITED-UNIT-I, VILLAGE KISHANPURA, BADDI, NALAGARH ROAD, TEHSIL NALAGARH,HIMACHAL PRADESH 174 101, MAHARASHTRA STATE, INDIA	INDIA	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X120.0 METERED DOSE CANNISTER
NDA/MAL/HDP/6046	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACYCLOVIR	ACYCLOVIR	200MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6047	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 150	TRASTUZUMAB (R-DNA ORIGIN)	150MG	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD BANGALORE-560 099	INDIA	PARENTERAL ORDINARY INFUSION DRY VIALS/BOTTLES	1.0X150.0 MG VIAL ,1X10ML VIAL OF WFI
NDA/MAL/HDP/6048	GLENMARK PHARMACEUTICAL LTD.	STAR PHARMACEUTICALS LTD	MOMATE AZ	MOMETASONE FUROATE / AZELASTINE HYDROCHLORIDE	50MCG/140MCG	GLENMARK PHARMACEUTICALS LTD-VILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA	INDIA	NASAL TOPICAL METERED DOSE AEROSOLS	1.0X150.0 METERED DOSE BOTTLE
NDA/MAL/HDP/6050	MICRO LABS LTD	LABOREX UGANDA LIMITED	ITACARE	ITRACONAZOLE	100MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER,1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6051	NOVARTIS PHARMA SERVICES	SURGIPHARM (U) LIMITED	EXFORGE HCT 10MG + 320MG + 25MG	AMLODIPINE BESYLATE + VALSARTAN + HYDROCHLOROTHIAZIDE	10MG + 320MG + 25MG	NORVATIS PHARMA STEIN-SCHAFFHAUSERSTRASSE 4332 STEIN	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6052	MICRO LABS LTD	LABOREX UGANDA LIMITED	MICROPIME	CEFEPIME HYDROCHLORIDE	1G	MICRO LABS LIMITED, BOMMASANDRA - PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10ML (WFI) LDPE VIAL

NDA/MAL/HDP/6053	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	4MG	LEK S.S POLAND UI PODLIPIE 16 95-010 STRYKOW-INDUSTRIAL ESTATES	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6054	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRIDE	GLIMEPIRIDE	1MG	LEK S.S POLAND UI PODLIPIE 16 95-010 STRYKOW-INDUSTRIAL ESTATES	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER,1.0X3.0X 10.0 TABLET BLISTER
NDA/MAL/HDP/6055	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A	LABOREX UGANDA LIMITED	EURARTESIM	PIPERAQUINE TETRAPHOSPHATE + DIHYDROARTEMISIN IN	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
NDA/MAL/HDP/6056	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	TELMISARTAN	TELMISARTAN	20MG	SANDOZ GRUP SAGLIK URUNLERI .-ILACLARI SANAYI VE A.S GEBZE 2, GOSB IHSAN DEDE CAD. 900 SOK 41480 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/6057	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	CORAM 5MG	AMLODIPINE BESYLATE	5MG	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6058	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	FENTANYL FRESENIUS	FENTANYL	100MCG/2ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X2.0 ML AMPOULE
NDA/MAL/HDP/6059	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	NEUROZONE	MECOBALAMIN + PREGABALIN	750MCG + 75MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6060	NOVARTIS ACCESS	SURGIPHARM (U) LIMITED	SALBUTAMOL	SALBUTAMOL	100MCG	AEROPHARM GMBH...-RUDOLSTADT ALLEMAGNE	GERMANY	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X200.0 METERED DOSE CONTAINER
NDA/MAL/HDP/6061	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	NASEHALER	MOMETASONE FUROATE	50MCG /SPRAY	CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775	INDIA	NASAL TOPICAL SPRAYS WITHOUT GAS	1.0X140.0 METERED DOSE BOTTLE
NDA/MAL/HDP/6062	AUROLAB	SWASTIK PHARMACEUTICAL LTD	OPRED	OFLOXACIN + PREDNISOLONE SODIUM PHOSPHATE	0.3W/V + 0.5%W/V	AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6063	CLARIS LIFESCIENCE LTD	REDDYS PHARMA LIMITED	ANSED	FLUMAZENIL	0.1MG/ML	CLARIS LIFE SCIENCES LTD-CHACHARWADI- VASANA,SANAND, AHMEDABAD GUJARAT- 382213 INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X5.0X5.0 ML AMPOULE

NDA/MAL/HDP/6064	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	JOCET 10	CETIRIZINE DIHYDROCHLORIDE	10MG	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 FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6065	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	PROXYREN	PIROXICAM	20MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6066	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	DREZ	IODINATED-POVIDONE	10%W/V	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6067	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	DIAZEPAM	DIAZEPAM	5MG	NEM LABORATORIES PVT LTD-133 KRISHNA INDUSTRIAL ESTATE VASAI (E) DIST THANE 401 210 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6068	EXIR PHARMACEUTICAL COMPANY	UNEED GLOBAL GROUP LIMITED	ZIMEXIR 250	AZITHROMYCIN DIHYDRATE	250MG	EXIR PHARMACEUTICAL COMPANY-2ND KM OF RING ROAD BOROUJERED 69189 IRAN	IRAN	ORAL SOLID ORDINARY CAPSULES	1.0X5.0 CAPSULE BLISTER
NDA/MAL/HDP/6069	EXIR PHARMACEUTICAL COMPANY	UNEED GLOBAL GROUP LIMITED	ZIMEXIR 200MG	AZITHROMYCIN DIHYDRATE	200MG/5ML	EXIR PHARMACEUTICAL COMPANY-2ND KM OF RING ROAD BOROUJERED 69189 IRAN	IRAN	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/6070	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S 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
NDA/MAL/HDP/6071	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S 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
NDA/MAL/HDP/6072	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICAL S LIMITED	HYDRALAZINE HYDROCHLORIDE	HYDRALAZINE HYDROCHLORIDE	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,1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6073	EVA PHARMA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MILGA	BENFOTIAMINE + PYRIDOXINE + CYANOCOBALAMIN	40MG + 60MG + 20MCG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6074	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICAL S LIMITED	CARDIOL CS	CARVEDILOL	25MG	MARCYRL PHARMACEUTICAL INDUSTRIES - WESTERN EXTENSION-PARTS NUMBER 5/6/7/8/9/10/11/12-BLOCK 20005, EL BOUR CITY	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6075	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OLOHISTINE	OLOPATADINE HYDROCHLORIDE	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6076	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICAL S 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 NAACL AMPOULE + 1*1 ML OF 5%W/V NAHCO3 AMPOULE
NDA/MAL/HDP/6078	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TIMOLOL MALEATE	TIMOLOL MALEATE	5MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6079	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	ALLERGEX	CHLORPHENIRAMIN E 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
NDA/MAL/HDP/6080	EXPHAR SA	SURGIPHARM (U) LIMITED	FEBRILEX JUNIOR	PARACETAMOL+CHL ORPHENIRAMINE 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
NDA/MAL/HDP/6081	EXPHAR SA	SURGIPHARM (U) LIMITED	ANTALGEX T	PARACETAMOL/TRA MADOL HYDROCHLORIDE	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
NDA/MAL/HDP/6082	EXPHAR SA	SURGIPHARM (U) LIMITED	CROMSOL	SODIUM CROMOGLYCATE	2%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP- 918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE

NDA/MAL/HDP/6086	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	ACEWEL-P	ACECLOFENAC+PAR ACETAMOL	100MG+500MG	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/6090	UNOSOURCE PHARMA LTD	ESCORTS PHARMACEUTICALS LIMITED	PROSTAR 200	PROGESTERONE	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
NDA/MAL/HDP/6092	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 1000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6093	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 625	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	500 MG + 125 MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6094	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPOTCLAV 375	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	250 MG + 125 MG	SPARSH BIO-TECH PVT. LTD-PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR-361 006, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6095	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	DIPGEN	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE	0.64 MG/G + 1 MG/G	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE,1.0X15.0 G TUBE
NDA/MAL/HDP/6096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	ABGYL-200	METRONIDAZOLE	200MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6099	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	HARIPIL-60	ARTESUNATE	60MG	PSYCHOTROPICS INDIA LTD -PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*5 ML OF 0.9% W/V NACL GLASS AMPOULE + 1*1 ML OF 5%W/V NAHCO3 GLASS AMPOULE
NDA/MAL/HDP/6102	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 80	TELMISARTAN	80MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6103	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 5	OLANZAPINE	5MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6104	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	FUROSEMIDE	FUROSEMIDE	10MG/ML	PSYCHOTROPICS INDIA LTD -PLOT NO. 12 & 12A, INDUSTRIAL PARK-II, PHASE-1, VILLAGE SALEMPUR, MEHDOOD-2 HARIDWAR-249403, UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY I V AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/6105	PSYCHTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	AZOPI 200	AZITHROMYCIN	200MG/5ML	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/6106	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	TREVOX 500	LEVOFLOXACIN HEMIHYDRATE	500MG	SQUARE PHARMACEUTICALS LTD-KALIAKOIR	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6107	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SULPREX	IPRATROPIUM BROMIDE+SALBUTAMOL SULPHATE	500MCG/2.5ML+2.5MG/2.5ML	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X10.0 AMPOULE CARTON
NDA/MAL/HDP/6108	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	TREVOX 750	LEVOFLOXACIN HEMIHYDRATE	750MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6109	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	MEXLO	LOMEFLOXACIN HYDROCHLORIDE	0.3%W/V	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6110	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	AMBROX	AMBROXOL HYDROCHLORIDE	15MG/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)-SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6111	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	MOTIFAST	DOMPERIDONE	10MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6112	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SULTOLIN	SALBUTAMOL SULPHATE	2.5MG/2.5ML	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	LUNG ADMINISTRATION LIQUID FOR INHALATION	1.0X10.0X2.5 ML AMPOULE
NDA/MAL/HDP/6114	FDC LTD	AIVEEN (U) LIMITED	ZOXAN	CIPROFLOXACIN	0.3% W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE

NDA/MAL/HDP/6116	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ZOLEDRO-DENK 4MG/5ML	ZOLEDRONIC ACID	4MG/5ML	HAMELN PHARMACEUTICALS GMBH-LANGES FELD 13 31789 HAMELN	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X5.0 ML VIAL
NDA/MAL/HDP/6117	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	GRAN-DENK	GRANISETRON HYDROCHLORIDE	1MG/ML	HAMELN PHARMACEUTICALS GMBH-LANGES FELD 13 31789 HAMELN	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X5.0 ML AMPOULE
NDA/MAL/HDP/6118	LEBEN LABORATORIES PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	L-TRIM DS	SULPHAMETHOXAZOLE + TRIMETHOPRIM	800MG + 160MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6119	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	SUPER CV	AMOXICILLIN SODIUM + POTASSIUM CLAVULANATE	1 G + 0.2 G	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0X1.2 G VIAL
NDA/MAL/HDP/6120	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	KMINE	KETAMINE HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/6121	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	DEXIREN	DEXKETOPROFEN TROMETAMOL	25MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6123	OCTOBER PHARMA	ABACUS PHARMA (AFRICA) LIMITED	MONOMAK	ISOSORBIDE NITRATE	20MG	OCTOBER PHARMA-1ST INDUSTRIAL ZONE STREET 25 PLOT 190 6TH OCTOBER CITY CAIRO	EGYPT	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6124	CLARIS LIFE SCIENCES LTD	REDDYS PHARMA LIMITED	SPIVA	PROPOFOL	1%W/V	CLARIS LIFE SCIENCES LIMITED-CHACHOSWADIII VASNA.AHMEDABAD-382213,INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/6126	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	DERMOTRACIN	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
NDA/MAL/HDP/6127	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	25MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGIO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE
NDA/MAL/HDP/6128	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYFLUR	FLURBIPROFEN SODIUM	0.03%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE

NDA/MAL/HDP/6129	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	TRIUMEQ	DOLUTEGRAVIR + 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
NDA/MAL/HDP/6130	ASTRA PHARMA (U) LIMITED	ASTRA PHARMA (U) LIMITED	IVYSINE EYE DROPS	TETRAHYDROZOLINE HYDROCHLORIDE	0.05%W/V	IVEE INFUSIONS EPZ LTD--LR NO.18474/84,ATHI RIVER BOX 25251 00100 NAIROBI KENYA ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6131	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	FERRACIN	IRON (III) HYDROXIDE SUCROSE COMPLEX	20MG/ML	RAFARM S.A-AGIO LOUKA STR PEANIA ATTIKI	GREECE	PARENTERAL ORDINARY I V AMPOULES	1.0X5.0X5.0 ML AMPOULE
NDA/MAL/HDP/6132	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID	KETOCONAZOLE	2%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/6133	UMEDICA LABORATORIES PVT LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/6134	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ZAMADOL P	TRAMADOL HYDROCHLORIDE+A CETAMINOPHEN	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
NDA/MAL/HDP/6135	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TRIXONE-S	CEFTRIAXONE SODIUM+SULBACTA M	1000MG+500 MG	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X20.0 ML VIAL
NDA/MAL/HDP/6137	BHARAT SERUMS AND VACCINES LTD	GITTOES PHARMACEUTICAL S 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

NDA/MAL/HDP/6139	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	SERVIN CAPSULE	FERROUS SULPHATE+FOLIC ACID+THIAMINE MONONITRATE+RIBOFLAVIN+PYRIDOXINE HYDROCHLORIDE+NICOTINAMIDE+ASCORBIC ACID	150MG+0.5MG+2MG+2MG+1MG+10MG+50MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6140	CLARIS OTSUKA LIMITED	REDDYS PHARMA LIMITED	KIDROLYTE	SODIUM ACETATE + DIBASIC POTASSIUM PHOSPHATE + MAGNESSIUM CHLORIDE + DEXTROSE MONONOHYDRATE + POTASSIUM CHLORIDE	(0.32G + 0.026G + 0.031G + 5.50G + 0.13G)/100ML	CLARIS OTSUKA LIMITED .-VILLAGE VASANA CHACHARWADI TAL:SANAD DIST - AHMEDABAD 382 213	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/6143	MARCYRL PHARMACEUTICAL INDUSTRIES	SHREEJI PHARMACEUTICALS LIMITED	CONTRACTUBEX	EXTRACT CEPAE FLUID +HEPARIN SODIUM+ALLANTOIN	10G+5000 I.U+1G/100G	MARCYRL PHARMACEUTICAL INDUSTRIES.-ELBOUR CITY CAIRO	EGYPT	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/6144	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NIKO	PARACETAMOL	500MG	NATIONAL HEALTHCARE PVT LTD-CHHATAPIRA 3 BARA	NEPAL	ORAL SOLID ORDINARY TABLETS	1.0X10.0X100.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/6150	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SERVIFLOX 500MG	CIPROFLOXACIN	500MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6152	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CARVEDIOL SANDOZ 12.5MG	CARVEDIOL	12.5MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6153	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	CARVEDIOL SANDOZ 25MG	CARVEDIOL	25MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6154	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	EXFORGE 5MG/320MG	AMLODIPINE + VALSARTAN	5 MG + 320 MG	NOVARTIS PHARMA STEIN AG-H-4332 STEIN SCHAFFHAUSERSTRASSE	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6159	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	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
NDA/MAL/HDP/6165	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	CEFTRISONE - 1000	CEFTRIAXONE 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
NDA/MAL/HDP/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

NDA/MAL/HDP/6167	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AKUROSE	IRON SUCROSE	20MG/ML	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III,-PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL,RANIPUR, 249 403	INDIA	PARENTERAL ORDINARY INFUSION AMPOULES	1.0X5.0X5.0 ML AMPOULE
NDA/MAL/HDP/6168	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LIMITED	K-HEM	FERROUS GLUCONATE + THIAMINE MONONITRATE + RIBOFLAVIN + PYRIDOXINE HCL + NIACINAMIDE + VITAMIN B12	300MG + 5MG + 5MG + 1.5MG +45MG + 15MCG	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/6169	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	INTELENCE	ETRAVIRINE	100MG	JANSSEN-CILAG S.P.A.-VIA C. JANSSEN BORGO S. MICHELE 04100 LATINA	ITALY	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE
NDA/MAL/HDP/6170	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ALACOT 0.1% EYE DROPS	OLOPATADINE HYDROCHLORIDE	0.1%W/V	SQUARE PHARMACEUTICALS LTD-KALIAKOIR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6171	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	SUXAMETHONIUM CHLORIDE	SUXAMETHONIUM CHLORIDE	50MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY DRY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/6172	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	PHYTOMENADIONE	PHYTOMENADIONE	10MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6173	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	MONTAIR 5	MONTELUKAST SODIUM	5MG	CIPLA LTD ----L139 TO L-146 VERNA INDUSTRIAL ESTATE VERNA SALCETTE GOA 403 722	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6174	ROTEXMEDICA GMBH ARZNEIMITTELWERK	GITTOES PHARMACEUTICALS LIMITED	FLUPHENAZINE DECANOATE INJECTION USP 25MG/ML	FLUPHENAZINE DECANOATE	25MG/ML	ROTEXMEDICA GMBH ARZEIMITTEL WERK-BUNSENSTRASSE 4, 22946 TRITTAU	GERMANY	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6175	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SERVIFLOX 250	CIPROFLOXACIN	250MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICKE-ALLEE	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/6179	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	ON.SETRON-DENK 4MG ODT	ONDANSETRON	4MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6181	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	AZINOWEL-500	AZITHROMYCIN	500MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6182	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	ALARID	KETOTIFEN FUMARATE	0.025%W/V	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6183	CIPLA LTD..	QUALITY CHEMICALS LTD - HUMAN	PRAZIQUANTEL TABLETS	PRAZIQUANTEL	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
NDA/MAL/HDP/6184	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 60MG	ETORICOXIB	60MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6185	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	DOLOFORTE DENK	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6186	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 90MG F.C. TABLETS	ETORICOXIB	90MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6188	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO LTD	KIMSY MEDS LTD	GIZLAN 150	IRBESATAN	150MG	DAR AI DAWA-NA UR PLANT,AMMAN,JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6189	UNEED 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

NDA/MAL/HDP/6190	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	D-LYTE	ANHYDROUS GLUCOSE,SODIUM CHLORIDE,TRISODIUM CITRATE DIHYDRATE,POTASSIUM 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
NDA/MAL/HDP/6191	AMOUN PHARMACEUTICALS COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	KAPRON AMPOULE	TRANEXAMIC ACID	500MG/5ML	AMOUN PHARMACEUTICAL CO. S.A.E-1ST INDUSTRIAL ZONE A, PLOTS NO. 1B,2,3,4,5 BLOCK 13015, EL-BOUR CITY, KALYOUBIA CAIRO EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X6.0X5.0 ML AMPOULE
NDA/MAL/HDP/6192	GLAXOSMITHKLINE LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	ENO FRUIT SALT ORANGE	SODIUM BICARBONATE + CITRIC ACID	55.80%W/W + 43.20 %W/W	GLAXOSMITHKLINE-LIKONI ROAD IND. AREA, NAIROBI	KENYA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X10.0X5.0 G SACHET,1.0X48.0 X5.0 G SACHET
NDA/MAL/HDP/6193	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES.	SURGIPHARM (U) LIMITED	CEFTRIAXONE SANDOZ	CEFTRIAXONE SODIUM	1G	SANDOZ GMBH-BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/6194	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	FENTANYL FRESENIUS	FENTANYL CITRATE	500MCG/10ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE
NDA/MAL/HDP/6195	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	MORPHINE SULPHATE FRESENIUS	MORPHINE SULPHATE	10MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6196	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	MORPHINE SULPHATE FRESENIUS	MORPHINE SULPHATE	15MG/ML	FRESENIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD, KORSTEN 6020, PORT ELIZABETH	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6197	UNEEED 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
NDA/MAL/HDP/6201	SPARSH BIO-TECH PVT. LTD	ABACUS PHARMA (AFRICA) LIMITED	AMOXICILLIN AND FLUCLOXACILLIN CAPSULES 500MG	AMOXICILLIN TRIHYDRATE + FLUCLOXACILLIN SODIUM	250MG + 250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/6202	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SALPRAZ 20	PANTOPRAZOLE 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

NDA/MAL/HDP/6203	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DEROX-5	AMLODIPINE BESILATE	5MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/6205	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ACICLOVIR	ACICLOVIR	400MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6207	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	GO!GEL	DICLOFENAC DIETHYLAMINE+MET HYL 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
NDA/MAL/HDP/6208	WOCKHARDT LTD	STAR PHARMACEUTICAL S LTD	WOCKLAV	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	200MG/5ML+ 28.5MG/5ML	MEDOPHARM PVT LTD-50, KAYARAMBEDU VILLAGE, GUDUVANANCHERRY - 603202, TAMIL NADU,	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6209	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	RESPIWEL 4	RISPERIDONE	4MG	AKUMS DRUGS & PHARMACEUTICALS LTD -- 19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6211	EXPHAR SA	SURGIPHARM (U) LIMITED	CLOFAINS	PARACETAMOL/DICLOFENAC SODIUM	500MG/50MG	MILAN LABORATORIES (INDIA) PVT LTD-PLOT NO.63-67 & 87,JAWAHAR CO.OP.INDUSTRIAL ESTATE LTD KAMOTHE,PANVEL DIST. THANE,MAHARASTRA-410209,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6213	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOXIN 250 DT	AMOXICILLIN TRIHYDRATE	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 SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X2.0X10.0 TABLET BLISTER,1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6214	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	VIXIB	DEXTROMETHORPHAN HYDROBROMIDE	33.33%W/W	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)-SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/6217	INDIAN IMMUNOLOGICALS LTD	TATA UGANDA LIMITED	ELOVAC -B	HEPATITIS B (RDNA)	20MCG/ML	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD)- RAKSHAPURAM GACHIBOWLI POST HYDERABAD 500032	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0X1.0 ML VIAL (1 DOSE VIAL)
NDA/MAL/HDP/6218	ASTRA ZENECA	MACNAUGHTON LIMITED	FORXIGA	DAPAGLIFLOZIN	10MG	BRISTOL-4601 HIGHWAY 62 EAST MOUNT VERNON INDIANA 47620 USA	UNITED STATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6223	AUROLAB	SWASTIK PHARMACEUTICAL LTD	AUROPROST- RT	LATANOPROST	0.005%W/V	AUROLAB.-SIVAGANGAI MAIN ROAD, VEERAPANJAN, MADURAI 625 020 TAMIL INDIA	INDIA	OPHTHALMIC DROPS	1.0X2.5 ML BOTTLE
NDA/MAL/HDP/6224	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	NICLOFEN	DICLOFENAC SODIUM	75MG/3ML	NITIN LIFESCIENCES LTD--RAMPUR ROAD PAONTA SAHIB DIST. SIRMOUR (H.P) 173 025	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X10.0X5.0X2. 0 ML AMPOULE
NDA/MAL/HDP/6226	IDA FOUNDATION	KIMSY MEDS LTD	AMOXICILLIN 500+ CLAVULANIC ACID 125MG BP	AMOXICILLIN + CLAVULANIC ACID	500MG+125M G	MICRO LABS LIMITED -PLOT 16 VEERASANDRA IND. AREA,ANEKAL TALUK,BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6227	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ISONIAZID	ISONIAZID	300MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H- 12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/6228	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	ACINET	AMOXICILLIN + POTASSIUM CLAVULANATE	500 MG + 125 MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6229	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	CO-FLUAMPICIL CAPSULES BP 500MG	FLUCLOXACILLIN SODIUM + AMPICILLIN TRIHYDRATE	250MG +250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE STRIP

NDA/MAL/HDP/6230	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	EMITINO	ONDANSETRON	4MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6231	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	D-ARTEPP DISPERSIBLE	DIHYDROARTEMISIN IN/PIPERAQUINE	20MG/160MG	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6234	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	D-ARTEPP	DIHYDROARTEMESININE/ 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
NDA/MAL/HDP/6235	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LIMITED	UNITED HEALTHCARE DISTRIBUTORS LTD	ANGINET 160MG	VALSARTAN	160MG	UNITED PHARMACEUTICAL MANUFACTURING COMPANY LTD-P.O BOX 69 AMMAN 11591 JORDAN NUZHAT SAHAB AL-RAQEEM NERA PUBLIC SECURITY HOUSING	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6236	MOONLINK PHARMACEUTICALS LTD	PLANET PHARMACEUTICAL S UGANDA LTD	FREMOL ADVANCE	PARACETAMOL + IBUPROFEN + CAFFEINE	325 MG + 400 MG + 40 MG	FREDUN PHARMACEUTICALS LTD-VEOOR PALGHAR (E) 401 404	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X40.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6237	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/6238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	NEBILONG -AM	NEBIVOLOL HYDROCHLORIDE + AMLODIPINE BESILATE	5MG + 5MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6239	BLISS GVS PHARMA LIMITED	DELMAW ENTERPRISES LIMITED	GSUNATE	ARTESUNATE	60MG	BLISS GVS PHARMA LTD- PLOT 73 -76 SILVER INDUSTRIAL ESTATE BHIMPORE DAMAN 396 210 (UT)	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
NDA/MAL/HDP/6242	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	D-ARTEPP	DIHYDROARTEMESININ/PIPERAQUINE PHOSPHATE	80MG/640MG	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X3.0 TABLET BLISTER

NDA/MAL/HDP/6243	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	SURVANTA	BERACTANT	100MG/4ML	ABBVIE NORTH CHICAGO FACILITY-1401 SHERDAN ROAD NORTH CHICAGO FACILITY ILLINOIS 60064 -4000	UNITED STATES	TOPICAL EXTERNAL INSTILLATION VIALS	1.0X4.0 ML VIAL, 1.0X8.0 ML VIAL
NDA/MAL/HDP/6244	CACHET PHARMACEUTICALS 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
NDA/MAL/HDP/6245	BIOLOGICAL E. LTD	ABACUS PHARMA (AFRICA) LIMITED	COSCOPIN LINCTUS	NOSCAPINE + CHLORPHENIRAMINE MALEATE + SODIUM CITRATE + AMMONIUM CHLORIDE	7MG+2 MG+3.25 MG+28 MG/5 ML.	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLTHAR (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6246	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	LUTHER	ARTEMETHER	80MG/ML	CIRON DRUGS AND PHARMACEUTICALS PVT. LTD-N-118, N119, N113, MIDC, TARAPUR, BOISAR, DIST. THANE 401506, INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X6.0X1.0 ML AMPOULE
NDA/MAL/HDP/6247	MILAN LABORATORIES LTD (INDIA) PVT LTD	GITTOES PHARMACEUTICALS LIMITED	MILOXY 250-DT	AMOXICILLIN TRIHYDRATE	250MG	MILAN LABORATORIES (INDIA) PVT LTD- PLOT NO 63/67/87 J.C.I.E LTD KAMOTHE PANVER, NAVI MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY OTHER TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6249	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL METRONIDAZOLE -200 TABLETS	METRONIDAZOLE	200MG	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
NDA/MAL/HDP/6250	REMINGTON PHARMACEUTICAL INDUSTRIES PVT LTD	HEALTHCARE LTD.	ROCIP EYE DROPS	CIPROFLOXACIN HYDROCHLORIDE	3MG/ML	REMINGTON PHARMACEUTICAL INDUSTRIES (PVT) LTD-18 KM MULTAN ROAD LAHORE 53800 PAKISTAN	PAKISTAN	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6256	HOVID BHD (IPOH SITE)	UNITED HEALTHCARE DISTRIBUTORS LTD	AZIMAX- 250	AZITHROMYCIN DIHYDRATE	250MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6257	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	EDURANT	RILPIVIRINE	25MG	JANSSEN CILAG S.P.A-VIA C.JANSSEN, BORGOMANERO ITALY	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/6264	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	PARACONICA 1000 MG IV	PARACETAMOL	10MG/ML	S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO-POTENZA (PZ) ITALY	ITALY	PARENTERAL ORDINARY I V VIALS	1.0X100.0 ML VIAL

NDA/MAL/HDP/6267	DENK PHARMA GMBH & CO KG	BENLE CONSULT LIMITED	TRAMADOL DENK 50	TRAMADOL HYDROCHLORIDE	50MG	LOSAN PHARMA GMBH- OTTO-HAHN-STR 13 79395 NEUENBURG	GERMANY	ORAL SOLID ORDINARY EFFERVESCENT TABLETS	1.0X10.0 TABLET BOTTLE
NDA/MAL/HDP/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, 1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6295	RANBAXY LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	LIRAPYN 75MG	PREGABALIN	75MG	RANBAXY LABORATORIES LTD-PAONTA SAHIB, DISTRICT – SIRMOUR, HIRMACHAL	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X4.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/6299	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLANGEM 5	OLANZAPINE	5MG	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	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/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, 1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6301	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLANGEM 10	OLANZAPINE	10MG	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	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6305	YELURI FORMULATIONS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	ELMOX-CV 375	AMOXICILLIN TRIHYDRATE +CLAVULANATE POTASSIUM	250MG+125MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM, MEDAK DIST.502325, TELANGANA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X5.0 TABLET BLISTER
NDA/MAL/HDP/6314	YELURI FORMULATIONS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	ELMOX-CV 625	AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	500MG+125MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM, MEDAK DIST.502325, TELANGANA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X5.0 TABLET BLISTER

