
GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1334 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.

MRF 15

Registration number: A04/2.1/1 I

Name of medicine: BOMATHAL

Dosage form: INJECTION

Active ingredients: EACH 250,0 ml VIAL CONTAINS:
THIOPENTONE SODIUM EQUIVALENT TO
THIOPENTONE 5,0 g

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

Applicant: MERIAL SOUTH AFRICA (PTY) LTD

Manufacturer: BOMAC LABORATORIES LTD, MANUKAU CITY,
AUCKLAND, NEW ZEALAND

Packer: BOMAC LABORATORIES LTD, MANUKAU CITY,
AUCKLAND, NEW ZEALAND

Laboratory:FPRC: BOMAC LABORATORIES LTD, MANUKAU CITY,
AUCKLAND, NEW ZEALAND
BIOINDUSTRIAL SERVICES cc, KEMPTON PARK,
RSA
FPRR: MERIAL S.A., HALFWAY HOUSE, RSA

Shelf-life: 30 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 32/7.1/0429

Name of medicine: HEXAL DILTIAZEM HCL 90

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DILTIAZEM HYDROCHLORIDE 90,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY

Laboratory:FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: HEXAL PHARMA, PINETOWN, RSA

Shelf-life: **24** months (provisional)

Date of registration: 11AUGUST 2006

MRF 15 (MBR 15)

Registration number: **3312.710202**

Name of medicine: **PHARMADYNE PARACETAMOL TABLETS**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
PARACETAMOL 500,0 mg**

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

Applicant: **PHARMADYNE HEALTHCARE (PTY) LTD**

Manufacturer: **BE-TABS PHARMACEUTICALS, ROODEPOORT**

Packer: **BE-TABS PHARMACEUTICALS, ROODEPOORT
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA**

Laboratory:FPRC: **BE-TABS PHARMACEUTICALS, ROODEPOORT**
FPRR: **PHARMADYNE HEALTHCARE, DURBAN NORTH,
RSA**

Shelf-life: **24 months**

Date of registration: **11 AUGUST 2006**

MRF 15

Registration number: 35/30.2/0013

Name of medicine: GAMMATET

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
HUMAN IMMUNOGLOBULIN 100,0 – 170,0 mg

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

Applicant: MC PHARMA (PTY) LTD

Manufacturer: CENTEON PHARMA GmbH, MARBURG/LAHN,
GERMANY

Packer: CENTEON PHARMA GmbH, MARBURG/LAHN,
GERMANY

Laboratory:FPRC: CENTEON PHARMA GmbH, MARBURG/LAHN,
GERMANY
FPRR: MC PHARMA, CENTURION, PRETORIA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 35/30.2/00 14

Name of medicine: MATERGAM

Dosage form: INJECTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
HUMAN IMMUNOGLOBULIN 100,0 – 170,0 mg

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

Applicant: MC PHARMA (PTY) LTD

Manufacturer: AVENTIS BEHRING GmbH, MARBURG, GERMANY

Packer: AVENTIS BEHRING GmbH, MARBURG, GERM

Laboratory:FPRC: AVENTIS BEHRING GmbH, MARBURG, GERM
FPRR: MC PHARMA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 37/30.1/0096

Name of medicine: STAMARIL MULTIDOSE

Dosage form: VACCINE

Active ingredients: EACH 0,5 ml DOSE CONTAINS:
YELLOW FEVER VIRUS STRAIN 17D/AB237 1000
LD 50

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

Applicant: AVENTIS PHARMA (PTY) LTD

Manufacturer: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
AVENTIS PASTEUR, VAL DE REUIL, FRANCE

Packer: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
AVENTIS PASTEUR, VAL DE REUIL, FRANCE

Laboratory:FPRC: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
AVENTIS PASTEUR, VAL DE REUIL, FRANCE
AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR: AVENTIS PHARMA, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 37/15.4/0691

Name of medicine: RELESTAT

Dosage form: DROPS

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
EPINASTINE HYDROCHLORIDE 0,50 mg

