
GENERAL NOTICES ALGEMENE KENNISGEWINGS

NOTICE 405 OF 2014

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		MRF 15		MRF 15	
Registration number:	06/17.1.6/07	Registration number:	08/3.1.2/03	Registration number:	09/3.1.2/19
Name of medicine:	MARBOCYL 10 %	Name of medicine:	PETCAM INJECTION 0.5%	Name of medicine:	CANIFLAM
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	ORAL SUSPENSION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MARBOFLOXACIN 100.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MELOXICAM 5.0 mg	Active ingredients:	EACH 1.0 ml SUSPENSION CONTAINS: MELOXICAM 1.5 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:	AFRIVET LOGISTICS (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CEVA ANIMAL HEALTH (PTY) LTD
Manufacturer:	VETOQUINOL, LURE, CEDEX, FRANCE	Manufacturer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA	Manufacturer:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE
Packer:	VETOQUINOL, LURE, CEDEX, FRANCE	Packer:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA	Packer:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE
Laboratory: FPRC:	VETOQUINOL, LURE, CEDEX, FRANCE BIOINDUSTRIAL SERVICES, KEMPTON PARK, JOHANNESBURG, RSA	Laboratory: FPRC:	CIPLA LTD, UNIT IX, VERNA, GOA, INDIA	Laboratory: FPRC:	CEVA SANTE ANIMALE, TRES LE BOIS, LOUDEAC, FRANCE BIOINDUSTRIAL SERVICES, KEMPTON PARK, JOHANNESBURG, RSA
FPRC:	AFRIVET LOGISTICS (PTY) LTD, KEMPTON PARK, JOHANNESBURG, RSA	FPRC:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA	FPRC:	CEVA ANIMAL HEALTH (PTY) LTD, RANDJESPAK, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	10/5.3.2/11	Registration number:	10/5.3.2/12	Registration number:	10/5.3.2/13
Name of medicine:	BREXACE 5	Name of medicine:	PETACE 20	Name of medicine:	BREXACE 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: BENAZEPRIL HYDROCHLORIDE 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:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	MRF 15	MRF 15
Registration number: 10/5.3.2/14 Name of medicine: PETACE 5 Dosage form: TABLET Active ingredients: BENAZEPRIL HYDROCHLORIDE 5.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ACCORD HEALTHCARE (PTY) LTD Manufacturer: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA Packer: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA Laboratory: FPRC: INTAS PHARMACEUTICALS LIMITED, TAL-SANAND, MATODA, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA FPRC: ACCORD HEALTHCARE (PTY) LTD, RIVONIA, RSA Shelf-life: 36 months Date of registration: 05 DECEMBER 2013	Registration number: 37/21.5.1/0013 Name of medicine: PULMAX 100 MDI Dosage form: DRY POWDER FOR INHALATION Active ingredients: BUDESONIDE 100.0 µg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BIOTECH LABORATORIES (PTY) LTD Manufacturer: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND Packer: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, RSA Laboratory: FPRC: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRC: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013	Registration number: 37/21.5.1/0014 Name of medicine: PULMAX 200 MDI Dosage form: DRY POWDER FOR INHALATION Active ingredients: BUDESONIDE 200.0 µg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BIOTECH LABORATORIES (PTY) LTD Manufacturer: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND Packer: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, RSA Laboratory: FPRC: NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRC: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	37/21.5.1/0015	Registration number:	41/11.4.3/0449	Registration number:	41/5.7.1/0555
Name of medicine:	PULMAX 400 MDI	Name of medicine:	RENNIE DUO	Name of medicine:	GULF CETIRIZINE 10
Dosage form:	DRY POWDER FOR INHALATION	Dosage form:	SUSPENSION	Dosage form:	TABLET
Active ingredients:	EACH ACTUATION CONTAINS: BUDESONIDE 400,0 µg	Active ingredients:	EACH 10,0 ml SUSPENSION CONTAINS: CALCIUM CARBONATE 1 200,0 mg MAGNESIUM CARBONATE 140,0 mg SODIUM ALGINATE 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 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:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BAYER (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND	Manufacturer:	BAYER SANTE FAMILIE, GAILLARD, FRANCE	Manufacturer:	ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:	NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	BAYER SANTE FAMILIE, GAILLARD, FRANCE	Packer:	ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC : NORTON (WATERFORD) LIMITED, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: BAYER SANTE FAMILIE, GAILLARD, FRANCE ROCHE PRODUCTS (PTY) LTD, NORTHLANDS, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENOAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA BIOCHEMICAL AND SCIENTIFIC CONSULTANTS, HILTON, KWAZULU NATAL, RSA	Laboratory:	FPRC ALEMBIC LIMITED, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPRR:	BAYER (PTY) LTD, ISANDO, RSA	FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, DURBAN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	41/20.1.1/0586	Registration number:	41/20.1.1/0587	Registration number:	42/3.2/0410
Name of medicine:	LIZORP 250 mg	Name of medicine:	LIZORP 500 mg	Name of medicine:	ASTERIX ALENDRONATE 70
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEPROZIL MONOHYDRATE EQUIVALENT TO ANHYDROUS CEPROZIL 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: CEPROZIL MONOHYDRATE EQUIVALENT TO ANHYDROUS CEPROZIL 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70,0 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	LITHA PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	PHARMACEUTICAL WORKS POLYPHARMA SA, STAROGARD, GDANSKI, POLAND
Packer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Packer:	PHARMACEUTICAL WORKS POLYPHARMA SA, STAROGARD, GDANSKI, POLAND
Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Laboratory:	FPRC: PHARMACEUTICAL WORKS POLYPHARMA SA, STAROGARD, GDANSKI, POLAND
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	42/2.7/0543	Registration number:	42/26/0742	Registration number:	42/3.2/0767
Name of medicine:	PARAFIZZ 500	Name of medicine:	CANOTEC	Name of medicine:	DYNA RISEDRONATE 5 mg