NDA/MAL/HDP/6315	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	ACE SYRUP, 100ML	PARACETAMOL	120MG/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)-SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6316	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	OSMOLAX	LACTULOSE	3.40G/5ML	SQUARE PHARMACEUTICAL LIMITED (PABNA UNIT)-SQUARE ROAD, SALGARIA PABNA-6600 BANGLADESH	BANGLADESH	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6317	YELURI FORMULATIONS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	ELMOX-CV L000	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X5.0 TABLET BLISTER,1.0X3.0X5.0 TABLET BLISTER
NDA/MAL/HDP/6322	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	CLAVACE 1000 MG	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	875MG + 125MG	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6325	LEBEN LABORATORIES PVT. LTD.	ANDYCO PHARMACY (UGANDA) LTD	PZQ TABLET	PRAZIQUANTEL	600MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/6337	LIFE PHARMA FZE	AIVEEN (U) LTD	GASTREX	SIMETHICONE	42 MG	LIFEPHARMA FZE JEBEL ALI FREE ZONE, PLOT NO. MO 0502,P.O. BOX 17404, DUBAI, UAE	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6339	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OXY-POL	OXYTETRACYCLINE HCL + POLYMYXIN B SULPHATE	5MG+10000IU /G	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE
NDA/MAL/HDP/6340	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	AXYLIN CAPSULES	AMPICILLIN TRIHYDRATE + CLOXACILLIN SODIUM	250MG +250 MG	LABORATORY & ALLIED LTD-PLOT NO. 209/10349 OFF MOMBASA ROAD, NAIROBI P.O. BOX 42875, NAIROBI, KENYA.	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6341	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	ROSUMAC 20	ROSUVASTATIN CALCIUM	20MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6342	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIFENAC EYE DROPS	DICLOFENAC SODIUM SALT	1MG/ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC DROPS	1.0X1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6345	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 600MG VAIL	AMOXYCILLIN SODIUM/CLAVULANATE POTASSIUM	500MG/100MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, S" OF OCTOBER CITY, EGYPT. PO. BOX 43, OCTOBER CITY. POSTAL CODE NO.12566	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/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
NDA/MAL/HDP/6354	EXPHAR SA.	SURGIPHARM (U) LIMITED	TIMOSOL ®	TIMOLOL MALEATE	0.5%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6360	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICAL S LTD	ETOCOXX 90MG	ETORICOXIB	90MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED-SUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGAON (EAST), MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6361	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN	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
NDA/MAL/HDP/6363	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MF-DAY 850	METFORMIN HYDROCHLORIDE	850MG	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 FILM-COATED TABLETS	1.0X10.0X14.0 TABLET BLISTER

NDA/MAL/HDP/6366	BEXIMCO PHARMACEUTICALS LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	ODYCIN EYE DROPS	MOXIFLOXACIN HYDROCHLORIDE	5MG/ML	"BEXIMCO PHARMACEUTICALS LTD-126 KATHALDIA, AUCHPARA, TONGI-1711, GAZIPUR."	BANGLADESH	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/6367	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	FINAGEN1	FINASTERIDE	1 MG	AUROBINDO PHARMA LIMITED, UNIT – III-SURVEY NO.:113 & 314,BACHUPALLY (VILLAGE)QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, TELANGANA STATE.INDIA.☐	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6368	SUN PHARMACEUTICAL INDUSTRIES LIMITED	STAR PHARMACEUTICALS LTD	ETOCOX 120MG	ETORICOXIB	120MG	SUN PHARMACEUTICAL INDUSTRIES LIMITED-SUN HOUSE, PLOT NO. 201 B/1 WESTERN EXPRESS HIGHWAY, GOREGAON (EAST), MUMBAI, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6369	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	AIVXIM SUSPENSION	CEFIXIME TRIHYDRATE	100MG/5ML	ASSOCIATED BIOTECH-VILLAGE : KISHANPURA, GURU MAJRA, BADDI, DISTT. SOLAN, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/6370	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYCROM EYE DROPS	SODIUM CROMOGLYCATE	2%W/V	IVEE INFUSIONS EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE, LR NO.18474/84, ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6372	ASTRA PHARMA (U) LTD	ASTRA PHARMA (U) LIMITED	IVYTIMOL EYE DROPS	TIMOLOL MALEATE	0.25%W/V	IVEE INFUSIONS EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE, LR NO.18474/84, ATHI RIVER,KENYA	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6374	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	PREDLEB-5 DT	PREDNISOLONE	5MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA– 444 104 (MS).	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X20.0 TABLET BLISTER
NDA/MAL/HDP/6377	REGAL PHARMACEUTICALS LTD	REGAL PHARMA U LIMITED	EPHICOL CAPSULES	CHLORPHENIRAMINE MALEATE+ PARACETAMOL+ CAFFEINE ANHYDROUS+ PHENYLEPHRINE HCL	2MG+500 MG+30 MG+5MG	REGAL PHARMACEUTICALS LTD..-PLOT 7879/18 OFF BABA DOGO ROAD, RUARAKA	KENYA	ORAL SOLID ORDINARY CAPSULES	1.0X12.0 CAPSULE BLISTER

NDA/MAL/HDP/6380	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MAGNABIOTIC 1200MG VIAL	AMOXICILLIN + CLAVULANIC ACID	1000MG+120 MG	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, S" OF OCTOBER CITY, EGYPT. PO. BOX 43, OCTOBER CITY. POSTAL CODE NO.12566	EGYPT	PARENTERAL ORDINARY DRY VIALS	1.0X1.2 G VIAL
NDA/MAL/HDP/6382	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MF-DAY 500	METFORMIN TABLETS BP	500MG	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 FILM-COATED TABLETS	1.0X10.0X14.0 TABLET BLISTER
NDA/MAL/HDP/6383	EXPHAR SA.	SURGIPHARM (U) LIMITED	EXXIB	CELECOXIB	200MG	GRACURE PHARMACEUTICALS LIMITED -E-1105, RIICO INDUSTRIAL AREA, PHASE-III BHIWADI, PIN-301019 DIST. ALWAR, RAJASTHAN, INDI	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6385	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KPI HEALTHCARE LIMITED	AMOXIKID-250	AMOXICILLIN	250MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD -PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1.0X10.0 TABLET STRIP
NDA/MAL/HDP/6386	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	JUSDEE 60K GRANULES	COLECALCIFEROL	60000 IU	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X8.0X1.0 G SACHET
NDA/MAL/HDP/6388	IPCA LABORATORIES LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/6389	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	METRONIDAZOLE BP	METRONIDAZOLE	0.5%W/V	ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6392	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	MET XL 50	METOPROLOL SUCCINATE	50 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID RETARD FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6396	NVS KENYA LTD	SURGIPHARM (U) LIMITED	LETROZOLE 2.5	LETROZOLE	2.5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6397	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	INDOSUPP 100	INDOMETHACIN	100 MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/6400	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	FENSUPP-100	DICLOFENAC SODIUM	100MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC ADULT SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/6401	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	SUPPOL 250 SUPPOSITORIES	ACETAMINOPHEN	250MG	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C.,KABILPORE,NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/6404	STEDMAN PHARMACEUTICALS PVT. LTD	VEERAM HEALTHCARE (U) LIMITED	STEDNAC GEL	ACECLOFENAC + LINSEED OIL + METHYL SALICYLATE	1.5%W/W + 3.0W/W +10.0%W/W	STEDMAN PHARMACEUTICALS PVT LIMITED- NO. C-4, SIDCO PHARMACEUTICAL COMPLEX, ALATHUR, THIRUPORUR, KANCHEEPURAM DIST 603 110, TAMILNADU, INDIA	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/6412	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BUCCAZOLE ORAL GEL	MICONAZOLE	2%W/W	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL TOPICAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/6418	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KPI HEALTHCARE LIMITED	AZOX 250	AZITHROMYCIN DIHYDRATE	250MG	THE JORDANIAN PHARMACEUTICAL MANUFACTURING COMPANY.-UM-AL-AMAD/PLANT (RAZI).P.O.BOX 151 UM-AL-AMAD 16197 JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6421	ALEMBIC PHARMACEUTICALS LIMITED.	GITTOES PHARMACEUTICALS LTD	TELLY-H	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6422	INTERNATIONAL ORGANIZATION FOR MIGRATION	AIVEEN (U) LIMITED	EMADON	ONDANSETRON	4MG	CORONA REMEDIES PVT LTD--VILLAGE JATOLI,POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. OLAN HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6431	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	BRUMOX 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6431	BRAWN LABORATORIES LTD	HEALTHCARE LTD.	BRUMOX 125	AMOXICILLIN TRIHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6433	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/6435	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/6436	GUILIN PHARMACEUTICALS CO.LTD	STAR PHARMACEUTICAL S LTD	MOXAF	MOXIFLOXACIN HYDROCHLORIDE	400 MG	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/6437	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	PILORECT	HYDROCORTISONE ACETATE +LIDOCAINE +ZINC OXIDE +ALLANTOIN	0.25%W/W+3 %W/W+5%W/W+0.5%W/W	MERIDIAN ENTERPRISES PVT. LTD-PLOT NO. 418, G.I.D.C., KABILPORE, NAVSARI GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X6.0 SUPPOSITORY STRIP
NDA/MAL/HDP/6439	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/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

NDA/MAL/HDP/6441	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	OFLOXACIN INTRAVENOUS INFUSION	OFLOXACIN	0.2%W/V	ABARIS HEALTHCARE PVT. LTD--PLOT NO: 1407-1411 VILLAGE: RAJPUR TALUKA: KADI, DIST.: MEHSANA 382 740, GUJARAT INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6442	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	AZITO SUSPENSION	AZITHROMYCIN DIHYDRATE	200 MG/5ML	ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/6447	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	AZIBRU 500	AZITHROMYCIN DIHYDRATE	500MG	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6448	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE-DEPOT 40 MG/ 1 ML VIAL	METHYLPREDNISOLONE ACETATE	40 MG/ ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1, EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X1.0 ML VIAL
NDA/MAL/HDP/6449	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	DESORAT SYRUP	DESORATIDINE	0.5MG/ML	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAHR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6455	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/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
NDA/MAL/HDP/6457	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MOXIWAR 400	MOXIFLOXACIN HYDROCHLORIDE	400MG	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 FILM-COATED TABLETS	1.0X2.0X5.0 TABLET BLISTER

NDA/MAL/HDP/6465	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/6466	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN ORAL TABLETS USP 500,000 I.U.	NYSTATIN	500,000IU	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6468	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	CIROLAZINE	HYDRALAZINE HYDROCHLORIDE	20MG/ML	CIRON DRUGS & PHARMACEUTICAL PVT LTD -1, PRABHAT NAGAR, GROUND FLOOR, JOGESHWARI (W), MUMBAI -400 102. INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/6469	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICAL S (U) LIMITED	JUSPRIN 81 E/C TABLETS	ASPIRIN	81MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X20.0 TABLET BLISTER
NDA/MAL/HDP/6470	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	MF-DAY 1000	METFORMIN HYDROCHLORIDE	1000MG	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 FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6471	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	CEFUZIME 500	CEFUROXIME AXETIL	500MG	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6475	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	MOXAL SUSPENSION	ALUMINIUM HYDROXIDE +MAGNESIUM HYDROXIDE	405 MG+100 MG/ 5ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/6476	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPIZOLONE-DEPOT	METHYLPREDNISOL ONE	80MG/2ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL RETARD VIALS	1.0X1.0X2.0 ML VIAL

NDA/MAL/HDP/6478	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	RANTAG INJECTION	RANITIDINE HYDROCHLORIDE	50MG/2ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	PARENTERAL ORDINARY AMPOULES	1.0X1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/6479	SWISS PARENTERALS PVT. LTD.	ROYAL PHARMA 2011 LIMITED	TRAMADOL HYDROCHLORIDE INJECTION 100MG/2ML	TRAMADOL HYDROCHLORIDE	100MG/2ML	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
NDA/MAL/HDP/6481	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	MOXAL PLUS CHEWABLE TABLETS	DRIED ALUMINIUM HYDROXIDE GEL+MAGNESIUM HYDROXIDE+SIMETH ICONE	200MG+200MG+25MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6483	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	MOXAL II SUSPENSION	ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE	215MG+80MG /5ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6485	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	CEFUZIME 750	CEFUROXIME SODIUM	750MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA, P.O.BOX:997,RAS AL KHAIMAH,U.A.E.	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X750.0 MG VIAL
NDA/MAL/HDP/6488	GUILIN PHARMACEUTICAL CO.LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	PARACETAMOL INJECTION	PARACETAMOL	300MG/2ML	GUILIN PHARMACEUTICAL CO LTD-NO.43 QILIDIAN ROAD GUILIN 541004 GUANGXI	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/6489	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICAL S LTD	ASCORIL-SF	SALBUTAMOL+BRO MHEXINE HYDROCHLORIDE+G UAIFENESIN	2MG+4MG+100MG/10ML	GLENMARK PHARMACEUTICALS LTD-VILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6490	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/6491	INTAS PHARMACEUTICALS LIMITED	NORVIK ENTERPRISES LIMITED	PREGATAS ME 75	PREGABALIN +MECOBALAMIN	75MG+750MG	INTAS PHARMACEUTICALS LIMITED -CAMP ROAD, SELAQUI-248197,DEHRADUN UTTARAKHAND, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6492	UMEDICA LABORATORIES PVT. LTD	GITTOES PHARMACEUTICAL S LIMITED	LIDOCAINE INJECTION BP 2%W/V	LIDOCAINE HYDROCHLORIDE	2%W/V	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 VIAL CARTON

NDA/MAL/HDP/6495	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	MACROLYN® 500 MG FILM COATED TABLETS	AZITHROMYCIN DIHYDRATE	500MG	DEVA HOLDING A. S.-ÇERKEZKÖY ORGANIZE SANAYİ BOLGESİ. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6496	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NEUROKEM 150	PREGABALIN	150MG	ALKEM LABORATORIES LTD--167/2, MAHATMA GANDHI UDYOG NAGAR DABHEL, AMALIYA, DAMAN(UT) 396 210 INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6498	MICRO LABS LIMITED	LABOREX UGANDA LIMITED	AMOXICILLIN DISPERSIBLE TABLETS 250 MG	AMOXICILLIN TRIHYDRATE	250MG	MICRO LABS LIMITED.-PLOT 16, VEERASANDRA IND. AREA,ANEKAL TALUK, BANGALORE INDIA	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/6501	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARTROGYL 200 TABLET	METRONIDAZOLE	200MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6505	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	CO-ARLUMETHER FORTE	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	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	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6507	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	ZITRAM P	ACETAMINOPHEN + TRAMADOL HYDROCHLORIDE	325MG + 37.5MG	IPCA LABORATORIES LTD-PLOT NO. 255/1, VILLAGE ATHAL, SILVASSA-396230, DADRA AND NAGAR HAVELI, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6512	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	AXACIP	CIPROFLOXACIN	200MG/100ML	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6520	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 8	ONDASENTRON	8MG	MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6523	EXPHAR SA.	SURGIPHARM (U) LIMITED	FLEXDOL	IBUPROFEN+METHO CARBAMOL	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
NDA/MAL/HDP/6529	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	PRAZQUANTEL TABLETS 600 MG	PRAZQUANTEL	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
NDA/MAL/HDP/6532	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/6534	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	REXIDIN	CHLORHEXIDINE GLUCONATE	0.2%W/V	INDOCO REMEDIES LTD, B-20, B-20 MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL TOPICAL LIQUIDS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6537	EXPHAR SA	SURGIPHARM (U) LIMITED	CARBOSOL	CARMELLOSE SODIUM	0.5%W/V	AHLCONPARENTERALS (INDIA) LIMITED-SP-918, PHASE-III, BHIWADI-301019, RAJASTHAN (INDIA) TEL: +91-1493-305300 (30 LINES) FAX: +91-1493-221045, 305345	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6540	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	VANCOLON	VANCOMYCIN HYDROCHLORIDE	1G	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/6541	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	DIALON 1000 MG	METFORMIN HYDROCHLORIDE	1000MG	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6544	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	ORAMAX 150MG	FLUCONAZOLE	150MG	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CAPSULES	1.0X1.0X1.0 CAPSULE BLISTER
NDA/MAL/HDP/6547	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	AMYDRAMINE PAEDIATRIC SYRUP	DIPHENHYDRAMINE HYDROCHLORIDE+SODIUM CITRATE+MENTHOL	7MG+28.5MG +0.55 MG/5 ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE

NDA/MAL/HDP/6548	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	CIROPAIN GEL	DICLOFENAC DIETHYLAMINE BP	1%W/W	CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	TOPICAL EXTERNAL GELS AND SOLS	1.0X20.0 G TUBE
NDA/MAL/HDP/6561	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	RISEK	OMEPRAZOLE	20MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY CAPSULES	1.0X14.0 CAPSULE BOTTLE
NDA/MAL/HDP/6568	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNADIP 50 TABLET	DICLOFENAC	50MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6573	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	EFAVIRENZ TABLETS USP 400MG	EFAVIRENZ	400MG	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	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/6574	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	ARCHIFAR	MEROPENEM	1G	MEDOCHÉMIE LTD COGOLS FACILITY-1-10 CONSTANTINOUPOLEOS STREET, ZAKAKI, LIMASSOL, CYPRUS	CYPRUS	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X1.0 G VIAL
NDA/MAL/HDP/6595	RAVIAN LIFE SCIENCE PVT. LTD	ROYAL PHARMA 2011 LIMITED	MOLURAV	LEVOCETIRIZINE DIHYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	RAVIAN LIFE SCIENCE PVT LTD-PLOT NO.34,SECTOR-8A,IIE,HARIDWAR-249403, UTTARKHAND	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6610	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND	ONDANSETRON HYDROCHLORIDE	2MG/ML	MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0X2.0 ML AMPOULE
NDA/MAL/HDP/6612	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APRAZOLE PLUS-20	OMEPRAZOLE + SODIUM BICARBONATE	20MG/6G + 1680MG/6G	AJANTA PHARMA LTD.-B-4-5-6, MIDC PAITHAN, AURANGABAD	INDIA	ORAL SOLID ORDINARY POWDERS	1.0X20.0X6.0 G SACHET
NDA/MAL/HDP/6613	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	OLMAT-40	OLMESARTAN MEDOXOMIL	40MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6614	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AXETINE	CEFUROXIME SODIUM	1.5MG	MEDOCHÉMIE LTD-1-10 ASTRONAFTON & CONSTANTINOPOLEOS 3505 LIMASSOL	CYPRUS	PARENTERAL ORDINARY VIALS	1.0X10.0 VIAL CARTON
NDA/MAL/HDP/6615	UNEED GLOBAL GROUP LIMITED	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

NDA/MAL/HDP/6616	SHIN POONG PHARMACEUTICALS CO.LTD	BOOTS PHARMACEUTICALS LIMITED	PYRAMAX	PYRONARIDINE TETRAPHOSPHATE + 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
NDA/MAL/HDP/6617	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APFLU	CHLOROPHENERAMINE + PARACETAMOL + VITAMIN C	0.5MG + 120MG + 50MG	AJANTA PHARMA LIMITED-31-0 MIDC INDUSTRIAL AREA CHIKALTHANA 431210 DIST AURANGABAD MAHARASHTRA STATE	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6619	ESAPHARMA S.R.L..	BYAMAKA PHARMACEUTICAL COMPANY LTD	ORANVATE	CLOBETASOL PROPIONATE	0.05G/100G	ESAPHARMA S.R.L.VIA-VIA ALCIDE DE GASPERI, 23, MELZO MI, ITALY	ITALY	TOPICAL EXTERNAL GELS AND SOLS	1.0X30.0 G TUBE
NDA/MAL/HDP/6620	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET 5MG	NEBIVOLOL HYDROCHLORIDE	5MG	BERLIN-CHEMIE AG-BERLIN-CHEMIE AG GLIENICKER WEG 125 D-12489 BERLIN	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER,1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/6621	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	BAROLE 20	RABEPRAZOLE	20MG	INVENTIA HEALTHCARE PVT. LTD .-FI – FI /1 ADDITIONAL AMBERNATH(EAST) – 421 506,MAHARASHTRA DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6622	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CEFIWEL-100 DT	CEFIXIME TRIHYDRATE	100MG	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 OTHER TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6623	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	REFINAC SR	DICLOFENAC SODIUM	100MG	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	ORAL SOLID RETARD ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6624	SQUARE PHARMACEUTICALS LTD.PABNA UNIT	GAMA PHARMACEUTICALS (U) LIMITED	CIPROKEN	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/V	SQUARE PHARMACEUTICALS LTD - DHAKA UNIT KALIAKOIR GAZIPUR	BANGLADESH	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6625	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/12.5	NEBIVOLOL HYDROCHLORIDE + HYDROCHLOROTHIAZIDE	5MG + 12.5MG	BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, -) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION, BATCH CONTROL) TEMPELHOFFER WEG 83 D-12347 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/6627	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS HONEY & LEMON	MULTI-INGREDIENT	MULTI-INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THAILAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK
NDA/MAL/HDP/6628	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	GITTOES PHARMACEUTICALS LIMITED	STREPSILS REGULAR	MULTI-INGREDIENT	MULTI-INGREDIENT	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED-RECKITT BENCKISER HEALTHCARE INTERNATIONAL-65 MOO 12,LARD KRABANG-BANGPLEE ROAD, BANGPLEE SAMUTPRAKARAN 10 540, THAILAND	THAILAND	ORAL SOLID ORDINARY LOZENGES	1.0X24.0 LOZENGE PACK,1.0X70.0 LOZENGE PACK
NDA/MAL/HDP/6629	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILET PLUS 5/25	NEBIVOLOL+HYDROCHLOROTHIAZIDE	5MG+25MG	) BERLIN-CHEMIE AG, SITE BRITZ (BULK PRODUCTION-TEMPELHOFFER WEG 83 D-12347 BERLIN GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER,1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/6630	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TOPRAZ 20	PANTOPRAZOLE	20MG	AUROBINDO PHARMA LIMITED (SEZ, UNIT – VII), -SURVEY NO.411, 425, 434, 435 & 458, APIIC, PLOT NO. SI GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT, HYDERABAD, ANDHRA PRADESH 500090, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6632	UMEDICA LABORATORIES PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	CIPROFLOXACIN	CIPROFLOXACIN	500MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6633	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	COLDRIIL	PARACETAMOL + CHLORPHENIRAMINE MALEATE + PSEUDOEPHEDRINE HCL	500MG + 30MG + 2MG	SHELYS PHARMACEUTICALS LIMITED-PLOT NO. 696, BLOCK NO. 32, MIKOCHENI 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,1.0X12.0X1.0X2.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/6634	UMEDICA LABORATORIES PVT. LTD	GITTOES PHARMACEUTICALS LIMITED	FIXDEP -120	FEXOFENADINE HYDROCHLORIDE	120MG	UMEDICA LABORATORIES PVT, VAPI-PLOT 221, GIDC II, VAPI-396195, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6636	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/6637	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/6638	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	COSAMIDE 50	LACOSAMIDE	50MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6640	MSN LABORATORIES PVT LTD	GOOD DAY PHARMACY LIMITED	SAFETELMI H (40/ 12.5)	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6645	MSN LABORATORIES PVT LTD	GOOD DAY PHARMACY LIMITED	SAFETELMI H (80/ 12.5)	TELMISARTAN + HYDROCHLOROTHIAZIDE	80MG + 12.5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6647	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	JOYCLAV -625	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500MG + 125MG	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	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6650	INDUS LIFE SCIENCES PVT LIMITED	PNR PHARMACEUTICALS LIMITED	INTRIAX-S-1	CEFTRIAZONE SODIUM+SULBACTAM SODIUM	1G+0.5G	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/6651	GOOD DAY PHARMACY LIMITED	GOOD DAY PHARMACY LIMITED	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

NDA/MAL/HDP/6652	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	LAMIVUDINE +TENOFVIR DISOPROXIL FUMARATE	LAMIVUDINE+TENOF OVIR 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
NDA/MAL/HDP/6653	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	METSAFE 500 ER	METFORMIN HYDROCHLORIDE	500MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6654	PANACEA BIOTEC LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/6655	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ATORLIP-20	ATORVASTATIN CALCIUM	20MG	CIPLA LTD -MIDC PATALGANGA MS 410 220 INDIA MFG LIC: 845	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6656	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PLENMOXI	MOXIFLOXACIN HYDROCHLORIDE	400MG	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	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6657	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	METFORMIN	METFORMIN HYDROCHLORIDE	500MG	CIPLA LTD-MIDC PATALGANGA 410 220 DIST. RAIGAD	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6658	MSN LABORATORIES LTD	GOOD DAY PHARMACY 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
NDA/MAL/HDP/6660	CLARIS INJECTABLES LTD	REDDYS PHARMA LIMITED	KETAJEX	KETAMINE	50MG/ML	CLARIS INJECTABLE LIMITED--CHACHARWADI VASANA AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/6663	PANACEA BIOTEC LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/6664	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 125 KID	AMOXICILLIN TRIHYDRATE	125MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1;SURVEY NO. 242/243/244,LAKHABAVAD,JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6665	REGAL PHARMACEUTICALS LTD	REGAL PHARMA (U) LTD	SALBUMOL SYRUP	SALBUTAMOL	2MG/5ML	REGAL PHARMACEUTICALS LTD-BABA DOGO ROAD, RAURAKA, NAIROBI, KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6666	MSN LABORATORIES LTD	GOOD DAY PHARMACY LIMITED	NEBIEM 5	NEBIVOLOL HYDROCHLORIDE	5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6667	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	SPAMOX 250 DT	AMOXICILLIN TRIHYDRATE	250MG	SPARSH BIO-TECH PVT. LIMITED-PLOT NO. 1; SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR-361 006, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/6669	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	SUPER WELGRA -100	SILDENAFIL CITRATE + DAPOXETINE HYDROCHLORIDE	100MG + 60MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/6670	AFRICURE PHARMACEUTICALS (INDIA) PRIVATE LIMITED,	ROYAL PHARMA 2011 LIMITED	METROSIM-200	METRONIDAZOLE	200MG	STRIDES SHASUN LTD.-PLOT 9-12 DEWAN & SONS INDL AREA VEOOR PALGHAR MAHARASTRA INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/6671	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	NOPEN	ASPRIRIN+CAFFEINE	350MG+30MG	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
NDA/MAL/HDP/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
NDA/MAL/HDP/6676	YSP INDUSTRIES(M) SDN BHD	ROYAL PHARMA 2011 LIMITED	CASPRIN	ACETYLSALICYLIC ACID	100MG	YSP INDUSTRIES SND.BHD-LOT 3,5&7 JOLAN P/7 SEC 13, KAWASAN PERINDUSTRIAN	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X1.0X30.0 CAPSULE BLISTER
NDA/MAL/HDP/6678	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	TUSQ-DX	CHLORPHENIRAMINE MALEATE + DEXTROMETHORPHAN HBR + PHENYLEPHRINE	2MG/5ML + 15MG/5ML + 5MG/5ML	BLUECROSS LABORATORIES LIMITED-A-12, M.I.D.C, NASHIK 422010	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X1.0X100.0 ML BOTTLE

NDA/MAL/HDP/6679	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	WOMIBAN TABLETS	ALBENDAZOLE	400MG	BLUE CROSS LABORATORIES LTD-A-12, M.I.D.C AMBAD NASHIK-422010 BLUE CROSS LABORATORIES LTD-L-17, VERNA INDUSTRIAL ESTATE,VERNA GOA-403722	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0 TABLET STRIP
NDA/MAL/HDP/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
NDA/MAL/HDP/6681	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	WELQUINE	LEVOFLOXACIN	0.5%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD. - PLANT III, PLOT NO. 2, 3, 4 & 5, SECTOR 6-B, IIE, SIDCUL, RANIPUR, HARIDWAR, UTTARAKHAND	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6682	BEIJING HOLLEY COTEC PHARMA CHINA	SUPER PHARMACEUTICALS LIMITED	PROCILIN	FORTIFIED PROCAINE BENZYL PENICILLIN	4MU	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100,SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD-PRIVATE ECONOMY GARDEN,XINYAN JINING CITY,SHANDONG,CHINA	CHINA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 VIAL CARTON,1.0X50.0 VIAL CARTON
NDA/MAL/HDP/6685	NEON LABORATORIES 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
NDA/MAL/HDP/6686	DAWA LIMITED	SUPER MEDIC LTD	DAWASOLONE	PREDNISOLONE	5MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER,1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6690	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	ADVANTAN OINTMENT	METHYLPREDNISOLONE ACEPONATE	0.1%W/W	BAYER HEALTH CARE MANUFACTURING S.R.I S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE
NDA/MAL/HDP/6691	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	AZITHROMYCIN SANDOZ	AZITHROMYCIN MONOHYDRATE	200MG/5ML	SANDOZ SRL LTD-LIVEZENI STREET 7A540472 TARGU MURES ROMANIA	ROMANIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/6692	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ASUNRA 100	DEFERASIROX	100MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X5.0X6.0 TABLET BLISTER

