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CONTENTS**INHOUD**

No.	Page No.	Gazette No.	No.	Bladsy No.	Koerant No.
GENERAL NOTICE			ALGEMENE KENNISGEWING		
Health, Department of			Gesondheid, Departement van		
<i>General Notice</i>			<i>Algemene Kennisgewing</i>		
761			761		
Medicines and Related Substances Act (101/1965): Medicines Control Council: Conditions of registration of a medicine in terms of the provisions of section 15(7)	3	34702	Wet op Beheer van Medisyne en Verwante Stowwe (101/1965): Medisynebeheerraad: Voorwaardes vir die registrasie van 'n medisyne in terme van die bepalings van artikel 15(7).....	4	34702

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 wetlike 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, ROSEN PARK,
BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

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, ROSEN PARK,
BELLVILLE

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/20.2.8/0073

Name of medicine: STRIDES EFAVIRENZ 200 mg

Dosage form: TABLET

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

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

Applicant: STRIDES SA
PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: STRIDES SA
PHARMACEUTICALS, ARCADIA,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/20.2.8/0074

Name of medicine: STRIDES EFAVIRENZ 600 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
EFAVIRENZ 600,0 mg

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

Applicant: STRIDES SA
PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: STRIDES SA
PHARMACEUTICALS, ARCADIA,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/21.3/0670

Name of medicine: SYNTHROID 25 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM 25,0 µg

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

Applicant: ABBOTT LABORATORIES SA (PTY)
LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA,
PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA,
PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0671

Name of medicine: SYNTHROID 50 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVOTHYROXINE SODIUM
50,0 µg

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

Applicant: ABBOTT LABORATORIES SA
(PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
JAYUYA, PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0672

Name of medicine: SYNTHROID 75 µg

Dosage form: TABLET

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

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

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/21.3/0673

Name of medicine: SYNTHROID 88 µg

Dosage form: TABLET

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

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

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0674

Name of medicine: SYNTHROID 100 µg

Dosage form: TABLET

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

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

Applicant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES, JAYUYA, PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/21.3/0675
 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
 Laboratory: FPRC: ABBOTT LABORATORIES,
 NORTH CHICAGO,
 ILLINOIS, USA
 FPRC/FPRR: ABBOTT LABORATORIES
 SA, CONSTANTIA KLOOF,
 JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 15 APRIL 2011

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

Registration number: 42/21.3/0681
 Name of medicine: SYNTHROID 300 µg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
 LEVOTHYROXINE SODIUM
 300,0 µg

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

Applicant: ABBOTT LABORATORIES
 SA (PTY) LTD

Manufacturer: ABBOTT LABORATORIES,
 JAYUYA, PUERTO RICO

Packer: ABBOTT LABORATORIES,
 JAYUYA, PUERTO RICO

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

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

Shelf-life: 24 months (Provisional)

Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/20.2.8/0884
 Name of medicine: STRIDES-STAVUDINE 30 mg &
 LAMIVUDINE 150 mg &
 NEVIRAPINE 200 mg

Dosage form: TABLET

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

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

Applicant: STRIDES SA
 PHARMACEUTICALS (PTY) LTD

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

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

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

FPRR: STRIDES SA
 PHARMACEUTICALS, ARCADIA,
 PRETORIA

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/15.4/1006
 Name of medicine: NEVANAC

Dosage form: EYE DROPS

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

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

Applicant: ALCON LABORATORIES
 (PTY) LTD

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

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

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

FPRR: ALCON LABORATORIES
 (SA), BRYANSTON,
 JOHANNESBURG

Shelf-life: 24 months

Date of registration: 15 APRIL 2011

MRF 15	
Registration number:	42/7.5/1050
Name of medicine:	ATORVASTATIN UNICORN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY COUNTY CORK, IRELAND
Packer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO
Laboratory:	FPRC: GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER LABORATORIES, RETREAT, CAPE TOWN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
	FPRR: PHARMACIA SA, SANDTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	15 APRIL 2011

MRF 15	
Registration number:	42/7.5/1051
Name of medicine:	ATORVASTATIN UNICORN 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY COUNTY CORK, IRELAND
Packer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO
Laboratory:	FPRC: GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER LABORATORIES, RETREAT, CAPE TOWN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
	FPRR: PHARMACIA SA, SANDTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	15 APRIL 2011