Dosage form:	TABLET	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 500,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: IRINOTECAN HYDROCHLORIDE TRIHYDRATE 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM HEMIPENTAHYDRATE EQUIVALENT TO RISEDRONATE SODIUM 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:	CIPLA MEDPRO (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA	Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Manufacturer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE
Packer:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA	Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Packer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS, GREECE
Laboratory: FPRC:	CIPLA LTD, KURKUMBH, TALUKA DAUND, POONA DISTRICT, MAHARASHTRA, INDIA	Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, JOHANNESBURG, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA
Shelf-life:	24 months	Shelf-life:	24 months – Product 24 hours stored at 2-8 °C – Diluted product 12 hours stored at or below 25 °C – Diluted product	Shelf-life:	60 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	42/3.2/0768	Registration number:	42/20.1./0998	Registration number:	43/26/0018
Name of medicine:	DYNA RISEDRONATE 35 mg	Name of medicine:	LEVONIC IV 500	Name of medicine:	DOXOLIP
Dosage form:	TABLET	Dosage form:	CONCENTRATE FOR INFUSION	Dosage form:	CONCENTRATE FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM HEMIPENTAHYDRATE EQUIVALENT TO RISEDRONATE SODIUM 35,0 mg	Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: LEVOFLOXACIN 500,0 mg	Active ingredients:	EACH VIAL CONTAINS: DOXORUBIN HYDROCHLORIDE 2,0 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:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND	Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Packer:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, GREECE PHARMANEL PHARMACEUTICALS S.A., ATHENS, GREECE	Packer:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND	Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	PHARMATHENS S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMACEUTICAL WORKS POLPHARMA S.A., STAROGARD GDANSKI, POLAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD, DISTRICT PANCMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	60 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/5.3/0099	Registration number:	43/5.3/0100	Registration number:	43/1.2/0339
Name of medicine:	ARICEPT ODT 5 mg	Name of medicine:	ARICEPT ODT 10 mg	Name of medicine:	DYNA SERTRALINE 50l
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 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:	PFIZER LABORATORIE (PTY) LTD	Applicant:	PFIZER LABORATORIE (PTY) LTD	Applicant:	LEBASI PHARMACEUTICALS cc
Manufacturer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN	Manufacturer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN	Manufacturer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA
Packer:	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE	Packer:	EISAI Co LTD, MISATO PLANT, KODAMA-GUM, SAITAM-KEN, JAPAN	Packer:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA SANDOZ CANADA Inc, BOUCHERVILLE, QUEBEC, CANADA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	Laboratory: FPRC:	PFIZER PGM, POCE-SUR-CISSE, AMBOISE PLANT, FRANCE SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	Laboratory: FPRC:	LUPIN LIMITED, VERNA INDUSTRIAL AREA, VERNA-SALCETTE, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA	FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA	FPRR:	LEBASI PHARMACEUTICAL cc, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

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MRF 15	Registration number: 43/5/3/0669 Name of medicine: ARIMER 10 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMAPLAN (PTY) LTD Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, GOVERNMENT INDUSTRIAL AREA, PHASE II, SILVASSA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRC: PHARMAPLAN (PTY) LTD, MIDRAND, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013	MRF 15 Registration number: 43/7/5/0837 Name of medicine: ASPAVOR 80 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMACIA SOUTH AFRICA (PTY) LTD Manufacturer: PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND Packer: GODECKE GmbH, FREIBURG, GERMANY Laboratory: FPRC: PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA FPRC: PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, RSA Shelf-life: 36 months Date of registration: 05 DECEMBER 2013	Registration number: 43/7/5/0839 Name of medicine: ATORVASTATIN PHARMACIA 80 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM TRIHYDRATE EQUIVALENT TO ATORVASTATIN 80.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMACIA SOUTH AFRICA (PTY) LTD Manufacturer: PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND Packer: GODECKE GmbH, FREIBURG, GERMANY Laboratory: FPRC: PFIZER PHARMACEUTICALS LLS, VEGA BAJA, PUERTO RICO, USA PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY, COUNTY CORK, IRELAND GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA LAB & BIOLOGICAL SERVICES (PTY) LTD, BRACKENHURST, ALBERTON, RSA FPRC: PHARMACIA SOUTH AFRICA (PTY) LTD, SANDTON, RSA Shelf-life: 36 months Date of registration: 05 DECEMBER 2013
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MRF 15	MRF 15	MRF 15
Registration number: 437/1.3/0927 Name of medicine: FLAMIPAX 10/5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg	Registration number: 437/1.3/0926 Name of medicine: FLAMIPAX 5/10 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	Registration number: 437/1.3/0925 Name of medicine: FLAMIPAX 5/5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BIOGARAN SA (PTY) LTD Manufacturer: LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND Packer: SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE GENEXI, FONTENAY-SOUS-BOIS, FRANCE	Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BIOGARAN SA (PTY) LTD Manufacturer: LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND Packer: SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE GENEXI, FONTENAY-SOUS-BOIS, FRANCE	Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BIOGARAN SA (PTY) LTD Manufacturer: LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND Packer: SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE GENEXI, FONTENAY-SOUS-BOIS, FRANCE