NDA/MAL/HDP/6698	COSMOS LTD	ASTRA PHARMA (U) LIMITED	ALBUZOL 400MG TABLETS	ALBENDAZOLE	400MG	COSMOS LIMITED--RANGWA ROAD, OFF LUNGA LUNGA ROAD,P.O BOX 414 33, NAIORBI INDUSTRIAL AREA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER,1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/6700	CACHET PHAMACUITICALS PVT LTD	ASTRA PHARMA (U) LIMITED	ARTIMED	DICLOFENAC SODIUM	50MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6701	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-ART DS	ARTEMETHER / LUMEFANTRINE	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
NDA/MAL/HDP/6703	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHCOLD PLUS	PARACETAMOL/ CAFFEINE/ PHENYLEPHRINE/ CHLORPHENIRAMIN E	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
NDA/MAL/HDP/6704	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHET	CETIRIZINE HCL	10MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X5.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6705	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHEWORM	MEBENDAZOLE	100MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/6706	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACH-E-WORM	MEBENDAZOLE	100MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/6707	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHFER	IRON + FOLIC ACID + VITAMIN B12	32MG/15ML + 0.5MG/15ML + 7.5MCG/15ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/6709	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHPAR	PARACETAMOL	500MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/6710	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	DIABIN TABLETS	METFORMIN	500MG	PHARMEDIC LAB (PVT) LTD-# 4263, 16KM MULTAN RD, LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6711	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACHPAR	PARACETAMOL	125MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6712	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CACID-O	OMEPRAZOLE	20MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/6713	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAMET	METOCLOPRAMIDE HYDROCHLORIDE	10MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6714	SEARLE PAKISTAN LIMITED	HEALTHCARE LTD.	HYDRYLLIN SYRUP	AMINOPHYLLINE+ AMMONIUM HCL+ DIPHENHYDRAMINE HCL	32MG +300MG+8MG	SEARLE PAKISTAN LTD-PLOT F-319, SITE KARACH, 75700 PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/6715	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAZITHRO	AZITHROMYCIN	200MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X15.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/6717	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CAZITHRO	AZITHROMYCIN	500MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/6718	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	CETPRO	CYPROHEPTADINE HYDROCHLORIDE	2MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/6720	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	COLESTOP	ATORVASTATIN	20MG	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6722	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 40	TELMISARTAN	40MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6724	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	CILZEC 80	TELMISARTAN	80MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/6728	COSMOS LTD	ASTRA PHARMA (U) LIMITED	CIPROCOS-500 TABLETS	CIPROFLOXACIN	500MG	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X10.0 TABLET BLISTER,10.0X10. 0 TABLET BLISTER
NDA/MAL/HDP/6729	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF 'C' LINCTUS	MULTI-INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE,1.0X60.0 ML BOTTLE
NDA/MAL/HDP/6730	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	CEFOTRIM-1000	CEFTRIAXONE	1000MG	PHARMEDIC LAB (PVT) LTD-# 4263, 16KM MULTAN RD, LAHORE PAKISTAN	PAKISTAN	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL + 5 ML AMPOULE OF WATER FOR INJECTION
NDA/MAL/HDP/6731	SANDOZ GMBH C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	PIPTAZO 4.5G	PIPERACILLIN SODIUM+TAZOBACT AM SODIUM	4G+0.5G	SANDOZ GMBH-BIOCHEMIESTRABE 10 A6250 KUNDL, TYROL, AUSTRIA	AUSTRIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 ML VIAL
NDA/MAL/HDP/6732	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSCOF EXPECTORANT ORIGINAL	MULTI-INGREDIENT	MULTI- INGREDIENT	COSMOS LTD.-RANGWE ROAD; OFF LUNGA LUNGA ROAD. P.O BOX 414 33, NAIROBI	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE,1.0X100. 0 ML BOTTLE
NDA/MAL/HDP/6733	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	LOMEXIN	FENTICONAZOLE	2%W/W	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X40.0 G TUBE

NDA/MAL/HDP/6734	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	EASCOF	BROMHEXIDINE HCL + SALBUTAMOL SULPHATE + GUAIPHENESIN	24MG/100ML + 42MG/100ML + 1G/ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6735	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	NAPREBEN	NAPROXEN BETAINE SODIUM	10%W/W	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	TOPICAL EXTERNAL GELS AND SOLS	1.0X25.0 G TUBE
NDA/MAL/HDP/6736	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SANDOSTATIN	OCTREOTIDE ACETATE	0.05MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/6738	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	SEEBRI BREEZHALER	GLYCOPYRRONIUM BROMIDE	50MCG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X1.0 CANNISTER CARTON + 30 CAPSULE BLISTER
NDA/MAL/HDP/6739	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	PACIFIC'S JACK & JILL CHILDREN'S FORMULA	DEXTROMETHORPHAN + CHLORPHENIRAMINE	10MG + 2MG / 5ML	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY LIQUIDS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/6740	SCHERING N.V.SA...	SURGIPHARM (U) LIMITED	TRAVOGEN CREAM	ISOCONAZOLE NITRATE	1%W/W	BAYER HEALTH CARE MANUFACTURING S.R.I S.P.A VIA SCHERING,21 20090 SEGRATE (MILAN) ITALY	ITALY	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/6741	NVS KENYA LTD	SURGIPHARM (U) LIMITED	ULTIBRO BREEZHALER	INDACATEROL MALEATE+GLYCOPYRRONIUM BROMIDE	110MCG+50MCG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	LUNG ADMINISTRATION INHALER CAPSULES	1.0X30.0 CAPSULE BLISTER
NDA/MAL/HDP/6742	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	RIFIN FORTE	RIFAMPICIN +ISONIAZID+ PYRAZINAMIDE+ETHAMBUTOL	150MG + 75MG+400MG +275MG	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	1.0X10.0X8.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/6745	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	TYZORIN MOUTH WASH	TIBEZONIUM IODIDE	0.05G/100ML	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	TOPICAL EXTERNAL LIQUIDS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/6746	KOPRAN LTD	TATA UGANDA LIMITED	FLUPEN-250	FLUCLOXACILLIN SODIUM	250MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/6747	PACIFIC PHARMACEUTICALS LTD	HEALTHCARE LTD.	TYZORIN	TIBEZONIUM IODIDE	5MG	PACIFIC PHARMACEUTICALS LTD-30TH KILOMETRE NULTAN ROAD LAHORE PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY LOZENGES	1.0X4.0X6.0 LOZENGE STRIP
NDA/MAL/HDP/6748	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	IBUFLAMAR 200	IBUPROFEN	200MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/6749	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	IBUFLAMAR-P	IBUPROFEN+PARACE TAMOL	400MG+500MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER, 1.0X10.0 X10.0 TABLET BLISTER
NDA/MAL/HDP/6750	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	NYTIN	NYSTATIN	500,000IU	KAMPALA PHARMACEUTICALS INDUSTRIES LTD.-PLOT M444B STRETCHER RD, NTINDA KLA UGANDA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CONTAINER
NDA/MAL/HDP/6751	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	METCHEK 850	METFORMIN	850MG	INDOCO REMEDIES LTD-B-20, MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6752	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	VITACEE	ASCORBIC ACID	100MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1000.0 TABLET CONTAINER, 1.0X 10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6753	BLUE CROSS LABORATORIES LIMITED	STAR PHARMACEUTICALS LTD	TUSQ X SYRUP	TERBUTALINE+BRO MHEXINE+GUAIFENESIN	1.25MG+4MG +50MG/5ML	BLUECROSS LABORATORIES LIMITED-A-12,M.I.D.C,NASHIK 422010	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6754	INDIAN IMMUNOLOGICALS LIMITED	TATA UGANDA LIMITED	ABHAYRAB	RABIES ANTIGEN DERIVED FROM RABIES VIRUS(L.PASTEUR 2061/VERO STRAIN)	>2.5 I.U PER VIAL	HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF INDIAN IMMUNOLOGICALS LTD) .-KOZHIPANNAI PUDUMUND P.O DR. BASAVIAH NAGAR UDHAGAMANDALAM PIN: 643007 TAMIL NADU	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.5 I.U VIAL 1*0.5ML DILUENT(0.9%W /V SODIUM CHLORIDE INJ. B.P) - 1 DOSE VIAL

NDA/MAL/HDP/6755	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	FLAMAR	METHYL NICOTINATE+MEPHE NESIN+METHYL SALICYLATE+MENTH OL	1%W/W+5%W/W+8%W/W+2%W/W	INDOCO REMEDIES LTD - 0-L-14 VERNA INDUSTRIAL AREA, VERNA, GOA-403722	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/6756	BETA HEALTHCARE	BETA HEALTHCARE UGANDA LIMITED	FEVERIX TOTO SUSPENSION	PARACETAMOL	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
NDA/MAL/HDP/6757	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	OSTEOFAM	DICLOFENAC SODIUM	50MG	INDOCOS REMEDIES LTD-L-14 VERNA INDUSTRIAL AREA VENA GOA-403722	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6758	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	ADCO-NAPAMOL	PARACETAMOL	500MG	ADCOCK INGRAM LIMITED-49C & D BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK, BANGALORE 560099, KARNATAKA STATE, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6759	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	BETAPYN	PARACETAMOL+COD EINE PHOSPHATE+DOXYL AMINE+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,1.0X1.0X9.0 TABLET BLISTER
NDA/MAL/HDP/6760	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	RIFAMPACIN/ ISONIAZID DISPERSIBLE TABLET	RIFAMPACIN + ISONIAZID	60 MG + 30 MG	MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/6761	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	DAWANOL TABLETS	PARACETAMOL+ACE TYLSALICYLIC ACID+CAFFEINE	200MG+300MG+30MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET CARTON
NDA/MAL/HDP/6762	COSMOS LTD	ASTRA PHARMA (U) LIMITED	FLUCOLD CAPSULES	MULTIINGREDIENT	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
NDA/MAL/HDP/6763	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	COMPRAL HEADACHE TABLETS	PARACETAMOL+ASPI RIN+CAFFEINE ANHYDROUS	100MG+400MG+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

NDA/MAL/HDP/6765	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	IBUCACH 200	IBUPROFEN	200MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/6766	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	LOCAINE A	LIDOCAINE HYDROCHLORIDE+A DRENALINE	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
NDA/MAL/HDP/6767	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MEDI-KEEL A	BENZOCAINE+CETYL PYRIDINIUM 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
NDA/MAL/HDP/6768	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MEDI-KEEL A BLACKCURRANT	BENZOCAINE+CETYL PYRIDINIUM 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
NDA/MAL/HDP/6769	ADCOCK INGRAM LIMITED	UGANDA HEALTH MARKETING GROUP LIMITED	MEDI-KEEL A HONEY & LEMON	BENZOCAINE+CETYL PYRIDINIUM 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
NDA/MAL/HDP/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
NDA/MAL/HDP/6772	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	PIOSAFE 30	PIOGLITAZONE HCL	30MG	ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6773	ARISTO PHARMACEUTICALS PVT LTD	NORVIK ENTERPRISES LIMITED	ACECLO	ACECLOFENAC	100MG	ARISTO PHARMACEUTICALS PVT LTD -PLOT NO 208 NEW INDUSTRIAL GREEN NO2 MANDIDEED 462046	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6774	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	AXCEL FLEMIN EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE +AMMONIUM CHLORIDE	12.5MG+130 MG/5ML	KOTRA PHARMA (M) SDN. BHD-1 JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA MALAYSIA	MALAYSIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6775	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYSOLONE	PREDNISOLONE ACETATE	1%W/V	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184 NAIROBI	KENYA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML VIAL

NDA/MAL/HDP/6776	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	M-FORLIN 500	METFORMIN	500MG	LINCOLN PHARMACEUTICAL LIMITED-TRIMAL ESTATE KHATRAJ KOLOL,GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6777	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/6778	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	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
NDA/MAL/HDP/6780	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYTIMOL	TIMOLOL MALEATE	0.5%W/V	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184 NAIROBI	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6781	IND-SWIFT LTD	TATA UGANDA LIMITED	NETAZOX-500	NITAZOXANIDE	500MG	IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6782	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYXOLOL	BETAXOLOL HYDROCHLORIDE	0.5%W/V	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184 NAIROBI	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6783	ABBVIE (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	FORANE	ISOFLURANE	99.9%W/V	AESICA QUEESNBOROUGH LTD .-NORTH ROAD, QUEENBOROUGH KENT ME 11 5EL, UNITED KINGDOM	UNITED KINGDOM	OTHER SYSTEMIC LIQUID INHALATIONS	1.0X250.0 ML BOTTLE
NDA/MAL/HDP/6784	IVEE INFUSIONS EPZ LTD	ASTRA PHARMA (U) LIMITED	IVYZOXAN	CIPROFLOXACIN HYDROCHLORIDE	0.3%W/V	IVEE INFUSION EPZ LTD-ATHI RIVER EXPORT PROCESSING ZONE LR NO. 18474184 NAIROBI	KENYA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6785	IND-SWIFT LTD	TATA UGANDA LIMITED	NETAZOX DT	NITAZOXANIDE	200MG	IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6787	IND-SWIFT LTD	TATA UGANDA LIMITED	NETAZOX	NITAZOXANIDE	100MG/5ML	IND-SWIFT LIMITED-INDUSTRIAL GROWTH CENTRE, PHASE I, SAMBA (JAMMU), J&K 184121, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/6788	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ROYAL VIT G	MULTI-INGREDIENTS	MULTI-INGREDIENTS	SOUTH EGYPT DRUG INDUSTRIES CO. (SEDICO)-1ST INDUSTRIAL ZONE, 5" OF OCTOBER CITY, EGYPT. PO. BOX 43, OCTOBER CITY. POSTAL CODE NO.12566	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/6790	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ABACUS PHARMA (AFRICA) LIMITED	LIMZER	OMEPRAZOLE + DOMPERIDONE	20MG + 30MG	INVENTIA HEALTHCARE PVT. LTD-FI – FI /1 ADDITIONAL AMBERNATH, M.I.D.C. AMBERNATH (EAST) – 421 506, DIST. THANE, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/6792	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA	DARUNAVIR	400MG	JANSSEN ORTHO LLC.--STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/6793	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	NEST	AMINOPHYLLINE	100MG	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/6794	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	ZOLID	LINEZOLID	600MG	HETERO LABS LIMITED UNIT V-APIIC PHARMA SEZ, S. NO. 439, 440, 441 & 458 MOLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR (DISTRICT). PIN 509301	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6796	SANCE LABORATORIES PVT LTD	DELMAR ENTERPRISES LIMITED	SANCEPH DS	CEPHALEXIN	125MG/5ML	SANCE LABORATORIES PVT. LTD.-VI/B, P.B. NO. 2, KOZHUVANAL, PALA, KOTTAYAM DISTRICT-686573, KERALA, INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6797	MARTINDALE PHARMACEUTICALS LTD	LABOREX UGANDA LIMITED	PETHIDINE INJECTION	PETHIDINE	100MG/2ML	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/6806	F. HOFFMANN- LA ROCHE	LABOREX UGANDA LIMITED	RECORMON	EPOETIN BETA	2000 IU/0.3ML	ROCHE DIAGNOSTICS GMBH MANNHEIM - SANDHOFFER STRABE 116, 68305, MANNHEIM	GERMANY	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X0.3 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/6807	GLAXOSMITHKLINE LTD	ERIS 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/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/6808	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	GLYGEN-500	METFORMIN HYDROCHLORIDE	500MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6810	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	CERVARIX	HUMAN PAPILLOMA VIRUS VACCINE (RDNA)	TYPE 16 L1 PROTEIN + TYPE 18 L1 PROTEIN + 3-0- DESACYL- 4'MONOPHOS PHORYL LIPID A(MPL)	GLAXOSMITHKLINE BOILOGICALS-S.A RUE DE L'INSTITUT 89 B-1330 RIXENSART	BELGIUM	PARENTERAL ORDINARY PRE- FILLED SYRINGES	1.0X10.0X0.5 ML VIAL, 1.0X0.5 ML PRE- FILLED SYRINGE (1 DOSE) + A 25 GAUGE NEEDLE
NDA/MAL/HDP/6811	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	COVALSAR- DENK 160/12.5	VALSARTAN + HYDROCHLOROTHIA ZIDE	160MG +12.5MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6812	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	NOFLOX	NORFLOXACIN	0.3%W/V	ABACUS PARENTERAL DRUGS LIMITED-PLOT 114, BLOCK 191	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6813	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	COVALSAR- DENK 320/12.5	VALSARTAN + HYDROCHLOROTHIA ZIDE	320MG +12.5MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6814	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	COVALSAR- DENK 80/12.5	VALSARTAN + HYDROCHLOROTHIA ZIDE	80MG +12.5MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X7.0 TABLET BLISTER
NDA/MAL/HDP/6815	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABCROM EYE DROPS	SODIUM CROMOGLYCATE	2%W/V	ABACUS PARENTERAL DRUGS LTD.-PLOT NO. 114, BLOCK 191, GWAGAMYA, KINGA, KAPEKE, MUKONO	UGANDA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6817	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	LETROZOLE DENK 2.5	LETROZOLE	2.5MG	HAUPT PHARMA MÜNSTER GMBH- SCHLEEBRÜGGENKAMP 15 48159 MÜNSTER,GERMANY	GERMANY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6820	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABBORI EAR DROPS	BORIC ACID	1.83%W/V	ABACUS PARENTERAL DRUGS LIMITED- BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OTIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/6821	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	MAGNESIUM SULPHATE INJECTION	MAGNESIUM SULPHATE	50%W/V	MARTINDALE PHARMACEUTICAL LIMITED - BAMPTON ROAD RMM38UG ENGLAND	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X10. 0 ML AMPOULE
NDA/MAL/HDP/6823	LABOREX UGANDA LIMITED	LABOREX UGANDA LIMITED	EPHEDRINE HYDROCHLORIDE	EPHEDRINE HYDROCHLORIDE	30MG/ML	MARTINDALE PHARMACEUTICALS .- ROMFORD ESSEX RM3 8UG UK	UNITED KINGDOM	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X1.0 ML AMPOULE

NDA/MAL/HDP/6826	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	ZINC SULFATE	ZINC SULFATE	20MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. – 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6833	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ON.SENTRON-DENK 8MG ODT	ONDANSETRON	8MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/6834	GLAXO SMITH KLINE LTD	ERIS LTD	RELVAR ELLIPTA 100/25	FLUTICASONE FUROATE + VILANTEROL	100MCG + 25MCG	GLAXO OPERATIONS UK LTD---HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X1.0 CANNISTER CARTON
NDA/MAL/HDP/6836	GLAXO SMITH KLINE LTD	ERIS LTD	RELVAR ELLIPTA 200/25	FLUTICASONE FUROATE + VILANTEROL	200MCG + 25MCG	GLAXO OPERATIONS UK LTD---HARMIRE ROAD, BARNARD CASTLE, DURHAM DL128 DT UK	UNITED KINGDOM	LUNG ADMINISTRATION METERED-DOSE POWDER INHALER	1.0X30.0 DOSE CANNISTER
NDA/MAL/HDP/6838	TORRENT PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	MEMENTOR 10	MEMANTINE HYDROCHLORIDE	10MG	TORRENT PHARMACEUTICAL LTD-AHMEDABAD-MEHSANA HIGHWAY,TALUKA-KADI,DIST.MEHSANA,INDRAD-282721	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6840	MEDICAL UNION PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	LIPINORM	ATORVASTATIN 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
NDA/MAL/HDP/6843	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	FYTOBACT	CEFOPERAZONE + SULBACTAM	604.96 MG + 570.03 MG	CADILA PHARMACEUTICALS LTD.-1389, TRASAD ROAD, DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/6844	IDA FOUNDATION	JOINT MEDICAL STORE (UPMB - UCMB)	BENZOIC ACID + SALICYLIC ACID	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	1.0X40.0 G TUBE,1.0X800.0 G CONTAINER
NDA/MAL/HDP/6845	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	FYTOBACT 2G	SULBACTAM SODIUM + CEFOPERAZONE SODIUM	1G + 1G	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X2.0 G VIAL
NDA/MAL/HDP/6857	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	BRUCIPRO TABLETS	CIPROFLOXACIN	500MG	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/6862	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/6865	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/6870	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	HYDROSONE 100MG	HYDROCORTISONE SODIUM SUCCINATE	100MG	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X5.0 ML VIAL
NDA/MAL/HDP/6872	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	NETRACORTIL EYE/EAR SUSPENSION	OXYTETRACYCLINE HYDROCHLORIDE +HYDROCORTISONE ACETATE+POLYMYXIN B SULPHATE	10MG+5MG+10000I.U	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/6874	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	CEZIN TABLETS	CETIRIZINE HYDROCHLORIDE	10MG	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6875	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 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
NDA/MAL/HDP/6881	ASTRA LIFECARE (INDIA) PVT. LTD	ASTRA PHARMA (U) LIMITED	ASTRALEVOFLOXA	LEVOFLOXACIN	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
NDA/MAL/HDP/6897	BROOKES PHARMACEUTICAL LABORATORIES L	HARLEYS UGANDA LIMITED	PYODINE GARGLE & MOUTH WASH	POVIDONE IODINE	1G/100ML	BROOKES PHARMACEUTICALS LABORATORIES (PAKISTAN) LTD-PLOT 58 SECTOR 15 KORANGI INDUSTRIAL AREA, KARACHI-PAKISTAN	PAKISTAN	ORAL TOPICAL LIQUIDS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/6914	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	PANZOLE TABLETS	PANTOPRAZOLE	40MG	CORONA REMEDIES PVT LIMITED-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/6924	I CARE PHARMA LIMITED	AIVEEN (U) LIMITED	NAC MR	DICLOFENAC POTASSIUM+PARACETAMOL+CHLORZOXAZONE	50MG+325MG +250MG	CORONA REMEDIES PVT LIMITED-VILLAGE JATOLI, POST OFFICE - OACHGHAT, TEHSIL SOLAN, DIST. SOLAN HIMACHAL PRADESH – 173223. INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6932	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE-200	SODIUM VALPROATE	200 MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6933	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	VALATE 500	SODIUM VALPROATE BP	500MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/6934	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	ANASTROZOLE 1 MG	ANASTROZOLE	1MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERICHKE-ALLEE 1, 39179 BARLEBEN,	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6935	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	SIMVASTATIN 40 MG	SIMVASTATIN	40MG	SANDOZ GRUP SAGLIK .-GEBZE 2 GOSB IHSAN DEDE CAD. 900. SOK 41480 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6948	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	D3 MUST 60 K	CHOLECALCIFEROL	60000IU	MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/6970	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND ORAL SOLUTION	ONDANSETRON	4MG/5ML	MANKIND PHARMA LTD--UNIT II VILLAGE KISHANPURA P.O JAMNIWALA TEHSIL PAONTA SAHIB DISTRICT SIRMOUR 173 025 HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/6974	MANKIND PHARMA LIMITED	TATA UGANDA LIMITED	VOMIKIND-MD 4	ONDANSETRON	4MG	MANKIND PHARMA LIMITED, UNIT-II. - VILLAGE KISHANPURA, P.O JAMNIWALA, PAONTA SAHIB IN H.P.	INDIA	ORAL SOLID ORDINARY ORALLY DISINTEGRATING TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6985	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	COLDRID SYRUP	CETIRIZINE DIHYDROCHLORIDE + PHENYLEPHRINE HCL + PARACETAMOL	2.5MG + 5MG + 125MG	MEDLEY PHARMACEUTICALS, LTD-PLOT 18/19 ZORIC CORSE WAY ROAD KACHIGAM DAMAN	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/6986	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	REPRAZ 20 TABLETS	RABEPRAZOLE SODIUM	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/6987	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	PORAZ CAPSULES	OMEPRAZOLE	20MG	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED CAPSULES	1.0X10.0X10.0 CAPSULE STRIP
NDA/MAL/HDP/6997	HETERO LABS LTD	ASTRA PHARMA (U) LIMITED	EC-PRAM 10	ESCITALOPRAM 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
NDA/MAL/HDP/6999	CIRON DRUGS & PHARMACEUTICAL PVT LTD	ROYAL PHARMA 2011 LIMITED	NYSTATIN ORAL SUSPENSION	NYSTATIN	100000 UNITS/5ML	MEPRO PHARMACEUTICALS LTD-N-118, N-119, N-113, MIDC TARAPUR, BOISAR DIST: THANE-401 506 MAHARASHTRA, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/7004	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	DUOCETZ	PARACETAMOL+TRAMADOL HYDROCHLORIDE	325MG+37.5 MG	MEGA LIFE SCIENCES PUBLIC COMPANY LIMITED..-515/1 MOO 4, SOI 8, BANGPOO INDUSTRIAL ESTATE, PATTANA 3 ROAD, PHRAEKSA, MUEANG	THAILAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7012	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP DVIR	DACLATASVIR + SOFOSBUVIR	60MG + 400MG	MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE
NDA/MAL/HDP/7013	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AZITHRAA 500	AZITHROMYCIN	500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/7014	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	ACEAAR 100 TABLET	ACECLOFENAC	100MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/7015	KOPRAN LIMITED	TATA UGANDA LIMITED	LOKIT	OMEPRAZOLE	20MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/7021	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNOFEC PLUS	ACECLOFENAC+PARACETAMOL	100MG+500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7022	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PINNAFLAM PLUS	DICLOFENAC SODIUM+PARACETAMOL	50MG+500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7023	EXPHAR SA.	SURGIPHARM (U) LIMITED	VERZOL ORAL SUSPENSION	ALBENDAZOLE	200 MG / 5 ML	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X10.0 ML BOTTLE
NDA/MAL/HDP/7024	EXPHAR SA.	SURGIPHARM (U) LIMITED	MICOZAL	KETOCONAZOLE	2%W/W	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/7029	ZIM LABORATORIES LTD	GITTOES PHARMACEUTICALS LIMITED	LIPIZAR 20	ATORVASTATIN CALCIUM (TRIHYDRATE)	20MG	ZIM LABORATORIES LTD-B-21/22, M.I.D.C. AREA, KALMESHWAR – 441501, DIST. NAGPUR, MAHARASHTRA,	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7030	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	ADOL EXTRA	PARACETAMOL+CAFFEINE	500MG+65MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X12.0 TABLET BLISTER
NDA/MAL/HDP/7035	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	GLYPRIDE 3MG	GLIMEPIRIDE	3MG	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7046	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICALS (U) LIMITED	XEMADERM 0.1% CREAM	MOMETASONE FUROATE	0.1%W/W	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	TOPICAL EXTERNAL CREAMS	1.0X30.0 G TUBE
NDA/MAL/HDP/7047	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICALS (U) LIMITED	XEMADERM0.1% OINTMENT	MOMETASONE FUROATE	0.1%W/W	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X30.0 G TUBE
NDA/MAL/HDP/7050	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICALS (U) LIMITED	PANDERM SKIN OINTMENT	NYSTATIN+NEOMYCIN SULFATE+GRAMICIDIN+TRIAMCINOLONE	10,000,000I.U +2.5MG+0.25MG+1MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE

NDA/MAL/HDP/7051	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GAMA PHARMACEUTICALS (U) LIMITED	DEXIPAN CREAM	DEXPANTHENOL	0.05%W/W	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE
NDA/MAL/HDP/7053	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	KETOVID CREAM	KETOCONAZOLE	2%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/7055	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST 400	ACICLOVIR	400MG	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	5.0X5.0 TABLET BLISTER
NDA/MAL/HDP/7057	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VIREST CREAM 5%	ACICLOVIR	5%W/W	HOVID BHD -121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	TOPICAL EXTERNAL CREAMS	1.0X5.0 G TUBE
NDA/MAL/HDP/7063	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	GRISEOFULVIN 500MG FILM-COATED TABLET	GRISEOFULVIN	500MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7070	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 1000 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	1000MG	HOVID BERHAD (CHEMOR SITE)--LOT 56442, 71/2, JALAN IPOH/CHEMOR 31200, PERAK. MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/7078	ICPA HEALTH PRODUCTS LTD	METRO PHARMACEUTICALS LIMITED	HEXIDINE®	CHLORHEXIDINE GLUCONATE	0.2 %W/V	ICPA HEALTH PRODUCTS LIMITED-286/287, GIDC, ANKLESHWAR-393002. GUJARAT, INDIA.	INDIA	TOPICAL EXTERNAL LIQUIDS	1.0X160.0 ML BOTTLE
NDA/MAL/HDP/7088	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LTD - WILSON	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
NDA/MAL/HDP/7090	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LTD	ENDOPROST	CARBOPROST TROMETHAMINE	125MCG/0.5ML	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
NDA/MAL/HDP/7091	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARLEFLOX 500 TABLETS	LEVOFLOXACIN HEMIHYDRATE	500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7093	PHARCO PHARMACEUTICALS LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DECLOPHEN 25 MG INFANTILE SUPPOSITORIES	DICLOFENAC SODIUM	25MG	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
NDA/MAL/HDP/7096	GAMA PHARMACEUTICALS (U) LIMITED	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DEXAPHEN SYRUP	DEXAMETHASONE + CHLORPHENIRAMINE MALEATE	10MG + 40MG/100ML	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/7098	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	ACEFORCE SP	ACECLOFENAC+PARACETAMOL+SERRATIPOPEPTIDASE	100MG+325MG+15MG	AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7100	STRIDES SHASUN LIMITED	DELMAR ENTERPRISES LIMITED	COMBIART 80/480MG	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	STRIDES SHASUN LIMITED --36/7, SURAGAJAKKANAHALLI, INDLAVADI CROSS, ANEKAL TALUK, BANGALORE – 562 106 INDIA	INDIA	ORAL LIQUID ORDINARY EFFERVESCENT POWDERS/GRANULES	1.0X6.0 SACHET CARTON
NDA/MAL/HDP/7101	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	ASTHAREN	SALBUTAMOL SULPHATE	4MG	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7102	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REPRAZINE	CHLORPROMAZINE HYDROCHLORIDE	100MG	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7105	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	TRAMACETAL TABLETS	ACETAMINOPHEN +TRAMADOL HYDROCHLORIDE	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
NDA/MAL/HDP/7106	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REVIVE	GLUCOSE ANHYDROUS + TRISODIUM CITRATE DIHYDRATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	13.5G + 2.9G + 2.6G + 1.5G	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X1.0 SACHET CARTON
NDA/MAL/HDP/7111	INDOCO REMEDIES LIMITED	TATA UGANDA LIMITED	MOFLOREN ED	MOXIFLOXACIN HYDROCHLORIDE	5MG/ML	INDOCO REMEDIES LTD---L-32, 33 & 34, VERNA IND. AREA, VERNA GOA-403722	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/7123	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	MARTINEZ 10	MONTELUKAST SODIUM	10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7124	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	VITAMIN E 400 MG.	VITAMIN E	400 MG	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT. P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X2.0X12.0 CAPSULE BLISTER
NDA/MAL/HDP/7130	LIFEPHARM FZE	AIVEEN (U) LTD - WILSON ROAD	HEMOVIT CAPSULES	DRIED FERROUS SULPHATE + FOLIC ACID	150MG +500MCG	ESKAYEF BANGLADESH LTD--400, TONGI INDUSTRIAL AREA, SQUIB ROAD TONGI-GAZIPUR BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7136	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN 100 MG / 2ML	AMIKACIN SULPHATE	100MG/2ML	EGYPTIAN INT.PHARMACEUTICAL INDUSTRIES CO. E.I.P.C.O --10TH OF RAMADAN CITY – INDUSTRIAL AREA B1- P.O BOX: 149 TENTH - EGYPT	EGYPT	PARENTERAL ORDINARY VIALS	1.0X1.0X2.0 ML VIAL
NDA/MAL/HDP/7139	LIFEPHARM FZE	AIVEEN (U) LIMITED	COLDIFED SYRUP	PSEUDOEPHEDRINE HYDROCHLORIDE+HYTRIPROLIDINE HYDROCHLORIDE	30MG+1.25M G/5ML	LIFEPHARMA FZE .-JEBEL ALI -DUBAI UAE	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE

NDA/MAL/HDP/7146	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	SUNTAC	RANITIDINE HYDROCHLORIDE	150 MG	SUNRISE INTERNATIONAL LABS LTD.-PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051	INDIA	ORAL SOLID ORDINARY CAPSULE	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7147	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	BIMAT	BIMATOPROST	0.03% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL
NDA/MAL/HDP/7148	SUNRISE INTERNATIONAL LABS LTD	ROYAL PHARMA 2011 LIMITED	OMEPSUN	OMEPRAZOLE	20 MG	SUNRISE INTERNATIONAL LABS LTD.-PLOT NO. 100, LANE 5, SECTOR II, PHASE II IDA CHERLAPALLY, HYDERABAD-500 051	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7149	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	OLOPAT OD	OLOPATADINE HYDROCHLORIDE	0.2% W/V	AJANTA PHARMA LIMITED-N-118, 119, MIDC, TARAPUR BOISAR, DIST. THANE 401506, MAHARASHTRA STATE, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X3.0 ML VIAL
NDA/MAL/HDP/7151	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	APDROPS DX	MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE SODIUM PHOSPHATE	5MG+1MG/ML	AJANTA PHARMA LIMITED-N-118, 119, MIDC, TARAPUR BOISAR, DIST. THANE 401506, MAHARASHTRA STATE, INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/7153	EXIR PHARMACEUTICAL COMPANY.	UNEED GLOBAL GROUP LIMITED	TYLOPHEN®	ACETAMINOPHEN	120MG/5ML	EXIR PHARMACEUTICAL COMPANY-2ND KM OF RING ROAD BOROUJERED 69189 IRAN	IRAN	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7154	ABARIS HEALTHCARE PVT. LTD	ROYAL PHARMA 2011 LIMITED	CIPROFLOXACIN HYDROCHLORIDE	CIPROFLOXACIN HYDROCHLORIDE	2MG/ML	ABARIS HEALTHCARE PVT LTD - -SURVEY NO. 1407-11, VILLAGE RAJPUR, TALUKA KADI DIST. MEHSANA, GUJARAT-382740	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/7162	ACG PHARMAPACK PVT. LTD	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	TEXAVIR	TENOFOVIR DISOPROXIL FUMARATE	300MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7175	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	TELPIL A 40/5 MG	TELMISARTAN + AMLODIPINE BESYLATE	40MG + 5MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7189	ACULIFE HEALTHCARE	SUPER MEDIC LTD	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
NDA/MAL/HDP/7202	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VILDAGLIPTIN	VILDAGLIPTIN	50MG	NOVARTIS PHARMA STEIN AG-SCHAFFHARVSERTRASSE CH-4332 STEIN SWITZERLAND.,NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7212	PHARMACO DISTRIBUTION (PTY) LTD	ECHO PHARMACY (U) LIMITED	PHARMALGAN	PARACETAMOL	10MG/ML	AMANTA HEALTHCARE LIMITED-PLOT NO. 876 N.H. NO. 8 VILLAGE-HIRIYALA TALUKA, MATAR, DIST KHEDA-387 411, GUJARAT	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7217	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARPANTO 40	PANTOPRAZOLE	40MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7218	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARTMIN 500	METFORMIN	500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7219	THEON PHARMACEUTICALS LTD	AIVEEN (U) LIMITED	THEOXONE -1 G	CEFTRIAXONE	1G	THEON PHARMACEUTICALS LTD.-VILLAGE SAINI MAJRA, TEHSIL NALAGARH DIST, SOLAN- 174101,	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/7227	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	NEMADOL 50	TRAMADOL HYDROCHLORIDE	50MG	NATIONAL HEALTHCARE PVT. LTD.-(WORKS: STERILE BLOCK) CHHATAPIPRA-3, BARA, NEPAL	NEPAL	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7228	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	AMOXICILLIN 250MG DISPERSIBLE TABLETS	AMOXICILLIN TRIHYDRATE	250 MG	SANDOZ GMBH BIOCHEMISTRASSE 10-6250 KUNDL, AUSTRIA	AUSTRIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7229	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	AARCIFLOX 500	CIPROFLOXACIN	500MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7230	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	HISTABLOC 2ML	RANITIDINE HYDROCHLORIDE	25MG/ML	NATIONAL HEALTHCARE PVT. LTD.--WORKS: STERILE BLOCK CHHATAPIPRA-3, BARA, NEPAL	NEPAL	PARENTERAL ORDINARY VIALS	1.0X10.0X2.0 ML VIAL

NDA/MAL/HDP/7231	NATIONAL HEALTHCARE PVT LTD	ANDYCO PHARMACY (UGANDA) LTD	LIGNAT 2%	LIDOCAINE HYDROCHLORIDE	2% W/V	NATIONAL HEALTHCARE PVT LTD-CHHATAPIRA 3 BARA	NEPAL	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/7238	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-10	NEBIVOLOL HYDROCHLORIDE	10MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7241	EXPHAR SA.	SURGIPHARM (U) LIMITED	GENTASOL	GENTAMICIN SULFATE	0.3%W/V	AHLCON PARENTERAL (I) LTD.--SP-918,BHLWADI (RAJ) INDIA M.LIC.: RAJ 2002	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/7243	BAL PHARMA LIMITED	HEALTHCARE LTD.	EMTRIM	TRIMETHOPRIM + SULPHAMETHOXAZOLE	80MG+400MG	BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7246	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	DESORAT	DESORATIDINE	5MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X10.0 TABLET STRIP
NDA/MAL/HDP/7248	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 20	ESOMEPRAZOLE	20MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7249	EVA PHARMA FOR PHARMACEUTICALS & MEDICAL APPLIANCES	GAMA PHARMACEUTICALS (U) LIMITED	ESOMELODAN 40	ESOMEPRAZOLE MAGNESIUM	40MG	EVA PHARMA FOR PHARMACEUTICALS AND MEDICAL APPLIANCES-176 EL SADAT ST. KAFR EL GABAL, PYRAMIDS, GIZA, EGYPT	EGYPT	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7255	ACULIFE HEALTHCARE	SUPER MEDIC LTD	NIRIXONE	CEFTRIAZONE SODIUM	1000MG	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*1 10ML WFI AMPOULE
NDA/MAL/HDP/7257	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	PAARPIN TABLET	PARACETAMOL	650 MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7258	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/10MG	EMITICITABINE + TENOFOVIR ALAFENAMIDE	200MG/10MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTAX 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
NDA/MAL/HDP/7263	NIPRO MIDDLE EAST FZE	ROYAL PHARMA 2011 LIMITED	VERMIKIL TABLET	ALBENDAZOLE	400MG	NIPRO JMI PHARMA LTD.-CHAUDDAGRAM, COMILLA BANGLADESH	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X25.0X1.0X2.0 TABLET BLISTER
NDA/MAL/HDP/7264	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	MIOPAN PLUS SUSPENSION	MAGALDRATE+SIME THICONE	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
NDA/MAL/HDP/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,PATALGANGADISTRICT - RAIGAD, MAHARASHTRA,INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7269	EXPHAR SA.	SURGIPHARM (U) LIMITED	FEBRILEX SYRUP	PARACETAMOL+DEX TROMETORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE	125MG+5MG+1MG/5 ML	GRACURE PHARMACEUTICAL LTD-E-1105, RIICO IND. AREA, PHASE III, BHIWADI, DISTRICT ALWAR (RAJASTHAN)	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X150.0 ML BOTTLE
NDA/MAL/HDP/7274	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR 0.5MG	ENTECAVIR	0.5MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7284	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	LIVERCOL 10	ROSUVASTATIN CALCIUM	10MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7286	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	TOBRIN OPHTHALMIC OINTMENT	TOBRAMYCIN	3MG/G	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B EGYPT	EGYPT	OPHTHALMIC OINTMENTS	1.0X5.0 G TUBE
NDA/MAL/HDP/7287	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	EPISTIGMIN 0.05%	NEOSTIGMINE METHYLSULPHATE	0.05%W/V	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	PARENTERAL ORDINARY AMPOULES	1.0X5.0X1.0 ML AMPOULE

NDA/MAL/HDP/7288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	KETESSE FILM COATED TABLETS	DEXKETOPROFEN TROMETAMOL	25MG	A.MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.I-VIA CAMPO DI PILE 67100 L'AQUILA	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7291	PHARCO PHARMACEUTICALS	GAMA PHARMACEUTICALS (U) LIMITED	DERMATIN CREAM	CLOTRIMAZOLE	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	1.0X12.0 G TUBE
NDA/MAL/HDP/7293	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LTD	ALRINAST	DESLORATADINE	5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7298	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	NEBILONG-2.5	NEBIVOLOL HYDROCHLORIDE	2.5 MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7309	SQUARE PHARMACEUTICALS LTD	GAMA PHARMACEUTICALS (U) LIMITED	BECLONIN 250 HFA INHALER	BECLOMETASONE DIPROPIONATE	250 MCG/PUFF	SQUARE PHARMACEUTICALS LIMITED-KALIAKOIR GAZIPUR – 1750, BANGLADESH	BANGLADESH	LUNG ADMINISTRATION METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/7312	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE OINTMENT 5%W/W	POVIDONE IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .-B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL OINTMENTS	1.0X15.0 G TUBE,1.0X125.0 G TUBE,1.0X250.0 G JAR
NDA/MAL/HDP/7313	PANACEA BIOTEC LTD	STAR PHARMACEUTICALS LTD	EASYFIVE-TT (FULLY LIQUID PENTAVALENT VACCINE)	DIPHTHERIA TOXOID + TETANUS TOXOID + INACTIVATED W-B, PERTUSSIS + HBSAG + HIB (PRP-TT)	30 IU + 60 IU + 4 IU + 10MCG + 10 MCG	PANACEA BIOTEC LTD--MALPUR, BADDI, TEHSIL, NALAGARH, DIST. SOLAN HIMACHAL PRADESH – 173 205	INDIA	PARENTERAL ORDINARY I M PRE FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/7319	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.	BUFFALO HEALTH CARE LTD	SIPROSAN 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.- ESENOĞA MERKEZ MAH CUBUK CAD NO.31 CUBUK ANKARA -TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER
NDA/MAL/HDP/7325	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş.	BUFFALO HEALTHCARE LTD	DALMAN AQ NASAL SPRAY	FLUTICASONE PROPIONATE	0.05%W/V	DROGSAN İLAÇLARI SAN. VE TİC. A.Ş. -- ESENOĞA MERKEZ MAH. ÇUBUK CADDESİ NO: 31 06760 ANKARA - TURKEY	TURKEY	NASAL SYSTEMIC UNIT DOSE AEROSOLS	1.0X1.0X120.0 METERED DOSE BOTTLE

NDA/MAL/HDP/7328	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTHCARE LTD	CARDIOSAN 10MG	AMLODIPINE BESILATE	10MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.- ESENBGA MERKEZ MAH CUBUK CAD NO.31 CUBUK ANKARA -TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7329	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR- MR	PARACETAMOL +ACECLOFENAC+CHL ORZOXAZONE	500 MG+100 MG +375 MG	DAWA LTD -PLOT NO.7879/8 BABA ROAD RUARAKA NAIROBI	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7334	IPCA LABORATORIES LTD	SURGIPHARM (U) 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
NDA/MAL/HDP/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
NDA/MAL/HDP/7336	MODI NUNDIPHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE GERMICIDE GARGLE 2% MINT	POVIDONE IODINE	2%W/V	G.S PHAMBUTOR PVT LTD-G.S PHAMBUTOR PVT LTD B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	ORAL TOPICAL LIQUIDS	1.0X50.0 ML BOTTLE,1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7337	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 150	DARUNAVIR	150MG	JANSSEN ORTHO LLC.--STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X240.0 TABLET BOTTLE
NDA/MAL/HDP/7339	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 16	CANDESARTAN CILEXETIL	16 MG	AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7342	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	ZEALARGY	RUPATADINE FUMERATE	10 MG	CADILA PHARMACEUTICALS LIMITED-1389 DHOLKA 387810 DISTRICT AHMEDABAD GUJARAT STATE	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7344	ACULIFE HEALTHCARE	SUPER MEDIC LTD	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
NDA/MAL/HDP/7346	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	REZN TABLETS	ZINC SULFATE MONOHYDRATE	20MG	RENE INDUSTRIES LIMITED-PLOT 680 KAMULI KIREKA	UGANDA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7348	MSD (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ISENTRESS 25 MG	RALTEGRAVIR POTASSIUM	25MG	PATHEON PHARMACEUTICALS INC.-2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA, MERCK SHARP & DOHME BV.- WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS, MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	UNITED STATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/7351	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV DS	CEFIXIME+CLAVULANIC ACID	50MG+31.25 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7353	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 500MG	METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/7355	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ARTEFAN SUSPENSION	ARTEMETHER+LUMEFANTRINE	180MG+1080 MG	AJANTA PHARMA LIMITED.-B-41516, MIDC INDUSTRIAL AREA, PAITHAN, AURANGABAD-431 148 DIST: AURANGABAD MAHARASHTRA, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7356	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN TABLET 500MG	METFORMIN HYDROCHLORIDE	500MG	HOVID BERHAD-121, JALAN TUNKU ABDUL RAHMAN, 30010 IPOH, PERAK, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER, 1.0X5.0X20.0 TABLET BLISTER
NDA/MAL/HDP/7357	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	PAMAGIN-C SYRUP	CETIRIZINE HYDROCHLORIDE+D EXTROMETHORPHAN HYDROBROMIDE+ACETAMINOPHEN+PHENYLEPHRINE HYDROCHLORIDE+ZINC GLUCONATE+MENTHOL	2.5MG+7.5MG +125MG+5MG +7.5MG+2.5MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7359	INDCHEMIE HEALTH SPECIALITIES PVT. LTD.	TATA UGANDA LIMITED	INDCLAV 625	AMOXICILLIN+CLAVULANATE POTASSIUM	500MG+125MG	INDCHEMIE HEALTH SPECIALITIES PVT LTD-VILLAGE THANA TEHSIL BADDI DIST SOLAN HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7362	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	TRAM-DOL-50	TRAMADOL HYDROCHLORIDE	50MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7364	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	MOKSEFEN 400 MG	MOXIFLOXACIN HYDROCHLORIDE	400MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0 TABLET BLISTER
NDA/MAL/HDP/7365	AUROCHEM PHARMACEUTICALS (1) LTD)	SUPER MEDIC LTD	DOLOACT MR	PARACETAMOL+ DICLOFENAC POTASSIUM+CHLOR ZOXAZONE	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
NDA/MAL/HDP/7366	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX	CEFIXIME	200MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/7367	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX 100 DS	CEFIXIME	100MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7369	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV DS	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	200MG+28.5 MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD,ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7370	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 625	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	500MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/7373	AUROCHEM LABORATORIES(INDIA) PVT LTD	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
NDA/MAL/HDP/7374	AUROCHEM LABORATORIES(INDIA) PVT LTD	SUPER MEDIC LTD	FUSIGO-HC CREAM	FUSIDIC ACID +HYDROCORTISONE 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
NDA/MAL/HDP/7376	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX CV 375	AMOXICILLIN+POTASSIUM CLAVULANATE	250MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD,ROORKEE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP

NDA/MAL/HDP/7377	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	XOMOX DS	AMOXICILLIN TRIHYDRATE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD-UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7378	AURONEXT PHARMA PRIVATE LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ERTAPIK	ERTAPENEM SODIUM	1 G	AURONEXT PHARMA PRIVATE LIMITED,-A-1128, RIICO INDUSTRIAL AREA, PHASE-III,BHIWADI-301019, DISTRICT- ALWAR (RAJASTHAN), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/7379	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYDROX 250	CEFADROXIL	250MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET STRIP
NDA/MAL/HDP/7380	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYDROX DS	CEFADROXIL	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7381	MODI MUNDI PHARMA PVT LTD	SURGIPHARM (U) LIMITED	BETADINE ANTISEPTIC CREAM 5%	POVIDONE-IODINE	5%W/W	G.S PHAMBUTOR PVT LTD .-B-172 RIICO IND ,BEHOR 301701 DIST ALWAR RAJASTHAN INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X10.0 G TUBE
NDA/MAL/HDP/7384	YURIA PHARM LTD	YURIA PHARM EAST AFRICA LIMITED	TIVORTIN	ARGININE HYDROCHLORIDE	42MG/ML	YURIA-PHARM, LTD-108, VERBOVETSKOGO STREET CHERKASSY, 18030, UKRAINE	UKRAINE	PARENTERAL ORDINARY AMPOULES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7386	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYLEXIN 125 DS	CEFALEXIN MONOHYDRATE	125MG/5ML	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7388	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYFIX CV 200	CEFIXIME+CLAVULANIC ACID	200MG+125MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT LTD--ROORKEE DISTT HARIDWAR	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET STRIP
NDA/MAL/HDP/7396	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	HARVONI	SOFOSBUVIR+LEDIPASVIR	400 MG+90 MG	PATHEON INC-MISSISSAUGA,ON L5N 7K9 CANADA	CANADA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE

NDA/MAL/HDP/7406	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ARENA	ADRENALINE	0.1% W/V	LINCOLN PARENTERAL LTD -11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/7421	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICALS LIMITED	GESIC ADL 200	IBUPROFEN	200MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7422	CODAL-SYNTO LTD	RENE PHARMACY LTD	SYNTOCLAV 625MG	AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	500MG+125MG	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
NDA/MAL/HDP/7424	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	ZINC SULFATE TABLETS USP 20MG	ZINC SULFATE MONOHYDRATE	20MG	MACLEODS PHARMACEUTICALS LTD - - VILLAGE THEDA P.O LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH INDIA 174101	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7441	VIRCHOW HEALTHCARE PVT LTD	SURGIPHARM (U) LIMITED	HYORTH XL	SODIUM HYALURONATE	8MG/ML	VIRCHOW BIOTECH PVT LTD-SURVEY NO. 172, PART GAGILLAPUR(P) QUTHBULLAPUR(MANDAL), R.R, DISTRICT, TELANGANA STATE, 500043.INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/7446	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	CIPLUME	CIPROFLOXACIN HYDROCHLORIDE	0.3% W/V	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML VIAL
NDA/MAL/HDP/7449	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	LAMIVUDINE/ TENOFOVIR DF 300/300MG	LAMIVUDINE+TENOF OVIR DISOPROXIL FUMARATE	300MG+300MG	CIPLA QUALITY CHEMICALS INDUSTRIES LIMITED--PLOT 1-7 1ST RING ROAD, LUZIRA INDUSTRIAL PARK P O BOX 34871, KAMPALA, UGANDA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7450	AUROCHEM LABORATORIES(INDIA) PVT LTD	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
NDA/MAL/HDP/7452	AUROCHEM LABORATORIES(INDIA) PVT LTD	SUPER MEDIC LTD	XTRADERM CREAM	BETAMETHASONE DIPROPIONATE + GENTAMICIN SULFATE + CLOTRIMAZOLE	0.64 MG/1 G + 0.1 MG/1 G + 10 MG/1 G	AUROCHEM LABORATORIES LTD -PLOT 08 PALGHAR 401404 MAHARASHTRA, INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X20.0 G TUBE

NDA/MAL/HDP/7453	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ANTIDIAZOX	NITAZOXANIDE	100MG/5ML	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7469	BROOKES PHARMA (PRIVATE) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ECZEMUS 0.03% OINTMENT	TACROLIMUS MONOHYDRATE	0.03%W/W	BROOKES PHARMA (PRIVATE) LIMITED-58-59, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI-74900	PAKISTAN	TOPICAL EXTERNAL OINTMENTS	1.0X1.0X10.0 G TUBE
NDA/MAL/HDP/7475	UNI MEDICO LAB	SHREEJI PHARMACEUTICALS LIMITED	UMOCLOX 500	AMPICILLIN TRIHYDRATE+CLOXACILLIN SODIUM	250MG+250MG	UNI MEDICOLABS.- 21-22 PHARMACITY SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7478	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	SIMVASTATIN 20 MG FILM-COATED TABLETS	SIMVASTATIN	20MG	SANDOZ GRUP SAGLIK -GEBZE 2 GOSB IHSAN DEDE CAD. 900. SOK 41480 GEBZE KOCAELI	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7481	ACCORD HEALTH CARE LTD	NORVIK ENTERPRISES LIMITED	SILDENAFIL ACCORD 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
NDA/MAL/HDP/7482	AUROCHEM LABORATORIES(INDIA) PVT LTD	SUPER MEDIC LTD	FUSIGO-B CREAM	FUSIDIC ACID BP AND BETAMETHASONE 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
NDA/MAL/HDP/7488	ACCORD HEALTH CARE LTD	NORVIK ENTERPRISES LIMITED	FINASTERIDE 5MG	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
NDA/MAL/HDP/7490	ACCORD HEALTH CARE LTD	NORVIK ENTERPRISES LIMITED	SILDENAFIL ACCORD 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
NDA/MAL/HDP/7491	DENK PHARMA GMBH & CO	BENLE CONSULT LIMITED	CIPRO-DENK 750	CIPROFLOXACIN HYDROCHLORIDE	750MG	ALLPHAMED PHARBIL ARZNEIMITTEL GMBH. -HILDEBRANDSTRABE 12 37081 GOTTINGEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7523	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	LEVOFLOX-DENK 5 MG/ML	LEVOFLOXACIN HEMIHYDRATE	5MG/ML	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH--INDUSTRIESTR. 3 34212 MELSUNGEN GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML VIAL
NDA/MAL/HDP/7531	LINCOLN PHARMACEUTICALS LTD	ABACUS PARENTERAL DRUGS LIMITED	FRUSO	FUROSEMIDE	10MG/ML	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X1.0X10.0X2.0 ML AMPOULE

NDA/MAL/HDP/7536	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	NETVAICAIN	BUPIVACAINE HYDROCHLORIDE + DEXTROSE	5MG + 80MG /ML	SWISS PARENTERALS PVT LTD---809 KERALA GIDC NR. BAVLA DIST AHMEDABAD 382 220 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X10.0X4.0 ML AMPOULE,1.0X10.0X4.0 ML AMPOULE
NDA/MAL/HDP/7539	SEV PHARMACEUTICALS LTD	SEV PHARMACEUTICALS LIMITED	COUGH LINCTUS	CHLORPHENIRAMINE	2MG/5ML	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X1000.0 ML JERRYCAN,1.0X200.0 ML BOTTLE
NDA/MAL/HDP/7541	SEV PHARMACEUTICALS LTD	SEV PHARMACEUTICALS LIMITED	CHLORHEXIDINE SCRUB	CHLORHEXIDINE GLUCONATE	4%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1000.0 ML JERRYCAN
NDA/MAL/HDP/7544	SEV PHARMACEUTICALS LTD	SEV PHARMACEUTICALS LIMITED	GLYCERIN OF BORAX	GLYCERINE+BORAX	12%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X22.0 ML BOTTLE
NDA/MAL/HDP/7546	SEV PHARMACEUTICALS LTD	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
NDA/MAL/HDP/7548	SEV PHARMACEUTICALS LTD	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
NDA/MAL/HDP/7552	SEV PHARMACEUTICALS LTD	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	ML BOTTLE, ML BOTTLE
NDA/MAL/HDP/7554	SEV PHARMACEUTICALS LTD	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 ML JERRYCAN
NDA/MAL/HDP/7556	SEV PHARMACEUTICALS LTD	SEV PHARMACEUTICALS LIMITED	SEVASTAT	CETRIMIDE + CHLORHEXIDINE	3%W/V+0.3%W/V	SEV PHARMACEUTICALS LIMITED-PLOT 100 NALUKOLONGO	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X1.0 L BOTTLE
NDA/MAL/HDP/7559	SEV PHARMACEUTICALS LTD	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
NDA/MAL/HDP/7560	SEV PHARMACEUTICALS LTD	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

NDA/MAL/HDP/7569	STRIDES SHASUN LIMITED .	DELMAW ENTERPRISES LIMITED	ARCOMETER	ARTEMETHER	80MG/ML	STRIDES ARCOLAB LTD -BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X6.0 ML AMPOULE,1.0X1.0X8.0 ML AMPOULE
NDA/MAL/HDP/7571	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	NEUROVIT FILM-COATED TABLET	THIAMINE MONONITRATE + PYRIDOXINE HCL + CYANOCOBALAMINE	97MG + 50MG + 100MG	HOVID BHD-LOT 56442, 7.5 MILE JALAN IPOH/CHEMO 31200 CHEMOR, PERAK MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7575	ACME FORMULATION PVT. LTD.	MARIE STOPES UGANDA LIMITED	MEDIPRIST	MIFEPRISTONE	200MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7586	AUROCHEM LABORATORIES(INDIA) PVT LTD	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
NDA/MAL/HDP/7589	AUROCHEM LABORATORIES(INDIA) PVT LTD	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
NDA/MAL/HDP/7594	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	HYDROCHLOROTHIAZIDE 25MG TABLETS	HYDROCHLOROTHIAZIDE	25MG	SALUTAS PHARMA GMBH-OTTO-VON-GUERCKE-ALLEE 1, 39179 BARLEBEN,	GERMANY	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/7611	FERRING GMBH	MACNAUGHTON LIMITED	PABAL	CARBETOCIN	100MCG/ML	FERRING GMBH.-11, WITTLAND	GERMANY	PARENTERAL ORDINARY VIALS	1.0X5.0X1.0 ML VIAL
NDA/MAL/HDP/7612	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	SOTHREX -BR	TERBUTALINE SULFATE+BROMHEXINE HYDROCHLORIDE+GUAFENESIN+MENTHOL	2.5MG+8MG+100MG+5MG/10ML	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7613	PSYCHOTROPICS INDIA LTD	ABACUS PHARMA (AFRICA) LIMITED	KETOPIIL	KETOCONAZOLE	2%W/V	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	TOPICAL EXTERNAL LIQUID SOAPS/WASHES	1.0X1.0X100.0 ML BOTTLE

NDA/MAL/HDP/7617	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	EFAVIRENZ, LAMIVUDINE & TENOFIVIR 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
NDA/MAL/HDP/7631	ADWIA	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMADOL 100MG SR TABLET	TRAMADOL HYDROCHLORIDE	100MG	ADWIA CO. S.A.E-10TH OF RAMADAN CITY, INDUSTRIAL AREA A2, EGYPT	EGYPT	ORAL SOLID RETARD TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7632	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 2.5 MG FILM-COATED TABLETS	BISOPROLOL FUMARATE	2.5MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X15.0 TABLET BLISTER
NDA/MAL/HDP/7634	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL	BISOPROLOL	5 MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/7635	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	BISOPROLOL 10MG FILM COATED TABLETS	BISOPROLOL FUMARATE	10MG	LEK S.A-95 - 010 STRYKÓW, PODLIPIE 16, POLAND,SALUTAS PHARMA GMBH-OTTO- VON-GUERICHKE-ALLEE	POLAND	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/7649	SAKAR HEALTHCARE LIMITED	TATA UGANDA LIMITED	PARABUFEN SUSPENSION	IBUPROFEN + PARACETAMOL	(100MG + 162.5MG)/5M L	SAKAR HEALTHCARE LIMITED-BLOCK NO. 10- 13, SARKHEJ-BAVLA HIGHWAY, VILL: CHANGODAR, DIST: AHMEDABAD- 382213, GUJARAT – INDIA.	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7651	MSD (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	JANUVIA 25	SITAGLIPTIN	25MG	MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7652	MSD (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	JANUVIA 100	SITAGLIPTIN	100MG	MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7653	MSD (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	JANUVIA 50	SITAGLIPTIN	50MG	MSD PTY LTD-117 16TH ROAD, HALFWAY HOUSE 1685	SOUTH AFRICA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7656	A.MENARINI INDUSTRIE FARMACEUTICHE RIUNITE	PHILLIPS PHARMACEUTICAL S (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

