
GENERAL NOTICE

NOTICE 761 OF 2011

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number: 07/17.3/31

Name of medicine: OTILAN

Dosage form: DROPS

Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
MICONAZOLE NITRATE 23,0 mg
POLYMXIN B 5500,0 iu
PREDNISOLONE ACETATE
5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PALGHAR, THANE,
MAHARASHTRA, INDIA

Packer: CIPLA LTD, PALGHAR, THANE,
MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, PALGHAR, THANE,
MAHARASHTRA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK,
BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/20.2.8/0001

Name of medicine: TRIPLAVAR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg
ZIDOVUDINE 300,0 mg
NEVIRAPINE 200,0 mg

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, (UNIT III), VERNA,
GOA, INDIA

Packer: CIPLA LTD, (UNIT III), VERNA,
GOA, INDIA

Laboratory: FPRC: CIPLA LTD, (UNIT III), VERNA,
GOA, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK,
BELLVILLE

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/20.2.8/0073

Name of medicine: STRIDES EFAVIRENZ 200 mg

Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: STRIDES SA
PHARMACEUTICALS (PTY) LTD

Manufacturer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA

Packer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA
COLUMBIA
PHARMACEUTICALS, BARDENE,
BOKSBURG
INSTITUTE FOR
PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
NOVARTIS SA, SPARTAN,
KEMPTON PARK

FPRR: STRIDES SA
PHARMACEUTICALS, ARCADIA,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15	
Registration number:	42/20.2.8/0074
Name of medicine:	STRIDES EFAVIRENZ 600 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
Laboratory: FPRC:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	15 APRIL 2011

MRF15	
Registration number:	42/21.3/0670
Name of medicine:	SYNTHROID 25 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 25,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ABBOTT LABORATORIES SA (PTY) LTD
Manufacturer:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
Packer:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
Laboratory: FPRC:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS, USA
FPRC/FPRR:	ABBOTT LABORATORIES SA, CONSTANTIA KLOOF, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 APRIL 2011

MRF 15	
Registration number:	42/21.3/0671
Name of medicine:	SYNTHROID 50 µg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 50,0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ABBOTT LABORATORIES SA (PTY) LTD
Manufacturer:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
Packer:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
Laboratory: FPRC:	ABBOTT LABORATORIES, JAYUYA, PUERTO RICO ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS, USA
FPRC/FPRR:	ABBOTT LABORATORIES SA, CONSTANTIA KLOOF, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	15 APRIL 2011

MRF 15

Registration number: 42/21.3/0672

Name of medicine: SYNTHROID 75 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 75,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Laboratory: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
FPRC: ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS, USA

FPRC/FPRR: ABBOTT LABORATORIES SA, CONSTANTIA KLOOF, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/21.3/0673

Name of medicine: SYNTHROID 88 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 88,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Laboratory: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
FPRC: ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS, USA

FPRC/FPRR: ABBOTT LABORATORIES SA, CONSTANTIA KLOOF, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0674

Name of medicine: SYNTHROID 100 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LEVOTHYROXINE SODIUM 100,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Laboratory: FPRC: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO
ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS, USA

FPRC/FPRR: ABBOTT LABORATORIES SA, CONSTANTIA KLOOF, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0675

Name of medicine: SYNTHROID 112 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
112,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES SA
(PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Laboratory: FPRC: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO, ILLINOIS,
USA

FPRC/FPRR: ABBOTT LABORATORIES SA,
CONSTANTIA KLOOF,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/21.3/0676

Name of medicine: SYNTHROID 125 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
125,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES
SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Laboratory: FPRC: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO,
ILLINOIS, USA

FPRC/FPRR: ABBOTT LABORATORIES
SA, CONSTANTIA KLOOF,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0677

Name of medicine: SYNTHROID 137 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
137,0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES
SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO,
ILLINOIS, USA

Laboratory: FPRC: ABBOTT LABORATORIES
SA, CONSTANTIA KLOOF,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0678
Name of medicine: SYNTHROID 150 µg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE
SODIUM 150,0 µg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ABBOTT LABORATORIES
SA (PTY) LTD
Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Laboratory: FPRC: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO,
ILLINOIS, USA
FPRC/FPRR: ABBOTT LABORATORIES SA
CONSTANTIA KLOOF,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/21.3/0679
Name of medicine: SYNTHROID 175 µg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
175,0 µg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ABBOTT LABORATORIES SA
(PTY) LTD
Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Laboratory: FPRC: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO, ILLINOIS,
USA
FPRC/FPRR: ABBOTT LABORATORIES
SA, CONSTANTIA KLOOF,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0680
Name of medicine: SYNTHROID 200 µg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
200,0 µg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ABBOTT LABORATORIES SA
(PTY) LTD
Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
Laboratory: FPRC: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO, ILLINOIS,
USA
FPRC/FPRR: ABBOTT LABORATORIES SA,
CONSTANTIA KLOOF,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0681

Name of medicine: SYNTHROID 300 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
300.0 µg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ABBOTT LABORATORIES
SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Laboratory: FPRC : ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO
ABBOTT LABORATORIES,
NORTH CHICAGO, ILLINOIS,
USA

FPRC/FPRR: ABBOTT LABORATORIES
SA, CONSTANTIA KLOOF,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/20.2.8/0884

Name of medicine: STRIDES-STAVUDINE 30 mg &
LAMIVUDINE 150 mg &
NEVIRAPINE 200 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
STAVUDINE 30,0 mg
LAMIVUDINE 150,0 mg
NEVIRAPINE 200,0 mg

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

Applicant: STRIDES SA
PHARMACEUTICALS (PTY) LTD

Manufacturer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA

Packer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA

Laboratory: FPRC: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA
COLUMBIA
PHARMACEUTICALS,
BARDENE, BOKSBURG

FPRR: STRIDES SA
PHARMACEUTICALS, ARCADIA,
PRETORIA

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/15.4/1006

Name of medicine: NEVANAC

Dosage form: EYE DROPS

Active ingredients: EACH 1,0 ml
SUSPENSION
CONTAINS:
NEPAFENAC 1,0 mg

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

Applicant: ALCON LABORATORIES
(PTY) LTD

Manufacturer: S.A. ALCON COUVREUR
N.V., PUURS, BELGIUM

Packer: S.A. ALCON COUVREUR
N.V., PUURS, BELGIUM

Laboratory: FPRC S.A. ALCON COUVREUR
N.V., PUURS, BELGIUM
RESEARCH INSTITUTE
FOR INDUSTRIAL
PHARMACY, NORTH
WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ALCON LABORATORIES
(SA), BRYANSTON,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/7.5/1050

Name of medicine: ATORVASTATIN UNICORN 10

Dosage form: TABLET

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

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

Applicant: PHARMACIA SOUTH AFRICA
(PTY) LTD

Manufacturer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS LLC,
VEGA BAJA, PUERTO RICO
PFIZER IRELAND
PHARMACEUTICALS,
RINGASKIDDY COUNTY CORK,
IRELAND

Packer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS LLC, VEGA
BAJA, PUERTO RICO

Laboratory: FPRC: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS LLC,
VEGA BAJA, PUERTO RICO
PFIZER LABORATORIES,
RETREAT, CAPE TOWN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
M&L LABORATORY SERVICES,
LIMBRO BUSINESS PARK,
SANDTON
LABORATORY & BIOLOGICAL
SERVICES, BRACKENHURST,
ALBERTON

FPRR: PHARMACIA SA, SANDTON,
JOHANNESBURG

Shelf-life: 36 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/7.5/1051

Name of medicine: ATORVASTATIN UNICORN 20

Dosage form: TABLET

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

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

Applicant: PHARMACIA SOUTH AFRICA
(PTY) LTD

Manufacturer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO
PFIZER IRELAND
PHARMACEUTICALS,
RINGASKIDDY COUNTY
CORK, IRELAND

Packer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO

Laboratory: FPRC: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO
PFIZER LABORATORIES,
RETREAT, CAPE TOWN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
M&L LABORATORY
SERVICES, LIMBRO
BUSINESS PARK, SANDTON
LABORATORY & BIOLOGICAL
SERVICES, BRACKENHURST,
ALBERTON

FPRR: PHARMACIA SA, SANDTON,
JOHANNESBURG

Shelf-life: 36 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/7.5/1052

Name of medicine: ATORVASTATIN UNICORN 40

Dosage form: TABLET

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

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

Applicant: PHARMACIA SOUTH AFRICA
(PTY) LTD

Manufacturer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO
PFIZER IRELAND
PHARMACEUTICALS,
RINGASKIDDY COUNTY
CORK, IRELAND

Packer: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO

Laboratory: FPRC: GODECKE GmbH, FREIBURG,
GERMANY
PFIZER PHARMACEUTICALS
LLC, VEGA BAJA, PUERTO
RICO
PFIZER LABORATORIES,
RETREAT, CAPE TOWN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
M&L LABORATORY
SERVICES, LIMBRO
BUSINESS PARK, SANDTON
LABORATORY & BIOLOGICAL
SERVICES, BRACKENHURST,
ALBERTON

FPRR: PHARMACIA SA, SANDTON,
JOHANNESBURG

Shelf-life: 36 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/2.6.5/1074

Name of medicine: DRL-QUETIAPINE 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 25,0 mg

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

Applicant: DR REDDY'S
LABORATORIES (PTY) LTD

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

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

Laboratory: FPRC: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/2.6.5/1075

Name of medicine: DRL-QUETIAPINE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 100,0 mg

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

Applicant: DR REDDY'S
LABORATORIES (PTY) LTD

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

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

Laboratory: FPRC: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE
FOR INDUSTRIAL
PHARMACY, NORTH-WEST
UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/2.6.5/1076

Name of medicine: DRL-QUETIAPINE 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 200,0 mg

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

Applicant: DR REDDY'S LABORATORIES
(PTY) LTD

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

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

Laboratory: FPRC: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/2.6.5/1077
Name of medicine: DRL-QUETIAPINE 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S
LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
Packer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months
Date of registration: 15 APRIL 2011

MRF15

Registration number: 43/2.6.5/0069
Name of medicine: OLEANZ RAPITAB 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND,
RSA
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 43/2.6.5/0070
Name of medicine: OLEANZ RAPITAB 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD, HALOL,
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND,
RSA
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number:	43/2.6.5/0429
Name of medicine:	DOPAQUEL 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	15 APRIL 2011

MRF15

Registration number:	43/2.6.5/0430
Name of medicine:	DOPAQUEL 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	15 APRIL 2011

MRF 15

Registration number:	43/2.6.5/0431
Name of medicine:	DOPAQUEL 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	15 APRIL 2011

MRF 15

Registration number: 43/2.6.5/0432
Name of medicine: DOPAQUEL 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S LABORATORIES
(PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS,
IRENE, CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months
Date of registration: 15 APRIL 2011