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

Applicant: ALLERGAN PHARMACEUTICALS (PTY) LTD

Manufacturer: ALLERGAN PHARMACEUTICALS, WESTPORT,
COUNTY MAYO, IRELAND

Packer: ALLERGAN PHARMACEUTICALS, WESTPORT,
COUNTY MAYO, IRELAND

Laboratory:FPRC: ALLERGAN PHARMACEUTICALS, WESTPORT,
COUNTY MAYO, IRELAND
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG
FPRR: ALLERGAN PHARMACEUTICALS, HALFWAY
HOUSE, RSA

Shelf-life: **24** months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 37/26/0692

Name of medicine: AZATHIOPRINE 50 PCH

Dosage form: TABLET

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

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

Applicant: PHARMACHEMIE (PTY) LTD

Manufacturer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS

Packer: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS

Laboratory:FPRC: PHARMACHEMIE BV, HAARLEM,
THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMACHEMIE, IRENE, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	38/13.8/0079
Name of medicine:	TRANS-VER-SAL
Dosage form:	PATCH
Active ingredients:	EACH 1,0 g CONTAINS: SALICYLIC ACID 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENOP HEALTHCARE (PTY) LTD
Manufacturer:	LEC-TEC CORPORATION, MINNETONKA, MINNESOTA, USA
Packer:	FRANKLIN MEDICAL PRODUCTS, MONTROSE, COLORADO, USA
Laboratory:FPRC:	LEC-TEC CORPORATION, MINNETONKA, MINNESOTA, USA FRANKLIN MEDICAL PRODUCTS, MONTROSE, COLORADO, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	GENOP HEALTHCARE, HALFWAY HOUSE, RSA
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: 38/1.2/0208

Name of medicine: YENTREVE 40

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DULOXETINE HYDROCHLORIDE EQUIVALENT TO
DULOXETINE 40,0 mg

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

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA

Packer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA
LILLY S.A., MADRID, SPAIN

Laboratory:FPRC: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA
LILLY S.A., MADRID, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: ELI LILLY, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15 (MBR 15)

Registration number: 38/24/02 12

Name of medicine: RESMED ORAL REHYDRATION SALTS B.P.

Dosage form: POWDER

Active ingredients: EACH SACHET CONTAINS:
SODIUM CHLORIDE 3,5 g
POTASSIUM CHLORIDE 1,5 g
SODIUM CITRATE 2,9 g
GLUCOSE ANHYDROUS 20,0 g

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

Applicant: RESMED HEALTHCARE

Manufacturer: FDC LTD, AURANGABAD, INDIA

Packer: FDC LTD, AURANGABAD, INDIA

Laboratory;FPRC: FDC LTD, AURANGABAD, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, PINETOWN, KZN

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 3811.210228

Name of medicine: YENTREVE 20

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
DULOXETINE HYDROCHLORIDE EQUIVALENT TO
DULOXETINE 20,0 mg

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

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA

Packer: ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA
LILLY S.A., MADRID, SPAIN

Laboratory:FPRC : ELI LILLY & CO, LILLY TECHNOLOGY CENTRE,
INDIANAPOLIS, USA
LILLY S.A., MADRID, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: ELI LILLY, BRYANSTON, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 38/2.7/0296

Name of medicine: M&P PARACETAMOL TABLETS

Dosage form: TABLET

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

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

Applicant: MDI cc

Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory:FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRR: MDI cc, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: 3813.2103 10

Name of medicine: NOVAGESIC

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PARACETAMOL 320,0 mg
CODEINE PHOSPHATE 8,0 mg
CAFFEINE 32,0 mg
MEPROBAMATE 150,0 mg

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

Applicant: MDI cc

Manufacturer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Packer: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE

Laboratory:FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
FPRR: MDI cc, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/21.5.1/034 1

Name of medicine: CIPLA-MOMETASONE

Dosage form: NASAL SPRAY

Active ingredients: EACH METERED SPRAY DELIVERS:
MOMETASONE FUROATE 50,0 ug

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

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

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/21.5.1/0342

Name of medicine: NEXONASE

Dosage form: NASAL SPRAY

Active ingredients: EACH METERED SPRAY DELIVERS:
MOMETASONE FUROATE 50,0 ug

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

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, **INDIA**

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

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

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A38/20.2.8/0378
Name of medicine:	TELZIR TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FOSAMPRENAVIR CALCIUM EQUIVALENT TO FOSAMPRENAVIR 700,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, U.K.
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, U.K. GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory:FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, U.K.
FPRC/FPRR:	GLAXOSMITHKLINES.A., EPPING, CAPE TOWN
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A38/20.2.8/0379

