

IMPORTANT NOTICE

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GENERAL NOTICE ALGEMENE KENNISGEWING

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.

KENNISGEWING 761 VAN 2011**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE
BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN
VERWANTE STOWWE, 1965 (WET 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wettlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleefyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleefydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number: 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:
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: 42/21.3/0673

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:
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: 42/21.3/0674

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
 FPRC/FPRR: ABBOTT LABORATORIES
 SA, CONSTANTIA KLOOF,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0678
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

MRF15	
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
 TENOFOVIR 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
 TENOFOVIR 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
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,
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,
FERNDALE, 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,
FERNDALE, 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
 EACH CAPSULE
 Active ingredients: CONTAINS:
 CICLOSPORIN 10,0 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: 07/25.3.21/04
 Name of medicine: ATOPICA 25
 Dosage form: SOFT CAPSULES
 EACH CAPSULE
 Active ingredients: 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: VETRIXIMOXIN 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:
 CEFALEXIN MONOHYDRATE
 EQUIVALENT TO CEFALEXIN 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:	41/21.2/0657
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 GENERIC 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: 412.5/0847
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: 412.5/0858
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: 412.5/0859
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: 41/7.1.3/0969
Name of medicine: TEKTURNA 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: 41/7.1.3/0970
Name of medicine: TEKTURNA 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: 41/7.1.3/0971
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: FPRC: GIDEON RICHTER LTD,
 BUDAPEST, HUNGARY
 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: AUOPERDAL 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: AUOPERDAL 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 LAHORATORIES
 LTD, No 41, QUTUBULLAPUR
 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: 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:	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, ROSENPAK, 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, ROSENPAK,
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, ROSENPAK,
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,
ROSENPAK, 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 (<i>Provisional</i>)
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 (<i>Provisional</i>)
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: 42/7.1.3/1068
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, MORNINGSIDE DRIVE, N'DABENI,
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, MORNINGSIDE DRIVE,
N'DABENI, 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, INDUSTRIAL, 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 HYDROCHLOROTHIAZID 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, ROSENPAK,
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, ROSEN PARK, 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-
 GROBENBRACH, 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-
 GROBENBRACH, 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: 43/20.2.8/0847
 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

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