
GOVERNMENT NOTICE GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. 74

6 February 2013

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.

MRF 15

Registration number:	07/13.3.124
Name of medicine:	CORTAVANCE
Dosage form:	CUTANEOUS SPRAY SOLUTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: Hydrocortisone aceponate 0.584 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	VIRBAC RSA (PTY) LTD
Manufacturer:	VIRBAC S.A. CARROS, CEDEX, FRANCE
Packer:	VIRBAC S.A. CARROS, CEDEX, FRANCE VIRBAC RSA, CENTURION, RSA
Laboratory: FPR:	VIRBAC S.A. CARROS, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	24 months In-use shelf life of 6 months stored at or below 25 °C or between 2 – 8 °C
Date of registration:	26 OCTOBER 2012

MRF-15

Registration number:	A39/20.2.2/0589
Name of medicine:	CANESTEN 3VC
Dosage form:	VAGINAL CREAM
Active ingredients:	EACH 1.0 g CREAM CONTAINS: CLOTRIMAZOLE 20.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BAYER (PTY) LTD
Manufacturer:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN
Packer:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN AKACIA PHARMACEUTICALS, ISANDO, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, JOHANNESBURG, RSA
Laboratory: FPR:	KERN PHARMA SL, TERASSA, BARCELONA, SPAIN AKACIA PHARMACEUTICALS, ISANDO, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, JOHANNESBURG, RSA
FPR:	BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

F 15

Registration number:	A39/7.1/0590
Name of medicine:	ASPEN NIMODIPINE IV
Dosage form:	INFUSION
Active ingredients:	EACH 50.0 ml SOLUTION CONTAINS: NIMODIPINE 10.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED
Manufacturer:	LABORATORIO REIG JOFRE, S.A., BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA
Packer:	LABORATORIO REIG JOFRE, S.A., BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA
Laboratory: FPR:	LABORATORIO REIG JOFRE, S.A., BARCELONA, SPAIN STRIDES ARCOLAB LIMITED, BANNERGHATTA, BANGALORE, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15		F 15	
Registration number:	A40/11.4.3/0153	Registration number:	41/3.1/0253
Name of medicine:	COVAN LANSOPRAZOLE 15	Name of medicine:	MEDOXICAM 15
Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: LANSOPRAZOLE 15,0 mg	Active ingredients:	EACH TABLET CONTAINS: MELOXICAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	LICONSA S.A., GUADALAJARA, SPAIN	Manufacturer:	MEDOCHÉMIE LTD, LIMASSOL, CYPRUS
Packer:	LICONSA S.A., GUADALAJARA, SPAIN	Packer:	MEDOCHÉMIE LTD, LIMASSOL, CYPRUS
Laboratory: FPRC:	LICONSA S.A., GUADALAJARA, SPAIN	Laboratory: FPRC:	MEDOCHÉMIE LTD, LIMASSOL, CYPRUS
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE, CLAYVILLE, OLIFANTSFONTEIN, RSA	FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	Shelf-life:	24 months
Shelf-life:	24 months	Date of registration:	26 OCTOBER 2012
Date of registration:	26 OCTOBER 2012		

MRF 15		MRF 15		MRF 15	
Registration number:	41/7.1.3/0770	Registration number:	41/7.1.3/0771	Registration number:	42/8.2/0193
Name of medicine:	EXFORGE 5/320 mg	Name of medicine:	EXFORGE 10/320 mg	Name of medicine:	ENOXAPARIN SODIUM 20 WINTHROP
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 5.0 mg Valsartan 320.0 mg	Active ingredients:	EACH TABLET CONTAINS: Amlodipine besylate equivalent to Amlodipine 10.0 mg Valsartan 320.0 mg	Active ingredients:	EACH 0.2 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 20.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD	Applicant:	NOVARTIS SA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND	Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory:	FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory:	FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory:	FPRC: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:	24 months	Shelf-life:	24 months	FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Shelf-life:	24 months
				Date of registration	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	42/8.2/0194	Registration number:	42/8.2/0195	Registration number:	42/8.2/0196
Name of medicine:	ENOXAPARIN SODIUM 40 WINTHROP	Name of medicine:	ENOXAPARIN SODIUM 60 WINTHROP	Name of medicine:	ENOXAPARIN SODIUM 80 WINTHROP
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH 0.4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40,0 mg	Active ingredients:	EACH 0.6 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 60,0 mg	Active ingredients:	EACH 0.8 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA
FPRR:	SANOI-AVENTIS S.A., MIDRAND, RSA	FPRR:	SANOI-AVENTIS S.A., MIDRAND, RSA	FPRR:	SANOI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		F 15	
Registration number:	42/8 2/0197	Registration number:	42/8 2/0198	Registration number:	42/20.1.2/0212
Name of medicine:	ENOXAPARIN SODIUM 100 WINTHROP	Name of medicine:	ENOXAPARIN SODIUM 300 WINTHROP	Name of medicine:	CLAMGEN IV 0.6
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 100.0 mg	Active ingredients:	EACH 3.0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 300.0 mg	Active ingredients:	EACH VIAL CONTAINS: AMOXICILLIN 500.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS WALTLOO, PRETORIA	FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	42/20.1.20213	Registration number:	42/20.1.10251	Registration number:	42/20.1.10252
Name of medicine:	CLAMGEN IV 1.2	Name of medicine:	LITHA PIPERACILLIN CO 20.250	Name of medicine:	LITHA PIPERACILLIN CO 30.375
Dosage form:	INJECTION	Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMOXICILLIN SODIUM EQUIVALENT TO AMOXICILLIN 1 000.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO 200.0 mg CLAVULANIC ACID	Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 2.0 g TAZOBACTAM SODIUM EQUIVALENT TO 0.250 g TAZOBACTAM	Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 3.0 g TAZOBACTAM SODIUM EQUIVALENT TO 0.250 g TAZOBACTAM
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	LITHA PHARMA (PTY) LTD	Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK	Manufacturer:	MITIM S.r.L, BRESCIA, ITALY	Manufacturer:	MITIM S.r.L, BRESCIA, ITALY
Packer:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK	Packer:	MITIM S.r.L, BRESCIA, ITALY	Packer:	MITIM S.r.L, BRESCIA, ITALY
Laboratory: FPRC:	GLAXO SMITHKLINE PHARMACEUTICALS, WORTHING, SUSSEX, UK GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRC:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, JOHANNESBURG, RSA	FPRC:	LITHA PHARMA (PTY) LTD, MIDRAND, RSA	FPRC:	LITHA PHARMA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15

MRF 15

MRF 15

MRF 15		MRF 15		MRF 15	
Registration number:	42/20.1.1/0253	Registration number:	42/3.1/0831	Registration number:	42/26/0961
Name of medicine:	LITHA PIPERACILLIN CO 4/0,5	Name of medicine:	VOLTAREN ACTI-GO SOFT GEL CAPSULE	Name of medicine:	TEMODAL 140 mg
Dosage form:	POWDER FOR INJECTION	Dosage form:	SOFT GEL CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH VIAL CONTAINS: PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g	Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC POTASSIUM 12,5 mg	Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 140,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LITHA PHARMA (PTY) LTD	Applicant:	NOVARTIS SA (PTY) LTD	Applicant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer:	MITIM S.r.L, BRESCIA, ITALY	Manufacturer:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY	Manufacturer:	ORION CORPORATION, TURKU, FINLAND
Packer:	MITIM S.r.L, BRESCIA, ITALY	Packer:	CARDINAL HEALTH GERMANY 405 GmbH, STEINBEISSTRASSE, SCHORNDORF, GERMANY	Packer:	ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM
Laboratory:	FPRC: MITIM S.r.L, BRESCIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA	Laboratory:	FPRC: ORION CORPORATION, TURKU, FINLAND SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM SGS LAB SIMON SA, WAVRE, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRC:	LITHA PHARMA (PTY) LTD, MIDRAND, RSA	FPRC:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	SCHERING-PLOUGH, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		F 15	
Registration number:	42/26/0962	Registration number:	43/5.4.1/0134
Name of medicine:	TEMODAL 180 mg	Name of medicine:	GULF PRAMIPEXOLE 0.125 mg
Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 180.0 mg	Active ingredients:	EACH TABLET CONTAINS: Pranipexole dihydrochloride monohydrate 0.125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SCHERING-PILOUGH (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	ORION CORPORATION, TURKU, FINLAND	Manufacturer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	ORION CORPORATION, TURKU, FINLAND SCHERING-PILOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM	Packer:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC:	ORION CORPORATION, TURKU, FINLAND SCHERING-PILOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM SGS LAB SIMON SA, WAVRE, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	ALEMBIC LIMITED (FORMULATION DIVISION), TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
FPRR:	SCHERING-PILOUGH, WOODMEAD, SANDTON, RSA	FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