MRF15

Registration number: 43/20.1.1/0758
Name of medicine: NOVAPIME 500 mg
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE
EQUIVALENT TO
CEFEPIME 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA
Packer: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA
Laboratory: FPRC: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: PHARMA DYNAMICS,
SILVERWOOD, WESTLAKE
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 43/20.1.1/0759
Name of medicine: NOVAPIME 1 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE
EQUIVALENT TO
CEFEPIME 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: LUPIN LTD, MANDIDEEP, RAISEN,
INDIA
Packer: LUPIN LTD, MANDIDEEP, RAISEN,
INDIA
Laboratory: FPRC: LUPIN LTD, MANDIDEEP, RAISEN,
INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD,
WESTLAKE
Shelf-life: 24 months (Provisional)
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 43/20.1.1/0760

Name of medicine: NOVAPIME 2 g

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFEPIME HYDROCHLORIDE
EQUIVALENT TO
CEFEPIME 2,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA

Packer: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA

Laboratory: FPRC: LUPIN LTD, MANDIDEEP,
RAISEN, INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: PHARMA DYNAMICS,
SILVERWOOD, WESTLAKE

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 44/20.2.8/0835

Name of medicine: ADCO-EMTEVIR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EMTRICITABINE 200,0 mg
TENOFIVIR DISOPROXIL
FUMARATE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Packer: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Laboratory: FPRC: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

FPRC/ FPRR: ADCOCK INGRAM LTD,
AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM
LTD, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 44/20.2.8/0836

Name of medicine: TEMECIT

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EMTRICITABINE 200,0 mg
TENOFIVIR DISOPROXIL
FUMARATE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Packer: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Laboratory: FPRC: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

FPRC/FPRR: ADCOCK INGRAM LTD,
AEROTON,
JOHANNESBURG
ADCOCK INGRAM LTD,
ERAND GARDENS,
MIDRAND

FPRR: ADCOCK INGRAM LTD,
ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 44/20.2.8/0837

Name of medicine: TENOBINE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EMTRICITABINE 200,0 mg
TENOFVIR DISOPROXIL
FUMARATE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: HETERO DRUG LTD,
METLA, HYDERABAD, INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Packer: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

Laboratory: FPRC: HETERO DRUG LTD,
JEEDIMETLA, HYDERABAD,
INDIA
ADCOCK INGRAM
HEALTHCARE, WADEVILLE,
GERMISTON

FPRC/FPRR: ADCOCK INGRAM LTD,
AEROTON,
JOHANNESBURG

FPRR: ADCOCK INGRAM LTD,
ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 08/3.1.2/012

Name of medicine: METACAM 5 mg/ml FOR
DOGS AND CATS

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
MELOXICAM 5,0 mg

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

Applicant: INGELHEIM
PHARMACEUTICALS
(PTY) LTD

Manufacturer: LABIANA LIFE SCIENCES
S.A., LES FONTS DE
TERRASSA,
BARCELONA, SPAIN

Packer: LABIANA LIFE SCIENCES
S.A., LES FONTS DE
TERRASSA,
BARCELONA, SPAIN

Laboratory: FPRC: LABIANA LIFE SCIENCES
S.A., LES FONTS DE
TERRASSA,
BARCELONA, SPAIN
WINTHROP
PHARMACEUTICALS,
WALTLOO, PRETORIA

FPRR: INGELHEIM
PHARMACEUTICALS,
FERNDAL, RANDBURG

Shelf-life: 36 months

Date of registration: 03 June 2011

Registration number: 08/3.1.2/013

Name of medicine: METACAM 15 mg/ml FOR
HORSES

Dosage form: SUSPENSION

Active ingredients: EACH 1,0 ml SUSPENSION
CONTAINS:
MELOXICAM 15,0 mg

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

Applicant: INGELHEIM
PHARMACEUTICALS (PTY) LTD

Manufacturer: BOEHRINGER INGELHEIM
VETMEDICA, ELWOOD,
KANSAS, USA

Packer: BOEHRINGER INGELHEIM
VETMEDICA, ELWOOD,
KANSAS, USA
BOEHRINGER INGELHEIM
VETMEDICA, ST JOSEPH,
MISSOURI, USA

Laboratory: FPRC: BOEHRINGER INGELHEIM
VETMEDICA, ELWOOD,
KANSAS, USA
WINTHROP
PHARMACEUTICALS,
WALTLOO, PRETORIA

FPRR: INGELHEIM
PHARMACEUTICALS,
FERNDAL, RANDBURG

Shelf-life: 36 months

Date of registration: 03 June 2011

MRF 15

Registration number: 43/5.2/0277

Name of medicine: DEZZOMIN 50

Dosage form: TABLET

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

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

Applicant: DEZZO TRADING 392 (PTY)
LTD t/a INDO PHARMA

Manufacturer: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA

Packer: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA

Laboratory: FPRC: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: DEZZO TRADING t/a INDO
PHARMA, ANCHORVILLE,
LENASIA

Shelf-life: 36 months

Date of registration: 03 June 2011

MRF15

Registration number: 43/5.2/0278

Name of medicine: DEZZOMIN 100

Dosage form: TABLET

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

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

Applicant: DEZZO TRADING 392 (PTY)
LTD t/a INDO PHARMA

Manufacturer: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA

Packer: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA

Laboratory: FPRC: INDOCO REMEDIES LTD,
VERNA, GOA, INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: DEZZO TRADING t/a INDO
PHARMA, ANCHORVILLE,
LENASIA

Shelf-life: 36 months

Date of registration: 03 June 2011

MRF 15

Registration number: 43/5.2/0279

Name of medicine: DEZZO ATENOLOL 50

Dosage form: TABLET

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

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

Applicant: DEZZO TRADING 392 (PTY) LTD t/a
INDO PHARMA

Manufacturer: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA

Packer: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA

Laboratory: FPRC: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: DEZZO TRADING t/a INDO
PHARMA, ANCHORVILLE, LENASIA

Shelf-life: 36 months

Date of registration: 03 June 2011

MRF 15

Registration number: 43/5.2/0280

Name of medicine: DEZZO ATENOLOL 100

Dosage form: TABLET

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

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

Applicant: DEZZO TRADING 392 (PTY) LTD t/a
INDO PHARMA

Manufacturer: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA

Packer: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA

Laboratory: FPRC: INDOCO REMEDIES LTD, VERNA,
GOA, INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: DEZZO TRADING t/a INDO PHARMA,
ANCHORVILLE, LENASIA

Shelf-life: 36 months

Date of registration: 03 June 2011

MRF15

Registration number: 42/20.2.8/0177

Name of medicine: LASTAVINE 30 mg/150 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
STAVUDINE 30,0 mg
LAMIVUDINE 150,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

Packer: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

Laboratory: FPRC: STRIDES ARCOLAB LTD, ANEKAL
TALUK, BANGALORE, INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA, RSA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG, RSA
RESEARCH INSTITUTE FOR
INDUSTRIA PHARMACY NORTH-
WEST UNIVERSITY,
POTCHEFSTROOM, RSA

FPRC/ FPRR: PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

FPRR: PHARMACARE LTD,
WODMEAD, SANDTON,
RSA

Shelf-life: 24 months

Date of registration: 01 October 2010

MRF 15

Registration number: 42/20.2.8/0178

Name of medicine: LASTAVINE 40 mg/150 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
STAVUDINE 40,0 mg
LAMIVUDINE 150,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA
PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

Packer: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA
PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

Laboratory: FPRC: STRIDES ARCOLAB LTD,
ANEKAL TALUK, BANGALORE,
INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA,
RSA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG,
RSA
RESEARCH INSTITUTE FOR
INDUSTRIA PHARMACY
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM, RSA

FPRC/ FPRR: PHARMACARE LTD, KORSTEN,
PORT ELIZABETH, RSA

FPRR: PHARMACARE LTD,
WODMEAD,
SANDTON, RSA

Shelf-life: 24 months

Date of registration: 01 October 2010

MRF 15

Registration number: 07/25.3.21/03
 Name of medicine: ATOPICA 10
 Dosage form: SOFT CAPSULES
 Active ingredients: EACH CAPSULE CONTAINS:
 CICLOSPORIN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 R.P. SCHERER GmbH & Co. KG, EBERBACH, GERMANY
 Manufacturer:
 Packer: ALLPACK GROUP AG, KAGENSTRASSE, REINACH, SWITZERLAND
 ALLPACK GROUP AG, PFEFFINGERSTR., REINACH, SWITZERLAND
 Laboratory: FPRC: NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
 NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 Shelf-life: 36 months
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 07/25.3.21/04
 Name of medicine: ATOPICA 25
 Dosage form: SOFT CAPSULES
 Active ingredients: EACH CAPSULE CONTAINS:
 CICLOSPORIN 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: R.P. SCHERER GmbH & Co. KG, EBERBACH, GERMANY
 Packer: ALLPACK GROUP AG, KAGENSTRASSE, REINACH, SWITZERLAND
 ALLPACK GROUP AG, PFEFFINGERSTR., REINACH, SWITZERLAND
 Laboratory: FPRC: NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
 NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 Shelf-life: 36 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 07/25.3.21/05
 Name of medicine: ATOPICA 50
 Dosage form: SOFT CAPSULES
 Active ingredients: EACH CAPSULE CONTAINS:
 CICLOSPORIN 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: R.P. SCHERER GmbH & Co. KG, EBERBACH, GERMANY
 Packer: ALLPACK GROUP AG, KAGENSTRASSE, REINACH, SWITZERLAND
 ALLPACK GROUP AG, PFEFFINGERSTR., REINACH, SWITZERLAND
 Laboratory: FPRC: NOVARTIS SANTE ANIMALE S.A.S, HUNINGUE, FRANCE
 NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 FPRR: NOVARTIS SOUTH AFRICA (PTY) LTD, SPARTAN, KEMPTON PARK
 Shelf-life: 36 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 07/25.3.21/06
Name of medicine: ATOPICA 100
Dosage form: SOFT CAPSULES
Active ingredients: EACH CAPSULE CONTAINS:
CICLOSPORIN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH AFRICA
(PTY) LTD

Manufacturer: R.P. SCHERER GmbH & Co.
KG, EBERBACH, GERMANY

Packer: ALLPACK GROUP AG,
KAGENSTRASSE, REINACH,
SWITZERLAND
ALLPACK GROUP AG,
PFEFFINGERSTR, REINACH,
SWITZERLAND

Laboratory: FPRC: NOVARTIS SANTE ANIMALE
S.A.S, HUNINGUE, FRANCE
NOVARTIS SOUTH AFRICA
(PTY) LTD, SPARTAN,
KEMPTON PARK

FPRR: NOVARTIS SOUTH AFRICA
(PTY) LTD, SPARTAN,
KEMPTON PARK

Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 38/2.7/0292
Name of medicine: ALFOXID
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml CONTAINS:
MEFENAMIC ACID 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A05/21.1/07
Name of medicine: VETRIMOXIN 50
Dosage form: POWDER
Active ingredients: EACH 100,0 g PRODUCT
CONTAINS:
AMOXYCILLIN
TRIHYDRATE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CEVA ANIMAL HEALTH
SOUTHERN AFRICA (PTY)
LTD

