Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 550 Pretoria, 8 April 2011 **No. 34184**

CONTENTS

No.		Page No.	Gazette No.
	GENERAL NOTICE		
Health, Department of			
General Notice			
194	Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provision of section 15 (7)	3	34184

INHOUD

No.		Bladsy No.	Koerant No.
	ALGEMENE KENNISGEWING		
Gesondheid, Departement van			
Algemene Kennisgewing			
194	Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisynebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15 (7).....	4	34184

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 194 OF 2011

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 194 VAN 2011

MEDISYNEBEHEERRAAD

VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965)

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleeftydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:	42/8.2/0150
Name of medicine:	INNOHEP 2 500 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,25 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 2 500,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF15

Registration number:	42/8.2/0151
Name of medicine:	INNOHEP 10 000 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 10 000,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	42/8.2/1109
Name of medicine:	INNOHEP 3 500 IU anti-Xa
Dosage form:	INJECTION
Active ingredients:	EACH 0,35 ml SOLUTION CONTAINS: TINZAPARIN SODIUM 3 500,0 IU anti-Xa
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Packer:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE
Laboratory: FPRC:	LABORATOIRES LEO S.A., VERNOUILLET CEDEX, FRANCE LEO PHARMACEUTICAL PRODUCTS LTD, BALLERUP, DENMARK
FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	26 NOVEMBER 2010

MRF 15

Registration number:	41/7.1.3/0506
Name of medicine:	VERSYLON 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	LUPIN LTD, VERNA, SALCETTE GOA, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	LUPIN LTD, VERNA, SALCETTE GOA, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH

MRF15

Registration number:	41/25/0756
Name of medicine:	NUTRIFLEX LIPID PLUS
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 2,26 g L-leucine 3,01 g L-methionine 1,88 g L-lysine 2,18 g L-phenylalanine 3,37 g L-threonine 1,74 g L-tryptophan 0,54 g L-valine 2,50 g L-arginine 2,59 g L-histidine 1,20 g L-alanine 4,66 g Glycine 1,58 g L-proline 3,26 g L-serine 2,88 g Sodium Chloride 0,402 g Calcium Chloride 0,47 g Magnesium Acetate 0,686 g Potassium Acetate 2,747 g Sodium dihydrogen phosphate 1,872 g Glucose 120,0 g Aspartic Acid 1,44 g Glutamic Acid 3,37 g Sodium Hydroxide 0,781 g Sodium Acetate 0,222 g Zinc Acetate 5,264 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY

MRF 15

Registration number:	41/25/0757
Name of medicine:	NUTRIFLEX LIPID PERI
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 1,87 g L-leucine 2,50, g L-methionine 1,57 g L-lysine 1,81 g L-phenylalanine 2,81,g L-threonine 1,46 g L-tryptophan 0,46 g L-valine 2,08 g L-arginine 2,16 g L-histidine 1,00 g L-alanine 3,88 g Glycine 1,32 g L-proline 2,72 g L-serine 2,40 g Sodium Chloride 0,865 g Calcium Chloride 0,353 g Magnesium Acetate 0,515 g Potassium Acetate 2,354 g Sodium dihydrogen phosphate 0,936 g Glucose 64,0 g Aspartic Acid 1,20 g Glutamic Acid 2,80 g Sodium Hydroxide 0,64 g Sodium Acetate 0,435 g Zinc Acetate 5,30 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY

Laboratory:	FPRC:	LUPIN LTD, VERNA, SALCETTE GOA, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORTEN, PORT ELIZABETH
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		11 FEBRUARY 2011

		B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSi PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG.
Shelf-life:		24 months
Date of registration:		11 FEBRUARY 2011

		B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Laboratory:	FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG.
Shelf-life:		24 months
Date of registration:		11 FEBRUARY 2011

MRF 15

Registration number:	41/25/0758
Name of medicine:	NUTRIFLEX LIPID PLUS WITHOUT ELECTROLYRES
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 2,26 g L-leucine 3,01 g L-methionine 1,88 g L-lysine 2,18 g L-phenylalanine 3,37 g L-threonine 1,74 g L-tryptophan 0,54 g L-valine 2,50 g L-arginine 2,59 g L-histidine 1,20 g L-alanine 4,66 g Glycine 1,58 g L-proline 3,26 g L-serine 2,88 g Glucose 120,0 g Aspartic Acid 1,44 g Glutamic Acid 3,37 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY

MRF15

Registration number:	41/25/0759
Name of medicine:	NUTRIFLEX LIPID SPECIAL
Dosage form:	INFUSION
Active ingredients:	EACH 1000,0 ml MIXTURE CONTAINS: L-isoleucine 3,28 g L-leucine 4,38 g L-methionine 2,74 g L-lysine 3,18 g L-phenylalanine 4,92 g L-threonine 2,54 g L-tryptophan 0,80 g L-valine 3,60 g L-arginine 3,78 g L-histidine 1,75 g L-alanine 6,79 g Glycine 2,31 g L-proline 4,76 g L-serine 4,20g Sodium Chloride 0,378 g Calcium Chloride 0,623 g Magnesium Acetate 0,91g Potassium Acetate 3,689 g Sodium dihydrogen phosphate 2,496 g Glucose 144,0 g Aspartic Acid 2,10 g Glutamic Acid 4,91 g Sodium Hydroxide 1,171 g Sodium Acetate 0,25 g Zinc Acetate 7,02 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY

MRF 15

Registration number:	42/5.7.1/0339
Name of medicine:	TELFAST SUSPENSION
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: FEXOFENADINE HYDROCHLORIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA

Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Laboratory: FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG.
Shelf-life:	24 months
Date of registration:	11 FEBRUARY 2011

Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Laboratory: FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG.
Shelf-life:	24 months
Date of registration:	11 FEBRUARY 2011

Packer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA
FPRC/FPRR	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	11 FEBRUARY 2011

MRF 15

Registration number:	43/20.2.8/0581
Name of medicine:	ARROW EFAVIRENZ
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:FPRC :	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA SEDEK AGRIKEM, KAMEELDRIFT-EAST, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
FPRR:	ARROW PHARMA SA, WOODMEAD
Shelf-life:	24 months (Provisional)
Date of registration:	11 FEBRUARY 2011

MRF15

Registration number:	44/20.2.8/0106
Name of medicine:	ADCO LAMIVUDINE AND ZIDOVUDINE 150/300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	11 FEBRUARY 2011

MRF 15

Registration number:	44/20.2.8/0107
Name of medicine:	ZILAM TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	11 FEBRUARY 2011

MRF 15

Registration number:	41/21.2/0658
Name of medicine:	ACCORD GLIMEPIRIDE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF15

Registration number:	41/11.4.3/0663
Name of medicine:	ACCORD OMEPRAZOLE 40 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: OMEPRAZOLE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG BE-TABS PHARMACEUTICALS, ROODEPOORT
Laboratory: FPRC:	SOFARIMEX INDUSTRIES QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG BE-TABS PHARMACEUTICALS, ROODEPOORT CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF 15

Registration number:	42/7.1.3/0325
Name of medicine:	LOSAAR PLUS 50/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
Laboratory:: FPRC	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
FPRR	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF 15

Registration number:	42/7.1.3/0326
Name of medicine:	LOSAAR PLUS 100/25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	SOFARIMEX INDUSTRIA QUIMICA e FARMACEUTICA, CACEM, PORTUGAL INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA BE-TABS PHARMACEUTICALS, ROODEPOORT COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	18 FEBRUARY 2011

MRF15

Registration number:	A40/3/0326
Name of medicine:	MICROVISC
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: SODIUM HYALURONATE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ECO PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN
Packer:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA ANALYCEN NORDIC AB, LIDKOPING, SWEDEN MIKROBIOLOGISKA LABORATORIET, GOTEBORG, SWEDEN
FPRR:	ECO PHARMACEUTICALS, NORTHWOLD, RANDBURG
Shelf-life:	36 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	A40/3/0327
Name of medicine:	MICROVISC PLUS
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: SODIUM HYALURONATE 14,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ECO PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN
Packer:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	BOHUS BIOTECH AB, STROMSTAD, SWEDEN PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA ANALYCEN NORDIC AB, LIDKOPING, SWEDEN MIKROBIOLOGISKA LABORATORIET, GOTEBORG, SWEDEN
FPRR:	ECO PHARMACEUTICALS, NORTHWOLD, RANDBURG
Shelf-life:	36 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/26/0162
Name of medicine:	CIPLA DOCETAXEL 20
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/26/0163
Name of medicine:	CIPLA DOCETAXEL 80
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/1.2/0297
Name of medicine:	GLENMARK CITALOPRAM 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BOUWER BARTLETT (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/26/0423
Name of medicine:	CIPLA PACLITAXEL 30 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml VIAL CONTAINS: PACLITAXEL 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/26/0424
Name of medicine:	CIPLA PACLITAXEL 100 mg/16,7 ml
Dosage form:	INJECTION
Active ingredients:	EACH 20,0 ml VIAL CONTAINS: PACLITAXEL 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/26/0425
Name of medicine:	CIPLA PACLITAXEL 300 mg/50 ml
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: PACLITAXEL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/25/0760
Name of medicine:	NUTRIFLEX LIPID SPECIAL WITHOUT ELECTROLYTES
Dosage form:	INFUSION
Active ingredients:	EACH 1 000,0 ml MIXTURE CONTAINS: L-isoleucine 3,28 g L-leucine 4,38 g L-methionine 2,74 g L-lysine 3,18 g L-phenylalanine 4,92 g L-threonine 2,54 g L-tryptophan 0,80 g L-valine 3,60 g L-arginine 3,78 g L-histidine 1,75 g L-alanine 6,79 g Glycine 2,31 g L-proline 4,76 g L-serine 4,20g Glucose 144,0 g Aspartic Acid 2,10 g Glutamic Acid 4,91 g Medium chain triglycerides 20,0 g Soya oil 20,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MELSUNGEN AG, PFIEFFEWIESEN, MELSUNGEN, GERMANY