F 15

MRF-15

MRF-15

Registration number:	43/2.2/0171	Registration number:	43/2.2/0172
Name of medicine:	MIDAZOLAM B BRAUN 1 mg/ml	Name of medicine:	MIDAZOLAM B BRAUN 5 mg/ml
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: MIDAZOLAM 1,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: MIDAZOLAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	B BRAUN MEDICAL (PTY) LTD	Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN	Manufacturer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Packer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN	Packer:	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN
Laboratory: FPRC	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA	Laboratory: FPRC	B. BRAUN MELSUNGEN AG, BERLIN, GERMANY B. BRAUN MEDICAL S.A., JAEN, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	43/20.1.1/0190	Registration number:	43/20.1.1/0191	Registration number:	43/26/0246
Name of medicine:	DRL LEVOFLOXACIN 250	Name of medicine:	DRL LEVOFLOXACIN 500	Name of medicine:	GENEXOL 300 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: Levofloxacin 250.0 mg	Active ingredients:	EACH TABLET CONTAINS: Levofloxacin 500.0 mg	Active ingredients:	EACH VIAL CONTAINS: PACLITAXEL 300.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	PHARMACORP cc
Manufacturer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA	Packer:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED (GENERICS), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DR REDDY'S LABORATORIES LIMITED (FTO/FM-II), QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA-SANAND, AHMEDABAD, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA	FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA	FPRR:	PHARMACORP cc, ARCADIA, PRETORIA, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.3/0301	Registration number:	43/7.1.3/0302	Registration number:	43/7.1.3/0303
Name of medicine:	VALANT 40	Name of medicine:	VALANT 80	Name of medicine:	VALANT 160
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA	Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA	Manufacturer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA
Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA ROPACK MIRABEAU, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMASCIENCE INC, ROYALMOUNT AVENUE, MONTREAL, QUEBEC, CANADA PHARMASCIENCE INC, DE L'ESPLANADE AVENUE, MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15	Registration number: 43/2.6.5/0446		Registration number: 43/2.6.5/0447		Registration number: 43/5.7.1/0451	
Name of medicine: PSYQUET 25		Name of medicine: SANDOZ QUETIAPINE 25		Name of medicine: SIBELIUM T 5 mg		
Dosage form: TABLET		Dosage form: TABLET		Dosage form: TABLET		
Active ingredients: EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 25,0 mg		Active ingredients: EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 25,0 mg		Active ingredients: EACH TABLET CONTAINS: FLUNARIZINE HYDROCHLORIDE EQUIVALENT TO FLUNARIZINE 5,0 mg		
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8		Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8		Conditions of registration: 1, 2, 3, 4, 5, 6, 7		
Applicant: SANDOZ SA (PTY) LTD		Applicant: SANDOZ SA (PTY) LTD		Applicant: JANSSEN PHARMACEUTICA (PTY) LTD		
Manufacturer: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY		Manufacturer: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY		Manufacturer: JANSSEN-CILAG S.P.A, LATINA, ITALY		
Packer: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA		Packer: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA		Packer: JANSSEN-CILAG S.P.A, LATINA, ITALY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA		
Laboratory: FPRC: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA		Laboratory: FPRC: SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA		Laboratory: FPRC: JANSSEN-CILAG S.P.A, LATINA, ITALY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA		
FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA		FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA		FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA		
Shelf-life: 24 months (Provisional)		Shelf-life: 24 months (Provisional)		Shelf-life: 24 months		
Date of registration: 26 OCTOBER 2012		Date of registration: 26 OCTOBER 2012		Date of registration: 26 OCTOBER 2012		

MRF 15	MRF 15	MRF 15
Registration number: 43/5.4.1/0505 Name of medicine: ACCORD ROPINIROLE 0,5 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ROPINIROLE HCl 0,5 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 36 months Date of registration: 26 OCTOBER 2012	Registration number: 43/5.4.1/0506 Name of medicine: ACCORD ROPINIROLE 0,25 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ROPINIROLE HCl 0,25 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 36 months Date of registration: 26 OCTOBER 2012	Registration number: 43/5.4.1/0507 Name of medicine: ACCORD ROPINIROLE 1 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ROPINIROLE HCl 1,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 36 months Date of registration: 26 OCTOBER 2012

MRF 15

Registration number: 43/5, 4, 1/0508
 Name of medicine: ACCORD ROPINIROLE 2 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: ROPINIROLE HCl 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
 Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
 FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
 Shelf-life: 36 months
 Date of registration: 26 OCTOBER 2012

MRF15

Registration number: 43/5, 4, 1/0509
 Name of medicine: ACCORD ROPINIROLE 5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: ROPINIROLE HCl 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
 Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
 FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
 Shelf-life: 36 months
 Date of registration: 26 OCTOBER 2012

MRF 15

Registration number: 43/26/0540
 Name of medicine: TEMODAL 100 mg/ml POWDER FOR INJECTION
 Dosage form: POWDER FOR INJECTION
 Active ingredients: EACH VIAL CONTAINS: TEMOZOLOMIDE 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SCHERING-PLOUGH (PTY) LTD
 Manufacturer: BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY
 Packer: BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM
 Laboratory: FPRC: BAXTER ONCOLOGY GmbH, HALLE/WESTFALEN, GERMANY SCHERING-PLOUGH LABO N.V., HEIST-OP-DEN-BERG, BELGIUM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
 FPRR: KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
 SCHERING-PLOUGH, WOODMEAD, SANDTON, RSA
 Shelf-life: 36 months
 Date of registration: 26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	43/18.3/0701	Registration number:	43/21.12/0726	Registration number:	43/2.6.5/0849
Name of medicine:	SORBISTERIT POWDER FOR ORAL SUSPENSION	Name of medicine:	LETOZ 2.5 TABLETS	Name of medicine:	PSYQUET 100
Dosage form:	POWDER FOR ORAL SUSPENSION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 1.0 g POWDER CONTAINS: CALCIUM POLYSTYRENE SULPHONATE 7.59 – 9.49 g	Active ingredients:	EACH TABLET CONTAINS: LETOZOLE 2.5 mg	Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 100.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	FRESENIUS KABI SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA	Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA	Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Laboratory: FPRC:	FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, ST. WENDEL, GERMANY BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRR:	FRESENIUS KABI SA (PTY) LTD, MIDRAND, RSA	FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA	FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	43/2.6.5/0850	Registration number:	43/2.6.5/0851
Name of medicine:	PSYQUET 200	Name of medicine:	PSYQUET 300
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY	Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA	Packer:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S. GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15

