
GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 434 OF 2008

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: 06/21.9/15
Name of medicine: RILEXINE ORAL PASTE
Dosage form: PASTE
Active ingredients: EACH 1,0 g PASTE CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: VIRBAC RSA (PTY) LTD
Manufacturer: VIRBAC SA, CARROS, CEDEX, FRANCE
Packer: VIRBAC SA, CARROS, CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA
Laboratory: FPRC: VIRBAC SA, CARROS, CEDEX, FRANCE
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG, RSA
FPRR: VIRBAC RSA, CENTURION, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 31/7.5/0516
Name of medicine: TEVA-GEMFIBROZIL 600 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
GEMFIBROZIL 600,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer: TEVA PHARMACEUTICAL INDUSTRIES,
NETANYA, ISRAEL
Packer: TEVA PHARMACEUTICAL INDUSTRIES,
NETANYA, ISRAEL
Laboratory: FPRC: TEVA PHARMACEUTICAL INDUSTRIES,
NETANYA, ISRAEL
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG, RSA
FPRR: TEVA PHARMACEUTICALS, RUIMSIG,
ROODEPOORT
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 36/30.3/0344
Name of medicine: OCTANATE 250
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR VIII 250,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
OCTAPHARMA S.A., LINGOLSHEIM, FRANCE

Packer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

Laboratory: FPRC: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR: JE ECKARD, MONUMENT PARK, PRETORIA, RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 36/30.3/0345
Name of medicine: OCTANATE 500
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR VIII
500,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
OCTAPHARMA S.A., LINGOLSHEIM,
FRANCE

Packer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

Laboratory: FPRC: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR: JE ECKARD, MONUMENT PARK, PRETORIA,
RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 36/30.3/0346
Name of medicine: OCTANATE 1000
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR VIII 1000,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
OCTAPHARMA S.A., LINGOLSHEIM, FRANCE
Packer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
Laboratory: FPRC: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR: JE ECKARD, MONUMENT PARK, PRETORIA, RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 37/30.3/0645
Name of medicine: OCTANINE F 250
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR IX
250,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
Packer: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA
Laboratory: FPRC: OCTAPHARMA PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR: JE ECKARD, MONUMENT PARK, PRETORIA,
RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 37/30.3/0646
Name of medicine: OCTANINE F 500
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR IX 500,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA
Packer: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA
Laboratory: FPRC: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR JE ECKARD, MONUMENT PARK, PRETORIA, RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 37/30.3/0647
Name of medicine: OCTANINE F 1000
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
HUMAN COAGULATION FACTOR IX
1000,0 iu

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JE ECKARD
Manufacturer: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA
Packer: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA
Laboratory: FPRC: OCTAPharma PHARMAZEUTIKA, VIENNA,
AUSTRIA

