
GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1739 OF 2007

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number: 37/26/0485
 Name of medicine: BLASTOLEM RU 10 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 CISPLATIN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: KEY ONCOLOGICS (PTY) LTD
 Manufacturer: LEMERY SA de CV, MEXICO
 Packer: LEMERY SA de CV, MEXICO
 Laboratory: LEMERY SA de CV, MEXICO
 FPRC: INSTITUTE FOR PHARMACEUTICAL SERVICES,
 SILVERTONDALE, RSA

FPRR: KEY ONCOLOGICS, SANDTON, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 37/26/0486
 Name of medicine: BLASTOLEM RU 50 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 CISPLATIN 50,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: KEY ONCOLOGICS (PTY) LTD
 Manufacturer: LEMERY SA de CV, MEXICO
 Packer: LEMERY SA de CV, MEXICO
 Laboratory: LEMERY SA de CV, MEXICO
 FPRC: INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE, RSA

FPRR: KEY ONCOLOGICS, SANDTON, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	38/7. 1.3/0121	Registration number:	38/24/0258
Name of medicine:	COVERTEX 8 mg	Name of medicine:	THALIDOMIDE PHARMION 50 mg
Dosage form:	TABLET	Dosage form:	CAPSULES
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: THALIDOMIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD	Applicant:	KEY ONCOLOGICS (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND	Manufacturer:	PENN PHARMACEUTICALS, GWENT, UK
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA	Packer:	PENN PHARMACEUTICALS, GWENT, UK
Laboratory:	FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY FRANCE SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	Laboratory:	FPRC: PENN PHARMACEUTICALS, GWENT, UK INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
Shelf-life:	FPRC: 24 months (Provisional)	Shelf-life:	FPRC: 36 months
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	38/2.7/0303
Name of medicine:	MEPROPAYNE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 320,0 mg CODEINE PHOSPHATE 8,0 mg CAFFEINE 32,0 mg MEPROBAMATE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	MDI cc
Manufacturer:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Packer:	PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE
Laboratory:	FPRC: PHARMANOVA (PVT) LTD, HARARE, ZIMBABWE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
Shelf-life:	FPRC: MDI cc, MENLO PARK, PRETORIA, RSA 24 months
Date of registration:	5 OCTOBER 2007

Registration number:	A39/21.2/0027
Name of medicine:	GLUCOPHAGE XR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK SANTE, CEDEX, FRANCE
Packer:	MERCK SANTE, CEDEX, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:	FPRC: MERCK SANTE, CEDEX, FRANCE MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Shelf-life:	FPRC: MERCK, MODDERFONTEIN, RSA 24 months
Date of registration:	5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	A39/10.2.1/0154	Registration number:	A39/15.4/0202
Name of medicine:	ASPEN SALBUTAMOL 100 ug	Name of medicine:	ALPHAGAN PURITE
Dosage form:	INHALER	Dosage form:	SOLUTION
Active ingredients:	EACH METERED DOSE CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 100,0 ug	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: BRIMONIDINE TARTRATE 1,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED	Applicant:	ALLERGAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	LABORATORIO ALDO-UNION, BARCELONA, SPAIN	Manufacturer:	ALLERGAN INC, WACO, TEXAS, USA
Packer:	LABORATORIO ALDO-UNION, BARCELONA, SPAIN	Packer:	ALLERGAN INC, WACO, TEXAS, USA
Laboratory:	FPRC: LABORATORIO ALDO-UNION, BARCELONA, SPAIN	Laboratory:	FPRC: ALLERGAN INC, WACO, TEXAS, USA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH PHARMACARE LTD, WOODMEAD, SANDTON	FPRR:	ALLERGAN PHARMACEUTICALS, HALFWAY HOUSE, RSA
Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	A39/26/0519
Name of medicine:	OXALIWIN 50 mg/10 ml
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	THISSEN LABORATORIES, BRAIN L'ALLEUD BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	THISSEN LABORATORIES, BRAIN L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA
Laboratory:	FPRC: THISSEN LABORATORIES, BRAIN L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC:	THISSEN LABORATORIES, BRAIN L'ALLEUD, BELGIUM BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	AVENTIS PHARMA, WALTLOO, PRETORIA SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	5 OCTOBER 2007