MRF 15

MRF 15

MRF 15

MRF 15

Registration number:	43/2.6.5/0853
Name of medicine:	SANDOZ QUETIAPINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	43/2.6.5/0854
Name of medicine:	SANDOZ QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Quetiapine hemifumarate equivalent to Quetiapine 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY
Packer:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ ILAC SANAYI VE TICARET A.S, GEBZE-KOCAELI, TURKEY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	43/21.3/0869
Name of medicine:	THYROTROPIN ALFA GENZYME 0,9 mg/ml
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: THYROTROPIN ALFA 0,9 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENZYME BIOPHARMACEUTICALS SA (PTY)
Manufacturer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA
Packer:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA
Laboratory: FPRC:	GENZYME CORPORATION, ALLSTON, MASSACHUSETTS, USA GENZYME CORPORATION, 45 NEW YORK AVENUE, FRAMINGHAM, MASSACHUSETTS, USA GENZYME CORPORATION, 76 NEW YORK AVENUE, FRAMINGHAM, MASSACHUSETTS, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	GENZYME BIOPHARMACEUTICALS SA (PTY) LTD, BRYANSTON, GAUTENG, RSA
Shelf-life:	36 months In-use shelf life of 24 hours stored at 2 – 8 °C
Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	43/11.4.3/1089	Registration number:	43/11.4.3/1090	Registration number:	43/7.5/1107
Name of medicine:	WATSON RANITIDINE 150	Name of medicine:	WATSON RANITIDINE 300	Name of medicine:	PROPAN ATORVASTATIN 10 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HCl EQUIVALENT TO RANITIDINE 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: RANITIDINE HCl EQUIVALENT TO RANITIDINE 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	Rx MANUFACTURING INC. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	Rx MANUFACTURING INC. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	ACTAVIS hf. HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	Rx MANUFACTURING INC. MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	Rx MANUFACTURING INC. MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	ACTAVIS hf. HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Laboratory:	FPRC: MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA	Laboratory:	FPRC: MISSISSAUGA, ONTARIO, CANADA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA	Laboratory:	FPRC: ACTAVIS hf. HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD WOODMEAD, RSA	FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD WOODMEAD, RSA	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Shelf-life:	24 months (Provisional)
				Date of registration:	26 OCTOBER 2012

MRF 15

Registration number:	437.5/1108
Name of medicine:	PROPAN ATORVASTATIN 20 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRC:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF15

Registration number:	437.5/1109
Name of medicine:	PROPAN ATORVASTATIN 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MMRF 15

Registration number:	437.5/1110
Name of medicine:	COVAN ATORVASTATIN 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.5/1111	Registration number:	43/7.5/1112	Registration number:	43/7.5/1113
Name of medicine:	COVAN ATORVASTATIN 20 mg	Name of medicine:	COVAN ATORVASTATIN 40 mg	Name of medicine:	RESTAN ATORVASTATIN 10 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA	Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA	Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15	MRF 15	MRF 15	MRF 15
Registration number: 437.5/1117 Name of medicine: ADCO ATORVASTATIN 20 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND Packer: ACTAVIS LTD, ZEJTUN, MALTA ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND FPRC/FPRR: ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	Registration number: 437.5/1118 Name of medicine: ADCO ATORVASTATIN 40 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND Packer: ACTAVIS LTD, ZEJTUN, MALTA ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND FPRC/FPRR: ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	Registration number: 437.5/1119 Name of medicine: ALCHOLTIN 10 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND Packer: ACTAVIS LTD, ZEJTUN, MALTA ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND FPRC/FPRR: ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.5/1120	Registration number:	43/7.5/1121	Registration number:	44/13.4.1/0095
Name of medicine:	ALCHOLIN 20 mg	Name of medicine:	ALCHOLIN 40 mg	Name of medicine:	MOMATE OINTMENT
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	OINTMENT
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg	Active ingredients:	EACH 1,0 g OINTMENT CONTAINS: MOMETASONE FUROATE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA	Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA	Packer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, JOHANNESBURG, RSA	FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA	Shelf-life:	24 months
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Date of registration:	26 OCTOBER 2012
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012		

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0098	Registration number:	44/26/0099	Registration number:	44/26/0100
Name of medicine:	DOCETAXEL WINTHROP 20 mg/1 ml RTU	Name of medicine:	DOCETAXEL WINTHROP 80 mg/4 ml RTU	Name of medicine:	TAXOTERE 20 mg/1 ml RTU
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 20,0 mg	Active ingredients:	EACH 4,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 80,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD	Applicant:	SANOFI-AVENTIS SA (PTY) LTD
Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM	Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM	Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM	Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM	Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM
Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory: FPRC:	AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA	FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA	FPRR:	SANOFI-AVENTIS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15	MRF 15	MRF 15
Registration number: 44/26/0101 Name of medicine: TAXOTERE 80 mg/4 ml RTU Dosage form: CONCENTRATE FOR SOLUTION FOR INFUSION Active ingredients: EACH 4,0 ml SOLUTION CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL 80,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANOFI-AVENTIS SA (PTY) LTD Manufacturer: AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM Packer: AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM Laboratory: FPRC: AVENTIS PHARMA DAGENHAM, ESSEX, UNITED KINGDOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA FPRR: SANOFI-AVENTIS SA (PTY) LTD, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	Registration number: 44/24/0102 Name of medicine: PHOSPHOSORB 660 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CALCIUM ACETATE 660,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: FRESENIUS KABI SA (PTY) LTD Manufacturer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY Packer: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY Laboratory: FPRC: FRESENIUS MEDICAL CARE DEUTSCHLAND GmbH, BAD HOMBURG, GERMANY FPRR: FRESENIUS KABI SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Shelf-life: 24 months In-use shelf life of 5 weeks stored at or below 25 °C Date of registration: 26 OCTOBER 2012	Registration number: 44/13, 12/0109 Name of medicine: EPIDUO 0,1 %/2,5 % Dosage form: GEL Active ingredients: EACH 1,0 g GEL CONTAINS: ADAPALENE 1,0 mg BENZOYL PEROXIDE 25,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: GALDERMA LABORATORIES S.A. (PTY) LTD Manufacturer: LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE Packer: LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE Laboratory: FPRC: LABORATOIRES GALDERMA, MONTDESIR, ALBY-SUR-CHERAN, FRANCE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA FPRR: GALDERMA LABORATORIES S.A., BRYANSTON, JOHANNESBURG Shelf-life: 36 months Date of registration: 26 OCTOBER 2012