MRF 15	
Registration number:	42/7.5/1052
Name of medicine:	ATORVASTATIN UNICORN 40
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACIA SOUTH AFRICA (PTY) LTD
Manufacturer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER IRELAND PHARMACEUTICALS, RINGASKIDDY COUNTY CORK, IRELAND
Packer:	GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO
Laboratory:	FPRC: GODECKE GmbH, FREIBURG, GERMANY PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PUERTO RICO PFIZER LABORATORIES, RETREAT, CAPE TOWN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, LIMBRO BUSINESS PARK, SANDTON LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
	FPRR: PHARMACIA SA, SANDTON, JOHANNESBURG
Shelf-life:	36 months
Date of registration:	15 APRIL 2011

MRF 15

Registration number: 42/2.6.5/1074
Name of medicine: DRL-QUETIAPINE 25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S
LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
Packer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR MANDAL,
RANGA REDDY, ANDHRA
PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months
Date of registration: 15 APRIL 2011

MRF15

Registration number: 42/2.6.5/1075
Name of medicine: DRL-QUETIAPINE 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S
LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S
LABORATORIES LTD,
QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE
FOR INDUSTRIAL
PHARMACY, NORTH-WEST
UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months
Date of registration: 15 APRIL 2011

MRF 15

Registration number: 42/2.6.5/1076
Name of medicine: DRL-QUETIAPINE 200
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
QUETIAPINE FUMARATE
EQUIVALENT TO
QUETIAPINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DR REDDY'S LABORATORIES
(PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S LABORATORIES
LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY,
ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR
INDUSTRIAL PHARMACY,
NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S
LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months
Date of registration: 15 APRIL 2011

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

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

MRF 15

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

MRF 15

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 v/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 v/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 v/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 v/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 v/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 v/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:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
FPRC:	SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIA PHARMACY NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/ FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	PHARMACARE LTD, WODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	01 October 2010

MRF 15

Registration number:	42/20.2.8/0178
Name of medicine:	LASTAVINE 40 mg/150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: STAVUDINE 40,0 mg LAMIVUDINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC	STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIA PHARMACY NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC/ FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA
FPRR:	PHARMACARE LTD, WODMEAD, SANDTON, RSA
Shelf-life:	24 months
Date of registration:	01 October 2010

MRF 15

Registration number: 07/25.3.21/03
Name of medicine: ATOPICA 10
Dosage form: SOFT CAPSULES
Active ingredients: EACH CAPSULE
 CONTAINS:
 CICLOSPORIN 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH AFRICA
 (PTY) LTD
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
Active ingredients: EACH CAPSULE
 CONTAINS:
 CICLOSPORIN 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH
 AFRICA (PTY) LTD
Manufacturer: R.P. SCHERER GmbH &
 Co. KG, EBERBACH,
 GERMANY

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

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

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

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

MRF 15

Registration number: 07/25.3.21/05
Name of medicine: ATOPICA 50
Dosage form: SOFT CAPSULES
Active ingredients: EACH CAPSULE CONTAINS:
 CICLOSPORIN 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH AFRICA
 (PTY) LTD
Manufacturer: R.P. SCHERER GmbH & Co.
 KG, EBERBACH, GERMANY

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

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

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

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

MRF 15

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: NOVARTIS SOUTH AFRICA
(PTY) LTD
Manufacturer: R.P. SCHERER GmbH & Co.
KG, EBERBACH, GERMANY
Packer: ALLPACK GROUP AG,
KAGENSTRASSE, REINACH,
SWITZERLAND
ALLPACK GROUP AG,
PFEFFINGERSTR, REINACH,
SWITZERLAND
Laboratory: FPRC: NOVARTIS SANTE ANIMALE
S.A.S, HUNINGUE, FRANCE
NOVARTIS SOUTH AFRICA
(PTY) LTD, SPARTAN,
KEMPTON PARK
FPRR: NOVARTIS SOUTH AFRICA
(PTY) LTD, SPARTAN,
KEMPTON PARK
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF15