15	MRF 15
Registration number:	A39/26/0521
Name of medicine:	OXALIWIN 50 mg/10 ml RTU
Dosage form:	INFUSION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: OXALIPLATIN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	BEN VENUE LABORATORIES INC, BEDFORD, OHIO, USA GLAXO WELLCOME PRODUCTION CO, NOTRE DAME DE BONDEVILLE, FRANCE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SANOFI WINTHROP INDUSTRIE, QUETIGNY, FRANCE AVENTIS PHARMA, DAGENHAM, ESSEX, UK
FPRC:	FPRC:
FPRC/FPRR:	FPRC/FPRR:
Shelf-life:	36 months
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: A39/11.4.3/0552
 Name of medicine: LANSOPRAZOLE-WINTHROP 15
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS: 15,0 mg
 LANSOPRAZOLE
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AVENTIS PHARMA (PTY) LTD
 Manufacturer: TAKEDA IRELAND LTD, WICKLOW, IRELAND
 AVENTIS PHARMA SPECIALITES, COMPIEGNE, FRANCE
 Packer: AVENTIS PHARMA, WALTLOO, PRETORIA
 Laboratory: FPRC: PRETORIA AVENTIS PHARMA SPECIALITES,
 COMPIEGNE, FRANCE
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRC/FPRR: AVENTIS PHARMA, WALTLOO, PRETORIA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A39/11.4.3/0553
 Name of medicine: LANSOPRAZOLE-WINTHROP 30
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS: 30,0 mg
 LANSOPRAZOLE
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AVENTIS PHARMA (PTY) LTD
 Manufacturer: TAKEDA IRELAND LTD, WICKLOW, IRELAND
 AVENTIS PHARMA SPECIALITES, COMPIEGNE, FRANCE
 Packer: AVENTIS PHARMA, WALTLOO, PRETORIA
 Laboratory: FPRC: AVENTIS PHARMA SPECIALITES,
 COMPIEGNE, FRANCE
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRC/FPRR: AVENTIS PHARMA, WALTLOO, PRETORIA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number:	A39/7.1.3/0560
Name of medicine:	RAN-QUINAPRIL PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	RANBAXY S.A. (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR	RANBAXY, CENTURION, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15.

Registration number:	A39/7.1.3/0561
Name of medicine:	RAN-QUINAPRIL FORTE PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	RANBAXY S.A. (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A39/7.1.3/0562	Registration number: A39/7.1.3/0563
Name of medicine: QUINPREN PLUS	Name of medicine: QUINPREN FORTE PLUS
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients: EACH TABLET CONTAINS: QUINAPRIL HYDROCHLORIDE EQUIVALENT TO QUINAPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RANBAXY S.A. (PTY) LTD	Applicant: RANBAXY S.A. (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA	Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA	Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRC: RANBAXY (S.A.), CENTURION, RSA	FPRC: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/15.4/0009	Registration number: A40/26/0051
Name of medicine: RETAANE	Name of medicine: PLATOSIN 10 mg/10 ml
Dosage form: SUSPENSION FOR DEPOT INJECTION	Dosage form: INJECTION
Active ingredients: EACH 0.5 ml SUSPENSION CONTAINS: ANECORTAVE ACETATE 15.0 mg	Active ingredients: EACH 10.0 ml VIAL CONTAINS: CISPLATIN 10.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: ALCON LABORATORIES (SA) (PTY) LTD	Applicant: PHARMACHEMIE (PTY) LTD
Manufacturer: ALCON MANUFACTURING LTD, FORT WORTH, TEXAS, USA	Manufacturer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS
Packer: ALCON MANUFACTURING LTD, FORT WORTH, TEXAS, USA	Packer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS
Laboratory: FPRC: ALCON MANUFACTURING LTD, FORT WORTH, TEXAS, USA	Laboratory: FPRC: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: ALCON LABORATORIES, BRYANSTON, RSA	FPRR: PHARMACHEMIE, RUIMSIG, ROODEPOORT
Shelf-life: 36 months	Shelf-life: 24 months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/26/0052	Registration number: A40/20.1.2/0088
Name of medicine: PLATOSIN 50 mg/50 ml	Name of medicine: CLAMENTIN 1000 mg
Dosage form: INJECTION	Dosage form: TABLET
Active ingredients: EACH 50,0 ml VIAL CONTAINS: CISPLATIN 50,0 mg	Active ingredients: EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 875,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: PHARMACHEMIE (PTY) LTD	Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS	Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS	Packer: SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory: FPRC: PHARMACHEMIE B.V., HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA GENERICS UK, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC: PHARMACHEMIE, RUIMSIG, ROODEPOORT	FPRC: MERCK GENERICS RSA, MODDERFONTEIN
Shelf-life: 24 months	Shelf-life: 24 Months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/15.1/0091

Name of medicine: ZOXAN EYE DROPS

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT
TO CIPROFLOXACIN 3,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: FDC LTD, WALUJ, AURANGABAD, INDIA

Packer: FDC LTD, WALUJ, AURANGABAD, INDIA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC: FDC LTD, WALUJ, AURANGABAD, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICALS
SERVICES, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG

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

FPRR: PHARMACARE LTD, WOODMEAD, SANDTON

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/2.5/0118

Name of medicine: SANDOZ TOPIRAMATE 25

Dosage form: TABLET

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

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

Applicant: SANDOZ S.A. (PTY) LTD

Manufacturer: SANDOZ PVT LTD, NAVI MUMBAI, INDIA

Packer: SANDOZ PVT LTD, NAVI MUMBAI, INDIA
SANDOZ S.A., SPARTAN, KEMPTON PARK

Laboratory: FPRC: SANDOZ PVT LTD, NAVI MUMBAI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRC/FPRR: SANDOZ S.A, SPARTAN, KEMPTON PARK