NDA/MAL/HDP/7660	SPECPHARM (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	TENEMCOM	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	200MG + 300MG	HETERO LABS LTD-22-110 IDA JEEDIMETLA HYDERABAD 500-055 ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7663	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED	ZENTAIR	ENTECAVIR MONOHYDRATE	1.0MG	CIPLA QUALITY CHEMICAL INDUSTRIES LIMITED-PLOT 1-7, LUZIRA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7670	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DICHLOR 50	CHLORTHALIDONE	50MG	IPCA LABORATORIES LTD-SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7671	IPCA LABORATORIES LTD	MEDVIN PHARMA LIMITED	DICHLOR-25	CHLORTHALIDONE	25MG	IPCA LABORATORIES LTD-SEJAVTA, RATLAM-457 002 (M.P.) INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7673	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	80MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND,NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SPAIN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7674	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABLEVOX	LEVOFLOXACIN HEMIHYDRATE	5G/L	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7675	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	VALSARTAN	VALSARTAN	160MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND,NOVARTIS FARMACEUTICA SA-RONDA DE SANTA MARIA,158, E-08210 BARBERA DEL VALLES BARCELONA SPAIN	SPAIN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/7681	ZEE PHARMACEUTICALS LTD	ZEE PHARMACEUTICALS LIMITED	ZEECEL 200	CELECOXIB	200MG	THE MADRAS PHARMACEUTICALS..-NO. 137B, OLD MAHABALIPURAM ROAD, KARAPAKKAM, CHENNAI 600096	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7682	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	AB-TETRA-250	TETRACYCLINE	250MG	JIANGSU PENGYAO PHARMACEUTICAL CO LTD .-NO. 10 CHAQUAN ROAD YICHENG TOWN YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7683	GLOBAL NAPI PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DELAREX	DESLOTRADINE	5MG	GLOBAL NAPI PHARMACEUTICALS -2ND INDUSTRIAL ZONE, NO.40, ST. NO 18, 6TH OCTOBER, GIZA,	EGYPT	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/7686	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTGENT	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
NDA/MAL/HDP/7687	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	DI - QUIN	DIHYDROARTEMISIN IN+PIPERAQUINE PHOSPHATE	40MG + 320MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X9.0 TABLET BLISTER
NDA/MAL/HDP/7688	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE 850MG TABLET	METFORMIN HYDROCHLORIDE	850MG	NKUNZI PHARMACEUTICALS-259 DAVIDSON ROAD, WADEVILLEGERMISTON, 1428 SOUTH AFRICA	SOUTH AFRICA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X300.0 TABLET CONTAINER,1.0X 60.0 TABLET CONTAINER,1.0X 4.0X15.0 TABLET BLISTER
NDA/MAL/HDP/7689	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	CUFO LOZENGES(LEMON)	2, 4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL	1.2MG + 0.6MG	UNIQUE PHARMACEUTICALS LABORATORIES-SURVEY NO. 101/2 AND 102/1, DAMAN INDUSTRIAL ESTATE, AIRPORT ROAD, KADAIYA, DAMAN – 396 210 INDIA	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER
NDA/MAL/HDP/7692	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICALS LIMITED	CEFECTRON-S 1.5 G	CEFOPERAZONE SODIUM+SULBACTAM SODIUM	1000MG + 500MG	AKUMS DRUGS & PHARMACEUTICALS LTD.- 2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.5 G VIAL + 1*10 ML LDPE AMPOULE OF SWFI
NDA/MAL/HDP/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
NDA/MAL/HDP/7701	VISSCO REHAILITATION AIDS PVT LTD	KIMSY MEDS LTD	FLUCONAZOLE TABLETS 200 MG	FLUCONAZOLE	200 MG	MYLAN LABORATORIES LIMITED, V-PLOT NO. H-12 & H-13, MIDC, WALUJ INDUSTRIAL AREA AURANGABAD- 431136 MAHARASTRA STATE, INDIA. V	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7706	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	CACEF 200	CEFPODOXIME PROXETIL	200MG	ALKEM LABORATORIES LIMITED -VILLAGE- THANA BADDI, YEHNALAGAR, DISTRICT SOLAN, HIMACHAL PRADESH INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X6.0 TABLET BLISTER

NDA/MAL/HDP/7707	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ZOLIGLIT 15	PIOGLITAZONE	15MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD .-NO. 172 & 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR - MANDAL RR DIST HYDERABAD 500100, TELANGANA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BLISTER
NDA/MAL/HDP/7708	LEBEN LABORATORIES PVT.LTD	ANDYCO PHARMACY (UGANDA) LTD	LAMPYKLOX CAPSULES	AMPICILLIN TRIHYDRATE+CLOXACILLIN SODIUM	250MG+250MG	LEBEN LABORATORIES PVT. LTD-PLOT NO. L-4, PHASE-III, MIDC, AKOLA- 444 104 (MS).	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/7709	NITIN LIFESCIENCES LTD	HEALTHCARE LTD.	DEXAMETHASONE SODIUM PHOSPHATE	DEXAMETHASONE 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
NDA/MAL/HDP/7710	MYLAN LABORATORIES LIMITED.	KIMSY MEDS LTD	FLUCONAZOLE	FLUCONAZOLE	50MG	MYLAN LABORATORIES LIMITED.-PLOT NO. H-12 & H-13 MIDC, WALUJ INDUSTRIAL AREA, AURANGABAD. - 431136, MAHARASHTRA STATE, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/7711	HOVID BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	DIABETMIN 850 MG	METFORMIN HYDROCHLORIDE	850MG	HOVID BHD (IPOH SITE)-121 ,JALAN TUNKU ABDUL RAHMAN , 30010 IPOH , PERAK , MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7715	JANSSEN-CILAG INTERNATIONAL NV	LABOREX UGANDA LIMITED	SIRTURO	BEDAQUILINE FUMARATE	100MG	RECIPHARM PHARMACEUTICALS PVT LTD-34TH KM, TUMKUR ROAD, T-BEGUR, NELAMANGALA TALUK BENGALURU, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X188.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/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 AMPOULE
NDA/MAL/HDP/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 AMPOULE

NDA/MAL/HDP/7724	FERRING GMBH	MACNAUGHTON LIMITED	MENOPUR	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU]	75 IU + 75 IU/ 4ML VIAL	FERRING (PTY) LTD-WITTLAND II 24146 KIEL	GERMANY	PARENTERAL ORDINARY DRY VIALS	10.0X4.0 ML VIAL 10*1ML CLEAR COLOURLESS GLASS AMPOULES CONTAINING 9.0MG/ML OF NACL
NDA/MAL/HDP/7726	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	100MG + 25MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/7727	SANDOZ KENYA LTD	SURGIPHARM (U) LIMITED	BIODROXIL 500MG/5ML	CEFADROXIL	500MG/5ML	SANDOZ GMBH BIOCHEMISTRASSE 10-6250 KUNDL, AUSTRIA	AUSTRIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/7728	NORVATIS PHARMA SERVICES INC.	SURGIPHARM (U) LIMITED	LINEX	LACTOBACILLUS ACIDOPHILUS + BIFIDOBACTERIUM INFANTIS + ENTEROCOCCUS FAECIUM	1.2 * 10 TO POWER 7 COLONY FORMING UNITS OF VIABLE LACTIC ACID BACTERIA SPECIES	LEK PHARMACEUTICALS-D.D VEROVŠKOVA 57, 1526 LJUBLJANA SLOVENIA	SLOVENIA	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X8.0 CAPSULE BLISTER
NDA/MAL/HDP/7735	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	IBUMOL 400	PARACETAMOL + IBUPROFEN	325MG + 400MG	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
NDA/MAL/HDP/7740	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	METHICOWEL 1500	METHYLCOBALAMIN	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
NDA/MAL/HDP/7745	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICAL S LIMITED	TAZOGARD	PIPERACILLIN +TAZOBACTAM	4G + 0.5G	AKUMS DRUGS & PHARMACEUTICALS LTD.- 2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X4.5 G VIAL ,2X10ML LDPE AMPOULES OF
NDA/MAL/HDP/7747	UNOSOURCE PHARMA LTD.	ESCORTS PHARMACEUTICAL S LIMITED	THERMODOL	PARACETAMOL	1.0%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.- 2, 3, 4, & 5, SEC-6B, I.I.E., SIDCUL, RANIPUR, HARIDWAR-249403 (INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/7760	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	OZACE MD 10	OLANZAPINE	10MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND,PSYCHOTROPICS INDIA LTD PLOT--NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7764	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS-H 40/12.5	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7784	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	LORATOL	LORATADINE	5MG/5ML	NOBEL ILAC DUZCE-SANAYIINVE TICARET A.S SANCARLAR 81100 DUZCE	TURKEY	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7828	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	DIZTROL 24	BETAHISTINE DIHYDROCHLORIDE	24MG	AUROBINDO PHARMA LIMITED, UNIT – III-SURVEY NO.:113 & 314,BACHUPALLY (VILLAGE)QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, TELANGANA STATE.INDIA.®	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7903	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	MELMET-1000SR	METFORMIN HYDROCHLORIDE	1000MG	MICRO LABS LTD--NO 92, SIPCOT, HOSUR-635 126,, TAMIL NADU, INDIA	INDIA	ORAL SOLID RETARD COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/7905	NABIQASIM INDUSTRIES (PVT) LTD.	JEET PHARMACEUTICALS LIMITED	ACEFYL	ACEFYLINE PIPERAZINE + DIPHENHYDRAMINE HYDROCHLORIDE	45MG +8MG	NABIQASIM INDUSTRIES (PVT) LIMITED-17/24, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN	PAKISTAN	ORAL LIQUID ORDINARY SYRUPS	1.0X120.0 ML BOTTLE
NDA/MAL/HDP/7906	AXA PARENTERALS LTD	GITTOES PHARMACEUTICALS LIMITED	IVMOL	PARACETAMOL	10MG/ML	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/7907	BHARAT SERUMS AND VACCINES LIMITED,	GITTOES PHARMACEUTICALS LIMITED	HUCOG 5000 HP	CHORIONIC GONADOTROPHIN	5000 I.U/ VIAL	BHARAT SERUMS & VACCINES LIMITED -PLOT NO. K-27, ADDITIONAL MIDC, AMBERNATH (E) MAHARASHTRA STATE 421501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X5000.0 I.U VIAL + 1*1ML 0.9%W/V NACL AMBER GLASS AMPOULE

NDA/MAL/HDP/7909	SANOFI-AVENTIS KENYA	LABOREX UGANDA LIMITED	LANTUS	INSULIN GLARGINE	100 UNITS/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY S C VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/7910	SANOFI-AVENTIS KENYA	LABOREX UGANDA LIMITED	LANTUS	INSULIN GLARGINE	100 UNITS/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY CARTRIDGES	1.0X5.0X3.0 ML CARTRIDGE
NDA/MAL/HDP/7911	SANOFI-AVENTIS KENYA	LABOREX UGANDA LIMITED	LANTUS SOLOSTAR	INSULIN GLARGINE	100 UNITS/ML	SANOFI-AVENTIS DEUTSCHLAND GMBH-INDUSTRIEPARK HOECHST, BRUNINGSTRASSEN, BUILDING D-65926 FRANKFURT AM MAIN, GERMANY	GERMANY	PARENTERAL ORDINARY PRE-FILLED PENS	1.0X5.0X3.0 ML PREFILLED PEN
NDA/MAL/HDP/7912	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	GLIMEWEL M-1	GLIMEPIRIDE + METFORMIN HYDROCHLORIDE	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
NDA/MAL/HDP/7928	MACK BROWN PHARMACEUTICALS PVT LIMITED	SHURIK LTD	COLDROP HERBAL COUGH SYRUP	MULTINGREDIENT	MULTINGREDIENT	META HERBALS PVT LTD-G-523, G.I.D.C, LODHIKA, VILLAGE METODA, KALAWAD ROAD, DISTRICT RAJKOT, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8007	BAYER AG	SURGIPHARM (U) LIMITED	ADALAT RETARD	NIFEDIPINE	20MG	BAYER PHARMA AG-D-51368 LEVERKUSEN, GERMANY	GERMANY	ORAL SOLID RETARD OTHER COATED TABLETS	6.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/8010	COSMOS LTD.	ASTRA PHARMA (U) LIMITED	METROZOLE TABLETS	METRONIDAZOLE	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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/8023	DENK PHARMA GMB H &CO. KG	BENLE CONSULT LIMITED	AMOXICLAV-DENK 500/62.5	AMOXICILLIN TRIHYDRATE + POTASSIUM CLAVULANATE	500 MG + 62.5 MG	PENCEF PHARMA GMBH-BRITENBACHSTR ASSE 13 D-13509 BERLIN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X8.0 TABLET BLISTER
NDA/MAL/HDP/8032	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR SULFATE/LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	600 MG + 300 MG	CIPLA LTD-A-33 & A-37/2/2 MIDC PATALGANGA 410220	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8043	DAFRA PHARMA GMBH	LABOREX UGANDA LIMITED	RABEZOL	RABEPRAZOLE SODIUM	20MG	BILIM PHARMACEUTICALS-GOSB 41480 GEBZE-KOCAELI/TURKE	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8061	PFIZER LABORATORIES (PTY) LTD	LABOREX UGANDA LIMITED	LYRICA 25MG	PREGABALIN	25 MG	PFIZER GMBH ARZEIMITELWORK - MOOSWADALLE 179090, FREIBERG GERMANY	GERMANY	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X14.0 CAPSULE BLISTER
NDA/MAL/HDP/8062	PFIZER LABORATORIES (PTY) LTD BELGIUM	LABOREX UGANDA LIMITED	PROSTIN E2	DINOPROSTONE	3MG	PHARMACIA AND UPJOHN S.P.A-RIJKSWEWEG 12, B-2870 PUURS	BELGIUM	VAGINAL TABLETS	1.0X4.0 TABLET STRIP
NDA/MAL/HDP/8063	PFIZER LABORATORIES (PTY) LTD ITALY	LABOREX UGANDA LIMITED	UNASYN 1.5	AMPICILLIN + SULBACTAM	1000 MG + 500 MG	HAUPT PHARMA LATINA S.R.L LATINA-SS 156KM 47,600-04100,BORGO SAN,MICHELE	ITALY	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X1.5 G VIAL
NDA/MAL/HDP/8073	NOVARTIS PHARMA AG	SURGIPHARM (U) LIMITED	TRILEPTAL	OXCARBAZEPINE	300MG	NOVARTIS PHARMA SPA,-TORRE ANNUNZIATA ITALY	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X50.0 TABLET CONTAINER
NDA/MAL/HDP/8078	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	APMOD 100/270	ARTESUNATE + AMODIAQUINE	100 MG + 270 MG	AJANTA PHARMA LTD .-B-4//5/6, MIDC INDUSTRIALAREA, PAITHAN-431 128, AURANGBAD	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X6.0 TABLET BLISTER,1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/8080	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CEFTONE	CEFTRIAZONE	1G	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LIMITED - -STRETCHER ROAD PLOT M444B NTINDA KAMPALA	UGANDA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL + 1*10 ML WATER FOR INJECTION
NDA/MAL/HDP/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
NDA/MAL/HDP/8084	AGILA SPECIALTIES PRIVATE LIMITED	KIMSY MEDS LTD	TAZPEN	PIPERACILLIN + TAZOBACTAM	4+0.5 G/VIAL	MYLAN LABORATORIES LIMITED(BETA LACTAM DIVISION)-NO. 152/6, 154/16 DORESANIPALYA, BILEKAHALLI, BANNERGHATTA ROAD BANGALORE - 560 076 INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X4.5 G VIAL

NDA/MAL/HDP/8085	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	CIPROL-500	CIPROFLOXACIN	500MG	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD -PLOT NO. M444B, STRETCHER ROAD, NTINDA, KAMPALA	UGANDA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8087	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ONDEM INJECTION 4MG/2ML	ONDANSETRON	4MG/2ML	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/8088	ALKEM LABORATORIES LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ONDEM INJECTION 8MG/4ML	ONDANSETRON	8MG/4ML	ALKEM LABORATORIES LTD-VILLAGE – THANA, BADDI TEHSIL – NALAGARH, DIST- SOLAN (HP), INDIA – 173205	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X4.0 ML AMPOULE
NDA/MAL/HDP/8089	KAMPALA PHARMACEUTICAL INDUSTRIES (1996) LTD	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KAM-AMOX	AMOXICILLIN	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
NDA/MAL/HDP/8090	HEBEI NOVASCON TRADING CO. LTD	RENE PHARMACY LTD	GENTAMYCIN INJECTION	GENTAMYCIN	80MG/2ML	ANHUI CHENGSHI MANUFACTURE MEDICINE CO LTD-NEW INDUSTRIAL ZONE BENGBU CITY ANHUI PROVINCE	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/8091	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	RENEGEL SUSPENSION	ALUMINIUM HYDROXIDE+MAGNESIUM TRISILICATE	120MG+250MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8092	LABORATORY & ALLIED LTD	HARLEYS UGANDA LIMITED	KEMOXYL 250MG	AMOXICILLIN	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
NDA/MAL/HDP/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
NDA/MAL/HDP/8095	DENK PHARMA GMBH & CO. KG	BENLE CONSULT LIMITED	COLOSAR-DENK 100/12.5	LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE	100MG + 12.5MG	DENK PHARMA GMBH & CO.KG-- PRINZREGENTSTR.79.81675 MUENCHEN, GERMANY, GOLLSTR, 1-D-845529 TITTMONING GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/8096	ABACUS PHARMA (A) LTD.	ABACUS PHARMA (AFRICA) LIMITED	BENZALIN	BENZATHINE BENZYL PENICILLIN 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
NDA/MAL/HDP/8097	SERUM INSTITUTE OF INDIA LTD.	NORVIK ENTERPRISES LIMITED	REPOITIN 5000	ERYTHROPOIETIN	5000IU/ 0.5ML	SERUM INSTITUTE OF INDIA LTD-212/2 HADAPSAR, PUNE, 411028, INDIA	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X6.0X0.5 ML PRE- FILLED SYRINGE
NDA/MAL/HDP/8098	ROYAL GROUP	HARLEYS UGANDA LIMITED	CHLORAMPHENICOL CAPSULES BP	CHLORAMPHENICOL	250MG	JIANGSU PENGYAO PHARMACEUTICAL CO LTD .-NO. 10 CHAQUAN ROAD YICHENG TOWN YIXING CITY JIANGSU PROVINCE	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER, 1.0X 10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8100	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	AMPICLOX	AMPICILLIN/ CLOXACILLIN	250MG/5ML	MEDREICH STERILAB LTD-12TH MILE, OLD MADRAS ROAD, VIRGONAGOR, BANGALORE 560049, INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8104	ABACUS PHARMA (AFRICA) LIMITED	ABACUS PHARMA (AFRICA) LIMITED	TELPRESS 40	TELMISARTAN	40MG	PSYCHOTROPICS INDIA LTD-PLOT NO. 46 & 49 SECTOR -6A IIE SIDCUL RANIPUR HARIDWAR 249403 UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8105	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	XERIN	LEVOCETIRIZINE HYDROCHLORIDE + MONTELUKAST SODIUM	5MG + 10MG	AKUMS DRUGS AND PHARMACEUTICALS LTD- PLANT-1 PLOT NO.19, 20&21 SECTOR-6A, 11E, SIDCUL, RAHIPUR DISTT; HARIDWAR, 249403, (UTTRAKHAND) INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8106	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PLENMOXI	MOXIFLOXACIN HYDROCHLORIDE	0.4%W/V	AKUMS DRUGS & PHARMACEUTICALS LTD.- PLANT III, PLOT NO. 19, 20, 21, SECTOR 6-A, IIE, SIDCUL, RANIPUR, DISTRICT: UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8107	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	WELRAB 20	RABEPRAZOLE SODIUM	20MG	AKUMS DRUGS & PHARMACEUTICALS LTD -- 19,20,21, SECTOR 6A, I.I.E, SIDCUL, RANIPUR, HARIDWAR 249403 DISTRICT: UTTARAKHAND INDIA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8108	MEDI PHARM INDUSTRIES LTD	MEDI PHARM INDUSTRIES (E.A) LTD	ORS	GLUCOSE ANHYDROUS+TRISODIUM CITRATE+SODIUM CHLORIDE+POTASSIUM CHLORIDE	6.75G + 1.45G + 1.3G + 0.75G	: MEDI PHARM INDUSTRIES LTD-PLOT 65, KAKAJJO ROAD, BWEOGERERE POSTAL ADDRESS : P.O.BOX 5917, KAMPALA.	UGANDA	ORAL LIQUID ORDINARY SOLUBLE POWDERS	1.0X10.0X25.0 G SACHET
NDA/MAL/HDP/8109	ABACUS PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	IRON FOLATE	FERROUS IRON + FOLIC ACID	65MG + 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

NDA/MAL/HDP/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,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8112	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MOXICLAV	AMOXICILLIN + CLAVULANIC ACID	156.25MG/5ML	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY.-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8113	MEDOCHÉMIE LTD	BOOTS PHARMACEUTICALS LIMITED	MOXICLAV FORTE	AMOXICILLIN + CLAVULANIC ACID	312.5MG/5ML	MEDOCHÉMIE LTD PHARMACEUTICAL INDUSTRY-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS INDUSTRIAL AREA	CYPRUS	ORAL SOLID ORDINARY POWDERS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8115	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LAMIVUDINE	LAMIVUDINE	150MG	MACLEODS PHARMACEUTICALS LTD.-PLOT NO. 25-27 SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN (UT) - 396210, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/8116	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	200MG + 300MG	MACLEODS PHARMACEUTICALS LTD.-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8118	MACLEODS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	LOPINAVIR + RITONAVIR	LOPINAVIR + RITONAVIR	200MG + 50MG	MACLEODS PHARMACEUTICALS LTD.-PLOT 25-27 SURVEY NO. 366 PREMEIRE INDUSTRIAL ESTATE KACHIGAN DAMAN 396210 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X120.0 TABLET BOTTLE
NDA/MAL/HDP/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,1.0X10.0X1.0 ML AMPOULE
NDA/MAL/HDP/8120	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	ABT	ALPHA-BETA ARTEETHER	75MG/ML	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X3.0X2.0 ML AMPOULE
NDA/MAL/HDP/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
NDA/MAL/HDP/8123	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	MYCIDAC- C	MYCOBACTERIUM W (HEAT KILLED) + SODIUM CHLORIDE	0.5 *10 TO POWER 9 BACILLI + 0.9%W/V	CADILA PHARMACEUTICALS LTD-1389 DHOLKA 387 810 DIST AHMEDABAD GUJARAT	INDIA	PARENTERAL RETARD I M PRE-FILLED SYRINGES	1.0X0.2 ML PRE-FILLED SYRINGE

NDA/MAL/HDP/8124	RENE PHARMACY(R) LTD..	RENE PHARMACY LTD	CODEINE PHOSPHATE	CODEINE PHOSPHATE	30 MG	CYANO PHARMA(P)-115-C IND ESTATE POLOGROUND, INDORE 452015	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X100.0 TABLET BOTTLE
NDA/MAL/HDP/8125	DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD	KIMSY MEDS LTD	MATADOR	LEVOFLOXACIN	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
NDA/MAL/HDP/8127	SWISS PARENTERALS PVT. LTD.	SHREEJI PHARMACEUTICAL S LIMITED	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	2% W/V	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X30.0 ML VIAL
NDA/MAL/HDP/8128	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ATOREG 10	ATORVASTATIN CALCIUM	10MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD .-NO. 172 & 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR - MANDAL RR DIST HYDERABAD 500100, TELANGANA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8129	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ATOREG 20	ATORVASTATIN 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
NDA/MAL/HDP/8130	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA 100	SILDENAFIL CITRATE	100MG	DEVA HOLDING A. S.-ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/8131	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	DEGRA	SILDENAFIL CITRATE	50MG	DEVA HOLDING A. S.-ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/8132	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	ZOLIGLIT 30	PIOGLITAZONE HYDROCHLORIDE	30MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD .-NO. 172 & 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR - MANDAL RR DIST HYDERABAD 500100, TELANGANA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8133	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	MYHEP	SOFOSBUVIR	400MG	MYLAN LABORATORIES LIMITEDD ,-F-4 & F-12,MIDC, MALEGAON,SIRRRRAR, NASHIK -422113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE
NDA/MAL/HDP/8134	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	SALPRAZ 40	PANTOPRAZOLE	40MG	AIZANT DRUG RESEARCH SOLUTIONS PVT LTD .-NO. 172 & 173, APPAREL PARK ROAD, DULAPALLY VILLAGE, QUTHBULLAPUR - MANDAL RR DIST HYDERABAD 500100, TELANGANA	INDIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X7.0 TABLET BLISTER

NDA/MAL/HDP/8135	BAL PHARMA LIMITED	SHREEJI PHARMACEUTICALS LIMITED	REGAMOL	PARACETAMOL	500MG	BAL PHARMA LTD-1, 2, 3 & SECTOR 69, SECTOR 4, IIE-PANTNAGAR UDHAM SINGH NAGAR, RUDRAPUR-263153 UTTARAKHAND-INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8137	IDA FOUNDATION	KIMSY MEDS LTD	DIAZEPAM	DIAZEPAM	10MG	GLAND PHARMA LIMITED-D. P PALLY NARSAPUR ROAD, HYDERABAD – 500 043, INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/8140	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	FUROSEMIDE	FUROSEMIDE	40MG	SANDOZ PVT LTD.--MIDC IND, AREA KALWE BLOCK VILLAGE DIGHE NAVI MUMBAI 400708	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0X25.0 TABLET BLISTER
NDA/MAL/HDP/8142	BAYER EAST AFRICA LTD	SURGIPHARM (U) LIMITED	XARELTO	RIVAROXABAN	2.5MG	BAYER PHARMA AG 51368 LEVERKUSEN-BAYER PHARMA AG 51368 LEVERKUSEN	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8143	NAARI AG	ECHO PHARMACY (U) LIMITED	LYDIA POSTPIL	LEVONORGESTREL	1.5MG	JAGSONPAL PHARMACEUTICALS LTD-PLOT NO.14-16,55-57,SECTOR-5,IIE PANT NAGAR,SIDCUL,RUDRAPUR UDHAM SINGH NAGAR,UTTARAKHAND-263153 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/8145	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR 10	MONTELUKAST SODIUM	10MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8146	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 4	MONTELUKAST SODIUM	4MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8147	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	DENK- AIR JUNIOR 5	MONTELUKAST SODIUM	5 MG	DENK PHARMA GMBH & CO. KG -GOLLSTR. 1 84529 TITTMONING	GERMANY	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8148	SPARSH BIO-TECH PVT LTD	ABACUS PHARMA (AFRICA) LIMITED	FLUCLOXACILLIN	FLUCLOXACILLIN	500MG	SPARSH BIO-TECH PVT. LTD.--PLOT NO. 1, SURVEY NO. 242/243/244, VILLAGE LAKHABAVAD POST KHODIYAR COLONY DISTRICT, JAMNAGAR – 361006 GUJARAT INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8149	GLAXO SMITHKLINE LTD	ERIS LTD	AVODART	DUTASTERIDE	0.5MG	GLAXOSMITHKLINE PHARMACEUTICALS SA .- GRUNWALDZKA 189 STREET, 60-322 POZNANA	POLAND	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8150	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	20MG	NOVARTIS PHARMA STEIN AG-CH. 4002 STEIN, SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER

NDA/MAL/HDP/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,1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/8152	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	15MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8154	AGOG PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	AGOGCORT	HYDROCORTISONE ACETATE	1%W/W	AGOG PHARMA LTD-PLOT NO.33,SECTOR II,VASAI,TALUKA INDL CO-OP ESTATE LTD,GAURAI PADA,VASAI(E)DIST.THANE INDIA	INDIA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/8155	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	JAKAVI	RUXOLITINIB	5MG	NOVARTIS PHARMA STEIN AG.-SCHAFF HAUSER STRASSE 4332, STEIN - SWITZERLAND	SWITZERLAND	ORAL SOLID ORDINARY TABLETS	1.0X4.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8156	TATA UGANDA LIMITED	GITTOES PHARMACEUTICALS LIMITED	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	DIPHThERIA + TETANUS + PERTUSSIS + HEPATITIS B + HAEMOPHILUS TYPE B CONJUGATE VACCINE	25 LF (≥ 30 IU)+5.5 LF (≥ 40 IU)+16 IOU (≥ 4.0 IU)+12.5MCG+11MCG	BIOLOGICAL E LTD-PLOT NO.1, S.P BIOTECHNOLOGY PARK, PHASE II KOLThER (V), SHAMEERPET(M), RANGA REDDY(DIST), ANDHRA PRADESH, INDIA 500078	INDIA	PARENTERAL ORDINARY I M VIALS	1.0X48.0X0.5 ML VIAL (1 DOSE VIAL),1.0X24.0X5.0 ML VIAL (10 DOSE VIAL)
NDA/MAL/HDP/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
NDA/MAL/HDP/8158	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRID SANDOZ	GLIMEPIRIDE	3MG	LEK S.S POLAND UI PODLIPIE 16 95-010 STRYKOW-INDUSTRIAL ESTATES	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/8160	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (CHERRY FLAVOUR)	ALGINIC ACID+ MAGNESIUM HYDROXIDE+ ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+250MG+250MG+125MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/8162	BHARAT SERUMS AND VACCINES LTD	TATA UGANDA LIMITED	HUMOG 75 HP	HIGHLY PURIFIED MENOTROPHIN [CORRESPONDING TO FOLLICLE STIMULATING HORMONE ACTIVITY (FSH) 75 IU + LUTEINISING HORMONE ACTIVITY (LH) 75 IU] /150 I.U	75 IU + 75 IU/ 150 I.U VIAL	BHARAT SERUMS AND VACCINES LTD- PLOT NO. K-27 ADDITIONAL MIDC AMBERNATH (E) 412 501	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 1*1 ML AMPOULE OF 0.9%W/V NA CL
NDA/MAL/HDP/8164	INDOCO REMEDIES LTD	TATA UGANDA LIMITED	ATM 200	AZITHROMYCIN DIHYDRATE	200MG/5ML	INDOCO REMEDIES LTD, B-20,-B-20 MIDC, WALUJ, AURANGABAB 431136 INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/8165	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	CUFO BLACK CURRANT	2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESOL	1.2MG + 0.6MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)-SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER
NDA/MAL/HDP/8166	UNIQUE PHARMACEUTICALS LABORATORIES	TATA UGANDA LIMITED	CUFO ORANGE	2,4 DICHLOROBENZYL ALCOHOL + AMYLMETACRESO	1.2MG + 0.6MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)-SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER
NDA/MAL/HDP/8168	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	UNASYN 750MG	SULTAMICILLIN TOSYLATE	750MG	HAUPT PHARMA LATINA S.R.L -STRADA STATALE 156 KM 47,600 04100 BORG SAN MICHELE LATINA,ITALY.	ITALY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X4.0 TABLET STRIP

NDA/MAL/HDP/8170	FOUNTIL LIFE SCIENCES PVT LTD.	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ULGICID (PINEAPPLE FLAVOUR)	ALGINIC + MAGNESIUM HYDROXIDE +DRIED ALUMINIUM HYDROXIDE + MAGNESIUM TRISILICATE +SIMETICONE	200MG+250MG+250MG+125MG/15ML	STEDMAN PHARMACEUTICALS PVT LTD...-C-4, SIDCO PHARMACEUTICAL COMPLEX ALATHUR, THIRUPORUR	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/8172	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	COAMOX-ACINO 875	AMOXICILLIN + CLAVULANIC ACID	875MG + 125 MG	LABESFAL LABORATORIES ALMIRO S.A-LAGEDOSANT, SOLVENIA	SLOVENIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X4.0 TABLET BLISTER
NDA/MAL/HDP/8177	MEGA LIFESCIENCES (AUSTRALIA) PTY LTD	ASTRA PHARMA (U) LIMITED	CILZEC PLUS	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	MSN LABORATORIES PVT. LIMITED-PLOT NO. 42 ANRICH INDUSTRIAL ESTATE, BOLLARAM MEDAK DISTRICT PIN CODE 502 325 ANDHRA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/8180	COSMOS LTD	ASTRA PHARMA (U) LIMITED	COSMOL TABLETS 500MG	PARACETAMOL	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,1.0X1000.0 TABLET CONTAINER
NDA/MAL/HDP/8182	STRIDES ARCOLAB LTD	ROYAL PHARMA 2011 LIMITED	STRICORT	HYDROCORTISONE	500MG	STRIDES ARCOLAB LTD -BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL RETARD DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/8183	STRIDES ARCOLAB LTD	ROYAL PHARMA 2011 LIMITED	STRICORT-100	HYDROCORTISONE SODIUM SUCCINATE	100MG	STRIDES ARCOLAB LTD -BILEKAHALLI OPP IIM BANNERGHATTA ROAD BANGALORE 560076 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X100.0 MG VIAL

NDA/MAL/HDP/8184	STRIDES ARCOLAB LIMITED	ROYAL PHARMA 2011 LIMITED	TETRACYCLINE	TETRACYCLINE HYDROCHLORIDE	250MG	STRIDES ARCOLAB LIMITED-DEWAN & SONS IND. AREA,VEOOR, PALGHAR, MAHARAstra	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER,1.0X 500.0 CAPSULE CONTAINER
NDA/MAL/HDP/8185	STRIDES ARCOLAB LTD	ROYAL PHARMA 2011 LIMITED	INDOMETHACIN CAPSULES	INDOMETHACIN	25MG	STRIDES ARCOLAB LIMITED-DEWAN & SONS IND. AREA,VEOOR, PALGHAR, MAHARAstra	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER,1.0X100 0.0 CAPSULE CONTAINER
NDA/MAL/HDP/8186	STRIDES ARCOLAB LTD	ROYAL PHARMA 2011 LIMITED	CELOVAN	VANCOMYCIN HYDROCHLORIDE	500MG	STRIDES ARCOLAB LIMITED .-OPP. 11M BILEKAHALLI, BANNERG	INDIA	PARENTERAL ORDINARY VIALS	1.0X500.0 G VIAL
NDA/MAL/HDP/8188	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/8189	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S LIMITED	ABACAVIR SULPHATE TABLETS	ABACAVIR SULPHATE	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	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/8190	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S 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
NDA/MAL/HDP/8191	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICAL S 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

NDA/MAL/HDP/8192	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	L-KELFIN	SULPHADOXINE + PYRIMETHAMINE	500MG + 25MG	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X3.0 TABLET BLISTER,1.0X50.0 X3.0 TABLET BLISTER,1.0X10.0 X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/8193	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/8194	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	SOLODEX-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
NDA/MAL/HDP/8195	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	RH-COM	RIFAMPICIN & ISONIAZID	150MG +75MG	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
NDA/MAL/HDP/8196	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	ANTI-THYROX	CARBIMAZOLE	5MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,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 BLISTER
NDA/MAL/HDP/8197	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	AMIKACIN	AMIKACIN SULPHATE	500MG/2ML	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY- 10TH OF RAMADAN CITY FIRST INDUSTRIAL AREA	EGYPT	PARENTERAL ORDINARY VIALS	1.0X2.0 ML VIAL

NDA/MAL/HDP/8198	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX DROPS	MULTI-INGREDIENT	MULTI-INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/8199	MEDLEY PHARMACEUTICALS LTD	MEDVIN PHARMA LIMITED	XYMEX SYRUP	MULTIVITAMIN/DIASTASE/PEPSIN	MULTI-INGREDIENT	MEDLEY PHARMACEUTICALS LTD-PLOT NO.18 AND 19, SURVEY NO.378/8 & 379/2, KEBRA INDUSTRIAL ESTATE, KACHIGAM, DAMAN-396210 INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/8200	MEDIPHARM INDUSTRIES LTD	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
NDA/MAL/HDP/8201	CIRON DRUGS AND PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	CENTROZINE	CETIRIZINE HYDROCHLORIDE	5MG/5ML	CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X60.0 ML BOTTLE
NDA/MAL/HDP/8202	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/8204	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGI PHARM (U) LIMITED	DOPAMINE HCL FRESENIUS	DOPAMINE HYDROCHLORIDE	200MG/5ML	FRESNIUS KABI MANUFACTURING SA (PTY) LTD-6 GIBAUD ROAD KORSTEN PORT ELIZABETH 6020	SOUTH AFRICA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X5.0 ML AMPOULE
NDA/MAL/HDP/8205	Y.S.P INDUSTRIES (M) SDN BHD	ROYAL PHARMA 2011 LIMITED	ANLODIN	AMLODIPINE BESYLATE	10MG	Y.S.P INDUSTRIES (M) SDN BDH - LOT 3,5 & 7 P/7 SECTION 13 KAWASAN PERINDUSTRIAN BANDAR BARU BANGI 43000 KAJANG SELANGOR DARUL EHSAN	MALAYSIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8206	BRAWN LABORATORIES LTD	ROYAL PHARMA 2011 LIMITED	BRULEXIN	CEFALEXIN MONOHYDRATE	125MG/5ML	BRAWN LABORATORIES LTD.-13, NIT, INDUSTRIAL AREA, FARIDABAD-121001, HARYANA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE

NDA/MAL/HDP/8207	NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	ZOMETA	ZOLEDRONIC ACID	4MG/5ML	NOVARTIS PHARMA STEIN AG ;- SCHAFFHAUSERSTRASSE CH 4332 STEIN-SWITZERLAND	SWITZERLAND	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/8208	CIRON DRUGS & PHARMACEUTICAL PVT LTD	RENE PHARMACY LTD	CHLORAMPHENICOL SODIUM SUCCINATE	CHLORAMPHENICOL 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
NDA/MAL/HDP/8209	CIRON DRUGS & PHARMACEUTICAL PVT LTD	RENE PHARMACY LTD	THIOPENTAL SODIUM INJECTION	THIOPENTAL SODIUM	1GM / VIAL	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X50.0X1.0 G VIAL
NDA/MAL/HDP/8210	CIRON DRUGS & PHARMACEUTICALS PVT LTD	RENE PHARMACY LTD	HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION BP	HYDROCORTISONE	100MG	CIRON DRUGS & PHARMACEUTICALS PVT LTD--N-118, 119 MIDC TARAPUR BOISAR DIST THANE 4011 506	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X50.0X100.0 MG VIAL
NDA/MAL/HDP/8211	SHELYS PHARMACEUTICALS LTD	BETA HEALTHCARE UGANDA LIMITED	MUCO-ASTHALIN SYRUP	SALBUTAMOL + BROMHEXINE	2MG/5ML + 4MG/5ML	BETA HEALTHCARE INTERNATIONAL LTD - - PLOT NO.209/6554,MOGADISHU ROAD,OFF LUNGA LUNGA INDUSTRIAL AREA, P.O.BOX 42569-001000 NAIROBI,KENYA	KENYA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8212	FDC LTD	AIVEEN (U) LIMITED	BACTIGEN EYE/EAR DROPS	GENTAMICIN	0.3%W/V	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	OPHTHALMIC VIALS	1.0X5.0 ML VIAL,1.0X10.0 ML VIAL
NDA/MAL/HDP/8213	FDC LTD	AIVEEN (U) LIMITED	ZOCON 200	FLUCONAZOLE	200MG	FDC LIMITED -B-8, M.I.D.C., INDUSTRIAL AREA, WALUJ – AURANGABAD- 431 136 MAHARASHTRA, INDIA.®	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X5.0X2.0 TABLET BLISTER
NDA/MAL/HDP/8216	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	SEFOTAX	CEFOTAXIME SODIUM	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
NDA/MAL/HDP/8217	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	METFOKANT	METFORMIN HYDROCHLORIDE	850MG	S KANT HEALTHCARE LTD-PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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

NDA/MAL/HDP/8219	PHARCO B PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	DERMATIN	CLOTRIMAZOLE	1%W/V	PHARCO PHARMACEUTICALS LTD-KILO 31 ALEXANDRIA, CAIRO DESERT ROAD, ARAB REPUBLIC OF EGYPT.P. O BOX 12, SIDI GABER, ALEXANDRIA EGYPT	EGYPT	TOPICAL EXTERNAL LIQUIDS	1.0X20.0 ML BOTTLE
NDA/MAL/HDP/8221	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NEMADOL	TRAMADOL HYDROCHLORIDE	50MG/ML	NATIONAL HEALTHCARE PVT LTD-CHHATAPIPRA 3 BARA	NEPAL	PARENTERAL ORDINARY AMPOULES	1.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/8222	MICRO LABS LTD	LABOREX UGANDA LIMITED	LUBREX	SODIUM CARBOXYMETHYL CELLULOSE	0.5%W/V	MICRO LABS LTD ..-57, SIPCOT INDUSTRIAL COMPLEX, HOSUR-635126, TAMIL NADU	INDIA	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/8223	IRAN MEDICAL GROUP COMPANY	UNEEED GLOBAL GROUP LIMITED	LORAXIME	CEFOTAXIME	1000MG/ML	EXIR PHARMACEUTICAL COMPANY-2ND KM OF RING ROAD BOROUJERED 69189 IRAN	IRAN	PARENTERAL ORDINARY DRY VIALS	1.0X1000.0 MG VIAL
NDA/MAL/HDP/8224	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	OPTIGENT	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
NDA/MAL/HDP/8225	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	ARTELIN 60	ARTESUNATE	60MG	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X60.0 MG VIAL + 1*1 ML AMPOULE OF 5.0%W/V SODIUM BICARBONATE INJECTION B.P + 1*5 ML AMPOULE OF 0.9%W/V NACL
NDA/MAL/HDP/8226	DEVA HOLDING A.S	SHREEJI PHARMACEUTICALS LIMITED	SALRES	SALBUTAMOL SULPHATE	120.5MCG/SPRAY	DEVA HOLDING A. S.-ÇERKEZKÖY ORGANIZE SANAYI BOLGESI. KARAAĞAÇ MAH. ATATÜRK CAD. NO: 32 KAPAKLI- TEKİRDAĞ/ TURKEY	TURKEY	LUNG ADMINISTRATION CFC-FREE METERED-DOSE INHALER	1.0X200.0 METERED DOSE CANNISTER
NDA/MAL/HDP/8227	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	ALZER 5	DONEPEZIL HYDROCHLORIDE	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

NDA/MAL/HDP/8228	AFRICURE PHARMACEUTICALS (INDIA) LTD	ROYAL PHARMA 2011 LIMITED	VITAMIN B-COMPLEX (BEEKO)	VITAMINS B1 + B2 + B6 + NIACINAMIDE	1MG +1MG +1MG +15MG	STRIDES SHASUN LTD .-PLOT 9-12 DEWAN & SONS INDL AREA VEOOR PALGHAR	INDIA	ORAL SOLID ORDINARY OTHER COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8229	CIPLA LTD.	QUALITY CHEMICALS LTD - HUMAN	ABACAVIR SULFATE + LAMIVUDINE	ABACAVIR SULFATE + LAMIVUDINE	60MG + 30MG	CIPLA LTD-A-33 & A-37/2/2 MIDC PATALGANGA 410220	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X60.0 TABLET BOTTLE
NDA/MAL/HDP/8230	LIFEPHARM FZE	AIVEEN (U) LIMITED	PANALIFE	PARACETAMOL	500MG	LIFE PHARMA FZE --JEBEL ALI FREE ZONE, PLOT NO. MO 0502, P.O. BOX 17404, DUBAI- UAE	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY TABLETS	1.0X2.0X12.0 TABLET BLISTER
NDA/MAL/HDP/8231	DENK PARMA GMBH & CO. KG	BENLE CONSULT LIMITED	ANASTROZOLE DENK	ANASTROZOLE	1MG	HAUPT PHARMA GMBH & CO KG- SCHLEEBRUGGENKAMP 15, 48159 MUNSTER, GERMANY	GERMANY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8232	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	MOMATE	MOMETASONE FUROATE MONOHYDRATE	50MCG/ SPRAY	GLENMARK PHARMACEUTICALS LTD-VILLAGE: KISHANPURA, BADDI NALAGARH DISTRICT SOLAN - 174101, INDIA,GLENMARK PHARMACEUTICALS LTD-VILLAGE, KISHANPURA, BADDI, NALAGARH ROAD, INDIA	INDIA	NASAL SYSTEMIC METERED-DOSE LIQUIDS	1.0X120.0 METERED DOSE BOTTLE
NDA/MAL/HDP/8233	CADILA HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	COLSTIM	FILGRASTIM	300µG/ML	CADILA HEALTHCARE LTD.--PLOT SURVEY NO. 23, 25/P, 37, 40/P, 42 TO 47 SARKHEJ BAVLA N.H NO.8A OPP.RAMDEV MASALA CHANGODAR TAL. SANAND DIST AHMEDABAD 382213	INDIA	PARENTERAL ORDINARY PRE-FILLED SYRINGES	1.0X1.0 ML PRE-FILLED SYRINGE
NDA/MAL/HDP/8234	ABBOT LABORATORIES S.A. (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	INFUVAC 2015	INACTIVATED INFLUEZA VACCINE-SURFACE ANTIGEN [A/CALIFORNIA/7/2009(H1N1) PDM09 + A/SWITZERLAND/9715293/2013(H3N2) + B/PHUKET/3073/2013-LIKE STRAINS]	15µG + 15µG +15µG	ABBOTT BIOLOGICALS B.V -ABBOTT BIOLOGICALS B.V VEERWEG 12 8121 AA OLST	NETHERLANDS	PARENTERAL ORDINARY I M PRE-FILLED SYRINGES	1.0X0.5 ML PRE-FILLED SYRINGE (1 DOSE)
NDA/MAL/HDP/8235	DAWA LIMITED	SUPER MEDIC LTD	ACEPAR	ACECLOFENAC + SERRATIOPEPTIDASE + PARACETAMOL	100MG + 15MG + 500MG	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8236	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LTD	HYDROGEN PEROXIDE	HYDROGEN PEROXIDE	6%W/V	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	TOPICAL EXTERNAL LIQUIDS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/8237	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR).	GOODMAN INTERNATIONAL LTD	BCOOL	CETYLPYRIDINIUM CHLORIDE + LIDOCAINE HYDROCHLORIDE	1MG +1MG	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)-AIRPORT ROAD, DIGDAGA STREET RAS AL KHAIMAH	UNITED ARAB EMIRATES	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X9.0 LOZENGE BLISTER
NDA/MAL/HDP/8238	MERIDIAN ENTERPRISES PRIVATE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	METROSUPP 500	METRONIDAZOLE	500MG	MERIDIAN ENTERPRISES PVT. LTD--PLOT NO. 418, G.I.D.C.,KABILPORE, NAVSARI 396424 GUJARAT,INDIA	INDIA	RECTAL SYSTEMIC SUPPOSITORIES	1.0X2.0X5.0 SUPPOSITORY STRIP
NDA/MAL/HDP/8239	GLAXOSMITHKLINE PHARMACEUTICAL KENYA LTD	ERIS LTD	UMBIPRO GEL	CHLORHEXIDINE	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
NDA/MAL/HDP/8240	STRIDES ARCOLAB LIMITED	VEERAM HEALTHCARE (U) LIMITED	EFAVIRENZ + EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	EFAVIRENZ + EMTRICITABINE + TENOFOVIR DISOPROXIL FUMARATE	600MG + 200MG + 300MG	STRIDES ARCOLAB LIMITED -36/7 SURAGAJAKKANAHALLI INDLAVADI CROSS ANEKAL TALUK BANGALORE 562 106	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8241	ACINO PHARMA AG	GOODMAN INTERNATIONAL LTD	CLOPACIN	CLOPIDOGREL BESILATE	75MG	ACINO PHARMA AG .-BIRSWEG 2 4253 LIESBERG BASEL LAND	SWITZERLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8242	IDA FOUNDATION	KIMSY MEDS LTD	TETRACYCLINE HYDROCHLORIDE	TETRACYCLINE HYDROCHLORIDE	1%W/W	CENTAUR PHARMACEUTICALS PVT LTD -- PLANT II PLOT 39-41 TIVIM INDUSTRIAL ESTATE KARASWADA MAPUSA GOA 403 526	INDIA	OPHTHALMIC OINTMENTS	1.0X50.0X5.0 G TUBE
NDA/MAL/HDP/8243	AUROCHEM LABORATORIES(INDIA) PVT LTD	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
NDA/MAL/HDP/8244	MYLAN PHARMACEUTICAL PRIVATE LIMITED, INDIA	KIMSY MEDS LTD	HERTRAZ 440	TRASTUZUMAB (R-DNA ORIGIN)	440MG	BIOCON LIMITED-SPECIAL ECONOMIC ZONE, PLOT NO.2-4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD BANGALORE-560 099	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X440.0 MG VIAL ,1X2X10ML VIALS OF WFI
NDA/MAL/HDP/8245	AXA PARENTERALS LTD	GITTOES PHARMACEUTICAL S LIMITED	MOXIFLOXACIN HYDROCHLORIDE	MOXIFLOXACIN HYDROCHLORIDE	0.5%W/V	AXA PARENTERAL LIMITED-PLOT NO.936,937&939, VILL. KISHANPUR, JAMALPUR,ROORKEE 247667, DISTT. HARIDWAR (UTTARAKHAND) INDIA.	INDIA	OPHTHALMIC DROPS	1.0X5.0 ML BOTTLE
NDA/MAL/HDP/8246	PHARMACIA S.P.A	ERIS LTD	ALDACTONE	SPIRONOLACTONE	25MG	PIRAMAL HEALTHCARE LIMITED-WALTON ROAD MORPETH NORTHUMBERLAND	UNITED KINGDOM	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8247	SAKAR HEALTH CARE PVT .LTD	ROYAL PHARMA 2011 LIMITED	E-DOL	TRAMADOL HYDROCHLORIDE	50MG/ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X5.0X2.0 ML AMPOULE
NDA/MAL/HDP/8248	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	CLAVACE SUSPENSION	AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	457MG/5ML	ALKEM LABORATORIES LTD--PLOT NO. 167/1, MAHATMA GANDHI UDYONG NAGAR, AMALIYA, DABHEL, DAMAN,396210 INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8249	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	PANZOL-D	PANTOPRAZOLE+DOMPERIDONE	20MG + 10MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8250	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	LUMARTEM DT	ARTEMETHER+LUMEFANTRINE	20MG+120MG	CIPLA LTD INDORE-PLOT 9 & 10 INDORE SEZ PITHAMPUR M.P 454 775	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X12.0 TABLET BLISTER,1.0X6.0 TABLET BLISTER,1.0X30.0X6.0 TABLET BLISTER,1.0X30.0X12.0 TABLET BLISTER
NDA/MAL/HDP/8251	HEALTHCARE PHARMACEUTICALS LTD	ECHO PHARMACY (U) LIMITED	FUROTIL	CEFUROXIME AXETIL	250MG	HEALTHCARE PHARMACEUTICALS LTD - RAJENDRAPUR GAZIPUR	BANGLADESH	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X6.0 TABLET BLISTER
NDA/MAL/HDP/8252	FRESENIUS KABI MANUFACTURING S.A (PTY) LTD	SURGIPHARM (U) LIMITED	PARACETAMOL FRESENIUS	PARACETAMOL	10MG/ML	FRESENIUS KABI AUSTRIA GMBH-AUSTRIA GMBH HAFNERSTRASSE 36 8055 GRAZ	AUSTRIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X10.0X50.0 ML VIAL
NDA/MAL/HDP/8253	REYOUNG PHARMACEUTICAL CO LTD	ROYAL PHARMA 2011 LIMITED	DICLOFENAC SODIUM	DICLOFENAC SODIUM	25MG/ML	REYOUNG PHARMACEUTICAL CO. LTD-NO. 6 ERLANGSHAN ROAD, YIYUAN, SHANDONG 256100	CHINA	PARENTERAL ORDINARY AMPOULES	10.0X10.0X3.0 ML AMPOULE
NDA/MAL/HDP/8254	MICRO LABS LTD	LABOREX UGANDA LIMITED	GRAMOCEF-CV	CEFIXIME TRIHYDRATE + CLAVULANIC ACID	200MG + 125MG	MICRO LABS LIMITED, BOMMASANDRA - PLOT NO. 121-124 4TH PHASE K.I.A.D.B BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK BANGALORE 560 099	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0 TABLET STRIP
NDA/MAL/HDP/8255	KORLYNS THERAPEUTICS LTD	MEDICATRIX (U) LTD	PROSTAN ED	LATANOPROST	0.005%W/V	LUNAN BETTER PHARMACEUTICAL CO., LTD.- NO.209, HONGQI AVENUE, LANSHAN DISTRICT LINYI, SHANDONG, 276006 CHINA +86-5398331258 †	CHINA	OPHTHALMIC DROPS	1.0X6.0X2.5 ML BOTTLE

NDA/MAL/HDP/8264	CACHET PHARMA PVT LTD	ASTRA PHARMA (U) LIMITED	EMITINO ORAL SOLUTION	ONDANSETRON	2MG/5ML	CACHET PHARMACEUTICALS PVT LTD - THANA BADDI 173205 DISTRICT SOLAN (HIMACHAL PRADESH) INDIA	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/8274	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	BICATERO 50	BICALUTAMIDE	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
NDA/MAL/HDP/8275	HETERO LABS LTD	ABACUS PHARMA (AFRICA) 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
NDA/MAL/HDP/8276	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	GEMTERO 1G	GEMCITABINE	1G	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 G VIAL
NDA/MAL/HDP/8277	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	GEMTERO 200MG	GEMCITABINE	200MG	HETERO LABS (UNIT VI), INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V),JEDCHERLA(M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA.	INDIA	PARENTERAL ORDINARY VIALS	1.0X200.0 MG VIAL
NDA/MAL/HDP/8278	HETERO LABS LTD	ABACUS PHARMA (AFRICA) LIMITED	ANATERO	ANASTROZOLE	1MG	HETERO LABS LTD, UNIT VI, INDIA-APIIC, FORMULATION SEZ, POLEPALLY (V), JEDCHERLA (M) MAHABOBNAGER DISTRICT ANDHRA PRADESH-509301, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8279	SAKAR HEALTHCARE PVT LTD	ROYAL PHARMA 2011 LIMITED	GENTACIN	GENTAMICIN SULPHATE	80MG/2ML	SAKAR HEALTH CARE PVT, LTD-BLOCK NO. 10-13,M.N DESAI PETROL PUMP,SARKHEJ-BAVLA ROAD,VILLAGE CHANGODAR DIST AHMEDABAD 382-213,GUJARAT-INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0X6.0X2.0 ML AMPOULE IN BLISTERS
NDA/MAL/HDP/8281	UNIMED INDIA	METAPLUS (U) LIMITED	CO-TRIMOXAZOLE TABLET BP	CO-TRIMOXAZOLE	480MG	UNIMED INDIA-86,MAROL COOPORATIVE ESTATE, M.V ROAD ANDHERE(E)MUMBAI 400059	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER

NDA/MAL/HDP/8282	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	BINOZYT 500	AZITHROMYCIN	500MG	SANDOZ SRL LTD-LIVEZENI STREET 7A540472 TARGU MURES ROMANIA	ROMANIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/8284	PHARMEDIC LABORATORIES(PVT) LIMITED	HEALTHCARE LTD.	CIPLOX-500 TABLETS	CIPROFLOXACIN	500MG	PHARMEDIC LABORATORIES LIMITED-16KM MULTAN ROAD,LAHORE-PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY TABLETS	10.0X10.0 TABLET BLISTER,1.0X1.0X 100.0 TABLET CONTAINER
NDA/MAL/HDP/8285	TATA UGANDA LIMITED	TATA UGANDA LIMITED	CUFO LOZENGES(HONEY LEMON)	2,4 DICHLOROBENZYL ALCOHOL + AMYL METACRESOL	1.2MG+ 0.6MG	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B CHEMICALS & PHARMACEUTICALS LTD)-SURVEY NO. 101/2 & 102/1 DAMAN INDUSTRIAL ESTATE KADAIYA DAMAN 396 210	INDIA	ORAL SOLID ORDINARY LOZENGES	1.0X2.0X12.0 LOZENGE BLISTER
NDA/MAL/HDP/8287	PHARCO PHARMACEUTICALS	GAMA PHARMACEUTICAL S (U) LIMITED	DERMATIN 1% POWDER	CLOTRIMAZOLE+ZIN C 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
NDA/MAL/HDP/8292	META PRODUCTS UGANDA LTD	METAPLUS (U) LIMITED	PARACETAMOL	PARACETAMOL	500MG	HEBEI JIHENG (GROUP) PHARMACEUTICAL CO LTD 368-HEBEI JIHENG (GROUP) PHARMACEUTICAL CO LTD 368 JIANSHE ST HENGSHUI CITY HEBEI 053000	CHINA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER
NDA/MAL/HDP/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
NDA/MAL/HDP/8309	INDUS PHARMA PVT LTD	HEALTHCARE LTD.	SNOLIP 20MG	ATORVASTATIN	200MG	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
NDA/MAL/HDP/8310	INDUS PHARMA PVT LTD	HEALTHCARE LTD.	MAXPAN-100	CEFIXIME	100MG/5ML	INDUS PHARMA (PVT) LTD ,-PLOTS NO. 64, 65, 66 & 67, SECTOR -27, KORANGI INDUSTRIAL AREA, KARACHI - 74900	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE

NDA/MAL/HDP/8312	CADILA PHARMACEUTICALS	KARURI PHARMACEUTICALS LTD.	TRICORT 40	TRIAMCINOLONE ACETONIDE	40MG/ML	CADILA PHARMACEUTICALS LTD DHOLKA ...- SURVEY NO. 1389, DHOLKA – 387 810, AHMEDABAD, GUJARAT STATE INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0 ML VIAL
NDA/MAL/HDP/8313	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICALS LTD	FULYZAQ DELAYED RELEASE TABLETS	CROFELEMER	125 MG	PATHEON PHARMACEUTICALS INC.-2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA	UNITED STATES	ORAL SOLID RETARD ENTERIC-COATED TABLETS	1.0X60.0 TABLET CONTAINER
NDA/MAL/HDP/8314	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	CIPROZIF – 500	CIPROFLOXACIN HYDROCHLORIDE	500MG	FREDUN PHARMACEUTICALS LTD-VEOOR PALGHAR (E) 401 404	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8315	JANSSEN-CILAG INTERNATIONAL NV	MEDICAL ACCESS (UGANDA) LIMITED	PREZISTA 75	DARUNAVIR	75MG	JANSSEN ORTHO LLC.--STATE ROAD 933 KM 0.1 MARNEY WARD GURABO PUERTO RICO 00778	UNITED STATES	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X480.0 TABLET BOTTLE
NDA/MAL/HDP/8316	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVIR 50 MG/ LAMIVUDINE 300 MG/ TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	"AUROBINDO PHARMA LIMITED-UNIT –VII, SEZ, TSIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P & 458/P, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOOB NAGAR DISTRICT -509 302 TELANGANA STATE, INDIA"	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8317	ACULIFE HEALTHCARE	SUPER MEDIC LTD	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
NDA/MAL/HDP/8318	ACULIFE HEALTHCARE	SUPER MEDIC LTD	B-CANE HEAVY	BUPIVACAINE HYDROCHLORIDE BP	5 MG/ML	ACULIFE HEALTHCARE PVT. LTD-VILLAGE SACHANA ,TALUKA - VIRAMGAM , AHMEDABAD 382150 GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X4.0 ML AMPOULE
NDA/MAL/HDP/8319	KOPRAN LIMITED	TATA UGANDA LIMITED	ERYKO-250	ERYTHROMYCIN STEARATE TABLETS BP	250MG	KOPRAN LTD-VILLAGE SAVROLI TAL KHARAPUR DIST RAIGAD 410 202	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER,1.0X100 0.0 TABLET CONTAINER,1.0X 500.0 TABLET CONTAINER
NDA/MAL/HDP/8320	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	STACEF 1 GM	CEFTRIAZONE SODIUM	1 GM	NATIONAL HEALTHCARE PVT. LTD.-(WORKS: STERILE BLOCK) CHHATAPIRA-3, BARA, NEPAL	NEPAL	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 G VIAL

NDA/MAL/HDP/8321	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	PROSTER- 200 CAPSULES	PROGESTERONE	200 MG	AKUMS DRUGS & PHARMACEUTICALS LTD .- 47, 48 SECTOR 6A I.I.E SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X10.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8322	GLENMARK PHARMACEUTICALS LTD	STAR PHARMACEUTICAL S LTD	GLEMONT L	MONTELUKAST SODIUM+LEVOCETIRIZINE DIHYDROCHLORIDE	10 MG + 5 MG	GLENMARK PHARMACEUTICALS LIMITED- UNIT-I, VILLAGE KISHANPURA, BADDI, NALAGARH ROAD, TEHSIL NALAGARH,HIMACHAL PRADESH 174 101, MAHARASHTRA STATE, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X14.0 TABLET BOTTLE
NDA/MAL/HDP/8323	MOONLINK PHARMACEUTICALS LTD	MOONLINK PHARMACEUTICAL S LTD	NEOPROFANE 400	IBUPROFEN	400 MG	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD.-NO. 10 CHAQUAN ROAD,YIXING CITY, CHINA	CHINA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8324	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	LOOBID TABLETS	OFLOXACIN + ORNIDAZOLE	200MG + 500 MG	CACHET PHARMACEUTICAL PVT LTD. HIMACHAL-THANA, BADDI, HIMACHAL PRADESH-173 205, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8325	PFIZER LABORATORIES LTD	LABOREX UGANDA LIMITED	UNASYN	SULTAMICILLIN	250MG/5ML	HAUPT PHARMA LATINA S.R.L -STRADA STATALE 156 KM 47,600 04100 BORGIO SAN MICHELE LATINA,ITALY.	ITALY	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X60.0 ML BOTTLE
NDA/MAL/HDP/8326	MEDOPHARM PRIVATE LIMITED	PLANET PHARMACEUTICAL S UGANDA LTD	MEDOMOX 250 DT	AMOXICILLIN	250MG	MEDOPHARM PVT LTD.-NO. 50 KAYARAMBEDU VILLAGE GUDUVANCHERY 603 203 CHENGALPET DISTRICT TAMIL NADU	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X2.0X10.0 TABLET BLISTER,1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8328	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICAL S LIMITED	AZITHROCIN	AZITHROMYCIN	500MG	ACME FORMULATION PVT LTD.-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/8329	LEBEN LABORATORIES PVT. LTD., INDIA	ANDYCO PHARMACY (UGANDA) LTD	ARTEFLO - 40	PROPRANOLOL HYDROCHLORIDE	40 MG	LEBEN LABORATORIES PVT LTD --L4 PHASEIII M.I.D.C AKOLA 444 104 MAHARASHTRA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8330	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICAL S LIMITED	COART	LUMEFANTRINE + ARTEMETHER	480 MG + 80 MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/8331	MICRO LABS LIMITED	PHILLIPS PHARMACEUTICAL S (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
NDA/MAL/HDP/8332	DEVA HOLDING A.S	SHREEJI PHARMACEUTICAL S LIMITED	AZITRO 500 MG	AZITHROMYCIN	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

NDA/MAL/HDP/8333	MICRO LABS LTD 92 SIPCOT INDUSTRIAL	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	AVAS-20	ATORVASTATIN	20MG	MICRO LABS LTD 92 SIPCOT -92 SIPCOT HOSUR 635 126 TAMIL NADU	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8334	PRIDE INTERNATIONAL	ROYAL PHARMA 2011 LIMITED	S-AUGPRO	AMOXICILLIN TRIHYDRATE+CLAVU LANIC ACID	200MG+ 28.5MG	ALKEM LABORATORIES LTD-PLOT 167/1 VILLABE DAHBEL AMALIYA DAMAN 396210	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8335	RIVA PHARMA FREE ZONE	WIDE SPECTRUM ENTERPRISES (U) LIMITED	RIVAMOX	AMOXICILLIN TRIHYDRATE	500MG	RIVA PHARMA FREE ZONE-NASR CITY CAIRO EGYPT	EGYPT	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8336	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KPI HEALTHCARE LIMITED	LACINE ® 50	LOSARTAN POTASSIUM	50MG	THE JORDANIAN PHARMACEUTICAL MANUFACTURING COMPANY.-UM-AL- AMAD/PLANT (RAZI).P.O.BOX 151 UM-AL- AMAD 16197 JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8337	SWISS PARENTERALS PVT LTD 304	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 120 MG	ARTESUNATE	120 MG	SWISS PARENTERALS PVT LTD.-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT	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
NDA/MAL/HDP/8338	PINNACLE LIFE SCIENCE PVT. LTD.	METRO PHARMACEUTICAL S LIMITED	ACEAAR P	ACECLOFENAC + PARACETAMOL	100MG +325MG	PINNACLE LIFE SCIENCE PVT LTD-KHASRA NO. 1328-1330, VILLAG MANPURA, TEHSIL, BADDI, DIST. SOLAN (HP)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X20.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8339	SPECPHARM (PTY) LTD	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	EFTENEM	EFAVIRENZ+EMITRIC ITABINE+TENOFVIR DISOPROXIL FUMARATE	600MG+200M G+300MG	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
NDA/MAL/HDP/8340	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LTD - MBARARA	MONTEMAC 5	MONTELUKAST SODIUM	5 MG	MACLEODS PHARMACEUTICALS LTD(BLOCK N2)-VILLAGE THEDA,P.O LODHI MAJRA,TEHSIL BADDI,HIMACHAL PRADESH 174101	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8341	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	GENVOYA	ELVITEGRAVIR+COBI CISTAT+EMITRICISTA BINE+TENOFVIR ALAFENAMIDE	150MG + 150MG + 200MG + 10MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTAX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE

NDA/MAL/HDP/8342	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS AND PHARMACEUTICALS PVT. LTD)	ROYAL PHARMA 2011 LIMITED	ANCOLIN 75	PREGABALIN	75MG	PSA INTERNATIONAL (EXPORT DIVISION OF PSA CHEMICALS & PHARMACEUTICALS PVT. LTD.) -B-21/22, MIDC AREA, KALMESHWAR- 441 501, NAGPUR, MAHARASHTRA	INDIA	ORAL SOLID ORDINARY OTHER CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8343	TROIKAA PHARMACEUTICALS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	XYKAA EXTEND 1000	PARACETAMOL BP(IMMEDIATE RELEASE)+ PARACETAMOL BP(EXTENDED RELEASE)	325MG+675M G	TROIKAA PHARMACEUTICALS LTD.-SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197 UTTARAKHAND, INDIA	INDIA	ORAL SOLID RETARD FILM- COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8344	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CELZA DRY SYRUP	CEFUROXIME AXETIL USP	125 MG/5 ML	ALKEM LABORATORIES LTD--PURANA BARRIER, VILLAGE THANA, BADDI, DISTT. SOLAN, HIMACHAL PRADESH	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE
NDA/MAL/HDP/8345	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CELZA 500	CEFUROXIME AXETIL USP	500 MG	ALKEM LABORATORIES LTD--PURANA BARRIER, VILLAGE THANA, BADDI, DISTT. SOLAN, HIMACHAL PRADESH	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8346	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ADERAN 8	CANDESARTAN CILEXETIL	8MG	AJANTA PHARMA LIMITED-B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8347	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.-NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X5.0X10.0 ML AMPOULE
NDA/MAL/HDP/8348	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 300MG/12.5MG	IRBESARTAN + HYDROCHLOROTHIA ZIDE	300MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSI CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/8349	TIL HEALTHCARE PVT LTD	KPI HEALTHCARE LIMITED	ASTYMIN-C DROPS	L-LEUCINE USP + L- ISOLEUCINE USP + L- LYSINE HYDROCHLORIDE USP + L- PHENYLALANINE USP + L-THREONINE USP + L-VALINE USP+ L- TRYPTOPHAN USP + DL-METHIONINE USP + ASCORBIC ACID BP	0.84M+1.43M G+1.84MG+1.18MG+3.66M G+1.00MG+1.00MG+5.00M G+100MG	TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL LIQUID ORDINARY DROPS	1.0X15.0 ML BOTTLE
NDA/MAL/HDP/8350	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.	KAIYUANTANG (U) LIMITED	FENTWELL 0.05MG/ML	FENTANYL CITRATE	0.05MG/ML	YICHANGHUMANWELL PHARMACEUTICAL CO., LTD.-NO.19,DALIAN ROAD, YICHANG DEVELOPING ZONE,HUBEI PROVINCE ,CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/8351	TIL HEALTHCARE PVT LTD	KPI HEALTHCARE LIMITED	ASTYMIN SYRUP			TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X200.0 ML BOTTLE
NDA/MAL/HDP/8353	AJANTA PHARMA LIMITED	ABACUS PHARMA (AFRICA) LIMITED	NURIFER CAPSULES	CARBONYL IRON + FOLIC ACID + VITAMIN B12 + VITAMIN C + ZINC SULFATE MONOHYDRATE	100MG+1.5 MG + 15 MCG + 75 MG + 61.8 MG	AJANTA PHARMA LIMITED-AJANTA PHARMA LIMITED B-4-5-6, MIDC AREA PAITHAN, AURANGABAD, 431148 DIST:AURANGABAD MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8354	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ABACUS PHARMA (AFRICA) LIMITED	ZORUXA	ZOLEDRONIC ACID	5MG/100ML	GLAND PHARMA LIMITED 143-148-D P PALLY, QUTHUBULLAPUL MANDAL, RANDA REDDY DIST, HYBERABAD, IN-500 043, INDIA	INDIA	PARENTERAL ORDINARY VIALS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8354	MEGA LIFESCIENCES PUBLIC COMPANY LTD	ASTRA PHARMA (U) 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 VIALS	ML VIAL
NDA/MAL/HDP/8355	AUROBINDOM PHARMA LIMITED	PHILLIPS PHARMACEUTICAL S (UGANDA) LIMITED	ONECLAPZ 75	CLOPIDOGREL	75MG	AUROBINDO PHARMA LTD--UNIT VII SEZ PLOT S1 SPECIAL ECONOMIC ZONE	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8356	UNOSOURCE PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LORFACT-D	DESLOTATIDINE	5MG,	AKUMS DRUGS & PHARMACEUTICALS LTD-19, 20,21 SECTOR 6A IIE SIDCUL RANIPUR HARIDWAR 249 403	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8357	FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED	SURGIPHARM (U) LIMITED	FRESENIUS PROPOVEN 1%	PROPOFOL	1% W/V	FRESENIUS KABI AUSTRIA GMBH PLANT GRAZ-HAFNERSTRASSE 36 A-8055 GRAZ AUSTRIA,FRESENIUS KABI AB PLANT UPPSALA-RAPSGATAN 7S-75174 UPPSALA SWEDEN	AUSTRIA	PARENTERAL ORDINARY OTHER INFUSIONS	1.0X10.0X20.0 ML VIAL,1.0X10.0X50.0 ML VIAL,1.0X10.0X100.0 ML VIAL
NDA/MAL/HDP/8358	TIL HEALTHCARE PVT LTD	KPI HEALTHCARE LIMITED	ASTYMIN FORTE	MULTI-INGREDIENT	MULTI-INGREDIENT	TIL HEALTH CARE-PLOT 100,WEST,R-5,SOUTH;SRICITY SEZ,CHERIVI,IRUHULAM,PSOT,SATYAVEDU MANDAL,CHITTOOR DISTRICT-ANDRA PRADESH-517588, INDIA	INDIA	ORAL SOLID ORDINARY CAPSULES	1.0X5.0X3.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8359	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ASUNATE 120	ARTESUNATE	120MG	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X120.0 MG VIAL + 1*10 ML SODIUM CHLORIDE IN GLASS AMPOULE + 1*2 ML SODIUM BICARBONATE IN GLASS AMPOULE
NDA/MAL/HDP/8392	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	IRBECOR PLUS 150MG/12.5MG	IRBESARTAN + HYDROCHLOROTHIAZIDE	150MG + 12.5MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş-3. ORGANİZE SANAYİ BÖLGESİ KUDDUSİ CAD. 23. SOK. NO:1 SELÇUKLU / KONYA	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8393	NATIONAL HEALTHCARE	ANDYCO PHARMACY (UGANDA) LTD	NACLOR EYE DROPS 10ML	CHLORAMPHENICOL	0.5% W/V	NATIONAL HEALTHCARE PVT. LTD.--WORKS: STERILE BLOCK CHHATAPIRA-3, BARA, NEPAL	NEPAL	OPHTHALMIC DROPS	1.0X10.0 ML BOTTLE
NDA/MAL/HDP/8394	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	RIFAMPICIN 75 MG ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE	75MG + 50MG + 150MG	MACLEODS PHARMACEUTICALS LTD., NO. 25-27-PLOT NO. 25-26-27, SURVEY NO.366, PREMIER INDUSTRIAL ESTATE ., DAMAN - 396210, KACHIGAM, DAMAN	INDIA	ORAL SOLID ORDINARY SOLUBLE TABLETS	1.0X100.0 TABLET CONTAINER

NDA/MAL/HDP/8395	MACLEODS PHARMACEUTICALS 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
NDA/MAL/HDP/8396	MARIE STOPEs INTERNATIONAL	MARIE STOPEs UGANDA LIMITED	BACK-UP	LEVONORGESTREL	1.5MG	ACME FORMULATION PVT LTD.- ROPAR ROAD NALAGARH DIST SOLAN (H.P) -174 101	INDIA	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0 TABLET BLISTER
NDA/MAL/HDP/8401	KAMPALA PHARMACEUTICAL INDUSTRIES 1996 LIMITED	KPI HEALTHCARE LIMITED	AZOX-500	AZITHROMYCIN DIHYDRATE	500MG	THE JORDANIAN PHARMACEUTICAL MANUFACTURING COMPANY.-UM-AL-AMAD/PLANT (RAZI).P.O.BOX 151 UM-AL-AMAD 16197 JORDAN	JORDAN	ORAL SOLID ORDINARY FILM- COATED TABLETS	1.0X1.0X3.0 TABLET BLISTER
NDA/MAL/HDP/8406	HETERO LABS LTD UNIT IX	ASTRA PHARMA (U) LIMITED	PIOGEN45	PIOGLITAZONE HYDROCHLORIDE	45MG	HETERO LABS LIMITED .-S.NO.10, I.D.A., GADDAPOTHARAM VILLAGE, JINNARAM MANDAL,MEDAK DISTRICT, ANDHRA PRADESH, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8407	INTAS PHARMACEUTICALS LTD	NORVIK ENTERPRISES LIMITED	TORTAS 20	TORSEMIDE	20MG	INTAS PHARMACEUTICALS LTD -CAMP ROAD, SELAQUI – 248 197 DEHRADUN (UK)	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/8412	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	AMINOPHYLLINE	AMINOPHYLLINE	25 MG / ML	SHANDONG XIER KANGTAI PHARMACEUTICAL CO. LTD-PRIVATE ECONOMY ZONE,YANZHOU DISTRICT,SHANDONG, CHINA PR	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X10.0 ML AMPOULE,1.0X5 0.0X10.0 ML AMPOULE
NDA/MAL/HDP/8413	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	CHLORAMPHENICOL CAPSULE BP	CHLORAMPHENICOL	250MG	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X 500.0 CAPSULE CONTAINER,1.0X 10.0X10.0 CAPSULE BLISTER

NDA/MAL/HDP/8417	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	TETRACYCLINE CAPSULE BP	TETRACYCLINE HYDROCHLORIDE	250MG	SHANDONG XIER KANGTAI PHARMACEUTICALS CO. LTD PRIVATE-PRIVATE ECONOMY ZONE,XINYAN TOWN, YANZHOU DISTRICT, JINING CITY,SHANDONG,CHINA PR	CHINA	ORAL SOLID ORDINARY CAPSULES	1.0X1000.0 CAPSULE CONTAINER,1.0X500.0 CAPSULE CONTAINER
NDA/MAL/HDP/8419	ROYAL PHARMA 2011 LIMITED	ROYAL PHARMA 2011 LIMITED	VB COMPLEX	VIT B1+ VIT B2 +VIT B3 + NICOTINAMIDE+PANTOTHENOL	10MG +1MG +1MG +16MG +0.5MG	KIVI PHARM CO. LTD .-NO.5 HANGTIAN STREET, DONGSHAN HIGH TECH INDUSTRIAL DEVELOPMENT ZONE,SHALINGZI TOWN, XUANHUA,ZHANGJIAKOU CITY,HEBEI 075100, CHINA	CHINA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE,1.0X100.0X2.0 ML AMPOULE
NDA/MAL/HDP/8424	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	HAEMRICH	FERRIC AMMONIUM CITRATE+ FOLIC ACID+PYRIDOXINE HCL + THIAMINE HCL + NICOTINAMIDE	50MG + 0.55MG +2.4MG + 1.2MG +11MG /5ML	LINCOLN PARENTERAL LTD-11, TRIMUL ESTATE KHATRAJ DISI. GANDHINAGAR-38272, GUJARAT	INDIA	ORAL LIQUID ORDINARY SYRUPS	1.0X90.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/8434	DAWA LIMITED	SUPER MEDIC LTD	DACINAZOLE	MICONAZOLE NITRATE	2%W/W	DAWA LTD-BABA DOGO ROAD RUARAKA	KENYA	TOPICAL EXTERNAL CREAMS	1.0X15.0 G TUBE
NDA/MAL/HDP/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,1.0X10.0X12.0 TABLET STRIP
NDA/MAL/HDP/8466	CIPLA LIMITED	QUALITY CHEMICALS LTD - HUMAN	LUMARTEM HS 80	ARTEMETHER + LUMEFANTRINE	80MG + 480MG	CIPLA LIMITED--UNIT 1,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
NDA/MAL/HDP/8467	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	GLUCOPHAGE XR 750MG	METFORMIN HYDROCHLORIDE	750MG	MERCK SANTE S.A.S-CENTRE DE PRODUCTION DE SEMOY 2 RUE DU PRESSIOIR VERT 45400 SEMOY,MERCK KGAA-250 FRANKFRUTER STRASSE 250-64293 DARMSTADT	FRANCE	ORAL SOLID ORDINARY TABLETS	1.0X4.0X15.0 TABLET BLISTER

NDA/MAL/HDP/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
NDA/MAL/HDP/8469	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	METHICOWEL INJECTION	METHYLCOBALAMIN	500MCG/ML	AKUMS DRUGS AND PHARMACEUTICALS LTD-PLANT III, PLOT NO 2,3,4 &5, SECTOR 6-B, IIE, SIDCUL RANIPUR HARIDWAR-249403 UTTARAKHAND INDIA	INDIA	PARENTERAL ORDINARY I M AMPOULES	1.0X5.0X1.0 ML AMPOULE
NDA/MAL/HDP/8470	LUPIN LIMITED	AIVEEN (U) LIMITED	IXIME 400	CEFIXIME	400MG	LUPIN LIMITED--198-202, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, BHOPAL-462 046, DIST. RAISEN, MADIA PRADESH INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X6.0 TABLET BLISTER
NDA/MAL/HDP/8471	LUPIN LIMITED	AIVEEN (U) LIMITED	IXIME FOR ORAL SUSPENSION	CEFIXIME	100MG/5ML	LUPIN LIMITED--198-202, NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, BHOPAL-462 046, DIST. RAISEN, MADIA PRADESH INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X75.0 ML BOTTLE
NDA/MAL/HDP/8472	CODAL-SYNTO LTD	RENE PHARMACY LTD	SYNTOCLAV 375MG	AMOXICILLIN + CLAVULANIC ACID	250MG + 125MG	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
NDA/MAL/HDP/8473	S K AGE EXPORTS	ABACUS PHARMA (AFRICA) LIMITED	NYSTATIN VAGINAL INSERTS	NYSTATIN	100000 I.U	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	VAGINAL TABLETS	1.0X10.0X10.0 TABLET STRIP
NDA/MAL/HDP/8474	GLAXOSMITH KLINE LTD	ERIS LTD	AUGMENTIN SACHETS 1G/125MG	AMOXICILLIN TRIHYDRATE+POTASSIUM CLAVULANATE	1000MG + 125MG	GLAXO WELLCOME PRODUCTION -Z.I DE LA PEYENNIERE 53100 MAYENNE FRANCE	FRANCE	ORAL LIQUID ORDINARY UNIT DOSE POWDERS	1.0X12.0 SACHET CARTON
NDA/MAL/HDP/8475	LINCOLN PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	OROCAN	MICONAZOLE	2%W/W	LINCOLN PHARMACEUTICALS LTD--TRIMUL ESTATE AFER VODSAR VILLAGE KHATJAT 382 721 GUJARAT VADSAR P.O.J TALUKA KALOH DIST GANDHINAGAR INDIA	INDIA	ORAL TOPICAL GELS AND SOLS	1.0X15.0 G TUBE
NDA/MAL/HDP/8476	AUROBINDO PHARMA LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	AURODANZ 8	ONDANSETRON HYDROCHLORIDE DIHYDRATE	8MG	AUROBINDO PHARMA LTD--UNIT-III SURVEY NO. 313 & 314, BACHUPALLY VILLAGE QUTHUBULLAPUR MANDAL RANGA REDDY DISTRICT TELANGANA STATE INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8477	WOCKHARDT LTD	TATA UGANDA 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
NDA/MAL/HDP/8480	SUN PHARMACEUTICAL INDUSTRIES LTD	STAR PHARMACEUTICALS LTD	ERTIVIX 1MG	ENTECAVIR MONOHYDRATE	1MG	SUN PHARMACEUTICALS INDUSTRIES LIMITED--SEZ UNIT 1,A-41,INDUSTRIAL AREA, PHASE VIIIA,S.A.S NAGAR,MOHALI-160071,PUNJAB,INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8481	LINCOLN PARENTERAL LIMITED	METRO PHARMACEUTICALS LIMITED	PARACETAMOL BP INJECTION	PARACETAMOL	150MG/ML	LINCOLN PARENTERAL LTD -11 TRIUL ESTATE KHATRAJ TAL KALOL DIST GANDHINAGAR GUJARAT	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X10.0X2.0 ML AMPOULE
NDA/MAL/HDP/8483	SANDOZ KENYA C/O NOVARTIS PHARMA SERVICES INC	SURGIPHARM (U) LIMITED	GLIMEPIRID SANDOZ® 2MG TABLETS	GLIMEPIRIDE	2MG	LEK S.A--U1, PODLIPIE 16, 95-0140 STRYKOW POLAND	POLAND	ORAL SOLID ORDINARY TABLETS	1.0X9.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8484	MEDOCHEMIE LTD	BOOTS PHARMACEUTICALS LIMITED	AVERNOL	CARVEDILOL	25MG	MEDOCHEMIE LTD-1-10 CONSTANTINOUPOLEOS TREET 3011 LIMASSOL	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8485	CACHET PHARMACEUTICALS PVT LIMITED	ASTRA PHARMA (U) LIMITED	TRIAXON	CEFIXIME	400MG	ALKEM LABORATORIES LTD .-VILLAGE THANA, BADDI, TEHSIL-NALAGARH, DISTT-SOLAN, (HP), INDIA-173205	INDIA	ORAL SOLID ORDINARY COATED TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8487	BAL PHARMA LIMITED	HEALTHCARE LTD.	EMTRIM FORTE	SULFAMETHOXAZOLE + TRIMETHOPRIM	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
NDA/MAL/HDP/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 TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8489	SWISS PARENTERALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	T-DOL	TRAMADOL HYDROCHLORIDE	100 MG / 2 ML	SWISS PARENTERALS LTD-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X2.0 ML AMPOULE
NDA/MAL/HDP/8490	ALTHEA PHARMA PVT LTD.	JOINT MEDICAL STORE (UPMB - UCMB)	SODIUM CHLORIDE	SODIUM CHLORIDE	0.9% W/V	ALTHEA PHARMA PVT LTD --PLOT NO. 374 SHED NO. E.,ALPHA INDUSTRIAL PARK , ATHIYAWAD DABHEL ,NANI DAMAN (U.T) 396210, INDIA	INDIA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE

NDA/MAL/HDP/8491	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CETROTIDE 0.25MG	CETRORELIX	0.25MG	ABBOTT BIOLOGICALS B.V VEERWEG -12,NL-8121 AA OLST THE NETHERLANDS,PIERRE FABRE MEDICAMENT -AQUITAINE PHARM INTERNATIONAL SITE 1	FRANCE	PARENTERAL ORDINARY COMBINATION PACK VIALS	1.0X1.0 VIAL CARTON,1.0X1.0 PREFILLED SYRINGE CARTON
NDA/MAL/HDP/8493	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	DESCOVY 200MG/25MG	EMTRICITABINE/TENOFOVIR ALAFENAMIDE	200MG + 25 MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTEX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9,ROTTENDORF PHARMA GMBH-OSTENFELDER STRAßE 51-61,59320 ENNIGERLOH,GERMANY	CANADA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8494	KOTRA PHARMA (M) SDN,BHD	UNITED HEALTHCARE DISTRIBUTORS LTD	VAXCEL CEFOTAXIME	CEFOPERAZONE SODIUM+SULBACTAM 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
NDA/MAL/HDP/8495	CACHET PHARMACEUTICALS PRIVATE LIMITED	ASTRA PHARMA (U) LIMITED	CACEF 50	CEFPODOXIME PROXETIL USP	50MG / 5ML	ALKEM LABORATORIES LTD.-VILLAGE THANA, BADDI, DISTT. SOLAN,HIMACHAL PRADESH 173205 INDIA.	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X30.0 ML BOTTLE
NDA/MAL/HDP/8496	THEON PHARMACEUTICALS LIMITED	AIVEEN (U) LIMITED	THEOXONE-500MG	CEFTRIAXONE	500MG	THEON PHARMACEUTICALS LIMITED.-VILLAGE SAINI MAJRA, TEHSIL NALAGARH, DISTT. SOLAN, HIMACHAL PRADESH 174 101 INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 MG VIAL
NDA/MAL/HDP/8497	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD	SWASTIK PHARMACEUTICAL LTD	TRYOXIM 500	CEFUROXIME AXETIL	500 MG	TWENTY FIRST CENTURY PHARMACEUTICALS PVT.LTD - -UNIT II, KHASRA NO: 282, NALHERI DEHVIRAN, NALHERA ANANTPUR,PUHANA - IQBALPUR ROAD, ROORKEE-247668. DIST.-HARIDWAR, UTTARAKHAND	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8498	GULF PHARMACEUTICAL INDUSTRIES(JULPHAR)	GOODMAN INTERNATIONAL LTD	TRIAZONE 0.5G	CEFTRIAXONE	0.5G	GULF PHARMACEUTICALS INDUSTRIES"JULPHAR"-P.O.BOX 997 AIRPORT ROAD,DIGDAGA STREET RAS AL KHAIMAH,U.A.E	UNITED ARAB EMIRATES	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON + 5 ML AMPOULE OF WATER FOR INJECTION
NDA/MAL/HDP/8499	YELURI FORMULATIONS PVT LTD	GITTOES PHARMACEUTICALS LIMITED	SOLOCEF 1000 MG	CEFTRIAXONE SODIUM	1000MG	YELURI FORMULATIONS PVT. LTD-SY. NO. 296 / 7 / 6 IDA BOLLARAM,MEDAK DIST.502325, TELANGANA,INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0 ML VIAL