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	44/3. 1/0298	Registration number:	44/32. 2/0546
Name of medicine:	VOLTAREN ACTI-GO SOFT GEL CAPSULE 25 mg	Name of medicine:	MOZOBIL
Dosage form:	SOFT GEL CAPSULE	Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC POTASSIUM 25,0 mg	Active ingredients:	EACH VIAL CONTAINS: PLERIXAFOR 20 mg/ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SA (PTY) LTD	Applicant:	GENZYME BIOPHARMACEUTICALS SOUTH AFRICA (PTY) LTD
Manufacturer:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY	Manufacturer:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM
Packer:	CATALENT GERMANY SCHORNDORF GmbH, STEINBEISSTRASSE, SCHORNDORF, GERMANY	Packer:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM
Laboratory: FPRC:	RP SCHERER GmbH & Co. KG, EBERBACH/BADEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	PATHEON UK LTD, SWINDON, WILTSHIRE, UNITED KINGDOM
FPRR:	M & L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA	FPRR:	GENZYME LTD, HAVERHILL, SUFFOLK, UNITED KINGDOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Shelf-life:	GENZYME BIOPHARMACEUTICALS, BRYANSTON, GAUTENG, RSA
Date of registration:	24 months	Date of registration:	24 months
	26 OCTOBER 2012		26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/10.2.2/0829	Registration number:	44/10.2.2/0830	Registration number:	44/10.2.2/0831
Name of medicine:	SINTAIR 4 mg	Name of medicine:	SINTAIR 5 mg	Name of medicine:	SINTAIR 10 mg
Dosage form:	CHEWABLE TABLET	Dosage form:	CHEWABLE TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg	Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA
Laboratory, FPRC:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA	Laboratory, FPRC:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA	Laboratory, FPRC:	TORRENT PHARMACEUTICALS LIMITED, INDRAD, MEHSANA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD,ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.2.3/0863	Registration number:	44/20.2.3/0864	Registration number:	44/10.2.2/0912
Name of medicine:	CIPLA CAPREOMYCIN	Name of medicine:	MEDPRO CAPREOMYCIN	Name of medicine:	GLENMONT 4
Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION	Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH VIAL CONTAINS: CAPREOMYCIN SULPHATE EQUIVALENT TO CAPREOMYCIN 1,0 g	Active ingredients:	EACH VIAL CONTAINS: CAPREOMYCIN SULPHATE EQUIVALENT TO CAPREOMYCIN 1,0 g	Active ingredients:	EACH CHEWABLE TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Packer:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD. (UNIT IX), VERNA, GOA, INDIA	Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSEN PARK, BELVILLE, RSA	FPRR:	CIPLA LIFE SCIENCES, ROSEN PARK, BELVILLE, RSA	FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15	
Registration number:	44/10.2.2/0913	Registration number:	44/10.2.2/0914
Name of medicine:	GLENMONT 5	Name of medicine:	GLENMONT 10
Dosage form:	CHEWABLE TABLET	Dosage form:	TABLET
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: Montelukast sodium equivalent to Montelukast 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD	Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA	Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA	Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA	FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012
Registration number:	44/10.1/0925	Registration number:	44/10.1/0925
Name of medicine:	MUCO GO 200 EFFERVESCENT TABLETS	Name of medicine:	MUCO GO 200 EFFERVESCENT TABLETS
Dosage form:	EFFERVESCENT TABLET	Dosage form:	EFFERVESCENT TABLET
Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACTOR PHARMA (PTY) LTD	Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY	Manufacturer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY
Packer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE EXTENSION, FLORIDA, RSA	Laboratory: FPRC:	TEMMLER PHARMA GmbH & CO. KG, MARBURG, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE EXTENSION, FLORIDA, RSA
FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	60 months (Aluminium tubes) 36 months (Polypropylene containers)	Shelf-life:	60 months (Aluminium tubes) 36 months (Polypropylene containers)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF15	
Registration number:	44/10.1/0927	Registration number:	46/20.2.8/0760
Name of medicine:	MUCATAK 200 EFFERVESCENT TABLETS	Name of medicine:	LAMIVUDINE WINTHROP 150 mg
Dosage form:	EFFERVESCENT TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACTOR PHARMA (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEMMER PHARMA GmbH & CO. KG, MARBURG, GERMANY	Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	TEMMER PHARMA GmbH & CO. KG, MARBURG, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	TEMMER PHARMA GmbH & CO. KG, MARBURG, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE EXTENSION, FLORIDA, RSA	Laboratory: FPRC:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRC:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	60 months (Aluminium tubes) 36 months (Polypropylene containers)	Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012
Registration number:	46/20.2.8/0682	Registration number:	46/20.2.8/0682
Name of medicine:	ATAZOR 300	Name of medicine:	ATAZOR 300
Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 300,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: ATAZANAVIR SULPHATE EQUIVALENT TO ATAZANAVIR 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EMCURE PHARMACEUTICALS SA (PTY) LTD	Applicant:	EMCURE PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA	Manufacturer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA	Packer:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA
Laboratory: FPRC:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM cc, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	EMCURE PHARMACEUTICALS INDIA, HINJWADI, PUNE, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM cc, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRC:	EMCURE PHARMACEUTICALS SA (PTY) LTD, MONDEOR, JOHANNESBURG, RSA	FPRC:	EMCURE PHARMACEUTICALS SA (PTY) LTD, MONDEOR, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0960	Registration number:	44/26/0961	Registration number:	44/26/0962
Name of medicine:	ACCORD TEMOZOLOMIDE 5	Name of medicine:	ACCORD TEMOZOLOMIDE 20	Name of medicine:	ACCORD TEMOZOLOMIDE 100
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 5,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 20,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15	MRF 15	MRF 15
Registration number: 44/26/0963 Name of medicine: ACCORD TEMOZOLOMIDE 250 Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: TEMOZOLOMIDE 250,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	Registration number: 44/26/0964 Name of medicine: TEMINTAS 5 Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: TEMOZOLOMIDE 5,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012	Registration number: 44/26/0965 Name of medicine: TEMINTAS 20 Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: TEMOZOLOMIDE 20,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA FPRR: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0966	Registration number:	44/26/0967	Registration number:	44/7.1.5/1049
Name of medicine:	TEMINTAS 100	Name of medicine:	TEMINTAS 250	Name of medicine:	LEVITRA ODT 10
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 100,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: TEMOZOLOMIDE 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: VARDENAFIL HYDROCHLORIDE EQUIVALENT TO VARDENAFIL 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	BAYER (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY BRECON PHARMACEUTICAL LTD, HAY-ON-WYE, HEREFORD, UNITED KINGDOM
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	BAYER (PTY) LTD, ISANDO, GAUTENG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	36 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/1.3.2/0224	Registration number:	45/1.3.2/0225	Registration number:	45/2.6.5/0361
Name of medicine:	ACCORD NALTREXONE	Name of medicine:	NALTIMA	Name of medicine:	QUETIAPINE MEDPRO 25
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: NALTREXONE HYDROCHLORIDE 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.6.5/0362	Registration number:	45/2.6.5/0363	Registration number:	45/2.6.5/0364
Name of medicine:	QUETIPINE MEDPRO 100	Name of medicine:	QUETIPINE MEDPRO 150	Name of medicine:	QUETIPINE MEDPRO 200
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENTPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENTPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENTPARK, BELVILLE, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF-15	MRF-15	MRF-15	MRF-15	MRF-15	MRF-15
Registration number:	45/2.6.5/0365	Registration number:	45/2.6.5/0366	Registration number:	45/2.6.5/0367
Name of medicine:	QUETIAPINE MEDPRO 300	Name of medicine:	CIPLA QUETIAPINE 25	Name of medicine:	CIPLA QUETIAPINE 100
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory, FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory, FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory, FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.6.5/0368	Registration number:	45/2.6.5/0369	Registration number:	45/2.6.5/0370
Name of medicine:	CIPLA QUETIAPINE 150	Name of medicine:	CIPLA QUETIAPINE 200	Name of medicine:	CIPLA QUETIAPINE 300
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD. (UNIT III), VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO, ROSENPARK, BELVILLE, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/26/0383	Registration number:	45/26/0384	Registration number:	45/26/0511
Name of medicine:	IRINOTECAN SAFELINE 40 mg/2 ml	Name of medicine:	IRINOTECAN SAFELINE 100 mg/5 ml	Name of medicine:	JEVTAMA
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION AND SOLVENT FOR DILUTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: Irinotecan hydrochloride trihydrate 40,0 mg	Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: Irinotecan hydrochloride trihydrate 100,0 mg	Active ingredients:	EACH VIAL CONTAINS: CABAZITAXEL 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD	Applicant:	SAFELINE PHARMACEUTICALS (PTY) LTD	Applicant:	SANOFL-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	VIANEX S.A., PALINI ATTICI, GREECE	Manufacturer:	VIANEX S.A., PALINI ATTICI, GREECE	Manufacturer:	AVENTIS PHARMA DAGENHAM, ESSEX, UK
Packer:	VIANEX S.A., PALINI ATTICI, GREECE	Packer:	VIANEX S.A., PALINI ATTICI, GREECE	Packer:	AVENTIS PHARMA DAGENHAM, ESSEX, UK
Laboratory:	FPRC: VIANEX S.A., PALINI ATTICI, GREECE M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory:	FPRC: VIANEX S.A., PALINI ATTICI, GREECE M&L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA	Laboratory:	FPRC: AVENTIS PHARMA DAGENHAM, ESSEX, UK WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA	FPRR:	SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA	FPRR:	SANOFL-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months
Date of registration:	28 OCTOBER 2012	Date of registration:	26 OCTOBER 2012	Date of registration:	26 OCTOBER 2012