Shelf-life: 24 months (provisional)

Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	A40/2.5/0119	Registration number:	A40/2.5/0120
Name of medicine:	SANDOZ TOPIRAMATE 50	Name of medicine:	SANDOZ TOPIRAMATE 100
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: TOPIRAMATE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ S.A. (PTY) LTD	Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, NAVI MUMBAI, INDIA	Manufacturer:	SANDOZ PVT LTD, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, NAVI MUMBAI, INDIA SANDOZ S.A., SPARTAN, KEMPTON PARK	Packer:	SANDOZ PVT LTD, NAVI MUMBAI, INDIA SANDOZ S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PVT LTD, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA	Laboratory:	FPRC: SANDOZ PVT LTD, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK	FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/2.5/0121	Registration number: A40/20.1.1/0198
Name of medicine: SANDOZ TOPIRAMATE 200	Name of medicine: MEDAXONE 1 g
Dosage form: TABLET	Dosage form: INJECTION
Active ingredients: EACH TABLET CONTAINS: TOPIRAMATE 200,0 mg	Active ingredients: EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: SANDOZ S.A. (PTY) LTD	Applicant: SPECPHARM (PTY) LTD
Manufacturer: SANDOZ PVT LTD, NAVI MUMBAI, INDIA	Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Packer: SANDOZ PVT LTD, NAVI MUMBAI, INDIA SANDOZ S.A., SPARTAN, KEMPTON PARK	Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
Laboratory: FPRC: SANDOZ PVT LTD, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA	Laboratory: FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK	FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life: 24 months (provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/20.1.1/0199

Name of medicine: MEDAXONE 250 mg

Dosage form: INJECTION

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

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

Applicant: SPECPHARM (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Laboratory: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
ANALYTICON, TERENURE, KEMPTON PARK

FPRC:

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/20.1.1/0200

Name of medicine: MEDAXONE 500 mg

Dosage form: INJECTION

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

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

Applicant: SPECPHARM (PTY) LTD

Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Laboratory: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
ANALYTICON, TERENURE, KEMPTON PARK

FPRC:

FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/2.9/0388	Registration number: A40/20.1.1/0393
Name of medicine: AUSTELL-TRAMADOL 50 mg	Name of medicine: STRIDES-CEFOTAMAX
Dosage form: CAPSULE	Dosage form: INJECTION
Active ingredients: EACH CAPSULE CONTAINS: TRAMADOL HYDROCHLORIDE 50,0 mg	Active ingredients: EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: AUSTELL LABORATORIES (PTY) LTD	Applicant: STRIDES S.A. PHARMACEUTICALS (PTY) LTD
Manufacturer: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA	Manufacturer: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA	Packer: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory: FPRC: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA	Laboratory: FPRC: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRC: AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG	FPRC: STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/10.2.1/0413	Registration number: A40/10.2.1/0414
Name of medicine: FORATEC HFA	Name of medicine: CIPLA-FORMOTEROL FUMARATE HFA
Dosage form: INHALER	Dosage form: INHALER
Active ingredients: EACH ACTUATION DELIVERS: FORMOTEROL FUMARATE 12,0 ug	Active ingredients: EACH ACTUATION DELIVERS: FORMOTEROL FUMARATE 12,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: CIPLA MEDPRO (PTY) LTD	Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA	Manufacturer: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA
Packer: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA	Packer: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA
Laboratory: FPRC: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA	Laboratory: FPRC: CIPLA LTD, (UNIT II), VERNA, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE	FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/11.4.3/0415	Registration number: A40/7.5/0474
Name of medicine: GULF RANITIDINE 300	Name of medicine: RAN-PRAVASTATIN 10
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 300,0 mg	Active ingredients: EACH TABLET CONTAINS: PRAVASTATIN SODIUM 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: GULF DRUG COMPANY (PTY) LTD	Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA	Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA	Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory: FPRC: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: GULF DRUG COMPANY, MOUNT EDGECOMBE, DURBAN, RSA	FPRR: RANBAXY, CENTURION, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/7.5/0475	Registration number: A40/7.5/0476
Name of medicine: RAN-PRAVASTATIN 20	Name of medicine: RAN-PRAVASTATIN 40
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: PRAVASTATIN SODIUM 20,0 mg	Active ingredients: EACH TABLET CONTAINS: PRAVASTATIN SODIUM 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RANBAXY (S.A.) (PTY) LTD	Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA	Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA	Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR: RANBAXY, CENTURION, RSA	FPRR: RANBAXY, CENTURION, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	
Registration number:	A40/1.2/0483
Name of medicine:	ZOSERT 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES, DADRA & NAGAR HAVELI, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: SUN PHARMACEUTICAL INDUSTRIES, DADRA & NAGAR HAVELI, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	
Registration number:	A40/1.2/0491
Name of medicine:	VENLAFAXINE-HEXAL 150 mg XL
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA SANDOZ S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/1.2/0492	Registration number: A40/1.2/0493
Name of medicine: SANDOZ VENLAFAXINE XL 150	Name of medicine: VENLAFAXINE-HEXAL 75 mg XL
Dosage form: CAPSULE	Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg	Active ingredients: EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: SANDOZ S.A. (PTY) LTD	Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA	Manufacturer: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA
Packer: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA	Packer: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA
Laboratory: FPRC: SANDOZ S.A., SPARTAN, KEMPTON PARK	Laboratory: FPRC: SANDOZ S.A., SPARTAN, KEMPTON PARK
FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK	FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	A40/1.2/0494	Registration number:	A40/20.2.8/0507
Name of medicine:	SANDOZ VENLAFAXINE XL 75	Name of medicine:	SONKE-EFAVIRENZ 200
Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ S.A. (PTY) LTD	Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA	Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:	SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA SANDOZ S.A., SPARTAN, KEMPTON PARK	Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: SANDOZ PRIVATE LTD, KALWE, NAVI MUMBAI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA ANALYTICON, TERENURE, KEMPTON PARK	Laboratory:	FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK	FPRR:	RANBAXY, CENTURION, RSA
Shelf-life:	24 months	Shelf-life:	24 months (provisional)
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/20.2.8/0508	Registration number: A40/1.2/0652
Name of medicine: SONKE-EFAVIRENZ 600	Name of medicine: AURO MIRTAZAPINE 15 mg
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: EFAVIRENZ 600.0 mg	Active ingredients: EACH TABLET CONTAINS: MIRTAZAPINE 15.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RANBAXY (S.A.) (PTY) LTD	Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA	Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA	Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM	Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
FPRR RANBAXY, CENTURION, RSA	FPRR: AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG
Shelf-life: 24 months (provisional)	Shelf-life: 24 months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	A40/1.2/0653	Registration number:	A40/1.2/0662
Name of medicine:	AURO MIRTAZAPINE 30 mg	Name of medicine:	ZYDUS-SERTRALINE 50
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg	Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA
Laboratory:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Laboratory:	ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG	FPRR:	ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: A40/11.4.3/0663	Registration number: A40/11.4.3/0667
Name of medicine: GULF RANITIDINE 150	Name of medicine: GULF RANITIDINE 75
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 150,0 mg	Active ingredients: EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 75,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: GULF DRUG COMPANY (PTY) LTD	Applicant: GULF DRUG COMPANY (PTY) LTD
Manufacturer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA	Manufacturer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Packer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA	Packer: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA
Laboratory: FPRC: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG	Laboratory: FPRC: ALEMBIC LTD, PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
FPRC: GULF DRUG COMPANY, MOUNT EDGEcombe, DURBAN, RSA	FPRC: GULF DRUG COMPANY, MOUNT EDGEcombe, DURBAN, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15	
Registration number:	A40/20.1.1/0720
Name of medicine:	AUROXIME TABLETS 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRC:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	
Registration number:	A40/20.1.1/0721
Name of medicine:	AUROXIME TABLETS 500 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRC:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	
Registration number:	A40/20.1.1/0725
Name of medicine:	AUROXIME TABLETS 125 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	
Registration number:	A40/5.10/0732
Name of medicine:	DANSET 4 mg
Dosage form:	INJECTION
Active ingredients:	EACH 2.0 ml SOLUTION CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	KLEVA S.A., ACHARNAI, GREECE
Packer:	KLEVA S.A., ACHARNAI, GREECE
Laboratory:	FPRC: KLEVA S.A., ACHARNAI, GREECE ANALYTICON, TEREURE, KEMPTON PARK
FPRR:	SPECPHARM HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: A40/5.10/0733
 Name of medicine: DANSET 8 mg
 Dosage form: INJECTION
 Active ingredients: EACH 4.0 ml SOLUTION CONTAINS:
 ONDANSETRON HYDROCHLORIDE EQUIVALENT
 TO ONDANSETRON 8,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: KLEVA S.A., ACHARNAI, GREECE
 Packer: KLEVA S.A., ACHARNAI, GREECE
 Laboratory: KLEVA S.A., ACHARNAI, GREECE
 ANALYTICON, TERENURE, KEMPTON PARK
 FPRC:
 FPRR: SPECPHARM HALFWAY HOUSE, MIDRAND
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/21.2/0745
 Name of medicine: METPHAGE 500 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: PHARMACARE LIMITED
 Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 Packer:
 Laboratory: SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY, POTCHEFSTROOM
 FPRC/FPRR:
 FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/21.2/0746
 Name of medicine: METPHAGE 850 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE 850,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: PHARMACARE LIMITED
 Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,
 NORTH-WEST UNIVERSITY, POTCHEFSTROOM
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 ASPEN PHARMACARE, WILSONIA, EAST LONDON
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: A40/20.2.8/0773
 Name of medicine: AURO-STAVUDINE POWDER FOR ORAL
 SOLUTION 1 mg/ml
 Dosage form: POWDER
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 STAVUDINE 1,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, ANDHRA
 PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, ANDHRA
 PRADESH, INDIA
 Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, ANDHRA
 PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG, RSA
 Shelf-life: 24 months (provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	41/20.1.1/0007
Name of medicine:	TAVALOX 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
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	FPRC: CIPLA LTD, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