Laboratory: FPRC	Laboratory: FPRC	Laboratory: FPRC
Shelf-life: 24 months Date of registration: 05 DECEMBER 2013	Shelf-life: 24 months Date of registration: 05 DECEMBER 2013	Shelf-life: 24 months Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.30928	Registration number:	43/7.1.30929	Registration number:	43/7.1.30930
Name of medicine:	FLAMPAX 10/10	Name of medicine:	REAPTAN 5/5	Name of medicine:	REAPTAN 5/10
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGinine 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	EACH TABLET CONTAINS: PERINDOPRIL ARGinine 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg		Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGinine 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 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:	BIOGARAN SA (PTY) LTD	Applicant:	BIOGARAN SA (PTY) LTD	Applicant:	BIOGARAN SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND
Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	LES LABORATORIES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	FPRR:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15

Registration number:	437/1.3/0931	Registration number:	437/1.3/0932	Registration number:	437/1.3/0933
Name of medicine:	REAPTAN 10/5	Name of medicine:	REAPTAN 10/10	Name of medicine:	COVERAM 5/5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SA (PTY) LTD	BIOGARAN SA (PTY) LTD	BIOGARAN SA (PTY) LTD	SERVIER LABORATORIES SA (PTY) LTD	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, LTD, ARKLOW, IRELAND	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND
Laboratory:	FPRC	FPRC	FPRC	FPRC	FPRC
FPRC:	INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSIEBIOTWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRC:	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	BIOGARAN SA (PTY) LTD, RIVONIA, RSA	BIOGARAN SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months	24 months	24 months	24 months	24 months
Date of registration:	05 DECEMBER 2013	05 DECEMBER 2013	05 DECEMBER 2013	05 DECEMBER 2013	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	437/1.3/0934	Registration number:	437/1.3/0935	Registration number:	437/1.3/0936
Name of medicine:	COVERAM 5/10	Name of medicine:	COVERAM 10/5	Name of medicine:	COVERAM 10/10
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg	Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 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:	SERVIER LABORATORIES SA (PTY) LTD	Applicant:	SERVIER LABORATORIES SA (PTY) LTD	Applicant:	SERVIER LABORATORIES SA (PTY) LTD
Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM GANNAT, FRANCE CENEXI FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM GANNAT, FRANCE CENEXI FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM GANNAT, FRANCE CENEXI FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC:
	LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA		LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA		LES LABORATORIES SERVIER INDUSTRIE GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRC:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA	FPRC:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA	FPRC:	SERVIER LABORATORIES SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.3/0937	Registration number:	43/7.1.3/0938	Registration number:	43/7.1.3/0939
Name of medicine:	MIXANVAL 5/5	Name of medicine:	MIXANVAL 5/10	Name of medicine:	MIXANVAL 10/5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 mg	Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 5.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5.0 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:	EGIS PHARMACEUTICALS SA (PTY) LTD	Applicant:	EGIS PHARMACEUTICALS SA (PTY) LTD		EGIS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND
Laboratory:	FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory:	FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory:	FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDISIEBIOSWTO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRC:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA	FPRC/FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA	FPRR:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.3/0940	Registration number:	43/20.1/0954	Registration number:	43/20.1.1/1025
Name of medicine:	MIXANVAL 10/10	Name of medicine:	CUBICIN	Name of medicine:	ADCO CIPROFLOXACIN 2 mg/ml
Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INFUSION	Dosage form:	INFUSION
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10.0 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10.0 mg	Active ingredients:	EACH VIAL CONTAINS: DAPTOMYCIN 500.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: CIPROFLOXACIN 2.0 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:	EGIS PHARMACEUTICALS SA (PTY) LTD	Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND	Manufacturer:	HOSPIRA INC., MCPHERSON, KANSA, USA	Manufacturer:	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND
Packer:	SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND QUALITY (BURNLEY) LIMITED, BURNLEY, LANCASTER, UK CHANELLE MEDICAL LIMITED, GALWAY, IRELAND TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA CREAPHARM, GANNAT, FRANCE CENEXI, FONTENAY-SOUS-BOIS, FRANCE MILLMOUNT HEALTHCARE LTD, NAVAN, MILLMOUNT HEALTHCARE LTD, DROGHEDA LOUTH, IRELAND	Packer:	HOSPIRA INC., MCPHERSON, KANSA, USA ASTRAZENECA UK LIMITED MACCLESFIELD, CHESHIRE, UK AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA	Packer:	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND
Laboratory: FPRC:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE SERVIER (IRELAND) INDUSTRIES LTD, ARKLOW, IRELAND ANPHARM PREDSEBIOSIWO FARMACEUTYZNE S.A., ANNOPOL, POLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	CUBIST PHARMACEUTICALS INC, LEXINGTON, MASSACHUSETTS, USA PPD DEVELOPMENT, MIDDLETON, WISCONSIN, USA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ACS DOBFAR INFO S.A., CAMPASCIO, SWITZERLAND ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
FPRC:	EGIS PHARMACEUTICALS SA (PTY) LTD, RIVONIA, RSA	FPRC:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA	FPRC:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	36 months at 2-8 °C – Product 48 hours at 2-8 °C – Reconstituted solution 12 hours at or below 25 °C – Reconstituted solution	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MMRF 15	
