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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 672 OF 2006

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 No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of 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 No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review 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 registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 672 VAN 2006**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 26 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgevind deur die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingstifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 35/20.1.2/0232

Name of medicine: AMOCLAN

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Packer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Laboratory:FPRC: HIKMA PHARMACEUTICALS, AMMAN, JORDAN
FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 35/20.1.2/0233

Name of medicine: AMOCLAN FORTE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 500,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 125,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: HIKMA PHARMACEUTICALS,AMMAN, JORDAN

Packer: HIKMA PHARMACEUTICALS,AMMAN, JORDAN

Laboratory:FPRC: HIKMA PHARMACEUTICALS,AMMAN, JORDAN
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 35/20.1.2/0249

Name of medicine: AMOCLAN S

Dosage form: POWDER FOR SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO 125,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 31,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Packer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Laboratory: FPRC: HIKMA PHARMACEUTICALS, AMMAN, JORDAN
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 35/20.1.2/0250

Name of medicine: AMOCLAN SF

Dosage form: POWDER FOR SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 62,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Packer: HIKMA PHARMACEUTICALS, AMMAN, JORDAN

Laboratory: FPRC: HIKMA PHARMACEUTICALS, AMMAN, JORDAN
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/30.1/0347

Name of medicine: INFANRIX HEXA

Dosage form: VACCINE

Active ingredients: EACH 0,5 ml DOSE CONTAINS:

DIPHTHERIA TOXOID	nlt 30,0 iu
TETANUS TOXOID	nlt 40,0 iu
PERTUSSIS TOXOID	25,0 ug
FILAMENTOUS HEMAGGLUTININ	25,0 ug
PERTACTIN	8,0 ug
RECOMBINANT HBsAg	10,0 ug
POLIO VIRUS Type 1 Mahoney strain	40,0 du
POLIO VIRUS Type 2 MEF-1 strain	8,0 du
POLIO VIRUS Type 3 Saukett strain	32,0 du
HAEMOPHILUS INFLUENZA TYPE B:	
PRP	10,0 ug
T	20,0 – 40,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GLAXOSMITHKLINE S.A. (PTY) LTD

Manufacturer: GLAXOSMITHKLINE BIOLOGICALS S.A.,
RIXENSART, BELGIUM
CHIRON BEHRING, MARBURG, GERMANY

Packer: GLAXOSMITHKLINE BIOLOGICALS
MANUFACTURING S.A., RIXENSART, BELGIUM
GLAXOSMITHKLINE BIOLOGICALS
MANUFACTURING S.A., WAVRE, BELGIUM
SACHSISCHES SERUMWERK DRESDEN,
DRESDEN, GERMANY
GLAXOSMITHKLINE S.A., ALCALA DE
HENARES, MADRID, SPAIN
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Laboratory:FPRC: GLAXOSMITHKLINE BIOLOGICALS S.A.,
RIXENSART, BELGIUM
FPRC/FPRR: GLAXOSMITHKLINE, EPPING, CAPE TOWN

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0349

Name of medicine: CRESTOR 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENCE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE

FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0350

Name of medicine: CRESTOR 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENURE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0351

Name of medicine: CRESTOR 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENCE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0353

Name of medicine: AZESTOR 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENCE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0354

Name of medicine: AZESTOR 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENCE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 36/7.5/0355

Name of medicine: AZESTOR 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ROSUVASTATIN CALCIUM EQUIVALENT TO
ROSUVASTATIN 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO

Packer: ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Laboratory:FPRC: ASTRAZENECA GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENURE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFIELD,
CHESHIRE, UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0046
Name of medicine:	CPL ALLIANCE CEFTRIAXONE 250
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
FPRC/FPRR:	ANALYTICON, KEMPTON PARK, RSA ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0048
Name of medicine:	CPL ALLIANCE CEFTRIAXONE 500
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
Laboratory:FPRC:	CADILA PHARMACEUTICALS LTD, AHMEDABAD, GUJARAT, INDIA
FPRC/FPRR:	ANALYTICON, KEMPTON PARK, RSA ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number: 37/20.1.1/0049

Name of medicine: CPL ALLIANCE CEFTRIAXONE 1000

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 1000,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ALLIANCE PHARMA (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory:FPRC: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
FPRC/FPRR: ANALYTICON, KEMPTON PARK, RSA
ALLIANCE PHARMA, VILLAGE MAIN,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 17 FEBRUARY 2006