MRF15

Registration number:	41/3.1/0762
Name of medicine:	ENBREL 25 mg PS
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: ETANERCEPT 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND WYETH BIOPHARMA, CLONDALKIN, DUBLIN
Packer:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

MRF 15

Registration number:	41/3.1/0763
Name of medicine:	ENBREL 50 mg PS
Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: ETANERCEPT 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND WYETH BIOPHARMA, CLONDALKIN, DUBLIN
Packer:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG

Laboratory: FPRC:	B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG COSI PHARMACEUTICALS, INDUSTRIA-WEST, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG.	
Shelf-life:	24 months	
Date of registration:	4 MARCH 2011	

Laboratory: FPRC:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND WYETH BIOPHARMA, CLONDALKIN, DUBLIN WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	
FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG	
Shelf-life:	24 months (Provisional)	
Date of registration:	4 MARCH 2011	

Laboratory: FPRC:	VETTER PHARMA-FERTIGUNG GmbH & Co, RAVENSBURG, GERMANY AMGEN INC RHODE ISLAND, WEST GREENWICH, RHODE ISLAND WYETH BIOPHARMA, CLONDALKIN, DUBLIN WYETH PHARMACEUTICALS, HAVANT, HAMPSHIRE, UK PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	
FPRR:	PFIZER LABORATORIES, SANDTON, JOHANNESBURG	
Shelf-life:	24 months (Provisional)	
Date of registration:	4 MARCH 2011	

MRF 15

Registration number:	41/11.5/0764
Name of medicine:	ANLAC SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 5,0 ml SYRUP CONTAINS: LACTULOSE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	LACSA, MERBANK, DURBAN
Packer:	DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA M&L LABORATORY SERVICES, ORMONDE, JOHANNSBURG
FPRR:	ARROW PHARMA S.A., SANDOWN, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/7.1/0782
Name of medicine:	MERCK AMLODIPINE 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/7.1/0783
Name of medicine:	MERCK AMLODIPINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory: FPRC	GENPHARM PHARMACEUTICALS INC, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	MERCK GENERICS, MODDERFONTEIN
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/5.2/0990
Name of medicine:	ASPEN GALANTAMINE 12 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE 12,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA
Packer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/5.2/0991
Name of medicine:	ASPEN GALANTAMINE 8 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA
Packer:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	ALPHAPHARM PTY LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/7.1.3/1000
Name of medicine:	NETRASOL CO 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	04 MARCH 2011

MRF 15

Registration number:	41/7.1.3/1001
Name of medicine:	NETRASOL CO 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months
Date of registration:	04 MARCH 2011