Registration number:	44/8.2/0041	Registration number:	44/8.2/0043
Name of medicine:	CLOPIDOGREL SANOFI-AVENTIS 300 mg	Name of medicine:	PLAVIX 300 mg
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDROGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDROGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE	Manufacturer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE
Packer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Packer:	SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory:	FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory:	FPRC: SANOFI WINTHROP INDUSTRIE, CARBON BLANC, CEDEX, FRANCE M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	FPRR:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months (Provisional)	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.5/0065	Registration number:	44/2.5/0066	Registration number:	44/2.5/0067
Name of medicine:	SODIUM VALPROATE PROPAIN 300 CR	Name of medicine:	SODIUM VALPROATE PROPAIN 500 CR	Name of medicine:	VANAPRO 300
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND	Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND	Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA	Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA	Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MMRF 15	
Registration number:	44/2.5/0068	Registration number:	44/2.5/0070
Name of medicine:	VANAPRO 500	Name of medicine:	ADCO SODIUM VALPROATE 500 CR
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 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:	ADCOCK INGRAM LIMITED
Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND	Manufacturer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND
Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA	Packer:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
Laboratory: FPRC:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	ORION CORPORATION, ORION PHARMA, ESPOO, FINLAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	Registration number: 44/2.5/0120 Name of medicine: KEPRACET 250 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Packer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Laboratory: FPRC: ACTAVIS HF, HAFNARF JORDUR, ICELAND FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/2.5/0121 Name of medicine: KEPRACET 500 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Packer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Laboratory: FPRC: ACTAVIS HF, HAFNARF JORDUR, ICELAND FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/2.5/0122 Name of medicine: KEPRACET 750 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Packer: ACTAVIS HF, HAFNARF JORDUR, ICELAND Laboratory: FPRC: ACTAVIS HF, HAFNARF JORDUR, ICELAND FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA Shelf-life: 24 months Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.5/0123	Registration number:	44/2.5/0124	Registration number:	44/2.5/0125
Name of medicine:	KEPRACET 1 000	Name of medicine:	ADCO LEVETIRACETAM 250	Name of medicine:	ADCO LEVETIRACETAM 500
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000.0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250.0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500.0 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND	Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND	Manufacturer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND
Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND	Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND	Packer:	ACTAVIS HF, HAFNARF JORDUR, ICELAND
Laboratory:	FPRC: ACTAVIS HF, ZEJTUN, MALTA	Laboratory:	FPRC: ACTAVIS HF, ZEJTUN, MALTA	Laboratory:	FPRC: ACTAVIS HF, ZEJTUN, MALTA
	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA		ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA		ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
	ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA
	ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA		ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA		ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA		ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	44/2 5/0126	ADCO LEVETIRACETAM 750	TABLET	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg	1, 2, 3, 4, 5, 6, 7 ADCOCK INGRAM LIMITED	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA	ACTAVIS HF, HAFNARF JORDUR, ICELAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	24 months	05 DECEMBER 2013
MRF 15	44/2 5/0127	ADCO LEVETIRACETAM 1 000	TABLET	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 mg	1, 2, 3, 4, 5, 6, 7 ADCOCK INGRAM LIMITED	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA	ACTAVIS HF, HAFNARF JORDUR, ICELAND ACTAVIS HF, ZEJTUN, MALTA	ACTAVIS HF, HAFNARF JORDUR, ICELAND ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	24 months	05 DECEMBER 2013
MRF 15	44/11 4 3/0208	NEXIUM 2,5 mg SACHETS	GRANULES	EACH SACHET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 2,5 mg	1, 2, 3, 4, 5, 6, 7 ASTRAZENECA PHARMACEUTICALS (PTY) LTD	ASTRAZENECA AB, SODERTALJE, SWEDEN	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA	24 months	05 DECEMBER 2013

MRF 15	MRF 15	MRF 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:	Laboratory:	Laboratory:
FPRC:	FPRC:	FPRC:
FPRR:	FPRR:	FPRR:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:
44/11.4/0209	44/3.2/0258	44/11.4/0209
NEXIUM 5 mg SACHETS	SANDOZ IBANDRONATE 2 mg/2 ml	NEXIUM 5 mg SACHETS
GRANULES	INJECTION	GRANULES
EACH SACHET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 5,0 mg	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MOHODRATE EQUIVALENT TO IBANDRONIC ACID 2,0 mg	EACH SACHET CONTAINS: ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 5,0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
ASTRAZENECA PHARMACEUTICALS (PTY) LTD	SANDOZ SA (PTY) LTD	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
ASTRAZENECA AB, SODERTALJE, SWEDEN	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY	ASTRAZENECA AB, SODERTALJE, SWEDEN
ASTRAZENECA AB, SODERTALJE, SWEDEN	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY	ASTRAZENECA AB, SODERTALJE, SWEDEN
AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY	AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
ASTRAZENECA AB, SODERTALJE, SWEDEN	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY	ASTRAZENECA AB, SODERTALJE, SWEDEN
AFRIKA BIOPHARMA MANUFACTURING CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	AFRIKA BIOPHARMA MANUFACTURING CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, RSA
24 months	24 months	24 months
05 DECEMBER 2013	05 DECEMBER 2013	05 DECEMBER 2013

MRF 15	Registration number: 44/7.1.3/0265 Name of medicine: CANDESARTAN RAN 8 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: RANBAXY (SA) (PTY) LTD Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/7.1.3/0266 Name of medicine: CANDESARTAN RAN 16 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: RANBAXY (SA) (PTY) LTD Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/7.1.3/0267 Name of medicine: CANDAGEN 8 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: RANBAXY (SA) (PTY) LTD Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA FPRR: RANBAXY (SA) (PTY) LTD, CENTURION, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/0268	Registration number:	44/3.2/0319	Registration number:	44/3.2/0320
Name of medicine:	CANDAGEN 16	Name of medicine:	BONATE 2 mg/2 ml	Name of medicine:	BONATE 6 mg/6 ml
Dosage form:	TABLET	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MONOHYDRATE EQUIVALENT TO IBANDRONIC ACID 2,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: IBANDRONATE SODIUM MONOHYDRATE EQUIVALENT TO IBANDRONIC ACID 6,0 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:	RANBAXY (SA) (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA	Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY	Manufacturer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA	Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, SIRMOUR, HIMACHAL PRADESH, INDIA KHULILEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	SIRTON PHARMACEUTICALS S.p.A., SETTEMBRE, VILLA GUARDIA, ITALY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	MRF 15						
	Registration number:	44/20.1.1/0421	Registration number:	44/20.1.1/0422	Registration number:	44/32.2/0631	
	Name of medicine:	LEVOFLOXACIN TRINITY 250	Name of medicine:	LEVOFLOXACIN TRINITY 500	Name of medicine:	MYCOKEM 500	
	Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET	
	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 250.0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 500.0 mg	Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500.0 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:	TRINITY PHARMA (PTY) LTD	Applicant:	TRINITY PHARMA (PTY) LTD	Applicant:	ALKEM LABORATORIES (PTY) LTD	
	Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Manufacturer:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA	
	Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Packer:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA	
	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ALKEM LABORATORIES LTD, NALAGARH, DISTT-SOLAN (HP), INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	
	FPRR:	TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA	FPRR:	TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA	FPRR:	ALKEM LABORATORIES (PTY) LTD, NOORDBRUG, POTCHEFSTROOM, RSA	
	Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months	
	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	

MRF 15		MRF 15		MRF 15	
Registration number:	44/21.10/0763	Registration number:	44/21.10/0764	Registration number:	44/26/0886
Name of medicine:	BRAVELLE 75 I.U.	Name of medicine:	BRAVELLE SOLVENT	Name of medicine:	IMALEK 100
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	SOLVENT FOR SOLUTION FOR INJECTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: UROFOLLITROPIN 75,0 I.U.	Active ingredients:	EACH AMPOULE CONTAINS: SODIUM CHLORIDE (0.9%) AND 1,0 ml WATER FOR INJECTION.	Active ingredients:	EACH TABLET CONTAINS: IMATINIB MESILATE EQUIVALENT TO IMTINIB 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:	FERRING (PTY) LTD	Applicant:	FERRING (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	FERRING GmbH, KIEL, GERMANY	Manufacturer:	HAUPT PHARMA WULFING GmbH, GRONAU, GERMANY WEIMER PHARMA, KIEL, GERMANY	Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD. HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Packer:	FERRING GmbH, KIEL, GERMANY FERRING INTERNATIONAL CENTER SA, VERGOGNAUSAZ, ST-PREX, SWITZERLAND DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA	Packer:	HAUPT PHARMA WULFING GmbH, GRONAU, GERMANY WEIMER PHARMA, KIEL, GERMANY FERRING PHARMA, KIEL, GERMANY FERRING INTERNATIONAL CENTER SA, VERGOGNAUSAZ, ST-PREX, SWITZERLAND DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA	Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD. HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC:	FERRING GmbH, KIEL, GERMANY LABOR L+S AG, BAD BOCKLET- GROENBACH, GERMANY LPT, HAMBURG, GERMANY PIPELINE BIOTECH A/S, TRIGE, DENMARK INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	FERRING GmbH, KIEL, GERMANY INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	SUN PHARMACEUTICAL INDUSTRIES LTD. HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENOAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	FERRING (PTY) LTD, IRENE, CENTURION, RSA	FPRR:	FERRING (PTY) LTD, IRENE, CENTURION, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/26/0887	Registration number:	44/1.2/0948	Registration number:	44/1.2/0949