Name of medicine: TELZIR ORAL SUSPENSION

Dosage form: SUSPENSION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
FOSAMPRENAVIR CALCIUM EQUIVALENT TO
FOSAMPRENAVIR 50,0 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO,
CANADA

Packer: GLAXOSMITHKLINE **INC**, MISSISSAUGA, ONTARIO,
CANADA
GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN

Laboratory:FPRC: GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO,
CANADA
GLAXO WELLCOME GmbH & CO, BAD OLDESLOE,
GERMANY
FPRC/FPRR: GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A38/4/0430
Name of medicine:	UBISTESIN
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ARTICAINE HYDROCHLORIDE 40,0 mg ADRENALINE HYDROCHLORIDE EQUIVALENT TO ADRENALINE 0,005 mg
Conditions of registration:	I, 2, 3, 4, 5, 6, 7
Applicant:	3M PHARMACEUTICALS S.A. (PTY) LTD
Manufacturer:	3M ESPE AG, SEEFELD, GERMANY
Packer:	3M ESPE AG, SEEFELD, GERMANY PHARMACEUTICAL ENTERPRISES, PINELANDS, RSA
Laboratory:FPRC:	3M ESPE AG, SEEFELD, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK 3M PHARMACEUTICALS, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A381410431

Name of medicine: UBISTESIN FORTE

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ARTICAINE HYDROCHLORIDE 40,0 mg
ADRENALINE HYDROCHLORIDE EQUIVALENT
TO ADRENALINE 0,01 mg

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

Applicant: 3M PHARMACEUTICALS S.A. (PTY) LTD

Manufacturer: 3M ESPE AG, SEEFELD, GERMANY

Packer: 3M ESPE AG, SEEFELD, GERMANY
PHARMACEUTICAL ENTERPRISES, PINELANDS,
RSA

Laboratory:FPRC : 3M ESPE AG, SEEFELD, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: 3M PHARMACEUTICALS, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0475

Name of medicine: APEX-CLARITHROMYCIN 250 mg TABLETS

Dosage form: TABLET

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

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS

Laboratory:FPRC: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: **60** months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0476

Name of medicine: APEX-CLARITHROMYCIN 500 mg TABLETS

Dosage form: TABLET

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

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS

Laboratory:FPRC: MEDOCHEMIE LTD, ZAKAKI, LIMASSOL, CYPRUS
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, AMALGAM,
JOHANNESBURG, RSA

Shelf-life: 60 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/4/0546

Name of medicine: CHIROCANE BAG 1,25 mg/ml

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LEVOBUPIVACAINE HYDROCHLORIDE
EQUIVALENT TO LEVOBUPIVACAINE 1,25 mg

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

Applicant: ABBOTT LABORATORIES S.A. (PTY) LTD

Manufacturer: ABBOTT LABORATORIES LTD, MOUNT-ROYAL,
QUEBEC, CANADA

Packer: ABBOTT LABORATORIES LTD, MOUNT-ROYAL,
QUEBEC, CANADA

Laboratory:FPRC: ABBOTT LABORATORIES LTD, MOUNT-ROYAL,
QUEBEC, CANADA
FPRC/FPRR: ABBOTT LABORATORIES S.A., CONSTANTIA
KLOOF, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/21.5.1/0629

Name of medicine: INFLAMMIDE 400 NOVOLIZER

Dosage form: INHALATION

Active ingredients: EACH METERED DOSE CONTAINS:
BUDESONIDE 400,0 ug

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

Applicant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer: AWD-PHARMA GmbH & CO, DRESDEN, GERMANY