MRF 15

Registration number: 37/34/0090

Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS
CONCENTRATE SW 127 A

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 210,68 g
POTASSIUM CHLORIDE 5,22 g
CALCIUM CHLORIDE 6,43 g
MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g
GLACIAL ACETIC ACID 6,31 g
GLUCOSE MONOHYDRATE EQUIVALENT
TO ANHYDROUS GLUCOSE 35,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: B. BRAUN MEDICAL (PTY) LTD

Manufacturer: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY

Packer: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY

Laboratory:FPRC: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: B. BRAUN MEDICAL, HONEYDEW, RANDBURG

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 37/34/0091

Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS
CONCENTRATE SW 139 A

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 210,68 g
POTASSIUM CHLORIDE 5,22 g
CALCIUM CHLORIDE 9,01 g
MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g
GLACIAL ACETIC ACID 6,31 g
GLUCOSE MONOHYDRATE EQUIVALENT
TO ANHYDROUS GLUCOSE 35,00 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: B. BRAUN MEDICAL (PTY) LTD

Manufacturer: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY

Packer: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY

Laboratory:FPRC: B. BRAUN SCHIWA GmbH, GLANDORF, GERMANY
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: B. BRAUN MEDICAL, HONEYDEW, RANDBURG

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/20.1.1/0130
Name of medicine:	CPL ALLIANCE NORFLOXACIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: NORFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ALLIANCE PHARMA (PTY) LTD
Manufacturer:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA
Packer:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA
Laboratory:	CADILA PHARMACEUTICALS, AHMEDABAD, GUJARAT, INDIA ANALYTICON, KEMPTON PARK, RSA ALLIANCE PHARMA, VILLAGE MAIN, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15

Registration number: 37/7.1/0376

Name of medicine: ROLAB-AMLODIPINE 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE MALEATE EQUIVALENT TO
AMLODIPINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Packer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 37/7.1/0377

Name of medicine: ROLAB-AMLODIPINE 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMLODIPINE MALEATE EQUIVALENT TO
AMLODIPINE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Packer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 37/20.1.1/0617

Name of medicine: BELEX 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: HOVID SDN. BHD., PERAK, MALAYSIA

Packer: HOVID SDN. BHD., PERAK, MALAYSIA

Laboratory:FPRC: HOVID SDN. BHD., PERAK, MALAYSIA
WRAPSA, CENTURION, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA-Q, INDUSTRIA, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
CONSULTING MICROBIOLOGICAL
LABORATORY, BEYERSPARK, RSA
FPRR: GULF DRUG CO, MOUNT EDGECOMBE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 37/20.1.1/0618

Name of medicine: BELEX 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: HOVID SDN. BHD., PERAK, MALAYSIA

Packer: HOVID SDN. BHD., PERAK, MALAYSIA

Laboratory:FPRC: HOVID SDN. BHD., PERAK, MALAYSIA
WRAPSA, CENTURION, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA-Q, INDUSTRIA, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
CONSULTING MICROBIOLOGICAL
LABORATORY, BEYERSPARK, RSA
FPRR: GULF DRUG CO, MOUNT EDGECOMBE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number: 37/3.2/0633

Name of medicine: OSTEONEXAL 10 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
POTASSIUM ALENDRONATE ANHYDRATE
EQUIVALENT TO ALENDRONIC ACID 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK

Packer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory:FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	37/3.2/0634
Name of medicine:	KALENDROMAX 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: POTASSIUM ALENDRONATE ANHYDRATE EQUIVALENT TO ALENDRONIC ACID 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD *
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: 37/3.1/0641

Name of medicine: DIFEN SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DICLOFENAC SODIUM 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: HOVID SDN. BHD., PERAK, MALAYSIA

Packer: HOVID SDN. BHD., PERAK, MALAYSIA

Laboratory:FPRC: HOVID SDN. BHD., PERAK, MALAYSIA
WRAPSA, CENTURION, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA-Q, INDUSTRIA, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
CONSULTING MICROBIOLOGICAL
LABORATORY, BEYERSPARK, RSA
FPRR: GULF DRUG CO, MOUNT EDGECOMBE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 37/3.1/0669

Name of medicine: RESMED DICLOFENAC 75 INJECTION

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
DICLOFENAC SODIUM 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED PHARMACEUTICALS