Name of medicine:	IMALEK 400	Name of medicine:	PRATALOPRAM 5 mg TABLETS	Name of medicine:	PRATALOPRAM 10 mg TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IMATINIB MESILATE EQUIVALENT TO IMTINIB 400,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 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:	PHARMAPLAN (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL DISTRICT, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULEKANI LABORATORY SERVICES, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	Registration number: 44/1.2/0950	Name of medicine: PRATALOPRAM 20 mg TABLETS	Dosage form: TABLET	Active ingredients: EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20.0 mg	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Applicant: AUROBINDO PHARMA (PTY) LTD	Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	Shelf-life: 24 months (Provisional)	Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/1.2/0951	Name of medicine: DOLIN 5 mg	Dosage form: TABLET	Active ingredients: EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5.0 mg	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Applicant: AUROBINDO PHARMA (PTY) LTD	Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	Shelf-life: 24 months (Provisional)	Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/1.2/0952	Name of medicine: DOLIN 10 mg	Dosage form: TABLET	Active ingredients: EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10.0 mg	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Applicant: AUROBINDO PHARMA (PTY) LTD	Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	Shelf-life: 24 months (Provisional)	Date of registration: 05 DECEMBER 2013

MRF 15	Registration number: 44/1.2/0953 Name of medicine: DOLIN 20 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/1.2/0954 Name of medicine: MARPREM 5 mg TABLETS Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013
MRF 15	Registration number: 44/1.2/0955 Name of medicine: MARPREM 10 mg TABLETS Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/1.2/0956	Registration number:	44/11.4.3/0981	Registration number:	44/11.4.3/0982
Name of medicine:	MARPREM 20 mg TABLETS	Name of medicine:	ADCO PANTOPRAZOLE IV	Name of medicine:	PANTOPRAZOLE COVAN INJECTION
Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: ESCITALPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 mg	Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 mg	Active ingredients:	EACH 15,0 ml SOLUTION CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 40,0 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN	Manufacturer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA	Packer:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHULLAPUR MANDAL, RANGA REDDY, DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	ALCALA FARMA S.L., ALCALA DE HENARES, MADRID, SPAIN ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	FPRC:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	MRF 15	MRF 15
Registration number: 44/21.12/1009	Registration number: 45/15.1/0034	Registration number: 45/26/0038
Name of medicine: ANABREZ 1	Name of medicine: FOXIN	Name of medicine: LILLY PEMETREXED 100 mg
Dosage form: TABLET	Dosage form: EYE DROPS	Dosage form: POWDER FOR SOLUTION FOR INFUSION
Active ingredients: EACH TABLET CONTAINS: ANASTROZOLE 1.0 mg	Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 30.0 mg	Active ingredients: EACH VIAL CONTAINS: PEMETREXED 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: PHARMAPLAN (PTY) LTD	Applicant: GULF DRUG COMPANY (PTY) LTD	Applicant: ELI LILLY (SA.) (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Manufacturer: MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA	Manufacturer: ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA	Packer: MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA	Packer: LILLY FRANCE, FEGERSHEIM, FRANCE
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, DISTRICT PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC: MERCK BIOSCIENCES LIMITED, TALUKA, MATAR DISTRICT, KHEDA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC: LILLY FRANCE, FEGERSHEIM, FRANCE ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRR: GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, DURBAN, RSA	FPRR: ELI LILLY (SA.) (PTY) LTD, BRYANSTON, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 05 DECEMBER 2013	Date of registration: 05 DECEMBER 2013	Date of registration: 05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/26/0039	Registration number:	45/20.1.1/0100	Registration number:	45/20.1.1/0101
Name of medicine:	LILLY PEMETREXED 500 mg	Name of medicine:	TARBACT 200	Name of medicine:	TARBACT 400
Dosage form:	POWDER FOR SOLUTION FOR INFUSION	Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: PEMETREXED 500,0 mg	Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg	Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 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:	ELI LILLY (S.A.) (PTY) LTD	Applicant:	RANBAXY (SA) (PTY) LTD	Applicant:	RANBAXY (SA) (PTY) LTD
Manufacturer:	ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA	Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Packer:	LILLY FRANCE, FEGERSHEIM, FRANCE	Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN
Laboratory: FPRC:	LILLY FRANCE, FEGERSHEIM, FRANCE ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ELI LILLY (S.A.) (PTY) LTD, BRYANSTON, RSA	FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA
Shelf-life:	24 months	Shelf-life:	24 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product	Shelf-life:	24 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0102	Registration number:	45/26/0184	Registration number:	45/26/0185
Name of medicine:	TARBACT SOLVENT	Name of medicine:	BLEOCIP	Name of medicine:	CIPLA BLEOCIP
Dosage form:	SOLUTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3.0 ml	Active ingredients:	EACH VIAL CONTAINS: BLEOMYCIN SULPHATE EQUIVALENT TO BLEOMYCIN	Active ingredients:	EACH VIAL CONTAINS: BLEOMYCIN SULPHATE EQUIVALENT TO BLEOMYCIN
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:	RANBAXY (SA) (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Manufacturer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA	Manufacturer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Packer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA	Packer:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA	Laboratory: FPRC:	CIPLA MEDPRO LTD, UNIT V, VERNA INDUSTRIAL ESTATE, VERNA, GOA, SALCETTE, INDIA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, RSA
Shelf-life:	60 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/32.2/0219	Registration number:	45/32.2/0220	Registration number:	45/32.2/0221
Name of medicine:	MYCOPHENOLATE ALKEM 250 mg	Name of medicine:	MYCOPHENOLATE ALKEM 500 mg	Name of medicine:	MYCOKEM 250