Packer: AWD-PHARMA GmbH & CO, DRESDEN, GERMANY
ROSCH-DELTA GmbH, RANSTADT/DAUERNHEIM,
GERMANY

Laboratory:FPRC: AWD-PHARMA GmbH & CO, DRESDEN, GERMANY
VIATRIS MANUFACTURING B.V., DIEMEN,
THE NETHERLANDS
AVENTIS PHARMA, WALTLOO, PRETORIA
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: INGELHEIM PHARMACEUTICALS, RANDBURG,
RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/2 1.210648

Name of medicine: CAMOX-METFORMIN 500 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 500,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (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
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: CAMOX PHARMACEUTICALS, AMALGAM, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/21.2/0649

Name of medicine: CAMOX-METFORMIN FORTE 850 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (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
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, AMALGAM, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/7.5/0678

Name of medicine: CAMOX – SIMVASTATIN 10mg

Dosage form: TABLET

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

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/7.5/0679

Name of medicine: CAMOX – SIMVASTATIN 20 mg

Dosage form: TABLET

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

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/7.5/0680

Name of medicine: CAMOX – SIMVASTATIN 40 mg

Dosage form: TABLET

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

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0720

Name of medicine: PHARMA DYNAMICS 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: PHARMA DYNAMICS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory:FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0721

Name of medicine: PHARMA DYNAMICS 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: PHARMA DYNAMICS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory:FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0724

Name of medicine: KLARIZON 250

Dosage form: TABLET

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

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
DIVPHARM MANUFACTURNG & PACKAGING,
LONGDALE, JOHANNESBURG, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory:FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A38/20.1.1/0725

Name of medicine: KLARIZON 500

Dosage form: TABLET

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

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory:FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A38/7.1/0728
Name of medicine:	TEVETEN PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EPROSARTAN MESYLATE EQUIVALENT TO EPROSARTAN 600,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SOLVAY PHARMA (PTY) LTD
Manufacturer:	SOLVAY PHARMACEUTICALS GmbH, NEUSTADT, GERMANY SOLVAY PHARMACEUTICALS B.V, OLST, THE NETHERLANDS
Packer:	SOLVAY PHARMACEUTICALS GmbH, NEUSTADT, GERMANY SOLVAY PHARMACEUTICALS B.V, OLST, THE NETHERLANDS
Laboratory:FPRC:	SOLVAY PHARMACEUTICALS GmbH, NEUSTADT, GERMANY SOLVAY PHARMACEUTICALS B.V, OLST, THE NETHERLANDS SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SOLVAY PHARMA, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A39/7.5/0031
Name of medicine:	INEGY 10/10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg EZETIMIBE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK SHARP & DOHME S.p.A, PAVIA, ITALY MSD TECHNOLOGY Pte. LTD, SINGAPORE
Packer:	MERCK SHARP & DOHME S.p.A, PAVIA, ITALY MERCK SHARP & DOHME BV, HAARLEM, THE NETHERLANDS MERCK SHARP & DOHME LTD, CRAMLINGTON, NORTHUMBERLAND, ENGLAND MSD, HALFWAY HOUSE, RSA
Laboratory:FPRC:	MERCK SHARP & DOHME S.p.A, PAVIA, ITALY MSD TECHNOLOGY Pte. LTD, SINGAPORE
FPRC/FPRR:	MSD, HALFWAY HOUSE, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/7.5/0032

Name of medicine: INEGY 10120

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg
EZETIMIBE 10,0 mg

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

Applicant: MSD (PTY) LTD

Manufacturer: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE

Packer: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MERCK SHARP & DOHME BV, HAAFUEM,
THE NETHERLANDS
MERCK SHARP & DOHME LTD, CRAMLINGTON,
NORTHUMBERLAND, ENGLAND
MSD, HALFWAY HOUSE, RSA

Laboratory:FPRC : MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE
FPRC:FPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A3917.510033

Name of medicine: INEGY 10140

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 40,0 mg
EZETIMIBE 10,0 mg

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

Applicant: MSD (PTY) LTD

Manufacturer: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE

Packer: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MERCK SHARP & DOHME BV, HAARLEM,
THE NETHERLANDS
MERCK SHARP & DOHME LTD, CRAMLINGTON,
NORTHUMBERLAND, ENGLAND
MSD, HALFWAY HOUSE, RSA