Manufacturer: UNIQUE PHARMACEUTICAL LABORATORIES,
GUJARAT, INDIA

Packer: UNIQUE PHARMACEUTICAL LABORATORIES,
GUJARAT, INDIA

Laboratory:FPRC: UNIQUE PHARMACEUTICAL LABORATORIES,
GUJARAT, INDIA
FPRR: RESMED PHARMACEUTICALS, SPRINGFIELD
PARK, DURBAN

Shelf-life: 24 months

Date of registration: 17 FEBRUARY 2006

MRF 15 (MBR 15)

Registration number: 38/20.1.1/0016

Name of medicine: BINOCLAR 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLARITHROMYCIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number: 38/20.1.1/0017

Name of medicine: BINOCLAR 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLARITHROMYCIN 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number: 38/20.1.1/0018

Name of medicine: SANDOZ-CLARITHROMYCIN 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLARITHROMYCIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0019
Name of medicine:	SANDOZ-CLARITHROMYCIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLARITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Packer:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/20.1.1/0024
Name of medicine:	CIPROBAY XR 1000
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 1000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD
Manufacturer:	BAYER AG, LEVERKUSEN, GERMANY
Packer:	BAYER AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMACEUTICAL CONTRACTORS, ISANDO, RSA
Laboratory:	FPRC: BAYER AG, LEVERKUSEN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
	FPRR: BAYER, ISANDO, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15

Registration number: 38/7.1.3/0116

Name of medicine: VECTORYL 8 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
RSA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/7.1.3/0119

Name of medicine: COVERSYL 8 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVIER LABORATORIES SOUTH AFRICA
(PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
RSA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA

FPRR: SERVIER LABORATORIES S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/7.1.3/0120

Name of medicine: PREXUM 8 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
RSA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
FRANCE
SERVIER IRELAND INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/3.1/0141

Name of medicine: PREXIGE 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS;
LUMIRACOXIB 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
A PSUR to be submitted at six-monthly intervals

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
ALLPACK AG, REINACH, SWITZERLAND
IVERS-LEE AG, BURGDORF, SWITZERLAND
KONAPHARMA AG, PRATTELN, SWITZERLAND
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
FPRC/FPRR: INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/3.1/0142

Name of medicine: PREXIGE 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LUMIRACOXIB 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
A PSUR to be submitted at six-monthly intervals

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
ALLPACK AG, REINACH, SWITZERLAND
IVERS-LEE AG, BURGDORF, SWITZERLAND
KONAPHARMA AG, PRATTELN, SWITZERLAND
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
FPRC/FPRR: INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/20.2.2/0148

Name of medicine: TERBICIL 1 % CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
TERBINAFINE HYDROCHLORIDE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Laboratory:FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA

FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/21.8.2/0188

Name of medicine: HEXAL-MPA 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MEDROXYPROGESTERONE ACETATE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: HEXAL,PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/21.8.2/0189

Name of medicine: HEXAL-MPA 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MEDROXYPROGESTERONE ACETATE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number: 38/5.10/0197

Name of medicine: HEXAL-ONDANSETRON 4 mg INJECTION

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SOLUPHARM, MELSUNGEN, GERMANY

Packer: SOLUPHARM, MELSUNGEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SOLUPHARM, MELSUNGEN, GERMANY
SALUTAS PHARMA, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABS, STAR STREET,
BOKSBURG, RSA

FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number: 38/5.10/0200

Name of medicine: ONDANSETRON HEXAL 4 mg INJECTION

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SOLUPHARM, MELSUNGEN, GERMANY

Packer: SOLUPHARM, MELSUNGEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory:FPRC: SOLUPHARM, MELSUNGEN, GERMANY
SALUTAS PHARMA, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABS, STAR STREET,
BOKSBURG, RSA

FPRR: ANALYTICON, TERENCE, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0217
Name of medicine:	ONDANSETRON HEXAL 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENCE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: 38/21.2/0223

Name of medicine: *DIAGLUCIDE MR 30 mg*

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER INDUSTRIES LTD, WICKLOW,
IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER INDUSTRIES LTD, WICKLOW,
IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVIER INDUSTRIES LTD, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANESBURG, RSA
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/10.1/0239

Name of medicine: DILINCT DRY COUGH SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
DEXTROMETHORPHAN
HYDROBROMIDE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Laboratory:FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 38/2.6.5/0259

Name of medicine: SOLIAN 100 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMISULPRIDE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANOFI-SYNTHELABO (PTY) LTD

Manufacturer: SANOFI WINTHROP INDUSTRIE, QUETIGNY,
FRANCE
SANOFI-SYNTHELABO, NEWCASTLE-ON-TYNE,
TYNE AND WEAR, U.K.