Dosage form:	CAPSULES	Dosage form:	CAPSULES	Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 500.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250.0 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:	ALKEM LABORATORIES (PTY) LTD	Applicant:	ALKEM LABORATORIES (PTY) LTD	Applicant:	ALKEM LABORATORIES (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA	Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA	Manufacturer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA	Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA	Packer:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA
Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ALKEM LABORATORIES LIMITED, BADDI, TEHSIL NALAGARH, DISTRICT SOLAN, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA	FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA	FPRR:	ALKEM LABORATORIES (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/8.3/0335	Registration number:	45/21.12/0425	Registration number:	45/21.12/0487
Name of medicine:	EQUIFER	Name of medicine:	EXERAN	Name of medicine:	ANASTRAZOLE WATSON
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: IRON (III)-HYDROXIDE SUCROSE COMPLEX EQUIVALENT TO IRON 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: EXEMESTANE 25.0 mg	Active ingredients:	EACH TABLET CONTAINS: ANASTRAZOLE 1.0 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:	EQUITY PHARMACEUTICALS (PTY) LTD	Applicant:	RANBAXY (SA) (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RAFARM S.A., PEANIA-ATTIKI, GREECE	Manufacturer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA	Manufacturer:	REMEDICA LTD, LIMASSOL, CYPRUS
Packer:	RAFARM S.A., PEANIA-ATTIKI, GREECE	Packer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA MILLMOUNT HEALTHCARE LTD, STAMULLEN, COUNTY MEALTH, IRELAND MILLMOUNT HEALTHCARE LTD, TRIM ROAD, COUNTY MEALTH, IRELAND	Packer:	REMEDICA LTD, LIMASSOL, CYPRUS DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIA, LONGDALE, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	RAFARM S.A., PEANIA-ATTIKI, GREECE INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	EIRGEN PHARMA LTD, WATERFORD, IRELAND SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	REMEDICA LTD, LIMASSOL, CYPRUS TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	EQUITY PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA	FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDTON, RSA
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15	MRF15									
	Registration number:	45/2.7/0531	Registration number:	42/20.1.1/0554	Registration number:	42/20.1.1/0555	Name of medicine:	TEICOPLANIN LITHA 200	TEICOPLANIN LITHA 400	
	Name of medicine:	PARACETAMIL FRESENIUS 10 mg/ml (50 ml)		TEICOPLANIN LITHA 200		TEICOPLANIN LITHA 400	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	POWDER FOR SOLUTION FOR INJECTION	
	Dosage form:	SOLUTION FOR INFUSION		POWDER FOR SOLUTION FOR INJECTION		POWDER FOR SOLUTION FOR INJECTION	Active ingredients:	EACH VIAL CONTAINS: PARACETAMOL 10,0 mg	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg	
	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: PARACETAMOL 10,0 mg		EACH VIAL CONTAINS: TEICOPLANIN 200,0 mg		EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8	
	Conditions of registration:	1, 2, 3, 4, 5, 6, 7		1, 2, 3, 4, 5, 6, 7, 8		1, 2, 3, 4, 5, 6, 7, 8	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	LITHA PHARMA (PTY) LTD	
	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD		LITHA PHARMA (PTY) LTD		LITHA PHARMA (PTY) LTD	Manufacturer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY	ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	
	Manufacturer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	Packer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY	ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	
	Packer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	Laboratory:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY	ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	
	Laboratory:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE		ANFARM HELLAS S.A., SCHIMATARI VOTIAS, GREECE	FPRC:	BODENE (PTY) LTD TRADING AS INTRAMED, PORT ELIZABETH, RSA	PHARMATHEN S.A., ATTIKIS, GREECE	
	FPRC:	BODENE (PTY) LTD TRADING AS INTRAMED, PORT ELIZABETH, RSA		PHARMATHEN S.A., ATTIKIS, GREECE		PHARMATHEN S.A., ATTIKIS, GREECE		CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	
		KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA		ATLASVILLE, BOKSBURG, RSA		ATLASVILLE, BOKSBURG, RSA				
		SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA								
		FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA					FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA	LITHA PHARMA (PTY) LTD, EDENVALE, RSA	
	FPRR:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, RSA		LITHA PHARMA (PTY) LTD, EDENVALE, RSA		LITHA PHARMA (PTY) LTD, EDENVALE, RSA	Shelf-life:	36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product	36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product	
	Shelf-life:	24 months		36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product		36 months – Product 24 hours stored at 2-8 °C- Reconstituted and diluted product	Date of registration:	05 DECEMBER 2013	05 DECEMBER 2013	
	Date of registration:	05 DECEMBER 2013		05 DECEMBER 2013		05 DECEMBER 2013				

MRF-15		MRF-15		MRF-15	
Registration number:	45/34/0556	Registration number:	45/20.2.8/0588	Registration number:	45/20.2.8/0589
Name of medicine:	SOLVENT FOR TEICOPLANIN LITHA	Name of medicine:	VALZOF 500 mg	Name of medicine:	VALZOF 1 g
Dosage form:	SOLUTION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3.0 ml	Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO CALACICLOVIR 500.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALACICLOVIR HYDROCHLORIDE EQUIVALENT TO CALACICLOVIR 1.0 g
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:	LITHA PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: ANFARM HELLAS S.A., SCHIMATARI VIOTIAS, GREECE PHARMATHEN S.A., ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, MIDRAND, RSA
FPRR:	LITHA PHARMA (PTY) LTD, EDENVALE, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSPARK, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSPARK, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2 5/0711	Registration number:	45/2 5/0712	Registration number:	45/2 5/0713
Name of medicine:	LEVETIRACETAM 250 BIOTECH	Name of medicine:	LEVETIRACETAM 750 BIOTECH	Name of medicine:	LEVETIRACETAM 1 000 BIOTECH