FPRR: JE ECKARD, MONUMENT PARK, PRETORIA,
RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 38/7.1.3/0117
Name of medicine: COVERON 8 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: EGIS PHARMACEUTICALS SOUTH AFRICA
 (PTY) LTD
Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
 FRANCE
 SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
 FRANCE
 SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
 TECHNIKON LABORATORIES, ROBERTVILLE, RSA
Laboratory: FPRC: LES LABORATOIRES SERVIER INDUSTRIE, GIDY
 FRANCE
 SERVIER IRELAND INDUSTRIES, WICKLOW, IRELAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG, RSA
FPRR EGIS PHARMACEUTICALS S.A., RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 38/7.1.3/0118
Name of medicine: CIRCATOR 8 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 PERINDOPRIL, TERT-BUTYLAMINE 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: EGIS PHARMACEUTICALS SOUTH AFRICA
 (PTY) LTD
 LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY FRANCE
Manufacturer: SERVIER IRELAND INDUSTRIES, WICKLOW,
 IRELAND
Packer: LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY FRANCE
 SERVIER IRELAND INDUSTRIES, WICKLOW,
 IRELAND
 TECHNIKON LABORATORIES, ROBERTVILLE,
 RSA
Laboratory: FPRC LES LABORATOIRES SERVIER INDUSTRIE,
 GIDY FRANCE
 SERVIER IRELAND INDUSTRIES, WICKLOW,
 IRELAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG, RSA
FPRR EGIS PHARMACEUTICALS S.A., RIVONIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 38/20.1.1/0235
Name of medicine: SANDOZ ROXITHROMYCIN 150
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ROXITHROMYCIN 150,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
Packer: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
NOVARTIS S.A., SPARTAN, KEMPRON PARK, RSA
Laboratory: FPRC: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
NOVARTIS S.A., SPARTAN, KEMPRON PARK, RSA
FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Shelf-life: 60 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 38/20.1.1/0236
Name of medicine: SANDOZ ROXITHROMYCIN 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ROXITHROMYCIN 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
Packer: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
NOVARTIS S.A., SPARTAN, KEMPRON PARK,
RSA
Laboratory: FPRC: THE UNITED PHARMACEUTICAL MFG CO,
AMMAN, JORDAN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
NOVARTIS S.A., SPARTAN, KEMPRON PARK,
RSA
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK,
RSA
Shelf-life: 60 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A38/15.1/0647
Name of medicine: CHLORAMPHENICOL EYE DROPS BP 0,5 % w/v
Dosage form: DROPS
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CHLORAMPHENICOL 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMACARE LIMITED
Manufacturer: FDC LIMITED, WALUJ DISTRICT, AURANGABAD, INDIA
Packer: FDC LIMITED, WALUJ DISTRICT, AURANGABAD, INDIA
Laboratory: FPRC: FDC LIMITED, WALUJ DISTRICT, AURANGABAD, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/7.1.3/0244
Name of medicine: ATACAND 32 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
CANDESARTAN CILEXETIL 32,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN
ASTRAZENECA PHARMACEUTICALS,
ALRODE, ALBERTON, RSA
Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN
ANALYTICON, TERENURE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: ASTRAZENECA PHARMACEUTICALS,
ALRODE, ALBERTON, RSA
Shelf-life: 36 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/8.5/0374
Name of medicine: THROMBOREDUCTIN 0,5 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
ANAGRELIDE HYDROCHLORIDE EQUIVALENT TO
ANAGRELIDE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: KEY ONCOLOGICS (PTY) LTD
Manufacturer: HAUPT PHARMA GmbH, WOLFRATSHAUSEN,
GERMANY
Packer: HAUPT PHARMA GmbH, WOLFRATSHAUSEN,
GERMANY
Laboratory: FPRC: HAUPT PHARMA GmbH, WOLFRATSHAUSEN,
GERMANY
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRC/FPRR: KEY ONCOLOGICS, SANDTON, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/20.1.1/0397
Name of medicine: SANDOZ CEFPODOXIME 40 mg/5 ml
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CEFPODOXIME PROXETIL EQUIVALENT TO
CEFPODOXIME 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ PRIVATE LTD, TURBHE, NAVI
MUMBAI, INDIA
Packer: SANDOZ PRIVATE LTD, TURBHE, NAVI
MUMBAI, INDIA
Laboratory: FPRC: SANDOZ PRIVATE LTD, TURBHE, NAVI
MUMBAI, INDIA
NOVARTIS, SPARTAN, KEMPTON PARK
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/20.1.1/0398
Name of medicine: SANDOZ CEFPODOXIME 100
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: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ PRIVATE LTD, TURBHE, NAVI MUMBAI,
INDIA
Packer: SANDOZ PRIVATE LTD, TURBHE, NAVI MUMBAI,
INDIA
Laboratory: FPRC: SANDOZ PRIVATE LTD, TURBHE, NAVI MUMBAI,
INDIA
NOVARTIS, SPARTAN, KEMPTON PARK
ANALYTICON, TERENCE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/20.2.8/0445
Name of medicine: DAS-NEVIRAPINE 200 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
NEVIRAPINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: 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
NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: STRIDES SA PHARMACEUTICALS,
ARCADIA, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/2.1/0447
Name of medicine: PROVIVE 1 %
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml EMULSION CONTAINS:
 PROPOFOL 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: CLARIS LIFESCIENCES LTD, ELLISBRIDGE,
 AHMEDABAD, INDIA
Packer: CLARIS LIFESCIENCES LTD, ELLISBRIDGE,
 AHMEDABAD, INDIA