Packer: SANOFI WINTHROP INDUSTRIE, QUETIGNY,
FRANCE
SANOFI-SYNTHELABO, NEWCASTLE-ON-TYNE,
TYNE AND WEAR, U.K.
PHARMACEUTICAL CONTRACTORS, ISANDO,
RSA

Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, QUETIGNY,
FRANCE
SANOFI-SYNTHELABO, NEWCASTLE-ON-TYNE,
TYNE AND WEAR, U.K.
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: SANOFI-SYNTHELABO, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	38/5.10/0273
Name of medicine:	HEXAL-ONDANSETRON 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SOLUPHARM, MELSUNGEN, GERMANY
Packer:	SOLUPHARM, MELSUNGEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:FPRC:	SOLUPHARM, MELSUNGEN, GERMANY SALUTAS PHARMA, BARLEBEN, GERMANY CONSULTING CHEMICAL LABS, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15 (MBR 15)

Registration number: A38/7.5/0371

Name of medicine: CIPLA-SIMVASTATIN 80

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 80,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15 (MBR 15)

Registration number:	A38/7.5/0373
Name of medicine:	SIMCARD 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
Laboratory:FPRC:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR:	CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: A38/5.7.1/0414

Name of medicine: FEXO 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/5.7.1/0415

Name of medicine: FEXO 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/5.7.1/0423

Name of medicine: CIPLA-FEXOFENADINE HYDROCHLORIDE 120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/5.7.1/0424

Name of medicine: CIPLA-FEXOFENADINE HYDROCHLORIDE 180

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 180,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/20.1.1/0608

Name of medicine: CEFTRIAXONE-COMBINOPHARM 1,0 g

Dosage form: POWDER FOR INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 1,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Packer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Laboratory:FPRC: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG

FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/20.1.1/0609

Name of medicine: CEFTRIAXONE-COMBINOPHARM 2,0 g

Dosage form: POWDER FOR INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 2,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Packer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Laboratory:FPRC: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/20.1.1/0610

Name of medicine: CEFTRIAXONE-COMBINOPHARM 250 mg

Dosage form: POWDER FOR INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Packer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Laboratory:FPRC: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/20.1.1/0611

Name of medicine: CEFTRIAXONE-COMBINOPHARM 500 mg

Dosage form: POWDER FOR INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Packer: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN

Laboratory:FPRC: REIG JOFRE, S.A., SANT ADRIA DELS BESOS,
SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG

FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/7.5/0707

Name of medicine: ARROW SIMVASTATIN 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD

Manufacturer: RX MANUFACTURING INC, ONTARIO, CANADA

Packer: RX MANUFACTURING INC, ONTARIO, CANADA
CONTRACT PHARMACEUTICALS, ONTARIO,
CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK

Laboratory: FPRC: RX MANUFACTURING INC, ONTARIO, CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: SEDEK AGRIKEM, KAMEELDRIFT
ARROW PHARMA, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/7.5/0708

Name of medicine: ARROW SIMVASTATIN 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD

Manufacturer: RX MANUFACTURING INC, ONTARIO, CANADA

Packer: RX MANUFACTURING INC, ONTARIO, CANADA
CONTRACT PHARMACEUTICALS, ONTARIO,
CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK

Laboratory: FPRC: RX MANUFACTURING INC, ONTARIO, CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: SEDEK AGRIKEM, KAMEELDRIFT
ARROW PHARMA, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A38/7.5/0709

Name of medicine: ARROW SIMVASTATIN 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD

Manufacturer: RX MANUFACTURING INC, ONTARIO, CANADA

Packer: RX MANUFACTURING INC, ONTARIO, CANADA
CONTRACT PHARMACEUTICALS, ONTARIO,
CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK

Laboratory:FPRC: RX MANUFACTURING INC, ONTARIO, CANADA
QUALITY LIMITED, BRIERCLIFFE, BURNLEY, UK
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SEDEK AGRIKEM, KAMEELDRIFT
FPRR: ARROW PHARMA, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/3.1/0008

Name of medicine: FENISTIL EMULGEL

Dosage form: GEL

Active ingredients: EACH 100,0 g GEL CONTAINS:
DICLOFENAC SODIUM 1,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS CONSUMER HEALTH, NYON,
SWITZERLAND