Manufacturer: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE

Packer: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE

Laboratory: FPRC: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE
BIO-INDUSTRIAL
SERVICES, KEMPTON
PARK

FPRR: CEVA ANIMAL HEALTH
SOUTHERN AFRICA (PTY)
LTD, RANDJIESPARK,
MIDRAND

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A38/11.10/0444
Name of medicine: GAVISCON 250 LEMON
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 SODIUM ALGINATE 250,0 mg
 SODIUM BICARBONATE 133,5 mg
 CALCIUM CARBONATE 80,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK

Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER PHARMACEUTICALS(PTY) LTD, ELANDSFONTEIN

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: A38/11.10/0445
Name of medicine: GAVISCON 500 LEMON
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 SODIUM ALGINATE 500,0 mg
 SODIUM BICARBONATE 267,0 mg
 CALCIUM CARBONATE 160,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER PHARMACEUTICALS(PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK

Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER PHARMACEUTICALS(PTY) LTD, ELANDSFONTEIN

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A38/11.10/0446
Name of medicine: GAVISCON 250 PEPPERMINT
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 SODIUM ALGINATE 250,0 mg
 SODIUM BICARBONATE 133,5 mg
 CALCIUM CARBONATE 80,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER PHARMACEUTICALS(PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK

Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD, ELANDSFONTEIN

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A38/11.10/0447

Name of medicine: GAVISCON 500 PEPPERMINT

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SODIUM ALGINATE 500,0 mg
SODIUM BICARBONATE
267,0 mg
CALCIUM CARBONATE
160,0 mg

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

Applicant: RECKITT BENCKISER
PHARMACEUTICALS (PTY) LTD

Manufacturer: RECKITT BENCKISER
HEALTHCARE (UK) LIMITED,
HULL, NORTHUMBERSIDE, UK

Packer: RECKITT BENCKISER
HEALTHCARE (UK) LIMITED,
HULL, NORTHUMBERSIDE, UK

Laboratory: FPRC: RECKITT BENCKISER
HEALTHCARE (UK) LIMITED,
HULL, NORTHUMBERSIDE, UK
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER
PHARMACEUTICALS(PTY) LTD,
ELANDSFONTEIN

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF15

Registration number: A38/4/0540

Name of medicine: CARBOCAINE A 2 %
(1:100 000)

Dosage form: TABLET

Active ingredients: EACH 1,8 ml CONTAINS:
MEPIVACAINE HCl 36,0 mg
ADRENALINE 18,0 µg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

Packer: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

Laboratory: FPRC: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

FPRR: ADCOCK INGRAM
LIMITED, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A38/4/0541

Name of medicine: CARBOCAINE A 2 %
(1:200 000)

Dosage form: TABLET

Active ingredients: EACH 1,8 ml CONTAINS:
MEPIVACAINE HCl
36,0 mg
ADRENALINE 9,0 µg

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

Applicant: ADCOCK INGRAM
LIMITED

Manufacturer: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

Packer: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

Laboratory: FPRC: PHARMA-Q (PTY) LTD,
INDUSTRIA,
JOHANNESBURG

FPRR: ADCOCK INGRAM
LIMITED, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A40/11.5/0050
 Name of medicine: SENOKOT DS 15 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SENNOSIDES A & B EQUIVALENT
 TO SENNOSIDE B 15,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: RECKITT BENCKISER
 PHARMACEUTICALS (PTY) LTD
 Manufacturer: RECKITT BENCKISER
 HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 Packer: RECKITT BENCKISER
 HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 Laboratory: FPRC: RECKITT BENCKISER
 HEALTHCARE, HULL, EAST
 YORKSHIRE, UK
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 FPRC/FPRR: RECKITT BENCKISER
 PHARMACEUTICALS,
 ELANDSFONTEIN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: A40/1.2/0345
 Name of medicine: TIMALIUM 25 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AGOMELATINE 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: EGIS PHARMACEUTICALS SA
 (PTY) LTD
 Manufacturer: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND) INDUSTRIES
 LTD., ARKLOW, IRELAND
 Packer: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND) INDUSTRIES
 LTD., ARKLOW, IRELAND
 TECHNIKON LABORATORIES
 (PTY) LTD, ROBERTVILLE,
 FLORIDA, RSA
 Laboratory: FPRC: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND) INDUSTRIES
 LTD., ARKLOW, IRELAND
 FPRR: EGIS PHARMACEUTICALS SA
 (PTY) LTD, RIVONIA
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A40/1.2/0346
 Name of medicine: MELINOR 25 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 AGOMELATINE 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: BIOGARAN SA (PTY) LTD
 Manufacturer: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND)
 INDUSTRIES LTD., ARKLOW,
 IRELAND
 Packer: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND)
 INDUSTRIES LTD., ARKLOW,
 IRELAND
 TECHNIKON LABORATORIES
 (PTY) LTD, ROBERTVILLE,
 FLORIDA, RSA
 Laboratory: FPRC: LES LABORATOIRES SERVIER
 INDUSTRIE, GIDIE, FRANCE
 SERVIER (IRELAND)
 INDUSTRIES LTD., ARKLOW,
 IRELAND
 FPRR: BIOGARAN SA (PTY) LTD,
 RIVONIA
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A40/1.2/0347
Name of medicine: VALDOXANE 25 mg

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AGOMELATINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SERVIER LABORATORIES SA (PTY) LTD
Manufacturer: LES LABORATOIRES SERVIER
INDUSTRIE, GIDIE, FRANCE
SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
Packer: LES LABORATOIRES SERVIER
INDUSTRIE, GIDIE, FRANCE
SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND
TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC: LES LABORATOIRES SERVIER
INDUSTRIE, GIDIE, FRANCE
SERVIER (IRELAND) INDUSTRIES LTD., ARKLOW, IRELAND

FPRR: SERVIER LABORATORIES SA (PTY) LTD, RIVONIA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: A40/11.10/0512
Name of medicine: GAVISCON TABLETS COOLMINT

Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SODIUM ALGinate 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: RECKITT BENCKISER
PHARMACEUTICALS (PTY) LTD
Manufacturer: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK
Packer: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK

Laboratory: FPRC: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK
RECKITT BENCKISER
PHARMACEUTICALS (PTY) LTD,
ELANDSFONTEIN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER
PHARMACEUTICALS(PTY) LTD,
ELANDSFONTEIN, KEMPTON
PARK, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A40/20.1.1/0774
Name of medicine: AURO-CEFALEXIN CAPSULES
250 mg

Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
CEFALEXIN MONOHYDRATE
EQUIVALENT TO CEFALExIN
250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LIMITED,
UNIT VI,PATANCHERU
MANDAL, MEDAK DISTRICT,
ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LIMITED,
UNIT VI,PATANCHERU
MANDAL, MEDAK DISTRICT,
ANDHRA PRADESH, INDIA

Laboratory: FPRC AUROBINDO PHARMA LIMITED,
UNIT VI,PATANCHERU
MANDAL, MEDAK DISTRICT,
ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A40/20.1.1/0775

Name of medicine: AURO-CEFALEXIN CAPSULES 500 mg

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS: CEFALOXIN MONOHYDRATE EQUIVALENT TO CEFALOXIN 500,0 mg

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

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/7.1.3/0083

Name of medicine: LOTENSIN CO 50 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg

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

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES, SIVERTONDALE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE SA, (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM

Shelf-life: 36 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/7.1.3/0087

Name of medicine: LOSACAR CO 50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg

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

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES, DEKGRAS ROAD, SILVERTONDALE, RETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTSCHEFSTROOM

FPRR: ZYDUS ALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA

Shelf-life: 36 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/0112

Name of medicine: AURO CEFADROXIL CAPSULES 500 mg

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CEFADROXIL MONOHYDRATE
EQUIVALENT TO CEFADROXIL
500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LIMITED,
UNIT VI, PATANCHERU MANDAL,
MEDAK DISTRICT, ANDHRA
PRADESH, INDIA

Packer: AUROBINDO PHARMA LIMITED,
UNIT VI, PATANCHERU MANDAL,
MEDAK DISTRICT, ANDHRA
PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LIMITED,
UNIT VI, PATANCHERU MANDAL,
MEDAK DISTRICT, ANDHRA
PRADESH, INDIA

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.11/0255

Name of medicine: ADCO TENYL 25 µg/h

Dosage form: PATCH

Active ingredients: EACH PATCH CONTAINS:
FENTANYL 25,0 µg/h

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LABORATORIOS BETA S.A.,
OVINCIA de La RIOJA, ARGENTINA

Packer: LABORATORIOS BETA S.A.,
PROVINCIA de La RIOJA,
ARGENTINA

Laboratory: FPRC: LABORATORIOS BETA S.A.,
PROVINCIA de La RIOJA,
ARGENTINA
ADCOCK INGRAM HEALTHCARE
(PTY) LTD, WADEVILLE,
GERMISTON
ADCOCK INGRAM HEALTHCARE
(PTY) LTD CLAYVILLE,
OLIFANTSFONTEIN

FPRR: ADCOCK INGRAM HEALTHCARE
(PTY) LTD, WADEVILLE,
GERMISTON
ADCOCK INGRAM HEALTHCARE
(PTY) LTD, CLAYVILLE,
OLIFANTSFONTEIN
ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.11/0256

Name of medicine: ADCO TENYL 50 µg/h

Dosage form: PATCH

Active ingredients: EACH PATCH CONTAINS:
FENTANYL 50,0 µg/h

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LABORATORIOS BETA S.A.,
PROVINCIA de La RIOJA,
ARGENTINA

Packer: LABORATORIOS BETA S.A.,
PROVINCIA de La RIOJA,
ARGENTINA

Laboratory: FPRC: LABORATORIOS BETA S.A.,
PROVINCIA de La RIOJA,
ARGENTINA
ADCOCK INGRAM
HEALTHCARE (PTY) LTD,
WADEVILLE, GERMISTON
ADCOCK INGRAM
HEALTHCARE (PTY) LTD
CLAYVILLE, OLIFANTSFONTEIN