MRF15

Registration number:	41/5.3/1015
Name of medicine:	GALANTIC 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/5.3/1016
Name of medicine:	GALANTIC 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/5.3/1017
Name of medicine:	GALANTIC 12
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 12,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory: FPRC:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/7.1.3/1031
Name of medicine:	RAN LOSARTAN PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/7.1.3/1034
Name of medicine:	RAN LOSARTAN FORTE PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	41/7.1.3/1035
Name of medicine:	LOHYPE PLUS 50/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	41/7.1.3/1036
Name of medicine:	LOHYPE FORTE PLUS 100/25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RANBAXY (SA), CENTURION
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/26/0020
Name of medicine:	ASPEN VINORELBIN 10 mg/1 ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/26/0021
Name of medicine:	ASPEN VINORELBIN 50 mg/5 ml
Dosage form:	INFUSION
Active ingredients:	EACH 5,0 ml VIAL CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/20.1.1/0079
Name of medicine:	MYLAN CEFTAZIDIME 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory: FPRC:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.1.1/0080
Name of medicine:	MYLAN CEFTAZIDIME 1 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 1,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory: FPRC::	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.1.1/0081
Name of medicine:	MYLAN CEFTAZIDIME 2 g
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO CEFTAZIDIME 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Packer:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY
Laboratory: FPRC:	LABORATORIO FARMACEUTICO C.T., SANREMO, ITALY G.E.T. SRL, SANREMO, ITALY GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/5.7.1/0344
Name of medicine:	FEXOFENADINE-WINTHROP SUSPENSION 6mg/ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: FEXOFENADINE HYDROCHLORIDE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA
Packer:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI-AVENTIS U.S. LLC, KANSAS CITY, MISSOURI, USA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	WINTHROP PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/3.2/0452
Name of medicine:	ACTONEL 75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS RISEDRONATE SODIUM 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANOFI AVENTIS SA (PTY) LTD
Manufacturer:	OSG NORWICH PHARMACEUTICALS, NORTH NORWICH, NEW YORK, USA PROCTER & GAMBLE PHARMACEUTICALS, MANATI, PUERTO RICO
Packer:	PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	PROCTER & GAMBLE PHARMACEUTICALS, WEITERSTADT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/34/0664
Name of medicine:	ZOBONE
Dosage form:	POWDER
Active ingredients:	EACH VIAL CONTAINS: ZOLEDRONIC ACID 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/20.2.8/0838
Name of medicine:	ASPEN ATAZANAVIR 150 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/20.2.8/0839
Name of medicine:	ASPEN ATAZANAVIR 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	42/1.2/1001
Name of medicine:	NEXITO 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	42/11.4.3/1003
Name of medicine:	NEXIAM 10 mg SACHETS
Dosage form:	GRANULES
Active ingredients:	EACH SACHET CONTAINS: ESOMEPRAZOLE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Laboratory: FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	43/20.2.8/0230
Name of medicine:	NEVIVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BLISS PHARMACEUTICALS cc
Manufacturer:	HETERO DRUG LTD, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUG LTD, JEEDIMETLA, HYDERABAD, INDIA
Laboratory: FPRC:	HETERO DRUG LTD, JEEDIMETLA, HYDERABAD, INDIA
FPRR:	BLISS PHARMACEUTICALS, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	43/20.2.8/0234
Name of medicine:	ATAZOR 100
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD t/a INDO PHARMA
Manufacturer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	DEZZO TRADING 392, t/a INDO PHARMA, ANCHORVILLE, LENASIA
Shelf-life:	36 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:		43/20.2.8/0235
Name of medicine:		ATAZOR 150
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		DEZZO TRADING 392 (PTY) LTD t/a INDO PHARMA
Manufacturer:		EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:		EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Laboratory:	FPRC:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	DEZZO TRADING 392, t/a INDO PHARMA, ANCHORVILLE, LENASIA
Shelf-life:		36 months
Date of registration:		4 MARCH 2011

MRF 15

Registration number:	43/20.2.8/0236
Name of medicine:	ATAZOR 200
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD t/a INDO PHARMA
Manufacturer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	DEZZO TRADING 392, t/a INDO PHARMA, ANCHORVILLE, LENASIA
Shelf-life:	36 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:		43/2.2/0247
Name of medicine:		MEDPLOZ 5 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 5,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		4 MARCH 2011

MRF15

Registration number:		43/2.2/0257
Name of medicine:		MEDPLOZ 10 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		4 MARCH 2011

MRF 15

Registration number:		43/7.1.3/0493
Name of medicine:		AURO LOSARTAN TABLETS 25 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:		AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		4 MARCH 2011

MRF 15

Registration number:	43/7.1.3/0494
Name of medicine:	AURO LOSARTAN TABLETS 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:	43/7.1.3/0495
Name of medicine:	AURO LOSARTAN TABLETS 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	43/7.1.3/0496
Name of medicine:	RASOL 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	43/7.1.3/0497
Name of medicine:	RASOL 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF15

Registration number:		43/7.1.3/0498
Name of medicine:		RASOL 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		4 MARCH 2011

MRF 15

Registration number:	43/20.2.8/0580
Name of medicine:	VIREF
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA SEDEK AGRIKEM, KAMEELDRIFT-EAST, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
FPRR:	ARROW PHARMA SA, WOODMEAD
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