Packer: NOVARTIS CONSUMER HEALTH, NYON,
SWITZERLAND

Laboratory:FPRC: NOVARTIS CONSUMER HEALTH, NYON,
SWITZERLAND
FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/20.2.8/0227

Name of medicine: VARI-INDINAVIR 400 mg

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
INDINAVIR 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: LEBASI PHARMACEUTICALS CC

Manufacturer: VARICHEM PHARMACEUTICALS (PVT) LTD,
HARARE, ZIMBABWE

Packer: VARICHEM PHARMACEUTICALS (PVT) LTD,
HARARE, ZIMBABWE

Laboratory:FPRC: VARICHEM PHARMACEUTICALS (PVT) LTD,
HARARE, ZIMBABWE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: LEBASI PHARMACEUTICALS,
POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/11.4.3/0251

Name of medicine: RAN-LANSOPRAZOLE 15

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/11.4.3/0252

Name of medicine: RAN-LANSOPRAZOLE 30

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/11.4.3/0253

Name of medicine: LANAZOLE 15

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULTY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/11.4.3/0254

Name of medicine: LANAZOLE 30

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 30,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/1.2/0286

Name of medicine: AUSTELL – SERTRALINE 50 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SERTRALINE HYDROCHLORIDE EQUIVALENT
TO SERTRALINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Laboratory:FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: AUSTELL LABORATORIES, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/1.2/0287

Name of medicine: AUSTELL – SERTRALINE 100 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SERTRALINE HYDROCHLORIDE EQUIVALENT
TO SERTRALINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Laboratory:FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: AUSTELL LABORATORIES, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.5/0300

Name of medicine: SANDOZ PRAVASTATIN 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PRAVASTATIN SODIUM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA

Packer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA

FPRC/ FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.5/0301

Name of medicine: SANDOZ PRAVASTATIN 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PRAVASTATIN SODIUM 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA

Packer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/ FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.5/0302

Name of medicine: SANDOZ PRAVASTATIN 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PRAVASTATIN SODIUM 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA

Packer: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: LEK PHARMACEUTICALS D.D, LJUBLJANA,
SLOVENIA
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA

FPRC/ FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/26/0314

Name of medicine: AVASTIN 100

Dosage form: INFUSION

Active ingredients: EACH 4,0 ml VIAL CONTAINS:
BEVACIZUMAB 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: GENENTECH INC, SOUTH FRANCISCO, CA, USA
GENENTECH INC, VACAVILLE, CA, USA

Packer: GENENTECH INC, SOUTH FRANCISCO, CA, USA
F. HOFFMANN-LA ROCHE LTD, KAISERAUGST,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Laboratory:FPRC: HOFFMANN-LA ROCHE AG,
GRENZACH-WYHLEN, GERMANY
FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/26/0315

Name of medicine: AVASTIN 400

Dosage form: INFUSION

Active ingredients: EACH 16,0 ml VIAL CONTAINS:
BEVACIZUMAB 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ROCHE PRODUCTS (PTY) LTD

Manufacturer: GENENTECH INC, SOUTH FRANCISCO, CA, USA
GENENTECH INC, VACAVILLE, CA, USA

Packer: GENENTECH INC, SOUTH FRANCISCO, CA, USA
F. HOFFMANN-LA ROCHE LTD, KAISERAUGST,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Laboratory:FPRC: HOFFMANN-LA ROCHE AG,
GRENZACH-WYHLEN, GERMANY
FPRC/FPRR: ROCHE PRODUCTS, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/6.2/0319

Name of medicine: SABAX AMIODARONE 150 mg/3 ml

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
AMIODARONE HYDROCHLORIDE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: HAUPT PHARMA LIVRON, LIVRON, FRANCE

Packer: HAUPT PHARMA LIVRON, LIVRON, FRANCE
PHARMA-Q, INDUSTRIA, JOHANNESBURG
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory:FPRC: HAUPT PHARMA LIVRON, LIVRON, FRANCE
CEBIPHAR, FONDETTES, FRANCE
FPRC/FPRR: PHARMA-Q, INDUSTRIA, JOHANNESBURG
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/6.2/0321

Name of medicine: ADCORONE

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml SOLUTION CONTAINS:
AMIODARONE HYDROCHLORIDE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: HAUPT PHARMA LIVRON, LIVRON, FRANCE