MRF 15		3F 15	
Registration number: 46/20.2.8/0012 Name of medicine: DUMIVA Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600.0 mg LAMIVUDINE 300.0 mg Conditions of registration: 1,2,3,4,5,6,7 Applicant: MYLAN (PTY) LTD Manufacturer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA Packer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA Laboratory: FPRC: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA FPRR: MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA Shelf-life: 24 months Date of registration: 26 OCTOBER 2012		Registration number: 46/20.2.8/0019 Name of medicine: HETERO TENOFOVIR 300 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: TENOFOVIR DISOPROXIL FUMARATE 300.0 mg Conditions of registration: 1,2,3,4,5,6,7 Applicant: HETERO DRUGS SA Manufacturer: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA Packer: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA Laboratory: FPRC: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA FPRR: HETERO DRUGS SA, JEAN PARK CHAMBERS, CENTURION, RSA Shelf-life: 36 months Date of registration: 26 OCTOBER 2012	Registration number: 46/20.2.8/0680 Name of medicine: DIVUWIN 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: WINTHROP PHARMACEUTICALS (PTY) LTD Manufacturer: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA Packer: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA Laboratory: FPRC: HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA FPRR: WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 26 OCTOBER 2012

MRF 15		F 15	
Registration number:	08/1.4.2/17	Registration number:	37/15.4/0341
Name of medicine:	DEXDOMITOR	Name of medicine:	ALLERCHROM EYE DROPS
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	EYEDROPS
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXMEDETOMIDINE HCl 0,5 mg	Active ingredients:	EACH 1,0 ml CONTAINS: SODIUM CROMOGLICATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PFIZER LABORATORIES (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND	Manufacturer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Packer:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND	Packer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Laboratory: FPRC:	ORION CORPORATION ORION PHARMA, TURKU, FINLAND SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	FDC LIMITED, WALUJ, AURANGABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA	FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

Registration number:	36/20.2.2/0233	Registration number:	37/15.4/0341
Name of medicine:	VARI MICONAZOLE 2 % m/m ORAL GEL	Name of medicine:	ALLERCHROM EYE DROPS
Dosage form:	ORAL GEL	Dosage form:	EYEDROPS
Active ingredients:	EACH 1,0 g GEL CONTAINS: MICONAZOLE 20,0 mg	Active ingredients:	EACH 1,0 ml CONTAINS: SODIUM CROMOGLICATE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LEBASI PHARMACEUTICALS CC	Applicant:	PHARMACARE LIMITED
Manufacturer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE	Manufacturer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Packer:	VARICHEM LABORATORIES, HARARE, ZIMBABWE	Packer:	FDC LIMITED, WALUJ, AURANGABAD, INDIA
Laboratory: FPRC:	VARICHEM LABORATORIES, HARARE, ZIMBABWE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	FDC LIMITED, WALUJ, AURANGABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA
FPRR:	LEBASI PHARMACEUTICALS CC, POTCHEFSTROOM, RSA	FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15	
Registration number:	38/11.5/0338	Registration number:	A40/2.5/0342
Name of medicine:	SUPERTABS NEW FORMULATION	Name of medicine:	EPIPROATE 400 mg/4 ml
Dosage form:	TABLET	Dosage form:	POWDER AND SOLVENT FOR INJECTABLE SOLUTION
Active ingredients:	EACH TABLET CONTAINS: BISACODYL 5,0 mg	Active ingredients:	EACH VIAL CONTAINS: SODIUM VALPROATE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	Manufacturer:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN
Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	Packer:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN
Laboratory: FPRC:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE S.A., SAN JOAN DESPI, BARCELONA, SPAIN RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Shelf-life:	24 months	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:	07 DECEMBER2012	Shelf-life:	24 months (Provisional)
		Date of registration:	07 DECEMBER2012
		Shelf-life:	24 months (Provisional)
		Date of registration:	07 DECEMBER2012
		Shelf-life:	24 months (Provisional)
		Date of registration:	07 DECEMBER2012

MRF 15		MRF 15		MRF 15	
Registration number:	A40/20.1.1/0390	Registration number:	A40/10.2/0624	Registration number:	41/7.3/0477
Name of medicine:	SPEC-CIPROFLOXACIN 400 IV	Name of medicine:	FENOVENT	Name of medicine:	AUSTIGRAN 50
Dosage form:	INJECTION	Dosage form:	LIQUID	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN 2.0 mg	Active ingredients:	EACH 5.0 ml CONTAINS: FENOTEROL HYDROBROMIDE 2.5 mg	Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SPECPHARM (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	ELPEN PHARMACEUTICAL CO. INC, PIKERMIA-ATTICA, GREECE	Manufacturer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	ELPEN PHARMACEUTICAL CO. INC, PIKERMIA-ATTICA, GREECE	Packer:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory: FPRC:	ELPEN PHARMACEUTICAL CO. INC, PIKERMIA-ATTICA, GREECE	Laboratory: FPRC:	SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC/FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	FPRR:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA 24 months (Provisional)	Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	41/7.3/0478	Registration number:	41/7.3/0479	Registration number:	41/7.3/0480
Name of medicine:	AUSTIGRAN 100	Name of medicine:	AUSTELL SUMATRIPTAN 50 mg	Name of medicine:	AUSTELL SUMATRIPTAN 100 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD	Applicant:	AUSTELL LABORATORIES (PTY) LTD	Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Manufacturer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Packer:	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA	FPRC:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA	FPRC:	AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

F 15

MRF15

MRF 15	Registration number: 41/7.3/0481	Registration number: 41/7.3/0482	Registration number: 41/21.5.1/0814
Name of medicine: SUMAGRAN 50 mg	Name of medicine: SUMAGRAN 100 mg	Name of medicine: SUMAGRAN 100 mg	Name of medicine: MYLAN DEXAMETHASONE 4 mg/ml
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET	Dosage form: INJECTION
Active ingredients: EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 50,0 mg	Active ingredients: EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg	Active ingredients: EACH TABLET CONTAINS: Sumatriptan succinate equivalent to Sumatriptan 100,0 mg	Active ingredients: EACH 1,0 ml CONTAINS: DEXAMETHASONE SODIUM PHOSPHATE 4 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUSTELL LABORATORIES (PTY) LTD	Applicant: AUSTELL LABORATORIES (PTY) LTD	Applicant: AUSTELL LABORATORIES (PTY) LTD	Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Manufacturer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Manufacturer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Manufacturer: VIANEX S.A (PLANT A), ATHENS-LAMIA, METAMORPHOSSIS- ATTICA, GREECE
Packer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Packer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Packer: IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA	Packer: VIANEX S.A (PTY) LTD, ATHENS-LAMIA, METAMORPHOSSIS- ATTICA, GREECE PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC :	Laboratory: FPRC :	Laboratory: FPRC :	Laboratory: FPRC
IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	IPCA LABORATORIES LIMITED, DADRA AND NAGAR HAVELI, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	VIANEX SA (PLANT A), ATHENS-LAMIA, METAMORPHOSSIS- ATTICA, GREECE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR: AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA	FPRR: AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA	FPRR: AUSTELL LABORATORIES (PTY) LTD, CROWN X3, JOHANNESBURG, RSA	FPRR: XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life: 36 months	Shelf-life: 36 months	Shelf-life: 36 months	Shelf-life: 24 months
Date of registration: 07 DECEMBER 2012	Date of registration: 07 DECEMBER 2012	Date of registration: 07 DECEMBER 2012	Date of registration: 07 DECEMBER 2012