FPRR: ADCOCK INGRAM
HEALTHCARE (PTY) LTD,
WADEVILLE, GERMISTON
ADCOCK INGRAM
HEALTHCARE (PTY) LTD,
CLAYVILLE, OLIFANTSFONTEIN
ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.11/0257
 Name of medicine: ADCO TENYL 75 µg/h
 Dosage form: PATCH
 Active ingredients: EACH PATCH CONTAINS:
 FENTANYL 75,0 µg/h
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 Packer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 Laboratory: FPRC: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD CLAYVILLE,
 OLIFANTSFONTEIN
 FPRR: ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, CLAYVILLE,
 OLIFANTSFONTEIN
 ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.11/0258
 Name of medicine: ADCO TENYL 100 µg/h
 Dosage form: PATCH
 Active ingredients: EACH PATCH CONTAINS:
 FENTANYL 100,0 µg/h
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 Packer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 Laboratory: FPRC: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD CLAYVILLE,
 OLIFANTSFONTEIN
 FPRR: ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, CLAYVILLE,
 OLIFANTSFONTEIN
 ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/26/0415
 Name of medicine: MITOXANTRON EBEWE 10 mg
 Dosage form: CONCENTRATE FOR
 SOLUTION FOR INFUSION
 Active ingredients: EACH VIAL CONTAINS:
 MITOXANTRONE HCl
 EQUIVALENT TO
 MITOXANTRONE 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: KEY ONCOLOGICS (PTY) LTD
 Manufacturer: EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
 Packer: EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
 Laboratory: FPRC: EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
 MIKROBIOLOGISCHES
 PRUFLABOR, INNSBRUCK,
 AUSTRIA
 LABOR L+SAG BAD BOCKLET,
 GERMANY
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: KEY ONCOLOGICS,
 HOUGHTON, JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/26/0416
Name of medicine: MITOXANTRON EBEWE 20 mg
Dosage form: CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients: EACH VIAL CONTAINS:
MITOXANTRONE HCl EQUIVALENT
TO MITOXANTRONE 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: KEY ONCOLOGICS (PTY) LTD
Manufacturer: EBEWE PHARMA GmbH Nfg.KG,
UNTERACH, AUSTRIA
Packer: EBEWE PHARMA GmbH Nfg.KG,
UNTERACH, AUSTRIA
Laboratory: FPRC: EBEWE PHARMA GmbH Nfg.KG,
UNTERACH, AUSTRIA
MIKROBIOLOGISCHES
PRUFLABOR, INNSBRUCK,
AUSTRIA
LABOR L+SAG BAD BOCKLET,
GERMANY
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: KEY ONCOLOGICS, HOUGHTON,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/20.2.8/0451
Name of medicine: INVI-RASE 500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SAQUINAVIR MESYLATE
EQUIVALENT TO
SAQUINAVIR 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ROCHE PRODUCTS (PTY) LTD
Manufacturer: ROCHE PHARMA S.A., MADRID,
SPAIN
Packer: ROCHE PHARMA S.A., MADRID,
SPAIN
F. HOFFMANN-LA ROCHE LTD,
KAISERAUGST SWITZERLAND
Laboratory: FPRC: ROCHE PHARMA S.A., MADRID,
SPAIN
F. HOFFMANN-LA ROCHE LTD,
BASEL, SWITZERLAND
FPRR: ROCHE PRODUCTS
(PTY) LTD,
NORTHLANDS, RSA
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/0646
Name of medicine: GULF CEFUROXIME 750
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFUROXIME SODIUM
EQUIVALENT TO
CEFUROXIME 750,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: GULF DRUG COMPANY (PTY)
LTD
Manufacturer: LABORATORIO REIG JOFRE,
TOLEDO, SPAIN
Packer: LABORATORIO REIG JOFRE,
TOLEDO, SPAIN
DIVPHARM MANUFACTURING
& PACKAGING, LONGDALE,
JOHANNESBURG
TECHNIKON LABORATORIES,
ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC: LABORATORIO REIG JOFRE,
TOLEDO, SPAIN
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
PHARMA-Q (PTY) LTD,
INDUSTRIAL WEST,
JOHANNESBURG
INSTITUTE FOR
PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA,
RSA
CONSULTING
MICROBIOLOGICAL
LABORATORY (PTY) LTD,
BEYERSPARK, RSA
FPRR: GULF DRUG COMPANY (PTY)
LTD, MOUNT EDGECOMBE,
DURBAN
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/21.2/0656
 Name of medicine: ACCORD GLIMEPIRIDE 1 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GLIMEPIRIDE 1,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD,
 MATODA, SANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD,
 MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD,
 MATODA, SANAND, AHMEDABAD, INDIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/21.2/0857
 Name of medicine: ACCORD GLIMEPIRIDE 2 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GLIMEPIRIDE 2,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ACCORD HEALTHCARE (PTY) LTD
 Manufacturer: INTAS PHARMACEUTICALS LTD,
 MATODA, ANAND, AHMEDABAD, INDIA
 Packer: INTAS PHARMACEUTICALS LTD,
 MATODA, SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD,
 MATODA, SANAND, AHMEDABAD, INDIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: ACCORD HEALTHCARE, RIVONIA, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.5/0846
 Name of medicine: TOPIRAN 50 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 TOPIRAMATE 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMACARE LTD
 Manufacturer: GENPHARM PHARMACEUTICALS
 INC., ETOBICOKE, ONTARIO,
 CANADA
 PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 Packer: GENPHARM PHARMACEUTICALS
 INC., ETOBICOKE, ONTARIO,
 CANADA
 PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 MC DERMOTT LABORATORIES T/A
 GERARD
 LABORATORIES, DUBLIN, IRELAND
 GENERICS UK LTD., POTTERS BAR,
 HERTFORDSHIRE, UK
 Laboratory: FPRC: GENPHARM PHARMACEUTICALS
 INC., ETOBICOKE, ONTARIO,
 CANADA
 PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL
 PHARMACY, NORTH WEST
 UNIVERSITY, POTCHEFSTROOM
 FPRR: PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 PHARMACARE LTD, WOODMEAD,
 RSA
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.5/0847

Name of medicine: TOPIRAN 100 mg

Dosage form: TABLET

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

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

Applicant: PHARMACARE LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON

Packer: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
MC DERMOTT LABORATORIES T/A
GERARD
LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD., POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
SABS PHARMACEUTICAL CHEMISTRY
LABORATORY, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
PHARMACARE LTD, WOODMEAD, RSA

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.5/0858

Name of medicine: TOPIRAN 25 mg

Dosage form: TABLET

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

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

Applicant: PHARMACARE LTD

Manufacturer: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON

Packer: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
MC DERMOTT LABORATORIES T/A
GERARD
LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD., POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC.,
ETOBICOKE, ONTARIO, CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
SABS PHARMACEUTICAL CHEMISTRY
LABORATORY, GROENKLOOF,
PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST LONDON,
WILSONIA, EAST LONDON
PHARMACARE LIMITED, WOODMEAD,
RSA

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.5/0859

Name of medicine: TOPIRAN 200 mg

Dosage form: TABLET

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

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

Applicant: PHARMACARE LTD

Manufacturer: GENPHARM PHARMACEUTICALS
INC., ETOBICOKE, ONTARIO,
CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST
LONDON, WILSONIA, EAST LONDON

Packer: GENPHARM PHARMACEUTICALS
INC., ETOBICOKE, ONTARIO,
CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST
LONDON, WILSONIA, EAST LONDON
MC DERMOTT LABORATORIES T/A
GERARD
LABORATORIES, DUBLIN, IRELAND
GENERICS UK LTD., POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: GENPHARM PHARMACEUTICALS
INC., ETOBICOKE, ONTARIO,
CANADA
PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST
LONDON, WILSONIA, EAST LONDON
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY, NORTH
WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: PHARMACARE LTD, KORSTEN, PE
ASPEN PHARMACARE EAST
LONDON, WILSONIA, EAST LONDON
PHARMACARE LTD, WOODMEAD,
RSA

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 4177.1.3/0969
 Name of medicine: TEKTURN 150
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 Aliskiren hemifumarate equivalent
 to Aliskiren 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
 Packer: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
 ALLPACK GROUP AG,
 REINACH, SWITZERLAND
 KONAPHARMA AG, PRATTELN,
 SWITZERLAND
 IVERS-LEE AG, BURGHOF,
 SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

Laboratory: FPRC: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
 NOVARTIS PHARMANALYTICA
 SA, LOCARNO, SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

FPRR: NOVARTIS SA (PTY) LTD,
 SPARTAN, KEMPTON PARK

Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 4177.1.3/0970
 Name of medicine: TEKTURN 300
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 Aliskiren hemifumarate
 equivalent to
 Aliskiren 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 Packer: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 ALLPACK GROUP AG,
 REINACH, SWITZERLAND
 KONAPHARMA AG,
 PRATTELN, SWITZERLAND
 IVERS-LEE AG, BURGHOF,
 SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

Laboratory: FPRC: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 NOVARTIS PHARMANALYTICA
 SA, LOCARNO, SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

FPRR: NOVARTIS SA (PTY) LTD,
 SPARTAN, KEMPTON PARK

Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 4177.1.3/0971
 Name of medicine: RASILEZ 150
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 Aliskiren hemifumarate
 equivalent to
 Aliskiren 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 Packer: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 ALLPACK GROUP AG,
 REINACH, SWITZERLAND
 KONAPHARMA AG,
 PRATTELN, SWITZERLAND
 IVERS-LEE AG, BURGHOF,
 SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

Laboratory: FPRC: NOVARTIS PHARMA STEIN
 AG, STEIN, SWITZERLAND
 NOVARTIS
 PHARMANALYTICA SA,
 LOCARNO, SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

FPRR: NOVARTIS SA (PTY) LTD,
 SPARTAN, KEMPTON PARK

Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/7.1.3/0972
Name of medicine: RASILEZ 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 Aliskiren hemifumarate equivalent
 to Aliskiren 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SA (PTY) LTD
Manufacturer: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
Packer: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
 ALLPACK GROUP AG,
 REINACH, SWITZERLAND
 KONAPHARMA AG, PRATTELN,
 SWITZERLAND
 IVERS-LEE AG, BURGHOF,
 SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

Laboratory: FPRC: NOVARTIS PHARMA STEIN AG,
 STEIN, SWITZERLAND
 NOVARTIS PHARMANALYTICA
 SA, LOCARNO, SWITZERLAND
 NOVARTIS SA, SPARTAN,
 KEMPTON PARK

FPRR: NOVARTIS SA (PTY) LTD,
 SPARTAN, KEMPTON PARK

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/7.1.3/0998
Name of medicine: SPEC-LOSARTAN CO 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM
 50,0 mg
 HYDROCHLOROTHIAZIDE
 12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., ATHENS,
 GREECE
Packer: SPECIFAR S.A., ATHENS,
 GREECE
 SPECPHARM HOLDINGS
 (PTY) LTD, HALFWAY HOUSE,
 MIDRAND
 DIVPHARM MANUFACTURING
 & PACKAGING (PTY) LTD,
 INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: SPECIFAR S.A., ATHENS,
 GREECE
 SPECPHARM HOLDINGS
 (PTY) LTD, HALFWAY HOUSE,
 MIDRAND
 CONSULTING CHEMICAL
 LABORATORY ATLASVILLE,
 BOKSBURG