Packer: HAUPT PHARMA LIVRON, LIVRON, FRANCE
PHARMA-Q, INDUSTRIA, JOHANNESBURG
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory:FPRC: HAUPT PHARMA LIVRON, LIVRON, FRANCE
CEBIPHAR, FONDETTES, FRANCE
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/20.2.3/0324

Name of medicine: RIFAMP-4

Dosage form: TABLETS

Active ingredients: EACH TABLET CONTAINS:
RIFAMPICIN 150,0 mg
PYRAZINAMIDE 400,0 mg
ETHAMBUTOL HYDROCHLORIDE 275,0 mg
ISONIAZID 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDICINE DEVELOPERS INTERNATIONAL cc

Manufacturer: RUSAN PHARMA LTD, GANDHIHAM-KUTCH,
INDIA

Packer: RUSAN PHARMA LTD, GANDHIHAM-KUTCH,
INDIA

Laboratory:FPRC: RUSAN PHARMA LTD, GANDHIHAM-KUTCH,
INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: MDI, MENLOPARK, PRETORIA, RSA

Shelf-life: 24 Months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.4/0490

Name of medicine: VESICARE 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SOLIFENACIN SUCCINATE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: YAMANOUCHI PHARMA (PTY) LTD

Manufacturer: YAMANOUCHI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS

Packer: YAMANOUCHI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: YAMANOUCHI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: YAMANOUCHI PHARMA, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.4/0491

Name of medicine: VESICARE 10 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SOLIFENACIN SUCCINATE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: YAMANOUCI PHARMA (PTY) LTD

Manufacturer: YAMANOUCI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS

Packer: YAMANOUCI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: YAMANOUCI EUROPE B.V., JG MEPPEL,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: YAMANOUCI PHARMA, BEDFORDVIEW, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.10/0511

Name of medicine: MERGENSIC 4 mg/2 ml

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.

Laboratory:FPRC: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
GENERICS UK LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.10/0512

Name of medicine: MERGENSIC 8 mg/4 ml

Dosage form: INJECTION

Active ingredients: EACH 4,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.

Laboratory:FPRC: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
GENERICS UK LTD, STATION CLOSE,
HERTFORDSHIRE, U.K.

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.10/0573

Name of medicine: ONDANTOR 4 mg/2 ml

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: PHARMATHEN S.A., ATTIKIS, GREECE

Packer: PHARMATHEN S.A., ATTIKIS, GREECE
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: PHARMATHEN S.A., ATTIKIS, GREECE
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/5.10/0574

Name of medicine: ONDANTOR 8 mg/4 ml

Dosage form: INJECTION

Active ingredients: EACH 4,0 ml SOLUTION CONTAINS:
ONDANSETRON HYDROCHLORIDE DIHYDRATE
EQUIVALENT TO ONDANSETRON 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: PHARMATHEN S.A., ATTIKIS, GREECE

Packer: PHARMATHEN S.A., ATTIKIS, GREECE
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: PHARMATHEN S.A., ATTIKIS, GREECE
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number:	A39/3.2/0598
Name of medicine:	MERCK-ALENDRONATE 70 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:FPRC:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0600

Name of medicine: PIRAMIL 1,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 1,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0601

Name of medicine: SANDOZ RAMIPRIL 2,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 2,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0602

Name of medicine: PIRAMIL 2,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 2,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0603

Name of medicine: PIRAMIL 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0604

Name of medicine: SANDOZ RAMIPRIL 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number:	A39/6.1/0609
Name of medicine:	CARDIJECT 250
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: DOBUTAMINE HYDROCHLORIDE EQUIVALENT TO DOBUTAMINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory:FPRC:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	PHARMAPLAN, MIDTAND, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: A39/7.1.3/0612

Name of medicine: SANDOZ RAMIPRIL 1,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 1,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH LTD, GAZIPUR,
BANGLADESH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/1.2/0640

Name of medicine: AUSTELL-PAROXETINE 20 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT
TO PAROXETINE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Laboratory:FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
INSTITUTE FOF PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: AUSTELL LABORATORIES, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number:	A39/1.2/0641
Name of medicine:	AUSTELL-PAROXETINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:FPRC:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: A39/3.1/0642

Name of medicine: PREXIGE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LUMIRACOXIB 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
A PSUR to be submitted at six-monthly intervals