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 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:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA	Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA	Manufacturer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA
Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA	Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA	Packer:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
Laboratory: FPCR:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA	Laboratory: FPCR:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA	Laboratory: FPCR:	HETERO DRUGS LTD, JEEDIMETLA, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRDOE, ALBERTON, RSA
FPCR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPCR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPCR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/5 3/0939	Registration number:	45/5 3/0940	Registration number:	45/5 3/0941
Name of medicine:	ALZIDO 5 mg	Name of medicine:	ALZIDO 10 mg	Name of medicine:	DONEPEZIL ZYDUS 5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 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:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	FPRR:	INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	FPRR:	INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/5.3/0942	Registration number:	45/2.7/11881	Registration number:	46/8.2/0111
Name of medicine:	DONEPEZIL ZYDUS 10 mg	Name of medicine:	PARACETAMIL FRESENIUS 10 mg/ml (100 ml)	Name of medicine:	ARELTO 15
Dosage form:	TABLET	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: PARACETAMOL 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: RIVAROXABAN 15,0 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:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	Applicant:	BAYER (PTY) LTD
Manufacturer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Manufacturer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA	Manufacturer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
Packer:	ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA	Packer:	FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA	Packer:	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY STEGEMANN LOHNVERPACKUNG & LOGISTISCHER SERVICES e.K., GREVEN, GERMANY
Laboratory:	FPRC: ZYDUS CADILLA HEALTHCARE (PTY) LTD, MORAIYA, TAL SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: FRESENIUS KABI GERMANY GmbH, FRIEDBURG, GERMANY FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA BODENE (PTY) LTD TRADING AS INTRAMED, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES (PTY) LTD, COVENTRY PARK, MIDRAND, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory:	FPRC: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF15	
Registration number:	46/20.2.8/0793	Registration number:	46/8.3/0849
Name of medicine:	ENDURANT	Name of medicine:	RAUTEVENE
Dosage form:	TABLET	Dosage form:	SOLUTION FOR INJECTION/CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: RILPVRINE HYDROCHLORIDE EQUIVALENT TO RILPVRINE 25,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: IRON (III)-HYDROCHLORIDE SUCROSE COMPLEX EQUIVALENT TO IRON 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED	Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	JANSSEN CILAG SpA, LATINA, ITALY	Manufacturer:	RAFARM S.A., PEANIA, ARRIKI, GREECE
Packer:	JANSSEN CILAG SpA, LATINA, ITALY	Packer:	RAFARM S.A., PEANIA, ARRIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIAL, LONGDALE, RSA
Laboratory:	FPRC: JANSSEN CILAG SpA, LATINA, ITALY ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA	Laboratory:	FPRC: RAFARM S.A., PEANIA, ARRIKI, GREECE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH WEST UNIVERSITY, POTCHEFSTROOM, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

Registration number:	47/20.1.8/0327
Name of medicine:	RIZENE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg EMTRICITABINE 200,0 mg FUMARATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Packer:	HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: HETETO LABS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA ADCOCK INGRAM LIMITED, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA ADCOCK INGRAM LIMITED-RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	47/20.2.8/0740	Registration number:	A40/34/0520	Registration number:	A40/34/0523
Name of medicine:	TENEMCOM	Name of medicine:	NICORETTE FRESHMINT 2 mg	Name of medicine:	NICORETTE FRESHMINT 4 mg
Dosage form:	TABLET	Dosage form:	GUM	Dosage form:	GUM
Active ingredients:	EACH TABLET CONTAINS: EMTRICITABINE 200,0 mg TENOFVIR DISOPROXIL FUMARATE 300,0 mg	Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 2,0 mg	Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 4,0 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:	SPECPHARM (PTY) LTD	Applicant:	JOHNSON & JOHNSON (PTY) LTD	Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	HETETO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, INDIA	Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN	Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	HETETO LABS LIMITED, UNIT II, JEEDIMETLA, HYDERABAD, INDIA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Packer:	MCNEIL AB, HELSINGBORG, SWEDEN	Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory: FPRC:	HETETO LABS LIMITED, UNIT V, JEEDIMETLA, HYDERAB, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013

MRF 15		MRF 15	
Registration number:	A40/34/0566	Registration number:	A40/34/0565
Name of medicine:	NICORETTE ICE MINT 4 mg	Name of medicine:	NICORETTE ICE MINT 2 mg
Dosage form:	GUM	Dosage form:	GUM
Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 4.0 mg	Active ingredients:	EACH PIECE OF GUM CONTAINS: NICORETTE RESINATE 20 % EQUIVALENT TO NICOTINE 2.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD	Applicant:	JOHNSON & JOHNSON (PTY) LTD
Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN	Manufacturer:	MCNEIL AB, HELSINGBORG, SWEDEN
Packer:	MCNEIL AB, HELSINGBORG, SWEDEN	Packer:	MCNEIL AB, HELSINGBORG, SWEDEN
Laboratory:	FPRC: JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory:	FPRC: JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA MCNEIL AB, HELSINGBORG, SWEDEN SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	05 DECEMBER 2013	Date of registration:	05 DECEMBER 2013