MRF 15

Registration number:		43/20.1.1/0647
Name of medicine:		DORIBAX 500 mg
Dosage form:		INFUSION
Active ingredients:		EACH VIAL CONTAINS: DORIPENEM MONOHYDRATE EQUIVALENT TO DORIPENEM 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:		SHIONOGI & CO LTD, IWATE, JAPAN
Packer:		SHIONOGI & CO LTD, IWATE, JAPAN ORTHO-MCNEIL PHARMACEUTICAL INC, SOUTH RARITAN, NEW JERSEY, USA
Laboratory:	FPRC:	SHIONOGI & CO LTD, IWATE, JAPAN ORTHO-MCNEIL PHARMACEUTICAL INC, SOUTH RARITAN, NEW JERSEY, USA
	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:		36 months
Date of registration:		4 MARCH 2011

MRF15

Registration number:		43/18.8/0648
Name of medicine:		RUBY
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,03 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMA DYNAMICS (PTY) LTD
Manufacturer:		LABORATORIOS LEON FARMA S.A., VILLAQUILAMBRE, LEON, SPAIN
Packer:		LABORATORIOS LEON FARMA S.A., VILLAQUILAMBRE, LEON, SPAIN
Laboratory:	FPRC:	LABORATORIOS LEON FARMA S.A., VILLAQUILAMBRE, LEON, SPAIN CONSULTING CHEMICAL LABORATORY, ATLASVILLE, BOKSBURG
	FPRR:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:		24 months (Provisional)
Date of registration:		4 MARCH 2011

MRF 15

Registration number:		43/20.1.6/0680
Name of medicine:		SUPIROBAN
Dosage form:		OINTMENT
Active ingredients:		EACH 1,0 g OINTMENT CONTAINS: MUPIROCIN 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		GLENMARK PHARMACEUTICALS SOUTH AFRICA (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS, BARDEZ, GOA, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
	FPRR:	GLENMARK PHARMACEUTICALS S.A., VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		4 MARCH 2011

MRF 15

Registration number:	43/30.2/0944
Name of medicine:	ACTEMRA 80
Dosage form:	INFUSION
Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: TOCILIZUMAB 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN
Packer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN F HOFFMANN-LA ROCHE LTD, WURMISWEG, KAISERAUGST, SWITZERLAND
Laboratory: FPRC:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN ROCHE PHARMA AG, GRENZACH-WYHLEN, GERMANY
FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	30 months
Date of registration:	4 MARCH 2011

MRF15

Registration number:	43/30.2/0945
Name of medicine:	ACTEMRA 200
Dosage form:	INFUSION
Active ingredients:	EACH 10,0 ml SOLUTION CONTAINS: TOCILIZUMAB 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN
Packer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN F HOFFMANN-LA ROCHE LTD, WURMISWEG, KAISERAUGST, SWITZERLAND
Laboratory: FPRC:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN ROCHE PHARMA AG, GRENZACH-WYHLEN, GERMANY
FPRR:	ROCHE PRODUCTS,
Shelf-life:	30 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	43/30.2/0946
Name of medicine:	ACTEMRA 400
Dosage form:	INFUSION
Active ingredients:	EACH 20,0 ml SOLUTION CONTAINS: TOCILIZUMAB 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN
Packer:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN F HOFFMANN-LA ROCHE LTD, WURMISWEG, KAISERAUGST, SWITZERLAND
Laboratory: FPRC:	CHUGAI PHARMA MANUFACTURING CO, UTSUNOMIYA-CITY, TOCHIGI, JAPAN ROCHE PHARMA AG, GRENZACH-WYHLEN, GERMANY
FPRR:	ROCHE PRODUCTS, ISANDO, RSA
Shelf-life:	30 months
Date of registration:	4 MARCH 2011

MRF 15

Registration number:	44/20.2.8/0108
Name of medicine:	PROPAN LAMIVUDINE AND ZIDOVUDINE 150/300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg ZIDOVUDINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	4 MARCH 2011

Registration number:	42/20.2.8/0687
Name of medicine:	ISENTRESS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RALTEGRAVIR POTASSIUM EQUIVALENT TO RALTEGRAVIR 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO INC, ELKTON, VIRGINIA, USA
Packer:	MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MSD, HALFWAY HOUSE, MIDRAND
Laboratory: FPRC:	MERCK & CO INC, ELKTON, VIRGINIA, USA MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS
FPRC/FPRR:	MSD, HALFWAY HOUSE, MIDRAND
Shelf-life:	36 months
Date of registration:	4 MARCH 2011