
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.
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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** wettlike 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 goedgegink 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
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 15

Registration number: 35/20.1.2/0233

Name of medicine: AMOCLAN FORTE

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS :**
AMOXYCILLIN TRIHYDRATE EQWALENT 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
AMOXYCILLIN
POTASSIUM CLAVULANATE EQUIVALENT TO 31,25 mg
CLAVULANIC ACID

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:**
AMOXICYLLIN TRIHYDRATE EQUIVALENT TO
AMOXICYLLIN 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
ROSWASTATIN 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, 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: 36/7.5/0350

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, 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: 36/7.5/0351

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-We: 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
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA**

FPRC/FPRR:

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:
ROSWASTATIN CALCIUM EQUIVALENT TO
ROSWASTATIN 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,
PTJERTO RICO
IPR PHARMACEUTICALS, CAROLINA,
PUERTO RICO**

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

Laboratory: FPRC: **ASTWENEC A GmbH, PLANKSTADT,
GERMANY
IPR PHARMACEUTICALS, CANOVANAS,
PUERTO RICO
ANALYTICON, TERENURE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ASTRAZENECA UK LTD, MACCLESFELD,
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 BICARBONATEHAEMODIALYSIS
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:	37/20.1.1/0 130
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-AMLODIPME 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,
GROENIUOOF, 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: OSTEHEXAL 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 (MBR 15)

Registration number: 37/3.210634

Name of medicine: **KALENDROMAX 10mg**

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
MORATORY, 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) LTDManufacturer: NOVARTIS LTD, TONGI, GAZIPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSAPacker: NOVARTIS LTD, TONGI, GAZPUR, BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSALaboratory: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, **TONGE**, GAZIPUR, **BANGLADESH**
NOVARTIS SA, SPARTAN, KEMPTON PARK, **RSA**

Packer: NOVARTIS LTD, TONGI, GAZPUR, **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, GAZPUR, BANGLADESH NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
Laboratory:FPRC:	NOVARTIS LTD, TONGI, GAZPUR, 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
DIV PHARM 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 SERVER INDUSTRIE, GIDY
FRANCE
SERVER IRELAND INDUSTRIES, WICKLOW,
IRELAND

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

Laboratory:FPRC: CES LABORATOIRES SERVIER INDUSTRE, GIDY
FRANCE
SERVER IRELAND INDUSTRIES, WICKLOW,
IRELAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA

FPRR: SERVER 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 **INDUSTRE, 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 SOUTHAFRICA (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: **INSPECTORATEM&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-We: **24 months.**

Date of registration: **7 APRIL 2006**

MRF 15

Registration number: 38/21.8.2/0 189

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, MELSTINGEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA**

Laboratory:FPRC: **SOLUPHARM, MELSUNGEN, GERMANY
SALUTAS PHARMA, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABS, 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 (MBR 15)

Registration number: 38/5.10/0200

Name of medicine: ONDANSETRON HEXAL 4 mg INJECTION

Dosage form: INJECTION

Active ingredients: EACH 1,0ml 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:	38/5.10/0217
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 ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	7 APRIL 2006

MRF 15

Registration number: 38/2.1.210223

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 SERVER INDUSTRIE,
GIDY, FRANCE
SERVER INDUSTRIES LTD, WICKLOW,
IRELAND

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

Laboratory:FPRC: LES LABORATOIRES SERVIER INDUSTRIE,
GIDY, FRANCE
SERVER 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, WADEWE,
GERMISTON, RSA**

Packer: **ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA**

Laboratory:FPRC/FPRR: **ADCOCK INGRAM HEALTHCARE, WADEWE,
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, TERENCE, 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: FPRR.	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA 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-Me: 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 SOUTHAFRICA (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 AGRKEM, 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: SEREK AGRKEM, 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

FPRR: SEDEK AGRIKEM, KAMEELDRIFT
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: A3911 1.4.310251

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
FPRR: CENTRE FOR QAULITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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 MORATORY 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: A3917.510301

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

Rate of registration: 7 APRIL 2006

MRF 15

Registration number: A39/7.5/0302

Name of medicine: SANDOZ PRAVASTATIN40

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: A39126103 14

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, SOUTHFRANCISCO, CA, USA
GENENTECH INC, VACAVILLE, CA, USA

Packer: GENENTECH INC, SOUTHFRANCISCO, 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: **A39/6.2/03 19**

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
FPRR: CONSULTING CHEMICAL LABORATORY,
STAR STREET, BOKSBURG, RSA
MDI, MENLOPARJS, 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 10mg

Dosage form: TABLET

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

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

Applicant: YAMANOUC PHARMA (PTY) LTD

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

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

Laboratory:FPRC: YAMANOUC EUROPE B.V., JG MEPPEL,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORY,
STAR STREET, BOKSBURG, RSA
FPRR: YAMANOUC 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

Registrationnumber: 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
ANALYTICON, TERENURE, KEMPTON PARK
NOVARTIS S.A., SPARTAN, KEMPTON PARK**

FPRC/FPRR:

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**

Rate 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
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: A39/7.1.3/0604

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: **CARDJECT 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
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: A39/1.2/0640

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 OF 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 SOUTHAFRICA (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: 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
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: A40/2.5/0011

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

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: A40/2.5/0012

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**

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: A40/2.5/0013

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
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-We: 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: I ,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: A40/2.5/0015

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 HYDROCHLORIDEXR 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: A4011.2/0031

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
FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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
FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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
FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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

FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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
FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
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

FPRR: CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, UNIVERSITY, POTCHEFSTROOM
RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months

Date of registration: 7 APRIL 2006

MRF 1s

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

Pate 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
FPRR: CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
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

Shew-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: A40/34/03 16

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
SOLVIA 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: A40/34/03 17

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

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, HOMBOURG,
FRANCE
CONFARMA SCHWEIZ AG, MUNCHENSTEIN,
SWITZERLAND

FPRR: GENERIX INTERNATIONAL, ATHLONE,
CAPE TOWN

Shelf-life: 24 months

Date of registration: 7 APRIL 2006