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: MDI CC
Manufacturer: PHARMANOVA (PVT) LTD,
HARARE, ZIMBABWE
Packer: PHARMANOVA (PVT) LTD,
HARARE, ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD,
HARARE, ZIMBABWE
FPRR: MDI CC, MENLO PARK,
PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 5 AUGUST 2011

MRF 15

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CEVA ANIMAL HEALTH
SOUTHERN AFRICA (PTY)
LTD
Manufacturer: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE
Packer: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE
Laboratory: FPRC: CEVA SANTE ANIMALE,
LOUDEAC, FRANCE
BIO-INDUSTRIAL
SERVICES, KEMPTON
PARK
FPRR: CEVA ANIMAL HEALTH
SOUTHERN AFRICA (PTY)
LTD, RANDJIESPARK,
MIDRAND
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF 15

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

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER
 PHARMACEUTICALS (PTY) LTD
Manufacturer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
Laboratory: FPRC: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER
 PHARMACEUTICALS(PTY) LTD,
 ELANDSFONTEIN

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

MRF15

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

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER
 PHARMACEUTICALS(PTY) LTD
Manufacturer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
Laboratory: FPRC: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED,
 HULL, NORTHUMBERSIDE, UK
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER
 PHARMACEUTICALS(PTY)
 LTD, ELANDSFONTEIN

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

MRF 15

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

Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER
 PHARMACEUTICALS(PTY) LTD
Manufacturer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED, HULL,
 NORTHUMBERSIDE, UK
Packer: RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED, HULL,
 NORTHUMBERSIDE, UK
Laboratory: FPRC RECKITT BENCKISER
 HEALTHCARE (UK) LIMITED, HULL,
 NORTHUMBERSIDE, UK
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA

FPRR: RECKITT BENCKISER
 PHARMACEUTICALS (PTY) LTD,
 ELANDSFONTEIN

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

MRF 15

Registration number: A38/11.10/0447
 Name of medicine: GAVISCON 500 PEPPERMINT
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SODIUM ALGINATE 500,0 mg
 SODIUM BICARBONATE 267,0 mg
 CALCIUM CARBONATE 160,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
 Manufacturer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK
 Packer: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK
 Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE (UK) LIMITED, HULL, NORTHUMBERSIDE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA
 FPRR: RECKITT BENCKISER PHARMACEUTICALS(PTY) LTD, ELANDSFONTEIN
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: A38/4/0540
 Name of medicine: CARBOCAINE A 2 % (1:100 000)
 Dosage form: TABLET
 Active ingredients: EACH 1,8 ml CONTAINS:
 MEPIVACAINE HCl 36,0 mg
 ADRENALINE 18,0 µg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: • ADCOCK INGRAM LIMITED
 Manufacturer: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 Packer: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 Laboratory: FPRC: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: A38/4/0541
 Name of medicine: CARBOCAINE A 2 % (1:200 000)
 Dosage form: TABLET
 Active ingredients: EACH 1,8 ml CONTAINS:
 MEPIVACAINE HCl 36,0 mg
 ADRENALINE 9,0 µg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 Packer: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 Laboratory: FPRC: PHARMA-Q (PTY) LTD, INDUSTRIA, JOHANNESBURG
 FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

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

MRF15

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

MRF 15

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

MRF 15

Registration number: A40/1.2/0347
Name of medicine: VALDOXANE 25 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
AGOMELATINE 25,0 mg

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

FPRR: SERVIER LABORATORIES SA (PTY)
LTD, RIVONIA

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

MRF15

Registration number: A40/11.10/0512
Name of medicine: GAVISCON TABLETS COOLMINT
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SODIUM ALGINATE 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: RECKITT BENCKISER
PHARMACEUTICALS (PTY) LTD
Manufacturer: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK
Packer: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK
Laboratory: RECKITT BENCKISER
HEALTHCARE (UK) LTD, HULL,
EAST YORKSHIRE, UK
FPRC: RECKITT BENCKISER
PHARMACEUTICALS (PTY) LTD,
ELANDSFONTEIN
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
SABS PHARMACEUTICAL
CHEMISTRY LABORATORY,
GROENKLOOF, PRETORIA

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

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

MRF 15

Registration number: A40/20.1.1/0774
Name of medicine: AURO-CEFALEXIN CAPSULES
250 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
CEFALEXIN MONOHYDRATE
EQUIVALENT TO CEFALEXIN
250,0 mg