Laboratory:FPRC: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE
FPRCIFPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/7.5/0034

Name of medicine: INEGY 10/80

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 80,0 mg
EZETIMIBE 10,0 mg

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

Applicant: MSD (PTY) LTD

Manufacturer: MERCK **SHARP** & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE

Packer: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MERCK SHARP & DOHME BV, HAARLEM,
THE NETHERLANDS
MERCK SHARP & DOHME LTD, CRAMLINGTON,
NORTHUMBERLAND, ENGLAND
MSD, HALFWAY HOUSE, RSA

Laboratory:FPRC: MERCK SHARP & DOHME S.p.A, PAVIA, ITALY
MSD TECHNOLOGY Pte. LTD, SINGAPORE
FPRC/FPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/20.1.1/0085

Name of medicine: BETRIAXON - 250

Dosage form: INJECTION

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Packer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: **24** months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/20,1,1/0086

Name of medicine: BETRIAXON - 500

Dosage form: INJECTION

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Packer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Laboratory:FPRC : AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/20.1.1/0087

Name of medicine: BETRIAXON - 1000

Dosage form: INJECTION

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Packer: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, PATANCHERU
MANDAL, MEDAK, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/7.1.3/0 136

Name of medicine: QUINAHEXAL 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 5,0 mg

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

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

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/7.1.3/0 137

Name of medicine: QUINAHEXAL 10

Dosage form: TABLET

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

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

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

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/21.8.2/0 161

Name of medicine: CLARO 35

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CYPROTERONE ACETATE 2,0 mg
ETHINYLESTRADIOL 0,035 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: HAUPT PHARMA MUNSTER GmbH, MUNSTER,
GERMANY

Packer: HAUPT PHARMA MUNSTER GmbH, MUNSTER,
GERMANY

Laboratory:FPRC : HAUPT PHARMA MUNSTER GmbH, MUNSTER,
GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/5.8/0196

Name of medicine: PANADO MEDSIP FOR CHILDREN

Dosage form: POWDER

Active ingredients: EACH SACHET CONTAINS:
PARACETAMOL 250,0 mg
ASCORBIC ACID 20,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory:FPRC : PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: **24** months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/5.8/0197

Name of medicine: L.C.C. HOT MEDICATION FOR CHILDREN

Dosage form: POWDER

Active ingredients: EACH SACHET CONTAINS:
PARACETAMOL 250,0 mg
ASCORBIC ACID 20,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory:FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/1.2/0337
Name of medicine:	AUSTELL-CITALOPRAM 10 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 10,0 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 INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG' RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/1.2/0338

Name of medicine: AUSTELL-CITALOPRAM 20 mg

Dosage form: TABLET

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

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

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
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/1,2/0339

Name of medicine: AUSTELL-CITALOPRAM40 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CITALOPRAM HYDROBROMIDE EQUIVALENT TO
CITALOPRAM 40,0 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
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A3911 1.210353

Name of medicine: HYOSPASMOL SYRUP

Dosage form: LIQUID

Active ingredients: EACH 5,0 ml LIQUID CONTAINS:
HYOSCINE-N-BUTYL BROMIDE 5,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory:FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM

FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/7.1/0370
Name of medicine:	AMLOPRESS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR:	CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: **A39/7.1/0371**

Name of medicine: **AMLOPRESS 10mg**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
AMLODIPINE BESYLATE EQUIVALENT TO
AMLODIPINE 10,0 MG**

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

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA**

Packer: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA**

Laboratory:FPRC: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA****

Shelf-life: **24 months (provisional)**

Date of registration: **11 AUGUST 2006**

MRF 15

Registration number: A39/1 1.5/0385

Name of medicine: PEGICOL

Dosage form: POWDER

Active ingredients: EACH SACHET CONTAINS:
MACROGOL 3350 6,563 g
SODIUM CHLORIDE 175,4 mg
SODIUM BICARBONATE 89,3 mg
POTASSIUM CHLORIDE 23,3 mg