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
ALLPACK AG, REINACH, SWITZERLAND
IVERS-LEE AG, BURGDORF, SWITZERLAND
KONAPHARMA AG, PRATTELN, SWITZERLAND
NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Shelf-life: 36 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A39/20.1.1/0646

Name of medicine: SABAX CIPROFLOXACIN 2 mg/ml

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CIPROFLOXACIN 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ACS DOBFAR INFO, CAMPASCIO,
SWITZERLAND

Packer: ACS DOBFAR INFO, CAMPASCIO,
SWITZERLAND

Laboratory:FPRC: ACS DOBFAR INFO, CAMPASCIO,
SWITZERLAND
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0010

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 2 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0011

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0012

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 25 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0013

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 50 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA
FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0014

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 100 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0015

Name of medicine: MERCK-LAMOTRIGINE DISPERSIBLE 200 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO

Packer: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA

Laboratory:FPRC: GENPHARM PHARMACEUTICALS INC,
ETOBICOKE, ONTARIO
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, UK
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA QUIMICA, BARCELONA, SPAIN
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, RSA
FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/3.1/0027

Name of medicine: ARTHROCOX 7,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MELOXICAM 7,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Packer: NOVARTIS S.A., SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS S.A., SPARTAN, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0029

Name of medicine: CIPLA-VENLAFAXINE HYDROCHLORIDE XR 37,5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 37,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0030

Name of medicine: CIPLA-VENLAFAXINE HYDROCHLORIDE XR 75

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0031

Name of medicine: CIPLA-VENLAFAXINE HYDROCHLORIDE XR 150

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0032

Name of medicine: VENLOR XR 37,5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 37,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0033

Name of medicine: VENLOR XR 75

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 75,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0034

Name of medicine: VENLOR XR 150

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
VENLAFAXINE HYDROCHLORIDE EQUIVALENT
TO VENLAFAXINE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0036

Name of medicine: RAN-LAMOTRIGINE 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0037

Name of medicine: RAN-LAMOTRIGINE 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0038

Name of medicine: RAN-LAMOTRIGINE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0039

Name of medicine: RAN-LAMOTRIGINE 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0040

Name of medicine: TOCLON 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0041

Name of medicine: TOCLON 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0042

Name of medicine: TOCLON 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/2.5/0043

Name of medicine: TOCLON 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Packer: RANBAXY LABORATORIES LTD, DEWAS, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD, DEWAS, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM

FPRR: RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/11.4.3/0072

Name of medicine: PANTOCID 40 mg INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
PANTOPRAZOLE SODIUM EQUIVALENT TO
PANTOPRAZOLE 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Laboratory:FPRC: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0107

Name of medicine: CITALOGEN 10

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROCHLORIDE EQUIVALENT
TO CITALOPRAM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory:FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0108

Name of medicine: CITALOGEN 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROCHLORIDE EQUIVALENT
TO CITALOPRAM 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory:FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/1.2/0109

Name of medicine: CITALOGEN 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROCHLORIDE EQUIVALENT
TO CITALOPRAM 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Packer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory:FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/20.2.8/0254

Name of medicine: AVOCOMB

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg
ZIDOVUDINE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE,
UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/20.2.8/0272

Name of medicine: LAMAID 150

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RANBAXY (S.A.) (PTY) LTD

Manufacturer: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA

Packer: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA

Laboratory:FPRC: RANBAXY LABORATORIES LTD,
HIMACHAL PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
CENTRE FOR QUALITY ASSURANCE,
UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/34/0316

Name of medicine: TAMSUL 0,4 SR

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TAMSULOSIN HYDROCHLORIDE 0,4 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GENERIX INTERNATIONAL SA (PTY) LTD

Manufacturer: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
ECZACIBASI, LULEBURGAZ, TURKEY

Packer: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
ECZACIBASI, LULEBURGAZ, TURKEY

Laboratory:FPRC: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND
ECZACIBASI, LULEBURGAZ, TURKEY
SOLVIAS AG, ZOFINGEN, SWITZERLAND
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
CONFARMA FRANCE SARL, HOMBURG,
FRANCE
CONFARMA SCHWEIZ AG, MUNCHENSTEIN,
SWITZERLAND

FPRR: GENERIX INTERNATIONAL, ATHLONE,
CAPE TOWN

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: A40/34/0317

Name of medicine: GENERIX TAMSULOSIN 0,4 SR

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TAMSULOSIN HYDROCHLORIDE 0,4 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GENERIX INTERNATIONAL SA (PTY) LTD

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