Registration number:	41/20.1.1/0008
Name of medicine:	TAVALOX 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
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	FPRC: CIPLA LTD, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	41/20.1.1/0007
Name of medicine:	TAVALOX 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
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	CIPLA LTD, SALCETTE, GOA, INDIA
FPRC:	FPRC:
FPRR:	FPRR:
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

Registration number:	41/20.1.1/0008
Name of medicine:	TAVALOX 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
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, SALCETTE, GOA, INDIA
Laboratory:	CIPLA LTD, SALCETTE, GOA, INDIA
FPRC:	FPRC:
FPRR:	FPRR:
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: 41/20.1.1/0009
 Name of medicine: TAVALOX 750
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN HEMIHYDRATE EQUIVALENT
 TO
 LEVOFLOXACIN 750,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: CIPLA MEDPRO (PTY) LTD
 Manufacturer: CIPLA LTD, SALCETTE, GOA, INDIA
 Packer: CIPLA LTD, SALCETTE, GOA, INDIA
 Laboratory: CIPLA LTD, SALCETTE, GOA, INDIA
 FPRC:
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/20.1.1/0010
 Name of medicine: CIPLA-LEVOFLOXACIN 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
 Applicant: CIPLA LIFE SCIENCES (PTY) LTD
 Manufacturer: CIPLA LTD, VERNA, SALCETTE, GOA,
 INDIA
 Packer: CIPLA LTD, VERNA, SALCETTE, GOA,
 INDIA
 Laboratory: CIPLA LTD, VERNA, SALCETTE, GOA,
 INDIA
 FPRC:
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/20.1.1/0011
 Name of medicine: CIPLA-LEVOFLOXACIN 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
 Applicant: CIPLA LIFE SCIENCES (PTY) LTD
 Manufacturer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 Packer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 Laboratory: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/20.1.1/0012
 Name of medicine: CIPLA-LEVOFLOXACIN 750
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LEVOFLOXACIN HEMIHYDRATE
 EQUIVALENT TO
 LEVOFLOXACIN 750,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: CIPLA LIFE SCIENCES (PTY) LTD
 Manufacturer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 Packer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 Laboratory: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.2/0071
 Name of medicine: DIAFORM 500
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE EQUIVALENT
 TO
 METFORMIN 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT,
 RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.2/0072
 Name of medicine: DIAFORM 850
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE
 EQUIVALENT TO
 METFORMIN 850,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 FPRC/FPRR: BE-TABS PHARMACEUTICALS,
 ROODEPOORT, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number: 41/20.2.8/0106	Registration number: 41/20.1.1/0138
Name of medicine: CIPLA-EFAVIRENZ 600	Name of medicine: BETAROXIME T 250
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg	Active ingredients: EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: CIPLA LIFE SCIENCES (PTY) LTD	Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
Manufacturer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA	Manufacturer: AUROBINDO PHARMA LTD, MEDAK, DISTRICT, ANDHRA PRADESH, INDIA
Packer: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA	Packer: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: CIPLA LTD, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRC: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE	FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	41/20.1.1/0139	Registration number:	41/1.2/0142
Name of medicine:	BETAROXIME T 500	Name of medicine:	ASPEN MIRTAZAPINE 15 mg
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500.0 mg	Active ingredients:	EACH TABLET CONTAINS: MIRTAZAPINE 15.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	BE-TABS PHARMACEUTICALS (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	AUROBINDO PHARMA LTD, MEDAK, DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Packer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC: AUROBINDO PHARMA LTD, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Laboratory:	FPRC: ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months (Provisional)	Shelf-life:	PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:	5 OCTOBER 2007	Date of registration:	24 months 5 OCTOBER 2007

MRF 15

Registration number:	41/1.2/0143
Name of medicine:	ASPEN MIRTAZAPINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC: ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number:	41/1.2/0144
Name of medicine:	ASPEN MIRTAZAPINE 45 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZAPINE 45,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:	FPRC: ALPHAPHARM PTY LTD, BRISBANE, QUEENSLAND, AUSTRALIA GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, STATION CLOSE, HERTFORDSHIRE, UK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: 41/20.2/0155

Name of medicine: METRONIDAZOLE B BRAUN 500 mg/100 ml

Dosage form: INFUSION

Active ingredients: EACH 100.0 ml SOLUTION CONTAINS:
METRONIDAZOLE 500.0 mg

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
B BRAUN MEDICAL S.A., BARCELONA, SPAIN

Packer: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
B BRAUN MEDICAL S.A., BARCELONA, SPAIN

Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN,
GERMANY
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
COSI PHARMACEUTICALS, INDUSTRIA-WEST,
JOHANNESBURG
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG,
RSA

Shelf-life: 36 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/5.7.1/0226

Name of medicine: ZYDUS DESLORATADINE 5 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DESLORATADINE 5.0 mg