FPRR: SPECPHARM (PTY) LTD,
 SANDTON, GAUTENG

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/7.1.3/0999
Name of medicine: SPEC-LOSARTAN CO 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM
 100,0 mg
 HYDROCHLOROTHIAZIDE
 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: SPECIFAR S.A., ATHENS,
 GREECE
Packer: SPECIFAR S.A., ATHENS,
 GREECE
 SPECPHARM HOLDINGS
 (PTY) LTD, HALFWAY
 HOUSE, MIDRAND
 DIVPHARM
 MANUFACTURING &
 PACKAGING (PTY) LTD,
 INDUSTRIA,
 JOHANNESBURG

Laboratory: FPRC: SPECIFAR S.A., ATHENS,
 GREECE
 SPECPHARM HOLDINGS
 (PTY) LTD, HALFWAY
 HOUSE, MIDRAND
 CONSULTING CHEMICAL
 LABORATORY,
 ATLASVILLE, BOKSBURG

FPRR: SPECPHARM (PTY) LTD,
 SANDTON, GAUTENG

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/1020
 Name of medicine: AUSVANIC-250
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN
 HEMIHYDRATE EQUIVALENT
 TO LEVOFLOXACIN 250,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES
 (PTY) LTD
 Manufacturer: IPCA LABORATORIES LIMITED,
 PLOT NO. 255/1
 DADRA AND NAGAR HAVELI,
 INDIA
 Packer: IPCA LABORATORIES LIMITED,
 PLOT NO. 255/1
 DADRA AND NAGAR HAVELI,
 INDIA
 Laboratory: FPRC: IPCA LABORATORIES LIMITED,
 PLOT NO. 255/1 DADRA AND
 NAGAR HAVELI, INDIA
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 INSTITUTE FOR
 PHARMACEUTICAL SERVICES,
 SILVERTONDALE, PRETORIA

 FPRR: AUSTELL LABORATORIES
 (PTY) LTD, SPRINGFIELD,
 JOHANNESBURG

 Shelf-life: 24 months (Provisional)
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/20.1.1/1021
 Name of medicine: AUSVANIC-500
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN
 HEMIHYDRATE EQUIVALENT
 TO LEVOFLOXACIN 500,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES
 (PTY) LTD
 Manufacturer: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR HAVELI,
 INDIA
 Packer: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR HAVELI,
 INDIA
 Laboratory: FPRC: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR HAVELI,
 INDIA
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 INSTITUTE FOR
 PHARMACEUTICAL
 SERVICES, SILVERTONDALE,
 PRETORIA

 FPRR: AUSTELL LABORATORIES
 (PTY) LTD, SPRINGFIELD,
 JOHANNESBURG

 Shelf-life: 24 months (Provisional)
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/1022
 Name of medicine: LEVOSTEL-250
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN
 HEMIHYDRATE
 EQUIVALENT TO
 LEVOFLOXACIN 250,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUSTELL LABORATORIES
 (PTY) LTD
 Manufacturer: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR
 HAVELI, INDIA
 Packer: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR
 HAVELI, INDIA
 Laboratory: FPRC: IPCA LABORATORIES
 LIMITED, PLOT NO. 255/1
 DADRA AND NAGAR
 HAVELI, INDIA
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 INSTITUTE FOR
 PHARMACEUTICAL
 SERVICES,
 SILVERTONDALE,
 PRETORIA

 FPRR: AUSTELL LABORATORIES
 (PTY) LTD, SPRINGFIELD,
 JOHANNESBURG

 Shelf-life: 24 months
 (Provisional)
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/1023
Name of medicine: LEVOSTEL-500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LEVOFLOXACIN
HEMIHYDRATE EQUIVALENT
TO LEVOFLOXACIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL LABORATORIES
(PTY) LTD
Manufacturer: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
INSTITUTE FOR
PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
FPRR: AUSTELL LABORATORIES
(PTY) LTD, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.9/1130
Name of medicine: JURNISTA 8 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
Hydromorphone HCl 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA
(PTY) LTD
Manufacturer: ALZA CORPORATION,
VACAVILLE, CALIFORNIA, USA
Packer: PSGA – ORTHO-MCNEIL
PHARMACEUTICAL INC.,
MOUNTAINVIEW,
CALIFORNIA, USA
Laboratory: FPRC: JANSSEN PHARMACEUTICA
NV, BEERSE, BELGIUM
FPRR: JANSSEN PHARMACEUTICA
(PTY) LTD, WOODMEAD,
SANDTON
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.9/1131
Name of medicine: JURNISTA 16 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
Hydromorphone HCl 16,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN
PHARMACEUTICA (PTY)
LTD
Manufacturer: ALZA CORPORATION,
VACAVILLE, CALIFORNIA,
USA
Packer: PSGA – ORTHO-MCNEIL
PHARMACEUTICAL INC.,
MOUNTAINVIEW,
CALIFORNIA, USA
Laboratory: FPRC: JANSSEN
PHARMACEUTICA NV,
BEERSE, BELGIUM
FPRR: JANSSEN
PHARMACEUTICA (PTY)
LTD, WOODMEAD,
SANDTON
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.9/1132

Name of medicine: JURNISTA 32 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
Hydromorphone HCl 32,0 mg

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

Applicant: JANSSEN PHARMACEUTICA
(PTY) LTD

Manufacturer: ALZA CORPORATION,
VACAVILLE, CALIFORNIA, USA

Packer: PSGA – ORTHO-MCNEIL
PHARMACEUTICAL INC.,
MOUNTAINVIEW, CALIFORNIA,
USA

Laboratory: FPRC: JANSSEN PHARMACEUTICA
NV, BEERSE, BELGIUM

FPRR: JANSSEN PHARMACEUTICA
(PTY) LTD, WOODMEAD,
SANDTON

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.9/1133

Name of medicine: JURNISTA 64 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
Hydromorphone HCl 64,0 mg

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

Applicant: JANSSEN PHARMACEUTICA
(PTY) LTD

Manufacturer: ALZA CORPORA
TION, VACAVILLE,
CALIFORNIA, USA

Packer: PSGA – ORTHO-MCNEIL
PHARMACEUTICAL INC.,
MOUNTAINVIEW,
CALIFORNIA, USA

Laboratory: FPRC: JANSSEN PHARMACEUTICA
NV, BEERSE, BELGIUM

FPRR: JANSSEN PHARMACEUTICA
(PTY) LTD, WOODMEAD,
SANDTON

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.9/1136

Name of medicine: JURNISTA 4 mg

Dosage form: TABLET

Active ingredients: EACH TABLET
CONTAINS:Hydromorphone
HCl 4,0 mg

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

Applicant: JANSSEN
PHARMACEUTICA (PTY)
LTD

Manufacturer: ALZA CORPORATION,
VACAVILLE, CALIFORNIA,
USA

Packer: PSGA – ORTHO-MCNEIL
PHARMACEUTICAL INC.,
MOUNTAINVIEW,
CALIFORNIA, USA

Laboratory: FPRC: JANSSEN
PHARMACEUTICA NV,
BEERSE, BELGIUM

FPRR: JANSSEN
PHARMACEUTICA (PTY)
LTD, WOODMEAD,
SANDTON

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0027

Name of medicine: AUSTELL LOSARTAN CO TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
EQUIVALENT TO
LOSARTAN 50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES LIMITED,
PLOT NO. 255/1 DADRA AND
NAGAR HAVELI, INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
INSTITUTE FOR
PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA

FPRR: AUSTELL LABORATORIES
(PTY) LTD, SPRINGFIELD,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/7.1.3/0028

Name of medicine: AUSTOZAAR-CO

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
EQUIVALENT TO
LOSARTAN 50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR HAVELI,
INDIA

Packer: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR HAVELI,
INDIA

Laboratory: FPRC: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR HAVELI,
INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
INSTITUTE FOR
PHARMACEUTICAL
SERVICES, SILVERTONDALE,
PRETORIA

FPRR: AUSTELL LABORATORIES
(PTY) LTD, SPRINGFIELD,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0029

Name of medicine: LORTAN-CO

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
EQUIVALENT TO
LOSARTAN 50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR
HAVELI, INDIA

Packer: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR
HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES
LIMITED, PLOT NO. 255/1
DADRA AND NAGAR
HAVELI, INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
INSTITUTE FOR
PHARMACEUTICAL
SERVICES,
SILVERTONDALE,
PRETORIA

FPRR: AUSTELL LABORATORIES
(PTY) LTD, SPRINGFIELD,
JOHANNESBURG

Shelf-life: 24 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/20.1.2/0038

Name of medicine: METPEN 125

Dosage form: POWDER FOR ORAL SOLUTION

Active ingredients: EACH 5,0 ml CONTAINS:
Phenoxymethylpenicillin
Potassium equivalent to
Phenoxymethylpenicillin
125,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Packer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Laboratory: FPRC: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA

FPRR: AUSTELL LABORATORIES (PTY) LTD, SPRINGFIELD, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/20.1.2/0039

Name of medicine: METPEN 250

Dosage form: POWDER FOR ORAL SOLUTION

Active ingredients: EACH 5,0 ml CONTAINS:
Phenoxymethylpenicillin
Potassium equivalent to
Phenoxymethylpenicillin
250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Packer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Laboratory: FPRC: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA

FPRR: AUSTELL LABORATORIES (PTY) LTD, SPRINGFIELD, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/20.1.2/0040

Name of medicine: AUSTELL - PEN VK 125

Dosage form: POWDER FOR ORAL SOLUTION

Active ingredients: EACH 5,0 ml CONTAINS:
Phenoxymethylpenicillin
Potassium equivalent to
Phenoxymethylpenicillin
125,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Packer: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA

Laboratory: FPRC: IPCA LABORATORIES LIMITED, GANDHIDHAM, GUJARAT, INDIA
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA

FPRR: AUSTELL LABORATORIES (PTY) LTD, SPRINGFIELD, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/20.1.2/0041
Name of medicine: AUSTELL - PEN VK 250
Dosage form: POWDER FOR ORAL SOLUTION
Active ingredients: EACH 5,0 ml CONTAINS:
Phenoxymethylpenicillin
Potassium equivalent to
Phenoxymethylpenicillin
250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUSTELL LABORATORIES
(PTY) LTD
Manufacturer: IPCA LABORATORIES LIMITED,
GANDHIDHAM, GUJARAT,
INDIA
Packer: IPCA LABORATORIES LIMITED,
GANDHIDHAM, GUJARAT,
INDIA
Laboratory: FPRC: IPCA LABORATORIES LIMITED,
GANDHIDHAM, GUJARAT,
INDIA
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA
INSTITUTE FOR
PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA,
RSA
FPRR: AUSTELL LABORATORIES
(PTY) LTD, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/21.12/0119
Name of medicine: ARIGOLINE 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CABERGOLINE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ARROW PHARMA SOUTH
AFRICA (PTY) LTD
Manufacturer: ARROW LABORATORIES,
CROYDON SOUTH, VICTORIA,
AUSTRALIA
Packer: ARROW LABORATORIES,
CROYDON SOUTH, VICTORIA,
AUSTRALIA
COBALT PHARMACEUTICALS
INC., MISSISSAUGA, CANADA
DIVPHARM MANUFACTURING
& PACKAGING (PTY) LTD,
LONGDALE, INDUSTRIA
Laboratory: FPRC: COBALT PHARMACEUTICALS
INC., MISSISSAUGA, CANADA
SEDEK AGRIKEM,
KAMEELDRIFT-EAST,
PRETORIA
FPRR: ARROW PHARMA SA (PTY)
LTD, WOODMEAD
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/26/0152
Name of medicine: EPICORD 10
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION
CONTAINS:
EPIRUBICIN
HYDROCHLORIDE 2.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE
(PTY) LTD
Manufacturer: INTAS
PHARMACEUTICALS,
MATODA, SANAND,
AHMEDABAD, INDIA
Packer: INTAS
PHARMACEUTICALS,
MATODA, SANAND,
AHMEDABAD, INDIA
Laboratory: FPRC: INTAS
PHARMACEUTICALS,
MATODA, SANAND,
AHMEDABAD, INDIA
CONSULTING CHEMICAL
LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: ACCORD HEALTHCARE,
RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/26/0153
Name of medicine: ACCORD EPIRUBICIN 10
Dosage form: INJECTION
Active ingredients: EACH 1.0 ml SOLUTION CONTAINS:
 EPIRUBICIN HYDROCHLORIDE
 2.0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE (PTY) LTD
Manufacturer: INTAS PHARMACEUTICALS, TODA,
 SANAND, AHMEDABAD, INDIA

Packer: INTAS PHARMACEUTICALS,
 MATODA, SANAND, AHMEDABAD,
 INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS,
 MATODA, SANAND, AHMEDABAD,
 INDIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA,
 RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/21.12/0248
Name of medicine: PROSTERID
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 FINASTERIDE 5.0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: GIDEON RICHTER LTD,
 BUDAPEST, HUNGARY

Packer: GIDEON RICHTER LTD,
 BUDAPEST, HUNGARY

Laboratory: GIDEON RICHTER LTD,
 BUDAPEST, HUNGARY
FPRC: CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG

FPRR: PHARMAPLAN (PTY) LTD,
 MIDRAND, RSA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0288
Name of medicine: SARTOC 100/25 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM 100.0
 mg
 HYDROCHLOROTHIAZIDE 25.0
 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: PHARMATHEN S.A. ATTIKIS,
 GREECE
 PHARMACARE LIMITED, PORT
 ELIZABETH, SA
 ASPEN PHARMACARE, EAST
 LONDON (PTY) LTD, WILSONIA,
 EAST LONDON, RSA

Packer: PHARMATHEN S.A. ATTIKIS,
 GREECE
 PHARMACARE LIMITED, PORT
 ELIZABETH, SA
 ASPEN PHARMACARE EAST
 LONDON (PTY) LTD, WILSONIA,
 EAST LONDON, RSA

Laboratory: FPRC PHARMATHEN S.A. ATTIKIS,
 GREECE
 PHARMACARE LIMITED, PORT
 ELIZABETH, SA
 ASPEN PHARMACARE, EAST
 LONDON (PTY) LTD, WILSONIA,
 EAST LONDON, RSA
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR
 INDUSTRIALPHARMACY,
 NORTH WEST UNIVERSITY,
 POTCHEFSTROOM, RSA

FPRR: PHARMACARE LIMITED, PORT
 ELIZABETH, RSA
 ASPEN PHARMACARE EAST
 LONDON (PTY) LTD, WILSONIA,
 EAST LONDON, RSA
 PHARMACARE LTD,
 WOODMEAD, RSA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/11.4.3/0313
Name of medicine: ASPEN PANTOPRAZOLE IV
Dosage form: POWDER FOR SOLUTION FOR INJECTION
Active ingredients: EACH VIAL CONTAINS:
PANTOPRAZOLE SODIUM
SESQUIHYDRATE
EQUIVALENT TO PANTOPRAZOLE 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMACARE LIMITED
Manufacturer: LABIANA PHARMACEUTICALS, S.L.U.,
BARCELONA, SPAIN
Packer: LABIANA PHARMACEUTICALS, S.L.U.,
BARCELONA, SPAIN
PHARMACARE LIMITED, KORSTEN, PORT
ELIZABETH, RSA
ASPEN PHARMACARE EAST LONDON
(PTY) LTD, WILSONIA, EAST LONDON,
RSA
Laboratory: FPRC: LABIANA PHARMACEUTICALS, S.L.U.,
BARCELONA, SPAIN
PHARMACARE LIMITED, PORT
ELIZABETH, SA
ASPEN PHARMACARE, EAST LONDON
(PTY) LTD, WILSONIA, EAST LONDON,
RSA
SABS PHARMACEUTICAL CHEMISTRY
LABORATORY, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM, RSA
FPRR: PHARMACARE LIMITED, PORT
ELIZABETH, RSA
ASPEN PHARMACARE EAST LONDON
(PTY) LTD, WILSONIA, EAST LONDON,
RSA
PHARMACARE LTD, WOODMEAD, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/2.6.5/0330
Name of medicine: AUROPERDAL 0,5 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/2.6.5/0331
Name of medicine: AUROPERDAL 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III
QUTHUBULLAPUR MANDAL, RANGA
REDDY, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/2.6.5/0332
Name of medicine: AUOPERDAL 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA,
 MEYERSDAL, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/2.6.5/0333
Name of medicine: AUOPERDAL 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/2.6.5/0334
Name of medicine: AUOPERDAL 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
 UNIT III QUTHUBULLAPUR
 MANDAL, RANGA REDDY,
 ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA,
 MEYERSDAL,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15	
Registration number:	42/20.1.1/0506
Name of medicine:	CIPLA AZITHROMYCIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Azithromycin dihydrate equivalent to Azithromycin 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT VII, VERNA, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, SOUTH AFRICA
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF15	
Registration number:	42/7.1.3/0519
Name of medicine:	ASPEN LABETALOL
Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: LABETALOL HCl 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ACROLAB LIMITED, BANGALORE, INDIA
Packer:	STRIDES ACROLAB LIMITED, BANGALORE, INDIA PHARMACARE LIMITED, PORT ELIZABETH, SA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	STRIDES ACROLAB LIMITED, BANGALORE, INDIA PHARMACARE LIMITED, PORT ELIZABETH, SA ASPEN PHARMACARE, EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
FPRR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON
Shelf-life:	36 months
Date of registration:	5 AUGUST 2011

MRF 15	
Registration number:	42/20.1.1/0632
Name of medicine:	LINTRIP 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, No 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, No 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC	DR REDDY'S LABORATORIES LTD, No 41, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF 15

Registration number: 42/20.1.1/0633
Name of medicine: LINTRIP 500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN HEMIHYDRATE
 EQUIVALENT TO LEVOFLOXACIN
 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
 No 4, QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
 No 4, QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 No 4, QUTHUBULLAPUR MANDAL,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY, NORTH
 WEST UNIVERSITY,
 POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/20.1.1/0642
Name of medicine: GULF CEFUROXIME 1 500
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 CEFUROXIME SODIUM
 EQUIVALENT TO
 CEFUROXIME 1 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: GULF DRUG COMPANY (PTY) LTD
Manufacturer: LABORATORIO REIG JOFRE,
 TOLEDO, SPAIN
Packer: LABORATORIO REIG JOFRE,
 TOLEDO, SPAIN
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA, RSA
Laboratory: LABORATORIO REIG JOFRE,
 TOLEDO, SPAIN
FPRC: SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 PHARMA-Q (PTY) LTD,
 INDUSTRIAL WEST,
 JOHANNESBURG
 INSTITUTE FOR
 PHARMACEUTICAL SERVICES,
 SILVERTONDALE, PRETORIA, RSA
 CONSULTING MICROBIOLOGICAL
 LABORATORY (PTY) LTD,
 BEYERSPARK, RSA
FPRR: GULF DRUG COMPANY (PTY) LTD,
 MOUNT EDGECOMBE, DURBAN
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/20.2.8/0696
Name of medicine: CIPLA NELFINAVIR
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 NELFINAVIR MESYLATE
 EQUIVALENT TO
 NELFINAVIR 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA MEDPRO (PTY) LTD
Manufacturer: CIPLA LTD, UNIT III, VERNA,
 GOA, INDIA
Packer: CIPLA LTD, UNIT III, VERNA,
 GOA, INDIA
Laboratory: FPRC CIPLA LTD, UNIT III, VERNA,
 GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK,
 BELLVILLE
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0723

Name of medicine: CIPLAZAR CO 50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Packer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Laboratory: FPRC: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK,
BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/7.1.3/0724

Name of medicine: CIPLAZAR CO 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
100,0 mg
HYDROCHLOROTHIAZIDE
25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Packer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Laboratory: FPRC: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK,
BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0725

Name of medicine: CIPLA-LOSARTAN AND
HYDROCHLOROTHIAZIDE
50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
50,0 mg
HYDROCHLOROTHIAZIDE
12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CIPLA LIFE SCIENCES (PTY)
LTD

Manufacturer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Packer: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

Laboratory: FPRC: CIPLA LTD, PATALGANGA,
RAIGAD, MAHARASHTRA,
INDIA
EMCURE PHARMACEUTICALS
LTD, HINJWADI, PUNE, INDIA

FPRR: CIPLA LIFE SCIENCES,
ROSENPARK, BELLVILLE

Shelf-life: 24 months
(Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0726

Name of medicine: CIPLA-LOSARTAN AND HYDROCHLOROTHIAZIDE 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM 100,0 mg
HYDROCHLOROTHIAZIDE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA

Packer: CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA

Laboratory: FPRC: CIPLA LTD, PATALGANGA, RAIGAD, MAHARASHTRA, INDIA
EMCURE PHARMACEUTICALS LTD, HINJWADI, PUNE, INDIA

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/1.2/0789

Name of medicine: STRATTERA 80 mg

Dosage form: CAPSULES

Active ingredients: EACH CAPSULE CONTAINS:
ATOMOXETINE 80,0 mg

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

Applicant: ELI LILLY SA (PTY) LTD

Manufacturer: LILLY Del CARIBE INC., CAROLINA, PUERTO RICO

Packer: LILLY S.A., ALCOBENDAS, MADRID, SPAIN

Laboratory: FPRC: LILLY Del CARIBE INC., CAROLINA, PUERTO RICO
LILLY S.A., ALCOBENDAS, MADRID, SPAIN
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA

FPRR: ELI LILLY SA (PTY) LTD, BRYANSTON, SOUTH AFRICA

Shelf-life: 36 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/26/0897

Name of medicine: EPICORD 50

Dosage form: INJECTION

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: ACCORD HEALTHCARE (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA

Packer: INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/26/0900
Name of medicine: ACCORD EPIRUBICIN 50
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
EPIRUBICIN HYDROCHLORIDE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ACCORD HEALTHCARE (PTY) LTD
Manufacturer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA
Packer: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: INTAS PHARMACEUTICALS, MATODA,
SANAND, AHMEDABAD, INDIA
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/7.1.3/1069
Name of medicine: ZARTAN CO 50/12,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM EQUIVALENT
TO LOSARTAN 50,0 mg
HYDROCHLOROTHIAZIDE 12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
Packer: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
DIVPHARM MANUFACTURING &
PACKAGING (PTY) LTD, LONGDALE,
INDUSTRIA
TECHNIKON LABORATORIES (PTY) LTD,
ROBERTVILLE, FLORIDA RSA
PHARMACEUTICAL ENTERPRISES (PTY)
LTD, MORNINGSID DRIVE, NDABENI,
PINELANDS

Laboratory: FPRC: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
DR. ECHEVARNE S.A. BARCELONA,
SPAIN
IDIFARMA,
DESARROLLOFARMACEUTICO S.L.,
NAVARRA, SPAIN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: PHARMA DYNAMICS (PTY) LTD,
SILVERWOOD, WESTLAKE, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/1069
Name of medicine: ZARTAN CO 100/25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM
EQUIVALENT TO
LOSARTAN 100,0 mg
HYDROCHLOROTHIAZIDE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
Packer: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
DIVPHARM MANUFACTURING &
PACKAGING (PTY) LTD, LONGDALE,
INDUSTRIA
TECHNIKON LABORATORIES (PTY)
LTD, ROBERTVILLE, FLORIDA, RSA
PHARMACEUTICAL ENTERPRISES
(PTY) LTD, MORNINGSID DRIVE,
NDABENI, PINELANDS

Laboratory: FPRC: LABORATORIES LICONSA S.A.,
AZUQUECA DE HENARES
(GUADALAJARA), SPAIN
DR. ECHEVARNE S.A. BARCELONA,
SPAIN
IDIFARMA,
DESARROLLOFARMACEUTICO S.L.,
NAVARRA, SPAIN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG

FPRR: PHARMA DYNAMICS (PTY) LTD,
SILVERWOOD, WESTLAKE, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/26/0009

Name of medicine: TEVA-FLUDARABINE 25

Dosage form: CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION

Active ingredients: EACH VIAL CONTAINS:
FLUDARABINE PHOSPHATE
50,0 mg/2 ml

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

Applicant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS

Packer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS

Laboratory: FPRC: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS
CONSULTING CHEMICAL LABORATORIES (PTY) LTD,
ATLASVILLE, BOKSBURG
INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES,
SILVERTONDALE, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY,
POTCHEFSTROOM
SABS PHARMACEUTICAL CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: TEVA PHARMACEUTICALS (PTY) LTD, ROODEPOORT, GAUTENG

Shelf-life: 24 months at 2 – 8 °C

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/21.12/0073

Name of medicine: ANASTROZOLE SANDOZ 1 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ANASTROZOLE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SANDOZ SA (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK

Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK
SABS PHARMACEUTICAL CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/26/0165

Name of medicine: EXIPLAT 50 mg

Dosage form: POWDER FOR SOLUTION FOR INFUSION

Active ingredients: EACH VIAL CONTAINS:
OXALIPLATIN 50,0 mg

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD
DISTRICT PANCHMAHAL, GUJARAT, INDIA

Packer: SUN PHARMACEUTICAL INDUSTRIES LTD
DISTRICT PANCHMAHAL, GUJARAT, INDIA

Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD
DISTRICT PANCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: PHARMAPLAN (PTY) LTD, MIDRAND, SOUTH AFRICA

Shelf-life: 36 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/26/0166
Name of medicine: EXIPLAT 100 mg
Dosage form: POWDER FOR SOLUTION FOR INFUSION
Active ingredients: EACH VIAL CONTAINS:
OXALIPLATIN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD
DISTRICT PANCHMAHAL,
GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL INDUSTRIES LTD
DISTRICT PANCHMAHAL,
GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL INDUSTRIES LTD DISTRICT PANCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN (PTY) LTD,
MIDRAND, SOUTH AFRICA
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/11.10/0195
Name of medicine: SALOFALK 500 mg
Dosage form: GRANULES
Active ingredients: EACH SACHET CONTAINS:
MESALAZINE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ORPHAN SA PHARMACEUTICALS (PTY) LTD
Manufacturer: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
Packer: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE,
JOHANNESBURG
Laboratory: FPRC: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
DR FALK PHARMA GmbH,
FREIBURG, GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: ORPHAN SA PHARMACEUTICALS (PTY) LTD, LONEHILL, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/11.10/0196
Name of medicine: SALOFALK 1 000 mg
Dosage form: GRANULES
Active ingredients: EACH SACHET CONTAINS:
MESALAZINE 1 000,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ORPHAN SA PHARMACEUTICALS (PTY) LTD
Manufacturer: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
Packer: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE,
JOHANNESBURG
Laboratory: FPRC: LOSAN PHARMA GmbH,
NEUENBURG, GERMANY
PHARBIL PHARMA GmbH,
BIELEFELD, GERMANY
DR FALK PHARMA GmbH,
FREIBURG, GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: ORPHAN SA PHARMACEUTICALS (PTY) LTD, LONEHILL, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0326
Name of medicine: OLEANZ 2,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 2,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES LTD,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN (PTY) LTD.,
MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/2.6.5/0327
Name of medicine: OLEANZ 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT,
INDIA
CONSULTING CHEMICAL
LABORATORIES LTD,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN (PTY) LTD. 16
ROAD, MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0328
Name of medicine: OLEANZ 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT, INDIA
Packer: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT, INDIA
Laboratory: FPRC: SUN PHARMACEUTICAL
INDUSTRIES LTD., DISTRICT
PANCHMAHAL, GUJARAT, INDIA
CONSULTING CHEMICAL
LABORATORIES LTD,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN (PTY) LTD.,
MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/21.12/0395
Name of medicine: FENRYDE 5
Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BRIMPHARM SA (PTY) LTD

Manufacturer: KERN PHARMA S.L., BARCELONA, SPAIN
ORION CORPORATION ORION PHARMA, TURKU, FINLAND

Packer: KERN PHARMA S.L., BARCELONA, SPAIN
ORION CORPORATION ORION PHARMA, TURKU, FINLAND
HAUPT PHARMA MUNSTER GmbH, MUNSTER, GERMANY

Laboratory: FPRC: KERN PHARMA S.L., BARCELONA, SPAIN
ORION CORPORATION ORION PHARMA, TURKU, FINLAND
CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA

FPRR: BRIMPHARM SA (PTY) LTD, ATHLONE, INDUSTRIA, CAPE TOWN

Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/26/0427
Name of medicine: VELCADE 1 mg
Dosage form: POWDER FOR SOLUTION FOR INJECTION

Active ingredients: EACH VIAL CONTAINS:
BORTEZOMIB 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: BEN VENUE LABORATORIES INC., BEDFORD, OHIO, USA

Packer: BEN VENUE LABORATORIES INC., BEDFORD, OHIO, USA
JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM

Laboratory: FPRC: JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM

FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, SOUTH AFRICA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/11.10/0442
Name of medicine: URSOFALK
Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
URSODEOXYCHOLIC ACID 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ORPHAN SA PHARMACEUTICALS (PTY) LTD

Manufacturer: LOSAN PHARMA GmbH, NEUENBURG, GERMANY
KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY

Packer: LOSAN PHARMA GmbH, NEUENBURG, GERMANY
KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: LOSAN PHARMA GmbH, NEUENBURG, GERMANY
KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY
DR FALK PHARMA GmbH, FREIBURG, GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: ORPHAN SA PHARMACEUTICALS (PTY) LTD, LONEHILL, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number:	43/7.1.3/0473
Name of medicine:	QUINAPRIL HYDROCHLOROTHIAZIDE ZYDUS 10/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF15

Registration number:	43/7.1.3/0474
Name of medicine:	QUINAPRIL HYDROCHLOROTHIAZIDE ZYDUS 20/12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF 15

Registration number:	43/10.2.2/0510
Name of medicine:	AMUCO 200 mg EFFERVESCENT
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	H & E PHARMA SA, BIOGGIO, SWITZERLAND
Packer:	H & E PHARMA SA, BIOGGIO, SWITZERLAND KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC	H & E PHARMA SA, BIOGGIO, SWITZERLAND SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	5 AUGUST 2011

MRF 15

Registration number: 43/10.2.2/0511
Name of medicine: CAMOX ACETYLCYSTEINE 200 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer: H & E PHARMA SA, BIOGGIO, SWITZERLAND
Packer: H & E PHARMA SA, BIOGGIO, SWITZERLAND
KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: H & E PHARMA SA, BIOGGIO, SWITZERLAND
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA

FPRR: CAMOX PHARMACEUTICALS (PTY) LTD, JOHANNESBURG, RSA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/10.2.2/0512
Name of medicine: APEX ACETYLCYSTEINE 200 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: ACETYLCYSTEINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer: H & E PHARMA SA, BIOGGIO, SWITZERLAND
Packer: H & E PHARMA SA, BIOGGIO, SWITZERLAND
KLOCKE PHARMA-SERVICE APPENWEIER, GERMANY
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG

Laboratory: FPRC: H & E PHARMA SA, BIOGGIO, SWITZERLAND
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA

FPRR: CAMOX PHARMACEUTICALS (PTY) LTD, JOHANNESBURG, RSA

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/20.1.1/0612
Name of medicine: CIPLA AZITHROMYCIN 500 INJ
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS: Azithromycin dihydrate equivalent to Azithromycin 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, UNIT IX, VERNA, GOA
Packer: CIPLA LTD, UNIT IX, VERNA, GOA