NDA/MAL/HDP/8500	AURONEXT PHARMA PRIVATE LIMITED	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	INEMPLUS 500	IMIPENEM+CILASTATIN	500MG +500MG	AURONEXT PHARMA PRIVATE LIMITED,-A-1128, RIICO INDUSTRIAL AREA, PHASE-III,BHIWADI-301019, DISTRICT- ALWAR (RAJASTHAN), INDIA.	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X500.0 G VIAL
NDA/MAL/HDP/8501	MEDREICH PLC	LABOREX UGANDA LIMITED	BIOZOLE	METRONIDAZOLE	125MG/5ML	MEDREICH LTD-4/3 OFF KANAPURA ROAD, AVALAHALLI, A, TEJKAMAL PHARMACEUTICAL PVT, SURVEY NO.6/2 ALADAHALLI,SOMAPURAHOBIL,NELAMANGALA TALUK,BANGALORE RURAL-562111,INDIA	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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/SYRUPS/DROPS	1.0X70.0 ML BOTTLE
NDA/MAL/HDP/8503	MEDREICH PLC	LABOREX UGANDA LIMITED	NORZOL	NORFLOXACIN + TINIDAZOLE	400MG + 600MG	MEDREICH STERILAB LIMITED-NO. 4/3, AVALAHALI ANJANAPURA POST,OFF KANAKAPWA ROAD, BANGALORE 560062 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8504	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	LEDVIR	LEDIPASVIR + SOFOSBUVIR	90MG + 400MG	MYLAN LABORATORIES LIMITED-F- 4 & F-12, MIDC, MALEGAON, SINNAR, NASHIK -422 113 MAHARASHTRA, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X28.0 TABLET BOTTLE
NDA/MAL/HDP/8522	PLANET PHARMACEUTICALS UGANDA LTD	PLANET PHARMACEUTICALS UGANDA LTD	DAYPENAM	MEROPENEM	500MG	SWISS PARENTERALS LTD-809 KERALA INDUSTRIAL ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT INDIA	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X10.0X500.0 MG VIAL
NDA/MAL/HDP/8601	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.	BUFFALO HEALTH CARE LTD	AMLOVAS 5MG	AMLODIPINE BESILATE	5 MG	DROGSAN İLAÇLARI SAN. VE TIC. A.Ş.-06760 ÇUBUK –ANKARA / TURKEY	TURKEY	ORAL SOLID ORDINARY TABLETS	1.0X2.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8602	MAVID PHARMACEUTICALS LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	KOFLIN COUGH FLU LINCTUS	CHLOPHENIRAMINE	2MG	MAVID PHARMACEUTICAL INDUSTRIES LIMITED-PLOT 490 BIRONGO, KITIIKO	UGANDA	ORAL LIQUID ORDINARY SYRUPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/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

NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/8606	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	DIPHEX COUGH EXPECTORANT	DIPHENHYDRAMINE HYDROCHLORIDE + 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
NDA/MAL/HDP/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
NDA/MAL/HDP/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
NDA/MAL/HDP/8617	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID PHARMACEUTICAL INDUSTRIES LIMITED	MAVID'S KEVLON	CHLORHEXIDINE 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
NDA/MAL/HDP/8637	BLISS GVS PHARMA LIMITED	DELMAR ENTERPRISES LIMITED	AGYCIN	AZITHROMYCIN DIHYDRATE	40MG/ML	BLISS GVS PHARMA LTD-PLOT.NO 10,SURVEY NO 38/1,DEWAN UDYOG NAGAR, ALIYALI VILLAGE, PALGHAR, TAL: PALGHAR DIST.THANE, MAHARASHTRA-INDIA	INDIA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X15.0 ML BOTTLE
NDA/MAL/HDP/8639	MSD (PTY) LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ISENTRESS 100MG	RALTEGRAVIR POTASSIUM	100MG	PATHEON PHARMACEUTICALS INC.-2110 E. GALBRAITH ROAD CINCINNATI, OH 45237-1625, USA, MERCK SHARP & DOHME BV.-WAARDERWEG 39 HAARLEM, - 2031 BN, NETHERLANDS, MSD (PTY) LTD. -117-16TH ROAD, HALFWAY HOUSE, 1685 SOUTH AFRICA	UNITED STATES	ORAL SOLID ORDINARY CHEWABLE TABLETS	1.0X1.0X60.0 TABLET BOTTLE

NDA/MAL/HDP/8640	UNOSOURCE PHARMA LTD.	ABACUS PHARMA (AFRICA) LIMITED	CORTUM 250	CEFUROXIME AXETIL	250MG	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
NDA/MAL/HDP/8641	CADILA PHARMACEUTICALS LIMITED	KARURI PHARMACEUTICALS LTD.	TELI H	TELMISARTAN + HYDROCHLOROTHIAZIDE	40MG + 12.5MG	CADILA PHARMACEUTICALS LIMITED- 1389,TRASAD ROAD, DHOLKA-382 225, AHMEDABAD GUJARAT STATE,INDIA.	INDIA	ORAL SOLID ORDINARY LAYERED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8643	SWISS PARENTERALS PVT LTD	ROYAL PHARMA 2011 LIMITED	ARTESUNATE 60MG	ARTESUNATE	60MG	SWISS PARENTERALS PVT LTD.-809 KERALA IND ESTATE GIDC NEAR BAVLA DIST AHMEDABAD 382220 GUJARAT	INDIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0X60.0 MG VIAL + 1*1*5ML AMPOULE OF 0.9%W/V NAACL + 1*1*1ML AMPOULE OF 5%W/V NAHCO3
NDA/MAL/HDP/8644	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	LOOBID SUSPENSION	OFLOXACIN + ORNIDAZOLE	50MG + 125MG / 5ML	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL LIQUID ORDINARY SUSPENSIONS	1.0X1.0X30.0 ML BOTTLE
NDA/MAL/HDP/8649	INJECTCARE PARENTERALS PVT. LTD	MATRIX (U) LTD	CEFCARE	CEFTRIAXONE SODIUM	1G	INJECTCARE PARENTERALS PVT. LTD.- PLOT130 SILVASSA ROAD GIDC VAPI 396195 GUJARAT	INDIA	PARENTERAL ORDINARY VIALS	1.0X10.0 ML VIAL
NDA/MAL/HDP/8650	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	CEFDIA 400MG	CEFIXIME TRIHYDRATE	400MG	NOBEL İLAÇ SAN. VE TİC. A.Ş.-81100 SANCAKLAR, DÜZCE-TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X5.0 TABLET BLISTER
NDA/MAL/HDP/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
NDA/MAL/HDP/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

NDA/MAL/HDP/8658	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 1000MG	METFORMIN HYDROCHLORIDE	1000MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X4.0X15.0 TABLET BLISTER
NDA/MAL/HDP/8659	SANDOZ GMBH, KUNDL	SURGIPHARM (U) LIMITED	METFORMIN 500MG	METFORMIN HYDROCHLORIDE	500MG	LEK S.A.-16 PODLIPIE STR. 95-010 STRYKOW	POLAND	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X6.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8660	GILEAD SCIENCE INC	MEDICAL ACCESS (UGANDA) LIMITED	VEMLIDY	TENOFOVIR ALAFENAMIDE	25MG	PATHEON INC.--TORONTO REGIONAL OPERATIONS 2100, SYNTAX COURT, MISSISSAUGA, ONTARIO, CANADA, L5N 7K9	CANADA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8661	AUROBINDO PHARMA LTD	GITTOES PHARMACEUTICALS LIMITED	DOLUTEGRAVIR TABLETS 50MG	DOLUTEGRAVIR SODIUM	50MG	AUROBINDO PHARMA LTD UNIT VII (SEZ) APIIC-PLOT NO. S1 SURVEY NO. 411,425,434,435 & 458 GREEN INDUSTRIAL PARK POLEPALLY VILLAGE MAHABOBNAGAR DISTRICT ANDHRA PRADESH	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8662	RENE INDUSTRIES LTD	RENE INDUSTRIES LIMITED	AMOXIREN-DS	AMOXICILLIN TRIHYDRATE	250MG/5ML	RENE INDUSTRIES LTD .-PLOT 680, KAMULI ROAD, KIREKA, P.O. BOX 6034, KAMPALA	UGANDA	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8665	CACHET PHARMACEUTICALS PVT LTD	ASTRA PHARMA (U) LIMITED	PAMAGIN-C	CETIRIZINE HYDROCHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + ACETAMINOPHEN + PHENYLEPHRINE HYDROCHLORIDE + ZINC GLUCONATE	5.0 MG +15 MG + 500 MG + 5 MG + 7.5 MG	CACHET PHARMACEUTICALS PVT LTD-VILLAGE AND POST THANA BADDI TEHSIL NALAGARH SOLAN DISTRICT HIMACHAL PRADESH 173 205	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8679	KWALITY AFRO ASIA LIMITED	KWALITY AFRO ASIA LTD	K COUGH-D	BROMOHEXINE HYDROCHLORIDE + AMMONIUM CHLORIDE + DEXTROMETHORPHAN HYDROBROMIDE + MENTHOL	8MG + 10MG + 100MG + 5MG	KWALITY AFRO-ASIA LTD-PLOT 165 KAWEMPE BOMBO ROAD	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE

NDA/MAL/HDP/8685	MSN LABORATORIES PRIVATE LIMITED	GOOD DAY PHARMACY 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
NDA/MAL/HDP/8686	CODAL-SYNTO LTD	RENE PHARMACY LTD	CODANOL	ATENOLOL	100 MG	MEDOCHEMIE LTD (FACTORY AZ)-2 MICHAEL ERAKLEOUS STREET, AGIOS ATHANASSIOS, INDUSTRIAL AREA, 4101 AGIOS ATHANASSIOS, LIMASSOL, CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8688	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 600	DARUNAVIR	600 MG	MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8689	MYLAN LABORATORIES LIMITED	KIMSY MEDS LTD	DURART 800	DARUNAVIR	800 MG	MYLAN LABORATORIES LTD --H-12 & H-13, MIDC, WALUJ,AURANGABAD- 431136 MAHARASHTRA, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/8691	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 1000	LEVETIRACETAM	1000MG	REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8692	GOODMAN INTERNATIONAL (U) LTD	GOODMAN INTERNATIONAL LTD	PARAFUSIV	PARACETAMOL	10 MG/ML	S.M FARMACEUTICI SRL-ZONA INDUSTRIALE, 85050 TITO-POTENZA (PZ) ITALY	ITALY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X50.0 ML VIAL,1.0X100.0 ML VIAL
NDA/MAL/HDP/8693	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	QUETRA 100MG/ML	LEVETIRACETAM	100 MG/ML	REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL LIQUID ORDINARY LIQUIDS	1.0X300.0 ML BOTTLE
NDA/MAL/HDP/8696	PHARCO PHARMACEUTICALS	WIDE SPECTRUM ENTERPRISES (U) LIMITED	BABY COL	SIMETICONE	40MG/0.6ML	PHARCO PHARMACEUTICALS-KILO 31 ALEXANDRIA-CAIRO DESERT ROAD AMRIYA ALEXANDRIA	EGYPT	ORAL LIQUID ORDINARY EMULSIONS	1.0X1.0X15.0 ML BOTTLE
NDA/MAL/HDP/8697	CADILA HEALTHCARE LIMITED.	ABACUS PHARMA (AFRICA) LIMITED	ZYPIRON 20	IRON SUCROSE	20MG/ML	CADILA HEALTHCARE LTD SARKHEJ-BAVLA NH NO.8A MORAIYA TAL SANAND DISTRICT AHMEDABAD 382210	INDIA	PARENTERAL ORDINARY VIALS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/8699	REMEDICA LTD	GOODMAN INTERNATIONAL LTD	ACETAZOLAMIDE	ACETAZOLAMIDE	250 MG	REMEDICA LTD.-AHARNON STREET, LIMASSOL INDUSTRIAL ESTATE,3056 LIMASSOL CYPRUS	CYPRUS	ORAL SOLID ORDINARY TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8743	CADILA PHARMACEUTICALS LTD	KARURI PHARMACEUTICALS LTD.	ISONIAZID	ISONIAZID	300 MG	CADILA PHARMACEUTICALS LIMITED.-1389, DHOLKA-387810, INDIA OPP.RAJVANSH APARTMENT, SATYA MARG, BODAKDEV, AHMEDABAD – 380054, GUJARAT, INDIA.	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X24.0X28.0 TABLET BLISTER
NDA/MAL/HDP/8814	MYLAN LABORATORIES LIMITED	KIMS MEDS LTD	ACRIPTEGA	DOLUTEGRAVIR SODIUM + LAMIVUDINE + TENOFOVIR DISOPROXIL FUMARATE	50MG + 300MG + 300MG	MYLAN LABORATORIES LIMITEDD ,-PLOT NO.11, 12 & 13, INDORE SPECIAL ECONOMIC ZONE, PHARMA ZONE, PHASE-II, SECTOR-III, PITHAMPUR-454775 DIST. DHAR, MADHYA PRADESH, INDIA.	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X30.0 TABLET BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/8816	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	ABPARA	PARACETAMOL	1%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	PARENTERAL ORDINARY INFUSION BAGS	1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8817	MEDIPHARM INDUSTRIES (E.A) LTD	MEDIPHARM SALES LIMITED	MEDISOLONE-15	PREDNISOLONE SODIUM PHOSPHATE	15MG/5ML	MEDIPHARM INDUSTRIES(EA) LTD-PLOT 65 KAKAJJO ROAD BWEYOGGERERE P.O.BOX 6218,KAMPALA,UGANDA	UGANDA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X5.0 ML BOTTLE
NDA/MAL/HDP/8818	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	LEVOTOP-PF	LEVOFLOXACIN HEMIHYDRATE	1.5%W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC DROPS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/8820	TROIKAA PHARMACEUTICALS LTD	ABACUS PHARMA (AFRICA) LIMITED	T-DOL P RAPID	TRAMADOL HYDROCHLORIDE + PARACETAMOL	37.5MG + 325MG	TROIKAA PHARMACEUTICALS LTD .-C-1 SARA INDUSTRIAL ESTATE SELAQUI DEHRADUN 248197	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8821	AUROBINDO PHARMA LTD	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ROFAST 10	ROSUVASTATIN CALCIUM	10MG	"AUROBINDO PHARMA LIMITED-UNIT –VII, SEZ, TSIC, PLOT NO. SI,S. NO.'S 411/P, 425/P, 434/P, 435/P & 458/P, GREEN INDUSTRIAL PARK, POLEPALLY VILLAGE, JEDCHERLA MANDAL, MAHABOON NAGAR DISTRICT -509 302 TELANGANA STATE, INDIA"	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8822	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PHARMA (AFRICA) LIMITED	ALIDO	LIDOCAINE HYDROCHLORIDE	2%W/V	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	PARENTERAL ORDINARY AMPOULES	1.0X1.0X30.0 ML VIAL
NDA/MAL/HDP/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
NDA/MAL/HDP/8824	AJANTA PHARMA LTD	ABACUS PHARMA (AFRICA) LIMITED	NEPAFLAM	NEPAFENAC	0.1% W/V	CIRON DRUGS & PHARMACEUTICALS PVT LTD-N-118, N-119 MIDC TARAPUR BOISAR DIST THANE 401506 MAHARASHTRA INDIA	INDIA	OPHTHALMIC SUSPENSIONS	1.0X1.0X5.0 ML VIAL
NDA/MAL/HDP/8825	LINCOLN PHARMACEUTICALS LTD	METRO PHARMACEUTICALS LIMITED	LAXALINK	LACTULOSE	3.35G/5ML	LINCOLN PARENTERAL LIMITED- 11, TRIMUL ESTATE, KHATRAJ, TAL. KALOL, DIST. GANDHINAGAR, GUJARAT, INDIA.	INDIA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X170.0 ML BOTTLE
NDA/MAL/HDP/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
NDA/MAL/HDP/8827	HETERO LABS LTD	ASTRA PHARMA (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
NDA/MAL/HDP/8835	RESONANT PHARMACEUTICALS	SHREEJI PHARMACEUTICALS LIMITED	TRIO-FAS(KIT)	AZITHROMYCIN DIHYDRATE + FLUCONAZOLE + SECNIDAZOLE	1000MG + 150MG + 2G	ACME FORMULATION PVT LTD.-ROPAR ROAD, NALAGARH, DIST. SOLAN, HIMACHAL PRADESH 174101 INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X4.0 TABLET BLISTER
NDA/MAL/HDP/8914	RENE INDUSTRIES LIMITED	RENE INDUSTRIES LIMITED	PEFLOREN 400	PEFLOXACIN MESILATE DIHYDRATE	400 MG	RENE INDUSTRIES LTD-PLOT 680, KAMULI ROAD, KIREKA, P.O BOX 6034, KAMPALA	UGANDA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8915	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD	WIDE SPECTRUM ENTERPRISES (U) LIMITED	ATOXIA 120 MG	ETORICOXIB	120 MG	UNITED PHARMACEUTICAL MANUFACTURING CO. LTD--P.O. BOX 69 AMMAN 11591 - AL-RAGEEM SAHAB - JORDAN	JORDAN	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X1.0X7.0 TABLET BLISTER

NDA/MAL/HDP/8916	MACLEODS PHARMACEUTICALS LTD.	NORVIK ENTERPRISES LIMITED	TAMSUMAC 0.4	TAMSULOSIN HYDROCHLORIDE	0.4MG	MACLEODS PHARMACEUTICALS LIMITED - BLOCK-N2 VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH – 174101 INDIA	INDIA	ORAL SOLID RETARD CAPSULES	1.0X1.0X10.0 CAPSULE BLISTER
NDA/MAL/HDP/8917	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-2 LLW TABLETS	RIFAMPICIN + ISONIAZID	150MG + 75MG	SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER
NDA/MAL/HDP/8918	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-3 LLW TABLETS	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 275MG	SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER
NDA/MAL/HDP/8919	SVIZERA LABS PRIVATE LTD	GITTOES PHARMACEUTICALS LIMITED	SCC-4 TABLETS	RIFAMPICIN + ISONIAZID + PYRAZINAMIDE + ETHAMBUTOL HYDROCHLORIDE	150MG + 75MG + 400MG + 275MG	SVIZERA LABS PRIVATE LIMITED-PLOT D-16/6 TTC INDUSTRIAL AREA MIDC TURBHE NAVI MUMBAI 400703, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X24.0X28.0 TABLET BLISTER
NDA/MAL/HDP/8920	MERCK (PTY) LTD	UNITED HEALTHCARE DISTRIBUTORS LTD	CRINONE 8% GEL	PROGESTERONE	90MG/APPLICATOR	FLEET LABORATORIES LTD --94 RICKMANSWORTH ROAD, WATFORD, HERT, WD18 7JJ, UNITED KINGDOM	UNITED KINGDOM	VAGINAL GELS AND SOLS	1.0X1.0X15.0 POUCH CARTON
NDA/MAL/HDP/8921	SUN PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	VESIZEN 5	SOLIFENACIN SUCCINATE	5 MG	SUN PHARMACEUTICALS LTD-,-SEZ UNIT –I, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8923	SUN PHARMACEUTICAL LTD	STAR PHARMACEUTICALS LTD	VESIZEN 10			SUN PHARMACEUTICALS LTD-,-SEZ UNIT –I, PLOT NO. A-41, INDUSTRIAL AREA, PHASE VIIIA S.A.S NAGAR MOHALI-160 071 PUNJAB, INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8925	ZIFAM PINNACLE PTY. LTD.	BOOTS PHARMACEUTICALS LIMITED	ZIFAMET 250	METRONIDAZOLE	250 MG	FREDUN PHARMACEUTICALS LTD --14, 15, 16, ZORABIAN INDUSTRIAL COMPLEX, VILLAGE, VEOOR, PALGHAR (EAST) DIST: THANE – 401 404 - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X10.0X1.0X10.0 TABLET BLISTER

NDA/MAL/HDP/8926	MSN LABORATORIES PRIVATE LIMITED	GOOD DAY PHARMACY LIMITED	GLUSIS 1000 ER	METFORMIN HYDROCHLORIDE	1000 MG	MSN LABORATORIES PRIVATE LIMITED (FORMULATIONS DIVISION) - -PLOT NO.: 42, ANRICH INDUSTRIAL ESTATE, BOLLARAM, MEDAK DISTRICT, 502 325, INDIA	INDIA	ORAL SOLID RETARD TABLETS	1.0X3.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8927	BIOLOGICAL E. LTD	PILLAR LOGISTICS 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
NDA/MAL/HDP/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/SYR UPS/DROPS	1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8929	OCTAPHARMA AG	PHILLIPS PHARMACEUTICALS (UGANDA) LIMITED	ALBUNORM	HUMAN ALBUMIN	20%W/V	OCTAPHARMA PRODUKTIONSGESELLSCHAFT DEUTSCHLAND MBH--WOLFGANG-MARGUERRE-ALLEE 1 31832 SPRINGE GERMANY	GERMANY	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X100.0 ML BOTTLE
NDA/MAL/HDP/8930	RESONANT PHARMACEUTICALS PVT LTD	SHREEJI PHARMACEUTICALS LIMITED	GASTRISAFE-(KIT)	CLARTHROMYCIN + ESOMEPRAZOLE MAGNESIUM DIHYDRATE + TINIDAZOLE	5000MG + 40MG + 500MG	ACME PHARMACEUTICAL PVT. LTD.-ROPAR ROAD NALAGARH, DIST. SOLAN, HIMACHAL PRADESH – 174101 - INDIA	INDIA	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X7.0X6.0 TABLET STRIP (2 TABLETS + 2 TABLETS + 2 CAPSULES)
NDA/MAL/HDP/8931	CARITAS HEALTHCARE PVT. LTD	REDDYS PHARMA LIMITED	SODIUM CHLORIDE INTRAVENOUS INFUSION BP	SODIUM CHLORIDE	0.9%W/V	SICHUAN KELUN PHARMACEUTICAL CO., LTD-SOUTH OF NO.2 ROAD, XINDU SATELLITE CITY INDUSTRIAL DEVELOPMENT ZONE, CHENGDU, SICHUAN PROVINCE 610500, P. R. CHINA	CHINA	PARENTERAL ORDINARY INFUSION VIALS/BOTTLES	1.0X500.0 ML BOTTLE
NDA/MAL/HDP/8932	S KANT HEALTHCARE LTD	ABACUS PHARMA (AFRICA) LIMITED	PRAZIQUANTEL	PRAZIQUANTEL	600 MG	S KANT HEALTHCARE LTD-1802-1805 GIDC PHASE III VAPI 396 195 GUJARAT	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X25.0X4.0 TABLET BLISTER
NDA/MAL/HDP/8933	CIPLA LTD	QUALITY CHEMICALS LTD - HUMAN	Q-TIB	SULFAMETHOXAZOLE + TRIMETHOPRIM + ISONIAZID + PYRIDOXINE HYDROCHLORIDE	800MG + 160MG + 300MG +25MG	CIPLA LIMITED>-A-33, A-37/2/2 & A-2, M.I.D.C, PATALANGA 410 220, DISTRICT RAIGAD, M.S, INDIA	INDIA	ORAL SOLID ORDINARY TABLETS	1.0X1.0X30.0 TABLET BOTTLE

NDA/MAL/HDP/8934	ABACUS PARENTERAL DRUGS LIMITED	ABACUS PARENTERAL DRUGS LIMITED	CYCLO P EYE DROPS	CYCLOPENTOLATE HYDROCHLORIDE	1.0%W/V	ABACUS PARENTERAL DRUGS LIMITED-BLOCK 191, PLOT NO. 114, GWAWANYA KINGA AND KAPEKA MUKONO DISTRICT, UGANDA.	UGANDA	OPHTHALMIC DROPS	1.0X1.0X10.0 ML VIAL
NDA/MAL/HDP/8935	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	FECLO GEL	DICLOFENAC DIETHYLAMMONIUM SALT	1%W/W	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	TOPICAL EXTERNAL EMULSION GELS	1.0X1.0X20.0 G TUBE
NDA/MAL/HDP/8936	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	40MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/8937	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	ESOFOLE	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	20MG	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	ORAL SOLID ORDINARY CAPSULES	1.0X2.0X7.0 CAPSULE BLISTER
NDA/MAL/HDP/8938	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD	HEALTHCARE LTD.	SULPHASIL	SILVER SULPHADIAZINE	1%W/W	AL-FAZAL PHARMA INDUSTRIES (PVT.) LTD-PLOT 20,21,22- DEFENCE INDUSTRIAL ZONE-MOMAN PURA, 16KM SHEIKHUPURA ROAD, (LAHORE) - PAKISTAN	PAKISTAN	TOPICAL EXTERNAL CREAMS	1.0X1.0X20.0 G TUBE
NDA/MAL/HDP/8939	FREDUN PHARMACEUTICALS LTD	MEDICINE PHARMACEUTICALS LTD	FREMOL PLUS	PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE + CHLORPHENIRAMINE MALEATE + CAFFEINE (ANHYDROUS)	325MG + 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
NDA/MAL/HDP/8940	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	RABIZA 20MG	RABEPRAZOLE SODIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER
NDA/MAL/HDP/8941	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.	CORE ACCESS LIMITED	LIVERCOL 20MG	ROSUVASTATIN CALCIUM	20MG	İLKO İLAÇ SANAYİ VE TİCARET A. Ş.-3. 42050 SELÇUKLU / KONYA TURKEY	TURKEY	ORAL SOLID ORDINARY FILM-COATED TABLETS	1.0X2.0X14.0 TABLET BLISTER

NDA/MAL/HDP/8944	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/8946	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/8947	GUILIN PHARMACEUTICALS CO.LTD.	STAR PHARMACEUTICAL S 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
NDA/MAL/HDP/8948	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)	GOODMAN INTERNATIONAL LTD	JULMENTIN ES	AMOXICILLIN TRIHYDRATE + CLAVULANATE POTASSIUM	600 MG / 5 ML + 42.9 MG / 5 ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR) DIGDAGA, AIRPORT STREET RAS AL KHAIMAH UNITED ARAB EMIRATES	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYRUPS/DROPS	1.0X1.0.100.0 ML BOTTLE
NDA/MAL/HDP/8949	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY	WIDE SPECTRUM ENTERPRISES (U) LIMITED	CETAL SUPOSITORIES	PARACETAMOL	120MG	EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E-10TH OF RAMADAN CITY INDUSTRIAL AREA B1,EGYPT	EGYPT	RECTAL SYSTEMIC SUPPOSITORIES	1.0X1.0X5.0 SUPPOSITORY BLISTER
NDA/MAL/HDP/8950	KOTRA PHARMA (M) SDN. BHD	UNITED HEALTHCARE DISTRIBUTORS	VAXCEL CEFEPIME-1G INJECTION	CEFEPIME HYDROCHLORIDE	1 G	KOTRA PHARMA (M) SDN. BHD. 1, JALAN TTC 12, CHENG INDUSTRIAL ESTATE, 75250 MELAKA, MALAYSIA	MALAYSIA	PARENTERAL ORDINARY DRY VIALS	1.0X1.0 VIAL CARTON
NDA/MAL/HDP/8951	MATRIX UGANDA LTD	MATRIX (U) LTD	VOREN ENTERIC MICROEN CAPSULATED CAPSULE	DICLOFENAC SODIUM	50MG	Y.S P INDUSTRIES (M) SDN BHD PLOT NO. 3, 5 & 7, JALAN P/7, SECTION 13, KAWASAN, PERINDUSTRIAN BANDAR BARU BANGI, 43000 KAJANG, SELANGOR DARUL EHSAN, MALAYSIA	MALAYSIA	ORAL SOLID ORDINARY ENTERIC-COATED TABLETS	1.0X10.0X10.0 TABLET BLISTER
NDA/MAL/HDP/8953	JOHNSON & JOHNSON (PTY) LTD	ERIS LTD	BENYLIN CHILDREN'S WET COUGH	GUAIFENESIN	100MG PER 10ML	JOHNSON & JOHNSON (PTY) LTD 241 MAIN ROAD, RETREAT 7945, SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X100.0 ML BOTTLE

NDA/MAL/HDP/8954	JOHNSON & JOHNSON (PTY) LTD	ERIS LTD	BENYLIN WET COUGH	GUAIFENESIN	200MG PER 10ML	JOHNSON & JOHNSON (PTY) LTD 241 MAIN ROAD, RETREAT 7945, SOUTH AFRICA	SOUTH AFRICA	ORAL LIQUID ORDINARY LIQUIDS	1.0X1.0X50.0 ML BOTTLE,1.0X1.0X 100.0 ML BOTTLE,1.0X1.0X 200.0 ML BOTTLE
NDA/MAL/HDP/8955	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR)	GOODMAN INTERNATIONAL LTD	CEFUZIME	CEFUROXIME AXETIL	125 MG / 5 ML	GULF PHARMACEUTICAL INDUSTRIES (JULPHAR) DIGDAGA, AIRPORT STREET RAS AL KHAIMAH UNITED ARAB EMIRATES	UNITED ARAB EMIRATES	ORAL LIQUID ORDINARY DRY SUSPENSIONS/SYR UPS/DROPS	1.0X50.0 ML BOTTLE