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

Applicant: NORGINE (PTY) LTD

Manufacturer: NORGINE LTD, HENGOED, MID-GLAMORGAN, UK

Packer: NORGINE LTD, HENGOED, MID-GLAMORGAN, UK

Laboratory:FPRC: NORGINE LTD, HENGOED, MID-GLAMORGAN, UK
READING SCIENTIFIC SERVICES LTD, WHITE
KNIGHTS, READING, UK
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: NORGINE, PARKMORE, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/2.5/0429

Name of medicine: NEUREXAL 100mg

Dosage form: CAPSULES

Active ingredients: EACH CAPSULE CONTAINS:
GABAPENTIN 100,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA

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

Laboratory:FPRC: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/2.5/0430
Name of medicine:	NEUREXAL 300 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5 , 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	CARDINAL HEALTH, SCHORNDORF, GERMANY PHARMA SCIENCE INC, QUEBEC, CANADA
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	CARDINAL HEALTH, SCHORNDORF, GERMANY PHARMA SCIENCE INC, QUEBEC, CANADA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/2.5/0431

Name of medicine: NEUREXAL 400 mg

Dosage form: CAPSULES

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

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA

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

Laboratory:FPRC : CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/2.5/0432

Name of medicine: GABAPENTIN HEXAL 100

Dosage form: CAPSULES

Active ingredients: EACH CAPSULE CONTAINS:
GABAPENTIN 100,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA

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

Laboratory:FPRC : CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK, RSA
HEXAL PHARMA, PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/2.5/0433

Name of medicine: GABAPENTIN HEXAL 300

Dosage form: CAPSULES

Active ingredients: EACH CAPSULE CONTAINS:
GABAPENTIN 300,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA

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

Laboratory:FPRC: CARDINAL HEALTH, SCHORNDORF, GERMANY
PHARMA SCIENCE INC, QUEBEC, CANADA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/2.5/0434
Name of medicine:	GABAPENTIN HEXAL 400
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	CARDINAL HEALTH, SCHORNDORF, GERMANY PHARMA SCIENCE INC, QUEBEC, CANADA
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:FPRC:	CARDINAL HEALTH, SCHORNDORF, GERMANY PHARMA SCIENCE INC, QUEBEC, CANADA SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENURE, KEMPTON PARK, RSA HEXAL PHARMA, PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A39/20.1.2/0488
Name of medicine:	AUSTELL-CO-AMOXICLAV 375 mg
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:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, GANDHIDHAM, GUJARAT, INDIA
Packer:	IPCA LABORATORIES LTD, GANDHIDHAM, GUJARAT, INDIA
Laboratory:FPRC:	IPCA LABORATORIES LTD, GANDHIDHAM, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSPECTORATE M&L, OFWONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, RSA
Shelf-life:	18 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/20.1.2/0489

Name of medicine: AUSTELL-CO-AMOXICLAV 625 mg

Dosage form: TABLET

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

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, GANDHIDHAM,
GUJARAT, INDIA

Packer: IPCA LABORATORIES LTD, GANDHIDHAM,
GUJARAT, INDIA

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

FPRR: AUSTELL LABORATORIES, SPRINGFIELD, RSA

Shelf-life: 18 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/26/0496
Name of medicine:	ELOXATIN 50mg/10 ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO(PTY) LTD
Manufacturer:	THISSEN LABORATORIES, BRAINE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	THISSEN LABORATORIES, BRAINE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	THISSEN LABORATORIES, BRANE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A39/26/0497
Name of medicine:	ELOXATIN 100mg/20 ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO(PTY) LTD
Manufacturer:	THISSEN LABORATORIES, BRAINE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	THISSEN LABORATORIES, BRAINE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	THISSEN LABORATORIES, BRAINE L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A3912610498
Name of medicine:	ELOXATIN 50mg/10 ml RTU
Dosage form:	INFUSION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO(PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC :	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA
FPRC/FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A39/26/0499
Name of medicine:	ELOXATIN 100mg/20 ml RTU
Dosage form:	INFUSION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	I, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:FPRC:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME de BONDEVILLE, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK AVENTIS PHARMA, WALTLOO, PRETORIA FPRC/FPRR: FPRR:
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/1.2/0548