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

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

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

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

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
SANAND, AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE S.A., VAN DER
HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months (Provisional)

Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	41/7.1.3/0286
Name of medicine:	ZARTAN 25 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND
Packer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Shelf-life:	FPRR: PHARMA DYNAMICS, WESTLAKE, RSA 24 months (Provisional)
Date of registration:	5 OCTOBER 2007

Registration number:	41/7.1.3/0287
Name of medicine:	ZARTAN 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND
Packer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
Laboratory:	FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS HF, KOPAVOGUR, ICELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Shelf-life:	FPRR: PHARMA DYNAMICS, WESTLAKE, RSA 24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: 41/7.1.3/0288
 Name of medicine: ZARTAN 12,5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
 TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
 PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
 Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
 FPRR: PHARMA DYNAMICS, WESTLAKE, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.1.3/0289
 Name of medicine: ZARTAN 100 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA
 TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
 PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN
 Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS HF, KOPAVOGUR, ICELAND
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
 FPRR: PHARMA DYNAMICS, WESTLAKE, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/1.2/0321

Name of medicine: IMIGEN 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SUMATRIPTAN SUCCINATE EQUIVALENT TO
SUMATRIPTAN 50,0 mg

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

Applicant: MERCK GENERICS RSA (PTY) LTD

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

Packer: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA y QUIMICA S.A, MOLLET DEL
VALLES, BARCELONA, SPAIN
GENERICS UK, STATION CLOSE, HERTFORDSHIRE

Laboratory: FPRC: GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA y QUIMICA S.A, MOLLET DEL
VALLES, BARCELONA, SPAIN
GENERICS UK, STATION CLOSE, HERTFORDSHIRE

FPRC/FPRR: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

FPRR: MERCK GENERICS RSA, MODDERFONTEIN

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/1.2/0322

Name of medicine: IMIGEN 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SUMATRIPTAN SUCCINATE EQUIVALENT TO
SUMATRIPTAN 100,0 mg

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

Applicant: MERCK GENERICS RSA (PTY) LTD

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

Packer: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA y QUIMICA S.A, MOLLET DEL
VALLES, BARCELONA, SPAIN
GENERICS UK, STATION CLOSE, HERTFORDSHIRE

Laboratory: FPRC: GENPHARM PHARMACEUTICALS, ETOBICOKE,
ONTARIO, CANADA
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK FARMA y QUIMICA S.A, MOLLET DEL
VALLES, BARCELONA, SPAIN
GENERICS UK, STATION CLOSE, HERTFORDSHIRE

FPRC/FPRR: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

FPRR: MERCK GENERICS RSA, MODDERFONTEIN

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15		MRF 15	
Registration number:	41/1 2/0360	Registration number:	41/1 2/0361
Name of medicine:	XIXIA-SUMATRIPTAN 50	Name of medicine:	XIXIA-SUMATRIPTAN 100
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50.0 mg	Active ingredients:	EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6	Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA	Manufacturer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA Y QUIMICA S.A. MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS UK, STATION CLOSE, HERTFORDSHIRE	Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA Y QUIMICA S.A. MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS UK, STATION CLOSE, HERTFORDSHIRE
Laboratory:	FPRC:	Laboratory:	FPRC:
	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA Y QUIMICA S.A. MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS UK, STATION CLOSE, HERTFORDSHIRE		GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA GERARD LABORATORIES, DUBLIN, IRELAND MERCK FARMA Y QUIMICA S.A. MOLLET DEL VALLES, BARCELONA, SPAIN GENERICS UK, STATION CLOSE, HERTFORDSHIRE
FPRC/FPRR:		FPRC/FPRR:	
	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON		MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
FPRR:		FPRR:	
	XIXIA PHARMACEUTICALS, MODDERFONTEIN		XIXIA PHARMACEUTICALS, MODDERFONTEIN
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007	Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0381
 Name of medicine: AURO-SIMVASTATIN 5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0382
 Name of medicine: AURO-SIMVASTATIN 10 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0383
 Name of medicine: AURO-SIMVASTATIN 20 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 20.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH
 FPRR: AUROBINDO PHARMA, ROSEBANK, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0384
 Name of medicine: AURO-SIMVASTATIN 40 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 40.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH
 FPRR: AUROBINDO PHARMA, ROSEBANK, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0385
 Name of medicine: AURO-SIMVASTATIN 80 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 80,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC:
 FPRR: AUROBINDO PHARMA, ROSEBANK, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/20.1.1/0390
 Name of medicine: MERCK-CIPROFLOXACIN IV
 Dosage form: INFUSION
 Active ingredients: EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: XIXIA PHARMACEUTICALS (PTY) LTD
 Manufacturer: BIOMENDI S.A., BERNEDO, ALAVA, SPAIN
 Packer: BIOMENDI S.A., BERNEDO, ALAVA, SPAIN
 DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
 Laboratory: BIOMENDI S.A., BERNEDO, ALAVA, SPAIN
 RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRC:
 FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0391
 Name of medicine: CHOLESTE 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
 Manufacturer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 Shelf-life: 48 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0392
 Name of medicine: CHOLESTE 20
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: SIMVASTATIN 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD
 Manufacturer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA
 Shelf-life: 48 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.5/0393