MRF 15	MRF 15	MRF 15
Registration number: 41/10.2.1/0908 Name of medicine: DUOLIN HFA INHALER Dosage form: METERED DOSE INHALER Active ingredients: EACH METERED DOSE CONTAINS: IPRATROPIUM BROMIDE MONOHYDRATE EQUIVALENT TO IPRATROPIUM BROMIDE 20,0 µg SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 100,0 µg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: CIPLA MEDPRO (PTY) LTD Manufacturer: CIPLA LIMITED GOA, UNIT (II), VERNA, SANCETTE, GOA, INDIA Packer: CIPLA LIMITED GOA, UNIT (II), VERNA, SANCETTE, GOA, INDIA Laboratory: FPRC: CIPLA LIMITED GOA, UNIT (II), VERNA, SANCETTE, GOA, INDIA FPRR: CIPLA MEDPRO (PTY) LTD, ROSENPARK, RSA Shelf-life: 24 months Date of registration: 07 DECEMBER 2012	Registration number: 42/20.1.1/0280 Name of medicine: MEROJECT 500 mg (POWDER FOR INJECTION) Dosage form: STERILE POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM ANHYDROUS 500,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE Packer: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE Laboratory: FPRC: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA FPRR: PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA Shelf-life: 24 months Date of registration: 07 DECEMBER 2012	Registration number: 42/20.1.1/0281 Name of medicine: MEROJECT 1 g (POWDER FOR INJECTION) Dosage form: STERILE POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM ANHYDROUS 1 000,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE Packer: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE Laboratory: FPRC: DEMO S.A, ATHENS-LAMIA, ATHENS, GREECE PHARMATHEN S.A, PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA FPRR: PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA Shelf-life: 24 months Date of registration: 07 DECEMBER 2012

F 15

MRF 15	MRF 15	MRF 15
Registration number: 42/20.1.1/0389 Name of medicine: ASPEN CEFPODOXIME 200 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 200,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMACARE LIMITED Manufacturer: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA Packer: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA Laboratory: FPRC: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA FPRR: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA Shelf-life: PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA Date of registration: 24 months (provisional) 07 DECEMBER 2012	Registration number: 42/20.1.1/0388 Name of medicine: ASPEN CEFPODOXIME 100 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 100,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMACARE LIMITED Manufacturer: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA Packer: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA Laboratory: FPRC: LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON, RSA FPRC/FPRR: PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA FPRR: PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA Shelf-life: 24 months (provisional) Date of registration: 07 DECEMBER 2012	Registration number: 42/2.9/0283 Name of medicine: TRAMAL SR 50 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: TRAMADOL HCl 50,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: JANSSEN PHARMACEUTICA (PTY) LTD Manufacturer: FAMACEUTICI FORMENTI ITALY, ORIGGIO, ITALY GRUNENTHAL GmbH, STOLBERG, GERMANY Packer: GRUNENTHAL GmbH, STOLBERG, GERMANY GRUNENTHAL GmbH, AACHEN, GERMANY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: GRUNENTHAL GmbH, STOLBERG, GERMANY SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 07 DECEMBER 2012

MRF 15	MRF 15	F 15
Registration number:	Registration number:	Registration number:
Name of medicine:	Name of medicine:	Name of medicine:
Dosage form:	Dosage form:	Dosage form:
Active ingredients:	Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:	Conditions of registration:
Applicant:	Applicant:	Applicant:
Manufacturer:	Manufacturer:	Manufacturer:
Packer:	Packer:	Packer:
Laboratory: FPRC:	Laboratory: FPRC:	Laboratory: FPRC:
FPRC:	FPRC:	FPRC:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:
45/11.4.3/0515	42/18.10/0538	42/20.1.1/0737
OMEPRAZOLE SAFELINE INJECTION 40 mg	OMSAI CAPSULES	FKSA CEFUROXIME 750 mg
INJECTION	CAPSULE	POWDER FOR SOLUTION FOR INJECTION
EACH VIAL CONTAINS: OMEPRAZOLE SODIUM EQUIVALENT TO OMEPRAZOLE 40,0 mg	EACH CAPSULE CONTAINS: TAMSULOSIN HYDROCHLORIDE 0,4 mg	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
SAFELINE PHARMACEUTICALS (PTY) LTD	PHARMAPLAN (PTY) LTD	BODENE (PTY) LTD (TRADING AS INTRAMED)
VIANEX S.A, PALINI ATTICI, GREECE	GEDEON RICHTER ROMANIA S.A, TARGU- MURES, ROMANIA	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
VIANEX S.A, PALINI ATTICI, GREECE	GEDEON RICHTER ROMANIA S.A, TARGU- MURES, ROMANIA	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
VIANEX S.A, PALINI ATTICI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	GEDEON RICHTER ROMANIA S.A, TARGU- MURES, ROMANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
SAFELINE PHARMACEUTICALS (PTY) LTD, FLORIDA, RSA	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
24 months	24 months	24 months
07 DECEMBER 2012	07 DECEMBER 2012	07 DECEMBER 2012

MRF 15

Registration number:	42/21.12/0760
Name of medicine:	TEVA ANASTROZOLE 1 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, Kfar Sava, Israel
Packer:	TEVA PHARMACEUTICAL INDUSTRIES LTD, Kfar Sava, Israel TEVA PHARMACEUTICAL WORKS PRIVATE, LIMITED COMPANY, GODOLO, HUNGARY
Laboratory:	FPRC
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUIMSIG, ROODEPORT, GAUTENG, RSA
Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	42/20.1.1/0986
Name of medicine:	FKSA CEFUROXIME 1 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BODENE (PTY) LTD (TRADING AS INTRAMED)
Manufacturer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Packer:	LABESFAL LABORATORIES ALMIRO SA (FRESENIUS KABI), LAGEDO, PORTUGAL
Laboratory:	FPRC
FPRR:	BODENE (PTY) LTD (TRADING AS INTRAMED), KORSTEN, PORT ELIZABETH, RSA
Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/7.5/0167
Name of medicine:	DYNATOR 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A. HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A. HUARTE-PAMPLONA, SPAIN
Laboratory:	FPRC
FPRR:	LABORATORIOS CINFA S.A. HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15		MRF15		MRF 15	
Registration number:	43/7.5/0168	Registration number:	43/7.5/0169	Registration number:	43/7.5/0170
Name of medicine:	DYNATOR 20 mg	Name of medicine:	DYNATOR 40 mg	Name of medicine:	DYNATOR 80 mg
Dosage form:	TABLET	Dosage form:	TABLE	Dosage form:	TABLE
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN	Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN	Packer:	LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN
Laboratory:	FPRC: LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A, HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF15		MRF 15	
Registration number:	43/7.5/0186	Registration number:	43/7.5/0187	Registration number:	43/7.5/0188
Name of medicine:	DYNA ATORVASTATIN 10 mg	Name of medicine:	DYNA ATORVASTATIN 20 mg	Name of medicine:	DYNA ATORVASTATIN 40 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC:
	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA		PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA		PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15	Registration number: 43/7.5/0189 Name of medicine: DYNA ATORVASTATIN 80 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA FPRC/FPRR: PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012
MRF 15	Registration number: 43/32.2/0240 Name of medicine: MYCOPHENOLATE HEXAL 500 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA Packer: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA Laboratory: FPRC: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012
MRF 15	Registration number: 43/32.2/0241 Name of medicine: MYCOCEPT 500 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA Packer: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA Laboratory: FPRC: SANDOZ PRIVATE LIMITED, KALWE, NAVI MUMBAI, INDIA FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0317
Name of medicine:	SEROMIND 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULLEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF-15