Name of medicine: CILATE

Dosage form: TABLET

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS,ROODEPOORT,RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A39/5.10/0581
Name of medicine:	VOMIZ 4 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life :	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A39/5.10/0582
Name of medicine:	VOMIZ 8 mg INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH AMPOULE CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:FPRC:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (provisional)
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A39/1.2/0635

Name of medicine: DANTRIX 50

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: MEKCK GENERICS RSA (PTY) LTD

Manufacturer: GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON

Packer: GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory:FPRC: GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON
GERARD LABORATORIES, DUBLIN, IRELAND
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: 11 AUGUST 2006

MRF 15

Registration number:	A39/1.2/0636
Name of medicine:	DANTRIX 100
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:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON
Packer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND 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:	11 AUGUST 2006

MRF 15

Registration number: A39/21.2/0638

Name of medicine: BIGSENS 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 500,0 mg

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

Applicant: ZYDUS HEALTHCARE S.A.(PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL &
CHEMICAL SERVICES, SILVERTONDALE, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A39/21.2/0639

Name of medicine: BIGSENS 850

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 mg

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

Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL &
CHEMICAL SERVICES, SILVERTONDALE, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/7.1/0057

Name of medicine: CORVADIL 5

Dosage form: TABLET

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

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

Applicant: UNICHEM S.A. (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Packer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Laboratory:FPRC: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL &
CHEMICAL SERVICES, SILVERTONDALE, RSA
FPRR: UNICHEM S.A., POTCHEFSTROOM, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/7.1/0058

Name of medicine: CORVADIL 10

Dosage form: TABLET

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

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

Applicant: UNICHEM S.A. (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Packer: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA

Laboratory:FPRC: UNICHEM LABORATORIES LTD, BARDEZ, GOA,
INDIA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL &
CHEMICAL SERVICES, SILVERTONDALE, RSA
FPRR: UNICHEM S.A., POTCHEFSTROOM, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/2 1.210149

Name of medicine: CIPLA-PIOGLITAZONE HYDROCHLORIDE 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PIOGLITAZONE HYDROCHLORIDE EQUIVALENT
TO PIOGLITAZONE 15,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, SALCETTE, GOA, INDIA

Laboratory:FPRC: CIPLA LTD, SALCETTE, GOA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: **24** months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/21.2/0150

Name of medicine: CIPLA-PIOGLITAZONE HYDROCHLORIDE 30

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PIOGLITAZONE HYDROCHLORIDE EQUIVALENT
TO PIOGLITAZONE 30,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, SALCETTE, GOA, INDIA

Laboratory:FPRC: CIPLA LTD, SALCETTE, GOA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/2.6.5/0204

Name of medicine: RISPERDAL QUICKLET 3 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO

Packer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG SpA, LATINA, ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE

Laboratory:FPRC : JANSSEN ORTHO LLC, GURABO, PUERTO RICO
JANSSEN-CILAG SpA, LATINA, ITALY
FPRCIFPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE

Shelf-life: **24** months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/2.6.5/0205

Name of medicine: RISPERDAL QUICKLET 4 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 4,0 mg

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: JANSSEN ORTHO LLC, GURABO, PUERTO RICO

Packer: JANSSEN ORTHO LLC, GUMBO, PUERTO RICO
JANSSEN-CILAG SpA, LATINA, ITALY
JANSSEN PHARMACEUTICA, HALFWAY HOUSE

Laboratory:FPRC: JANSSEN ORTHO LLC, GUMBO, PUERTO RICO
JANSSEN-CILAG SpA, LATINA, ITALY
FPRC/FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.8/0244

Name of medicine: CIPLA DUOVIR

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: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory:FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK,
BELLVILLE, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A40/2.5/0273
Name of medicine:	AUSTELL-LAMOTRIGINE 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:	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 INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A40/2.5/0274
Name of medicine:	AUSTELL-LAMOTRIGINE 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:	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, GROENJSLOOF, PRETORIA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A40/2.5/0275
Name of medicine:	AUSTELL-LAMOTRIGINE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	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 INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A40/2.5/0276
Name of medicine:	AUSTELL-LAMOTRIGINE 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:	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 INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	AUSTELL LABORATORIES, AMALGAM, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A40/7.1/03 12