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

FPRR: AUROBINDO PHARMA,
MEYERSDAL, JOHANNESBURG

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

MRF 15

Registration number: A40/20.1.1/0775
Name of medicine: AURO-CEFALEXIN CAPSULES 500 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS: CEFALOXIN MONOHYDRATE EQUIVALENT TO CEFALOXIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/7.1.3/0083
Name of medicine: LOTENSIN CO 50 TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES, SIVERTONDALE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE SA, (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/7.1.3/0087
Name of medicine: LOSACAR CO 50/12,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA
Packer: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA
Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL AND CHEMICAL SERVICES, DEKGRAS ROAD, SILVERTONDALE, RETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH WEST UNIVERSITY, POTSCHEFSTROOM
FPRR: ZYDUS ALTHCARE SA (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life: 36 months
Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/20.1.1/0112
 Name of medicine: AURO CEFADROXIL CAPSULES 500 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS: CEFADROXIL MONOHYDRATE EQUIVALENT TO CEFADROXIL 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 AUGUST 2011

MRF15

Registration number: 41/2.11/0255
 Name of medicine: ADCO TENYL 25 µg/h
 Dosage form: PATCH
 Active ingredients: EACH PATCH CONTAINS: FENTANYL 25,0 µg/h
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: LABORATORIOS BETA S.A., OVINCIA de La RIOJA, ARGENTINA
 Packer: LABORATORIOS BETA S.A., PROVINCIA de La RIOJA, ARGENTINA
 Laboratory: FPRC: LABORATORIOS BETA S.A., PROVINCIA de La RIOJA, ARGENTINA
 ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON
 ADCOCK INGRAM HEALTHCARE (PTY) LTD CLAYVILLE, OLIFANTSFONTEIN
 FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON
 ADCOCK INGRAM HEALTHCARE (PTY) LTD, CLAYVILLE, OLIFANTSFONTEIN
 ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.11/0256
 Name of medicine: ADCO TENYL 50 µg/h
 Dosage form: PATCH
 Active ingredients: EACH PATCH CONTAINS: FENTANYL 50,0 µg/h
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: LABORATORIOS BETA S.A., PROVINCIA de La RIOJA, ARGENTINA
 Packer: LABORATORIOS BETA S.A., PROVINCIA de La RIOJA, ARGENTINA
 Laboratory: FPRC: LABORATORIOS BETA S.A., PROVINCIA de La RIOJA, ARGENTINA
 ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON
 ADCOCK INGRAM HEALTHCARE (PTY) LTD CLAYVILLE, OLIFANTSFONTEIN
 FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON
 ADCOCK INGRAM HEALTHCARE (PTY) LTD, CLAYVILLE, OLIFANTSFONTEIN
 ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 41/2.11/0257
Name of medicine: ADCO TENYL 75 µg/h
Dosage form: PATCH

Active ingredients: EACH PATCH CONTAINS:
 FENTANYL 75,0 µg/h

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
Packer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
Laboratory: FPRC: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD CLAYVILLE,
 OLIFANTSFONTEIN

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

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

MRF15

Registration number: 41/2.11/0258
Name of medicine: ADCO TENYL 100 µg/h
Dosage form: PATCH

Active ingredients: EACH PATCH CONTAINS:
 FENTANYL 100,0 µg/h

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
Packer: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
Laboratory: FPRC: LABORATORIOS BETA S.A.,
 PROVINCIA de La RIOJA,
 ARGENTINA
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD, WADEVILLE,
 GERMISTON
 ADCOCK INGRAM HEALTHCARE
 (PTY) LTD CLAYVILLE,
 OLIFANTSFONTEIN

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

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

MRF 15

Registration number: 41/26/0415
Name of medicine: MITOXANTRON EBEWE 10 mg
Dosage form: CONCENTRATE FOR
 SOLUTION FOR INFUSION

Active ingredients: EACH VIAL CONTAINS:
 MITOXANTRONE HCl
 EQUIVALENT TO
 MITOXANTRONE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: KEY ONCOLOGICS (PTY) LTD
Manufacturer: EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
Packer: EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
Laboratory: FPRC EBEWE PHARMA GmbH Nfg.KG,
 UNTERACH, AUSTRIA
 MIKROBIOLOGISCHES
 PRUFLABOR, INNSBRUCK,
 AUSTRIA
 LABOR L+SAG BAD BOCKLET,
 GERMANY
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG

FPRR: KEY ONCOLOGICS,
 HOUGHTON, JOHANNESBURG

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

MRF 15

Registration number: 41/26/0416
Name of medicine: MITOXANTRON EBEWE 20 mg
Dosage form: CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients: EACH VIAL CONTAINS:
MITOXANTRONE HCI 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
 GENERICS UK LTD., POTTERS BAR,
 HERTFORDSHIRE, UK
 Laboratory: FPRC: GENPHARM PHARMACEUTICALS
 INC., ETOBICOKE, ONTARIO,
 CANADA
 PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 SABS PHARMACEUTICAL
 CHEMISTRY LABORATORY,
 GROENKLOOF, PRETORIA
 RESEARCH INSTITUTE FOR
 INDUSTRIAL
 PHARMACY, NORTH WEST
 UNIVERSITY, POTCHEFSTROOM
 FPRR: PHARMACARE LTD, KORSTEN, PE
 ASPEN PHARMACARE EAST
 LONDON, WILSONIA, EAST LONDON
 PHARMACARE LTD, WOODMEAD,
 RSA
 Shelf-life: 24 months
 Date of registration: 5 AUGUST 2011

MRF 15

Registration number:	41/2.5/0847
Name of medicine:	TOPIRAN 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON MC DERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND 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

MRF15

Registration number:	41/2.5/0858
Name of medicine:	TOPIRAN 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON MC DERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND 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 LIMITED, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	5 AUGUST 2011

MRF 15

Registration number:	41/2.5/0859
Name of medicine:	TOPIRAN 200 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON
Packer:	GENPHARM PHARMACEUTICALS INC., ETOBICOKE, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PE ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON MC DERMOTT LABORATORIES T/A GERARD LABORATORIES, DUBLIN, IRELAND 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: 41/7.1.3/0969
Name of medicine: TEKTRNA 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: TEKTRNA 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

MRF 15

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

MRF 15	
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 LAHBORATORIES 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

MRF 15	
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, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0723
 Name of medicine: CIPLAZAR CO 50/12,5

Dosage form: TABLET

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

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

Applicant: CIPLA MEDPRO (PTY) LTD

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

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

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

FPRR: CIPLA MEDPRO, ROSEN PARK,
 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, ROSEN PARK,
 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,
 ROSEN PARK, BELLVILLE

Shelf-life: 24 months
 (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/7.1.3/0726

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

Dosage form: TABLET

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

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

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

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

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

FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF15

Registration number: 42/1.2/0789

Name of medicine: STRATTERA 80 mg

Dosage form: CAPSULES

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

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

Applicant: ELI LILLY SA (PTY) LTD

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

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

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

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

Shelf-life: 36 months

Date of registration: 5 AUGUST 2011

MRF 15

Registration number: 42/26/0897

Name of medicine: EPICORD 50

Dosage form: INJECTION

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

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

Applicant: ACCORD HEALTHCARE (PTY) LTD

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

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

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

FPRR: ACCORD HEALTHCARE, RIVONIA, RSA

Shelf-life: 24 months (Provisional)

Date of registration: 5 AUGUST 2011

MRF 15

Registration number:	42/26/0900
Name of medicine:	ACCORD EPIRUBICIN 50
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 2,0 mg
Conditions of registration	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	5 AUGUST 2011

MRF15

Registration number:	42/7.1.3/1068
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: BRIMPHEM 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: BRIMPHEM 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, ROSENPARK,
BELVILLE, SOUTH AFRICA

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

MRF 15

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

MRF15

Registration number: 43/2.5/0617
Name of medicine: ASPEN GABAPENTIN 100 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
GABAPENTIN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: KERN PHARMA S.L., TERRASSA,
BARCELONA, SPAIN
Packer: KERN PHARMA S.L., TERRASSA,
BARCELONA, SPAIN
MPF B.V. (Manufacturing Packaging
Farmaca), RX OUDEHASKE, THE
NETHERLANDS
SOFARIMEX INDUSTRIA QUIMICA
e FARMACEUTICA, Lca, 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,
Lca, 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