Registration number:	43/2.6.5/0318
Name of medicine:	RAN QUETIAPINE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULLEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0319
Name of medicine:	RAN QUETIAPINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULLEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15

Registration number: 43/2.6.5/0320
 Name of medicine: SEROMIND 100
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
 FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 07 DECEMBER 2012

MRF15

Registration number: 43/2.6.5/0321
 Name of medicine: RAN QUETIAPINE 200
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
 FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 07 DECEMBER 2012

MRF 15

Registration number: 43/2.6.5/0322
 Name of medicine: SEROMIND 300
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
 FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 07 DECEMBER 2012

MRF 15

Registration number:	43/2.6.5/0323
Name of medicine:	SEROMIND 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF-15

Registration number:	43/20.1.1/0632
Name of medicine:	REFOBACIN PLUS BONE CEMENT 20
Dosage form:	BONE CEMENT
Active ingredients:	EACH 22.4 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0.3 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET- GROSSENBRACH GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNBURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS
Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET- GROSSENBRACH GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNBURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS
Laboratory:	FPRC: MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA
FPRR:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF-15

Registration number:	43/2.6.5/0684
Name of medicine:	RAN QUETIAPINE 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRC/FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

3F 15

MRF 15

MRF 15		MRF 15		3F 15	
Registration number:	43/20.1.1/0702	Registration number:	43/20.1.1/0703	Registration number:	43/21.2/0957
Name of medicine:	REFOBACIN PLUS BONE CEMENT 40	Name of medicine:	REFOBACIN PLUS BONE CEMENT 60	Name of medicine:	DIAMICRON MR 60 mg
Dosage form:	BONE CEMENT	Dosage form:	BONE CEMENT	Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH 44,9 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0,6 g	Active ingredients:	EACH 67,4 g OF POWDER CONTAINS: GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN 0,8 g	Active ingredients:	EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD	Applicant:	MC PHARMA (PTY) LTD	Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS	Manufacturer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS	Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARLOW, IRELAND
Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN	Packer:	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN	Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
	aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET-GROSSENBRACH, GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS		aap BIOMATERIALS GmbH & CO. KG, DIEBURG, GERMANY EMCM B.V. NIJMEGEN, THE NETHERLANDS BIOMET CEMENTING TECHNOLOGIES AB, SJÖBO, SWEDEN BIOMET ORTHOPAEDICS SWITZERLAND, KEZERS, SWITZERLAND ROSE MEDIZIN-UND STERILISIERTECHNIK GmbH, TRIER, GERMANY STERIGENICS, ZOETERMEER, THE NETHERLANDS LABOR L&S AG, BAD BOCKLET-GROSSENBRACH, GERMANY ACILAR AG, MORFELDEN-WALLDORF, GERMANY FARMALYSE BV, ZAANDAM, THE NETHERLANDS MAINSITE SERVICES GmbH & CO KG, OBERNURG, GERMANY BACTIMM BV, NIJMEGEN, THE NETHERLANDS		LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA
FPRC/FPRR:		FPRC/FPRR:		FPRR:	
	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA		MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, CENTURION, RSA		SERVIER LABORATORIES SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15	MRF 15	MRF 15
Registration number: 43/21.2/0958 Name of medicine: GLUCTAM MR 60 mg Dosage form: MODIFIED RELEASE TABLET Active ingredients: EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: EGIS PHARMACEUTICALS SA (PTY) LTD Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA FPRR: EGIS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012	Registration number: 43/21.2/0959 Name of medicine: DIASTAL MR 60 mg Dosage form: MODIFIED RELEASE TABLET Active ingredients: EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: BIOGARAN SA (PTY) LTD Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA FPRC/FPRR: BIOGARAN SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012	Registration number: 43/21.2/0960 Name of medicine: DIAGLUCIDE MR 60 mg Dosage form: MODIFIED RELEASE TABLET Active ingredients: EACH TABLET CONTAINS: GLICLAZIDE 60,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: BIOGARAN SA (PTY) LTD Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND MILLMOUNT HEALTHCARE LTD, NAVAN, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA M & L LABORATORY SERVICES (PTY) LTD, LIMBRO BUSINESS PARK, SANDTON, RSA FPRR: BIOGARAN SA (PTY) LTD, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 07 DECEMBER 2012

MRF 15		MRF15		MRF 15	
Registration number:	43/26/1019	Registration number:	43/26/1021	Registration number:	43/5.4.1/1062
Name of medicine:	ACCORD CISPLATIN 10	Name of medicine:	ACCORD CISPLATIN 50	Name of medicine:	PEXOLA ER 0,375 mg
Dosage form:	INFUSION SOLUTION	Dosage form:	INFUSION SOLUTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: CISPLATIN 10,0 mg	Active ingredients:	EACH VIAL CONTAINS: CISPLATIN 50,0 mg	Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 0,375 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15

Registration number:	43/5.4.1/1063
Name of medicine:	PEXOLA ER 0,75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 0,75 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory:	FPRC: BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDAL, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF15

Registration number:	43/5.4.1/1064
Name of medicine:	PEXOLA ER 1,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory:	FPRC: BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDAL, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MMRF 15

Registration number:	43/5.4.1/1065
Name of medicine:	PEXOLA ER 3,0 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 3,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY
Laboratory:	FPRC: BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDAL, RANDBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15	
Registration number:	43/5.4.1/1066	Registration number:	44/15.2/0045
Name of medicine:	PEXOLA ER 4,5 mg	Name of medicine:	OZURDEX
Dosage form:	TABLET	Dosage form:	INTRAVITREAL IMPLANT
Active ingredients:	EACH TABLET CONTAINS Pramipexole dihydrochloride monohydrate equivalent to Pramipexole 4,5 mg	Active ingredients:	EACH IMPLANT CONTAINS: DEXAMETHASONE 700,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY	Manufacturer:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND
Packer:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY	Packer:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND
Laboratory: FPRC:	BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG, INGELHEIM am RHEIN, GERMANY PHAST GmbH, HOMBURG/SAAR, GERMANY	Laboratory: FPRC:	ALLERGAN PHARMACEUTICALS IRELAND, WESTPORT, COUNTY MAYO, IRELAND INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FENDALE, RANDBURG, RSA	FPRR:	ALLERGAN PHARMACEUTICALS (PTY) LTD, RANDJESPAK EXT. 11, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