Name of medicine: CHOLESTE 40

Dosage form: TABLET

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

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

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Packer: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

Laboratory: AUROBINDO PHARMA, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRC/FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 48 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.12/0422

Name of medicine: FINCAR 5

Dosage form: TABLET

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

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

Packer: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

Laboratory: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELVILLE

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.2/0519
 Name of medicine: SULPHONUR 1 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GLIMEPIRIDE 1.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: SPECIPHARM (PTY) LTD
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Laboratory: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 ANALYTICON, TERENURE, KEMPTON PARK
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.2/0520
 Name of medicine: SULPHONUR 2 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 GLIMEPIRIDE 2.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: SPECIPHARM (PTY) LTD
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Laboratory: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 ANALYTICON, TERENURE, KEMPTON PARK
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/21.2/0521
 Name of medicine: SULPHONUR 4 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: SPECIPHARM (PTY) LTD
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE
 Laboratory: SPECIFAR S.A., VARVARA, ATHENS, GREECE ANALYTICON, TERENURE, KEMPTON PARK, RSA
 FPRC:
 Shelf-life: 24 months (Provisional)
 Date of registration: 5 OCTOBER 2007
 FPRR: SPECIPHARM, HALFWAY HOUSE, MIDRAND

MRF 15

Registration number: 41/1.2/0529
 Name of medicine: AUROZAPINE 15 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS: MIRTAZAPINE 15,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: AUROBINDO PHARMA (PTY) LTD
 Manufacturer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Packer: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 Laboratory: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
 FPRC:
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007
 FPRR: AUROBINDO PHARMA, ROSEBANK, RSA

MRF 15	MRF 15
Registration number:	41/1.2/0530
Name of medicine:	AUROZAPINE 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MIRTAZAPINE 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

Registration number:	41/1.2/0531
Name of medicine:	AURO-CITALOPRAM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	5 OCTOBER 2007

MRF 15	MRF 15
Registration number: 41/7.3/0676	Registration number: 41/7.3/0677
Name of medicine: RAN-SUMATRIPTAN 50	Name of medicine: RAN-SUMATRIPTAN 100
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 50,0 mg	Active ingredients: EACH TABLET CONTAINS: SUMATRIPTAN SUCCINATE EQUIVALENT TO SUMATRIPTAN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6	Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RANBAXY (SA) (PTY) LTD	Applicant: RANBAXY (SA) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA	Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA	Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR: RANBAXY S.A., CENTURION, RSA	FPRR: RANBAXY S.A., CENTURION, RSA
Shelf-life: 24 months	Shelf-life: 24 months
Date of registration: 5 OCTOBER 2007	Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.3/0678
 Name of medicine: MIGO 50
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SUMATRIPTAN SUCCINATE EQUIVALENT TO
 SUMATRIPTAN 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 KHULULEKANI LABORATORY SERVICES,
 MIDRAND, RSA

FPRC: RANBAXY S.A., CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.3/0679
 Name of medicine: MIGO 100
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SUMATRIPTAN SUCCINATE EQUIVALENT
 TO
 SUMATRIPTAN 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: RANBAXY (SA) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 KHULULEKANI LABORATORY SERVICES,
 MIDRAND, RSA

FPRC: RANBAXY S.A., CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	41/20.2.8/0680
Name of medicine:	AURO-ZIDOVUDINE CAPSULES 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

Registration number:	41/20.2.8/0681
Name of medicine:	AURO-ZIDOVUDINE CAPSULES 250 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ZIDOVUDINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	5 OCTOBER 2007

MRF 15

Registration number: 41/7.1/0881

Name of medicine: AMLODIPINE-WINTHROP 5 mg

Dosage form: TABLET

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

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

Applicant: SANOFI-SYNTHELABO (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, PILERNE,
BARDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES LTD, PILERNE,
BARDEZ, GOA, INDIA
AVENTIS PHARMA, WALTLOO, PRETORIA

Laboratory: FPRC: UNICHEM LABORATORIES LTD, PILERNE,
BARDEZ, GOA, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRC/FPRR: AVENTIS PHARMA, WALTLOO, PRETORIA

FPRR: SANOFI-SYNTHELABO, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15

Registration number: 41/7.1/0882

Name of medicine: AMLODIPINE-WINTHROP 10 mg

Dosage form: TABLET

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

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

Applicant: SANOFI-SYNTHELABO (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD,
PILERNE, BARDEZ, GOA, INDIA

Packer: UNICHEM LABORATORIES LTD,
PILERNE, BARDEZ, GOA, INDIA
AVENTIS PHARMA, WALTLOO, PRETORIA

Laboratory: FPRC: UNICHEM LABORATORIES LTD,
PILERNE, BARDEZ, GOA, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRC/FPRR: AVENTIS PHARMA, WALTLOO, PRETORIA