Laboratory: FPRC: CIPLA LTD, UNIT IX, VERNA, GOA

FPRR: CIPLA LIFE SCIENCES (PTY) LTD, ROSEN PARK, BELVILLE, SOUTH AFRICA

Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/20.1.1/0614
Name of medicine: ZITRO 500 INJ
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 Azithromycin dihydrate equivalent to
 Azithromycin 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, UNIT IX, VERNA, GOA
Packer: CIPLA LTD, UNIT IX, VERNA, GOA
Laboratory: FPRC: CIPLA LTD, UNIT IX, VERNA, GOA
FPRR: CIPLA LIFE SCIENCES (PTY) LTD,
 ROSENPARK, BELLVILLE, SOUTH
 AFRICA
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/2.5/0617
Name of medicine: ASPEN GABAPENTIN 100 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 GABAPENTIN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: KERN PHARMA S.L., TERRASSA,
 BARCELONA, SPAIN
Packer: KERN PHARMA S.L., TERRASSA,
 BARCELONA, SPAIN
 MPF B.V. (Manufacturing Packaging
 Farmaca), RX OUDEHASKE, THE
 NETHERLANDS
 SOFARIMEX INDUSTRIA QUIMICA
 e FARMACEUTICA, Lda, AGUALVA,
 CACEM, PORTUGAL
Laboratory: FPRC: KERN PHARMA S.L., TERRASSA,
 BARCELONA, SPAIN
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY, NORTH
 WEST UNIVERSITY,
 POTCHEFSTROOM
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
FPRR: PHARMACARE LIMITED,
 WOODMEAD, SANDTON.
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.5/0618
Name of medicine: ASPEN GABAPENTIN 300 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 GABAPENTIN 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: KERN PHARMA S.L., TERRASSA, BARCELONA,
 SPAIN
Packer: KERN PHARMA S.L., TERRASSA, BARCELONA,
 SPAIN
 MPF B.V. (Manufacturing
 Packaging Farmaca), RX
 OUDEHASKE, THE
 NETHERLANDS
 SOFARIMEX INDUSTRIA
 QUIMICA e FARMACEUTICA,
 Lda, AGUALVA, CACEM,
 PORTUGAL
Laboratory: FPRC: KERN PHARMA S.L., TERRASSA, BARCELONA,
 SPAIN
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH WEST UNIVERSITY,
 POTCHEFSTROOM
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
FPRR: PHARMACARE LIMITED,
 WOODMEAD, SANDTON.
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/18.3/0672
Name of medicine: BARRS MIST. POT. CIT
Dosage form: SOLUTION
Active ingredients: EACH 5,0 ml CONTAINS:
Potassium citrate 1,5 g
Citric acid monohydrate 0,25 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: BARRS PHARMACEUTICAL
INDUSTRIES cc
Manufacturer: BARRS PHARMACEUTICAL
INDUSTRIES cc, NDABENI, CAPE
TOWN
Packer: BARRS PHARMACEUTICAL
INDUSTRIES cc, NDABENI, CAPE
TOWN
Laboratory: FPRC: BARRS PHARMACEUTICAL
INDUSTRIES cc, NDABENI, CAPE
TOWN
FPRR: BARRS PHARMACEUTICAL
INDUSTRIES cc, NDABENI, CAPE
TOWN
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/21.12/0733
Name of medicine: LETROZOLE ADCO 2,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LETROZOLE 2,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HAUPT PHARMA MUNSTER GmbH,
MUNSTER, GERMANY
Packer: HAUPT PHARMA MUNSTER GmbH,
MUNSTER, GERMANY
Laboratory: FPRC: HAUPT PHARMA MUNSTER GmbH,
MUNSTER, GERMANY
UMWELTLABOR ACB, MUNSTER,
GERMANY
LABOR L+S AG, BAD BOCKLET-
GROENBRACH, GERMANY
ADCOCK INGRAM HEALTHCARE
(PTY) LTD, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
(RESEARCH AND DEVELOPMENT),
AEROTON, JOHANNESBURG
FPRR: ADCOCK INGRAM HEALTHCARE
(PTY) LTD, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD,
(RESEARCH AND DEVELOPMENT),
AEROTON, JOHANNESBURG
ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/21.12/0734
Name of medicine: FEMZOLE 2,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LETROZOLE 2,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: HAUPT PHARMA MUNSTER
GmbH, MUNSTER, GERMANY
Packer: HAUPT PHARMA MUNSTER
GmbH, MUNSTER, GERMANY
Laboratory: FPRC: HAUPT PHARMA MUNSTER
GmbH, MUNSTER, GERMANY
UMWELTLABOR ACB,
MUNSTER, GERMANY
LABOR L+S AG, BAD BOCKLET-
GROENBRACH, GERMANY
ADCOCK INGRAM
HEALTHCARE (PTY) LTD,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD,
(RESEARCH AND
DEVELOPMENT), AEROTON,
JOHANNESBURG
FPRR: ADCOCK INGRAM
HEALTHCARE (PTY) LTD,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD,
(RESEARCH AND
DEVELOPMENT), AEROTON,
JOHANNESBURG
ADCOCK INGRAM LTD, ERAND
GARDENS, MIDRAND
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/20.2.8/0780

Name of medicine: INTELENCE

Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: JANSSEN-CILAG S.P.A,
LATINA, ITALY

Packer: JANSSEN-CILAG S.P.A,
LATINA, ITALY
SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE,
MIDRAND

Laboratory: FPRC: JANSSEN-CILAG S.P.A,
LATINA, ITALY
SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE,
MIDRAND

FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/2.6.5/0796

Name of medicine: SEREZ 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO QUETIAPINE
25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: LASARA TRADERS (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA

Packer: PENDOPHARM INC (DIVISION
OF PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND

Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND

FPRR: LASARA TRADERS (PTY) LTD,
MORELETA PARK, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0797

Name of medicine: SEREZ 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: LASARA TRADERS (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA

Packer: PENDOPHARM INC
(DIVISION OF
PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND

Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND

FPRR: LASARA TRADERS (PTY) LTD, MORELETA PARK,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0798
Name of medicine: SEREZ 200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO QUETIAPINE
200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: LASARA TRADERS (PTY) LTD
Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC, CANADA
Packer: PENDOPHARM INC (DIVISION
OF PHARMASCIENCE),
MONTREAL, QUEBEC, CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS (PTY)
LTD, HALFWAY HOUSE,
MIDRAND
Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC, CANADA
SPECPHARM HOLDINGS (PTY)
LTD, HALFWAY HOUSE,
MIDRAND
FPRR: LASARA TRADERS (PTY) LTD,
MORELETA PARK, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/2.6.5/0799
Name of medicine: SEREZ 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO QUETIAPINE
300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: LASARA TRADERS (PTY) LTD
Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
Packer: PENDOPHARM INC (DIVISION
OF PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND
Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND
FPRR: LASARA TRADERS (PTY) LTD,
MORELETA PARK, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0800
Name of medicine: QUETOSER 25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: LASARA TRADERS (PTY)
LTD
Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
Packer: PENDOPHARM INC
(DIVISION OF
PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND
Laboratory: FPRC PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND
FPRR: LASARA TRADERS (PTY)
LTD, MORELETA PARK,
PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0801

Name of medicine: QUETOSER 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO QUETIAPINE
100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: LASARA TRADERS (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA

Packer: PENDOPHARM INC (DIVISION
OF PHARMASCIENCE),
MONTREAL, QUEBEC, CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS (PTY)
LTD, HALFWAY HOUSE,
MIDRAND

Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC, CANADA
SPECPHARM HOLDINGS (PTY)
LTD, HALFWAY HOUSE,
MIDRAND

FPRR: LASARA TRADERS (PTY) LTD,
MORELETA PARK, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/2.6.5/0802

Name of medicine: QUETOSER 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO QUETIAPINE
200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: LASARA TRADERS (PTY) LTD

Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA

Packer: PENDOPHARM INC (DIVISION
OF PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND

Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY HOUSE,
MIDRAND

FPRR: LASARA TRADERS (PTY) LTD,
MORELETA PARK, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/2.6.5/0803

Name of medicine: QUETOSER 300

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: LASARA TRADERS (PTY)
LTD

Manufacturer: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA

Packer: PENDOPHARM INC
(DIVISION OF
PHARMASCIENCE),
MONTREAL, QUEBEC,
CANADA
ROPACK INC, MONTREAL,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND

Laboratory: FPRC: PHARMASCIENCE INC,
MONTREAL, QUEBEC,
CANADA
SPECPHARM HOLDINGS
(PTY) LTD, HALFWAY
HOUSE, MIDRAND

FPRR: LASARA TRADERS (PTY)
LTD, MORELETA PARK,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/20.1.1/0841

Name of medicine: MYLAN LEVOFLOXACIN 250 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOFLOXACIN HEMIHYDRATE
EQUIVALENT TO LEVOFLOXACIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 43/20.1.1/0842

Name of medicine: MYLAN LEVOFLOXACIN 500 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOFLOXACIN HEMIHYDRATE
EQUIVALENT TO LEVOFLOXACIN 500,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG
MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG

FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 43/20.2.3/0847

Name of medicine: INOXOR 30 mg/150 mg/200 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg
STAVUDINE 30,0 mg
NEVIRAPINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III QUTHUBULLAPUR, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA LIMITED, UNIT III QUTHUBULLAPUR, ANDHRA PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III QUTHUBULLAPUR, ANDHRA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND

FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 44/20.1.1/0012
Name of medicine: DYNA CEFPODOXIME 100 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 Cefpodoxime Proxetil equivalent to
 Cefpodoxime 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: LUPIN LIMITED, RAISEN, MADHYA
 PRADESH, INDIA

Packer: LUPIN LIMITED, RAISEN, MADHYA
 PRADESH, INDIA

Laboratory: FPRC: CONSULTING CHEMICAL
 LABORATORIES (PTY) LTD,
 ATLASVILLE, BOKSBURG

FPRR: PHARMA DYNAMICS (PTY) LTD,
 WESTLAKE, CAPE TOWN

Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 44/30.1/0058
Name of medicine: ZOSTAVAX
Dosage form: INJECTION
Active ingredients: EACH 0,65 ml DOSE CONTAINS:
 LIVE ATTENUATED OKA/MERCK
 STRAIN OF VARICELLA-ZOSTER
 VIRUS, 19 400,0 PFU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MSD. (PTY) LTD
Manufacturer: MERCK & CO., INC, WEST POINT,
 PENNSYLVANIA, USA

Packer: MERCK & CO., INC, WEST POINT,
 PENNSYLVANIA, USA
 MERCK SHARP & DOHME B.V.,
 HAARLEM, NETHERLANDS

Laboratory: FPRC: MERCK & CO. INC, WEST POINT,
 PENNSYLVANIA, USA
 MERCK SHARP & DOHME B.V.,
 HAARLEM, NETHERLANDS

FPRR: MSD (PTY) LTD, HALFWAY HOUSE,
 SOUTH AFRICA

Shelf-life: 18 months stored at 2 – 8°C
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 45/20.2.3/0037
Name of medicine: PASER GRANULES
Dosage form: GRANULES
Active ingredients: EACH PACKET CONTAINS:
 AMINOSALICYLIC ACID 4,0 g

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: JACOBUS PHARMACEUTICAL
 COMPANY INC., PLAINSBORO,
 NJ, USA
 THE COATING PLACE, INC.,
 VERONA, WISCONSIN, USA

Packer: JACOBUS PHARMACEUTICAL
 COMPANY INC., PLAINSBORO,
 NJ, USA
 FUTURE PAK LTD., WIXAM,
 MICHIGAN, USA
 RYT-WAY PACKAGING
 COMPANY, LAKEVILLE,
 MINNESOTA, USA

Laboratory: FPRC JACOBUS PHARMACEUTICAL
 COMPANY INC., PLAINSBORO,
 NJ, USA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 RESEARCH INSTITUTE FOR
 INDUSTRIAL PHARMACY,
 NORTH WEST UNIVERSITY,
 POTCHEFSTROOM

FPRR: PHARMAPLAN (PTY) LTD,
 MIDRAND

Shelf-life: 36 months at 2 – 8 °C
Date of registration: 5 AUGUST 2011