Registration number:	44/1.2/0114	Name of medicine:	YELATE 30
Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 30,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA	FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/1.2/0115	Registration number:	44/1.2/0116	Registration number:	44/1.2/0117
Name of medicine:	YELATE 60	Name of medicine:	DRL DULOXETINE 30	Name of medicine:	DRL DULOXETINE 60
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 60,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 30,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: Duloxetine hydrochloride equivalent to Duloxetine 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0205	Registration number:	44/26/0556	Registration number:	44/26/0557
Name of medicine:	SPRYCEL 100 mg TABLETS	Name of medicine:	AXTERE 20	Name of medicine:	AXTERE 80
Dosage form:	TABLET	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: DASATINIB 100,0 mg	Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg	Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB COMPANY, MT VERNON, INDIANA, USA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	BRISTOL-MYERS SQUIBB COMPANY, MT VERNON, INDIANA, USA BRISTOL-MYERS SQUIBB COMPANY, EPERNON, FRANCE BRISTOL-MYERS SQUIBB S.R.L., ANAGNI, ITALY	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	BRISTOL-MYERS SQUIBB COMPANY, EPERNON, FRANCE BRISTOL-MYERS SQUIBB S.R.L., ANAGNI, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA NKUNZI PHARMACEUTICALS (PTY) LTD, WADEVILLE, GERMISTON, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA
FPRC:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA	FPRC:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRC:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0558	Registration number:	44/26/0559	Registration number:	44/26/0728
Name of medicine:	ACCORD DOCETAXEL 20	Name of medicine:	ACCORD DOCETAXEL 80	Name of medicine:	ACCORD DOCETAXEL DILUENT
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg	Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 80,0 mg	Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION q.s 1,0 ml POLYETHYLENE GLYCOL 400 130,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0729	Registration number:	44/1.2/0851	Registration number:	44/1.2/0852
Name of medicine:	AXTERE DILUENT	Name of medicine:	ACCORD ESCITALOPRAM 10	Name of medicine:	ACCORD ESCITALOPRAM 20
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION q.s 1.0 ml POLYETHYLENE GLYCOL 400 130,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, VILLAGE MATODA, TALUKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, GAUTENG, RSA
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.2.8/0085	Registration number:	45/20.2.8/0086	Registration number:	45/8.2/0175
Name of medicine:	DIZOVIN 100	Name of medicine:	DIZOVIN 300	Name of medicine:	NPLATE 250 µg
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 100,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 300,0 mg	Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: ROMIPLOSTIM 250,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Manufacturer:	PATHEON S.p.A, MONZA, ITALY
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Packer:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA	Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA	Laboratory: FPRC:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS
FPRC:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	BATSWADI PHARMACEUTICALS (PTY) LTD, PETER PLACE, BRYANSTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	60 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/8.2/0176	Registration number:	45/2.6.5/0694	Registration number:	45/2.6.5/0695
Name of medicine:	NPLATE 500 µg	Name of medicine:	SIZONORM 25 mg	Name of medicine:	SIZONORM 100 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ROMIPLOSTIM 500,0 µg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD	Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD	Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	PATHEON S.p.A, MONZA, ITALY	Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Packer:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS	Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC:	AMGEN EUROPE BV (ABR), BREDA, THE NETHERLANDS	Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	BATSWADI PHARMACEUTICALS (PTY) LTD, PETER PLAGE, BRYANSTON, RSA	FPRC:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA	FPRC:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	60 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.6.5/0696	Registration number:	45/2.6.5/0697	Registration number:	45/20.2.8/0768
Name of medicine:	SIZONORM 200 mg	Name of medicine:	SIZONORM 300 mg	Name of medicine:	VIRAMUNE XR 50 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SUN PHARMACEUTICALS SA (PTY) LTD	Applicant:	SUN PHARMACEUTICALS LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Manufacturer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA
Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Packer:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA	Packer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	SUN PHARMACEUTICALS INDUSTRIES LIMITED, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON RD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRC:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA	FPRC:	SUN PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA	FPRC:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.2.8/0769	Registration number:	45/20.2.8/0770	Registration number:	45/20.2.8/0771
Name of medicine:	VIRAMUNE XR 100 mg	Name of medicine:	VIRAMUNE XR 400 mg	Name of medicine:	ALVIR XR 50 mg
Dosage form:	MODIFIED RELEASE TABLET	Dosage form:	MODIFIED RELEASE TABLET	Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA	Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA	Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
Laboratory:	FPRC: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory:	FPRC: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory:	FPRC: BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.2.8/0772	Registration number:	45/20.2.8/0773	Registration number:	45/20.2.8/0774
Name of medicine:	ALVIR XR 100 mg	Name of medicine:	ALVIR XR 400 mg	Name of medicine:	NEVIRAPINE XR IP 50 mg
Dosage form:	MODIFIED RELEASE TABLET	Dosage form:	MODIFIED RELEASE TABLET	Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 50 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA
Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA	Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA	Packer:	BOEHRINGER INGELHEIM ROXANE INC, WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA	FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA	FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15	
Registration number:	45/20.2.8/0775	Registration number:	45/20.2.8/0776
Name of medicine:	NEVIRAPINE XR IP 100 mg	Name of medicine:	NEVIRAPINE XR IP 400 mg
Dosage form:	MODIFIED RELEASE TABLET	Dosage form:	MODIFIED RELEASE TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 100 mg	Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE (ANHYDROUS) 400 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD	Applicant:	INGELHEIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA	Manufacturer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA
Packer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA	Packer:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, GRAND RAPIDS, MICHIGAN, USA SIXARP, LLC – PRAXIS PACKAGING SOLUTIONS, COLUMBUS, OHIO, USA DRA PHARMACEUTICALS, IRENE, PRETORIA, RSA
Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory: FPRC:	BOEHRINGER INGELHEIM ROXANE INC., WILSON ROAD, COLUMBUS, OHIO, USA BOEHRINGER INGELHEIM ROXANE INC., OAK STREET, COLUMBUS, OHIO, USA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA	FPRR:	INGELHEIM PHARMACEUTICALS (PTY) LTD, FERNDALE, RANDSBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

Registration number:	45/20.2.8/0825	Registration number:	45/20.2.8/0825
Name of medicine:	RICOVIR	Name of medicine:	RICOVIR
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Tenofovir disoproxil fumarate 300,0mg	Active ingredients:	EACH TABLET CONTAINS: Tenofovir disoproxil fumarate 300,0mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA	Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.2.8/0886	Registration number:	46/20.2.8/0020	Registration number:	46/20.2.8/0021
Name of medicine:	MACLEODS NEVIRAPINE 200 mg	Name of medicine:	EFAMAT 50 mg	Name of medicine:	EFAMAT 100 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NEVIRAPINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTON, PRETORIA, RSA	Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		MRF 15		MRF 15	
Registration number:	46/20.2.8/0022	Registration number:	46/26/0866	Registration number:	46/32.4/0867
Name of medicine:	EFAMAT 200 mg	Name of medicine:	HERCLON	Name of medicine:	HERCLON BWFI
Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INFUSION	Dosage form:	DILUENT FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 200,0 mg	Active ingredients:	EACH VIAL CONTAINS: TRASTUZUMAB 440,0 mg	Active ingredients:	EACH VIAL CONTAINS: Bacteriostatic water for injection 20,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD	Applicant:	ROCHE PRODUCTS (PTY) LTD	Applicant:	ROCHE PRODUCTS (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA GENENTECH INC., VACAVILLE, CALIFORNIA, USA	Manufacturer:	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA GENENTECH INC., VACAVILLE, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	Packer:	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND GP GRENZACH PRODUCTIONS, GRENZACH-WYHLEN, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA	Laboratory: FPRC:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	Laboratory: FPRC:	F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA	FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	48 months
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012

MRF 15		RF 15	
Registration number:	46/26/0868	Registration number:	47/20.2.8/0188
Name of medicine:	RISTOVA 100	Name of medicine:	MACLEODS EMTRICITABINE AND TENOFOVIR 200 mg/300 mg
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: RITUXIMAB 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENFOVIR DISOPROXIL FUMARATE 300,0
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ROCHE PRODUCTS (PTY) LTD	Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY	Manufacturer:	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Packer:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	Packer:	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	GENENTECH INC., SOUTH SAN FRANCISCO, CALIFORNIA, USA ROCHE DIAGNOSTICS GmbH, MANNHEIM, GERMANY F. HOFFMANN-LA ROCHE LTD, KAISERAUGST SWITZERLAND F. HOFFMANN-LA ROCHE LTD, BASEL, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LIMITED, KACHIGAM, DAMAN, INDIA MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, DEGRAS ROAD, SILVERTONDALE, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES CC, COVENTRY PARK, MIDRAND, RSA
FPRR:	ROCHE PRODUCTS (PTY) LTD, ILLOVO, JOHANNESBURG, RSA	FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	30 months	Shelf-life:	24 months (Provisional)
Date of registration:	07 DECEMBER 2012	Date of registration:	07 DECEMBER 2012