FPRR: SANOFI-SYNTHELABO, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 5 OCTOBER 2007

MRF 15	MRF 15
Registration number:	38/10.1/0219
Name of medicine:	CHIEF COUGH SYRUP – HONEY FLAVOUR
Dosage form:	SYRUP
Active ingredients:	EACH 5.0 ml SYRUP CONTAINS: GUAIPHENESIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRC:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (provisional)
Date of registration:	16 NOVEMBER 2007

Registration number:	A40/2.2/0753
Name of medicine:	ADCO MIDAZOLAM INJECTION 5 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 5.0 ml AMPOULE CONTAINS: MIDAZOLAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRC:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Shelf-life:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG 24 months (Provisional)
Date of registration:	16 NOVEMBER 2007

MRF 15

Registration number:	A40/2.2/0754
Name of medicine:	ADCO MIDAZOLAM INJECTION 15 mg/3 ml
Dosage form:	INJECTION
Active ingredients:	EACH 3.0 ml AMPOULE CONTAINS: MIDAZOLAM 15.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	16 NOVEMBER 2007

MRF 15

Registration number:	A40/2.2/0755
Name of medicine:	ADCO MIDAZOLAM INJECTION 50 mg/10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 10.0 ml AMPOULE CONTAINS: MIDAZOLAM 50.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	16 NOVEMBER 2007

MRF 15

Registration number: 41/21.12/0221

Name of medicine: FINPECIA 1 mg

Dosage form: TABLET

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

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

Packer: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

Laboratory: FPRC: CIPLA LTD, VIRGONAGAR, BANGALORE, INDIA

FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 Months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0231

Name of medicine: ZYDORIN TABLETS

Dosage form: TABLET

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

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON,
JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE,
WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON,
JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, BRYANSTON,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15	MRF 15
Registration number: 41/20.2.8/0232	Registration number: 41/20.2.8/0233
Name of medicine: NERIV TABLETS	Name of medicine: RETLAM TABLETS
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: NEVIRAPINE 200,0 mg	Active ingredients: EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED	Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE, GERMISTON	Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: ADCOCK INGRAM HEALTHCARE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG	Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Laboratory: FPRC/FPFR: ADCOCK INGRAM HEALTHCARE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG	Laboratory: FPRC/FPFR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
FPFR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG	FPFR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (provisional)
Date of registration: 16 NOVEMBER 2007	Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0234

Name of medicine: ZETRODIN TABLETS

Dosage form: TABLET

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

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0308

Name of medicine: LAVOS SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LAMIVUDINE 10,0 mg

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0508
 Name of medicine: ZYDORIN SYRUP ALCOHOL AND SUGAR FREE
 Dosage form: SYRUP
 Active ingredients: EACH 5.0 ml SYRUP CONTAINS:
 ZIDOVUDINE 50.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0509
 Name of medicine: ZYDORIN SYRUP
 Dosage form: SYRUP
 Active ingredients: EACH 5.0 ml SYRUP CONTAINS:
 ZIDOVUDINE 50.0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
 Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
 Shelf-life: 24 months (Provisional)
 Date of registration: 16 NOVEMBER 2007

MRF 15	MRF 15
Registration number: 41/20.2.8/0512	Registration number: 41/20.2.8/0513
Name of medicine: ZETRODIN SOLUTION ALCOHOL AND SUGAR FREE	Name of medicine: ZETRODIN SYRUP
Dosage form: SOLUTION	Dosage form: SYRUP
Active ingredients: EACH 5.0 ml SOLUTION CONTAINS: ZIDOVUDINE 50,0 mg	Active ingredients: EACH 5.0 ml SYRUP CONTAINS: ZIDOVUDINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM LIMITED	Applicant: ADCOCK INGRAM LIMITED
Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON	Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG	FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 16 NOVEMBER 2007	Date of registration: 16 NOVEMBER 2007

MRF 15	MRF 15
Registration number:	41/20.2.8/0515
Name of medicine:	RETLAM SOLUTION ALCOHOL AND SUGAR FREE
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LAMIVUDINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory:	FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	16 NOVEMBER 2007

Registration number:	41/20.2.8/0516
Name of medicine:	LAVOS SOLUTION ALCOHOL AND SUGAR FREE
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LAMIVUDINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory:	FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
FPRR:	ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0927

Name of medicine: RENZIR 600 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: 600.0 mg
EFAVIRENZ

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0928

Name of medicine: REFAVIN 600 mg

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS: 600.0 mg
EFAVIRENZ

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG

FPRR: ADCOCK INGRAM LTD, BRYANSTON, JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007

MRF 15

Registration number: 41/20.2.8/0929

Name of medicine: ADCO-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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON

Packer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON

Laboratory: FPRC/FPFR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON
ADCOCK INGRAM LTD, AEROTON,
JOHANNESBURG

FPFR: ADCOCK INGRAM LTD, BRYANSTON,
JOHANNESBURG

Shelf-life: 24 months (Provisional)

Date of registration: 16 NOVEMBER 2007