Name of medicine: AMLATE 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: DR. REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR. REDDY'S LABORATORIES LTD, RANGA
REDDY, ANDHRA PRADESH, INDIA

Packer: DR. REDDY'S LABORATORIES LTD, RANGA
REDDY, ANDHRA PRADESH, INDIA

Laboratory:FPRC: DR. REDDY'S LABORATORIES LTD, RANGA
REDDY, ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: DR. REDDY'S LABORATORIES, ROSEBANK,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A40/7.1/03 13
Name of medicine:	AMLATE 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:	DR. REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR. REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR. REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	DR. REDDY'S LABORATORIES LTD, RANGA REDDY, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	DR. REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number:	A40/20.1.1/0333
Name of medicine:	BINOZYT 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN MONOHYDRATE EQUIVALENT TO AZITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	NOVARTIS BANGLADESH, GAZIPUR, BANGLADESH LEK PHARMA TECH S.R.L., TARGU MURES, ROMANIA
Packer:	NOVARTIS BANGLADESH, GAZIPUR, BANGLADESH LEK PHARMA TECH S.R.L., TARGU MURES, ROMANIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	NOVARTIS BANGLADESH, GAZIPUR, BANGLADESH LEK PHARMA TECH S.R.L., TARGU MURES, ROMANIA NOVARTIS, SPARTAN, KEMPTON PARK ANALYTICON, TERENURE, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	11 AUGUST 2006

MRF 15

Registration number: A40120.1.1 10334

Name of medicine: SANDOZ AZITHROMYCIN 500

Dosage form: TABLET

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

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
LEK PHARMA TECH S.R.L., TARGU MURES,
ROMANIA

Packer: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
LEK PHARMA TECH S.R.L., TARGU MURES,
ROMANIA
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS BANGLADESH, GAZIPUR,
BANGLADESH
LEK PHARMA TECH S.R.L., TARGU MURES,
ROMANIA
NOVARTIS, SPARTAN, KEMPTON PARK
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Dare of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.2/0343

Name of medicine: DERMAX 125

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT TO
TERBINAFINE 125,0 mg

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

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Laboratory:FPRC: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICAL SRVICES,
SILVERTONDALE, RSA
FPRR: DR REDDY'S LABORATORIES, ROSEBANK, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.2/0344

Name of medicine: DERMAX 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT TO
TERBINAFINE 250,0 mg

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

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Laboratory:FPRC: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICAL SRVICES,
SILVERTONDALE, RSA
FPRR: DR REDDY'S LABORATORIES, ROSEBANK, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/1.2/0366

Name of medicine: BERON 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MIRTAZAPINE 15,0 mg

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/1.2/0367

Name of medicine: BERON 30

Dosage form: TABLET

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, ANDHRA PRADESH, INDIA
FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT,RSA

Shelf-life: 24 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.8/0376

Name of medicine: AURO-LAMIVUDINETABLETS 150 mg

Dosage form: TABLET

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

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

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.8/0381

Name of medicine: AURO-LAMIZIDO

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: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Laboratory:FPRC : AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG, RSA

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.8/0382

Name of medicine: AURO-NEVIRAPINE TABLETS 200 MG

Dosage form: TABLET

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

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

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG

Shelf-life: **24** months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.8/0383

Name of medicine: AURO-ZIDOVUDINE TABLETS 300 mg

Dosage form: TABLET

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

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

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG

Shelf-life: 24 months (provisional)

Date of registration: 11 AUGUST 2006

MRF 15

Registration number: A40/20.2.2/040 1

Name of medicine: FINDERM 125

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT TO
TERBINAFINE 125,0 mg

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

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA

Laboratory:FPRC: DR REDDY'S LABORATORIES LTD,
ANDHRA PRADESH, INDIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: DR REDDY'S LABORATORIES, ROSEBANK,
JOHANNESBURG, RSA

Shelf-life: 36 months

Date of registration: 11 AUGUST 2006

MRF 15

Registration number:	A40/20.2.2/0402
Name of medicine:	FINDERM 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	DR REDDY'S LABORATORIES LTD, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRR:	DR REDDY'S LABORATORIES, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	11 AUGUST 2006