Laboratory: FPRC: CLARIS LIFESCIENCES LTD, ELLISBRIDGE,
 AHMEDABAD, INDIA
 CONSULTING CHEMICAL LABORATORIES, STAR
 STREET, BOKSBURG, RSA

FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/2.6.5/0478
Name of medicine: RISPERIDONE HEXAL 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
Packer: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG

Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
 GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 ANALYTICON, TERENURE, KEMPTON PARK

FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/2.6.5/0479
Name of medicine: RISPERIDONE HEXAL 2 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/2.6.5/0480
Name of medicine: RISPERIDONE HEXAL 3 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 3,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
Packer: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN,
GERMANY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/2.6.5/0481
Name of medicine: RISPERIDONE HEXAL 4 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

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

Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 ANALYTICON, TERENCE, KEMPTON PARK

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

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/21.5.1/0506
Name of medicine: SYMBICORD RAPIHALER 80:4,5
Dosage form: INHALATION
Active ingredients: EACH ACTUATION DELIVERS:
 BUDESONIDE 80,0 ug
 FORMOTEROL FUMARATE 4,5 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ASTRAZENECA PHARMACEUTICALS
Manufacturer: ASTRAZENECA DUNKERQUE
 PRODUCTION, DUNKERQUE, FRANCE

Packer: ASTRAZENECA DUNKERQUE
 PRODUCTION, DUNKERQUE, FRANCE
 ASTRAZENECA PHARMACEUTICALS,
 ALRODE, ALBERTON, RSA

Laboratory: FPRC: ASTRAZENECA DUNKERQUE
 PRODUCTION, DUNKERQUE, FRANCE
 ANALYTICON, TERENCE, KEMPTON PARK
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

 FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS,
 ALRODE, ALBERTON, RSA

Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A39/21.5.1/0507
Name of medicine: SYMBICORD RAPIHALER 160:4,5
Dosage form: INHALATION
Active ingredients: EACH ACTUATION DELIVERS:
BUDESONIDE 160,0 ug
FORMOTEROL FUMARATE 4,5 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer: ASTRAZENECA DUNKERQUE PRODUCTION,
DUNKERQUE, FRANCE
Packer: ASTRAZENECA DUNKERQUE PRODUCTION,
DUNKERQUE, FRANCE
ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA
Laboratory: FPRC: ASTRAZENECA DUNKERQUE PRODUCTION,
DUNKERQUE, FRANCE
ANALYTICON, TERENURE, KEMPTON PARK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRC/FPRR: ASTRAZENECA PHARMACEUTICALS, ALRODE,
ALBERTON, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/11.10/0049
Name of medicine: GAVISCON ADVANCE PEPPERMINT
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
SODIUM ALGINATE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: RECKITT BENCKISER PHARMACEUTICALS
(PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE, HULL,
EAST YORKSHIRE, UK
Packer: RECKITT BENCKISER HEALTHCARE, HULL,
EAST YORKSHIRE, UK
DR REDDY'S LABORATORIES LTD,
BEVERLY, EAST YORKSHIRE, UK
PHARMAPACK UK LTD, WIRRAL,
MERSEYSIDE, UK
Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE, HULL,
EAST YORKSHIRE, UK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: RECKITT BENCKISER PHARMACEUTICALS,
ELANDSFONTAIN, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/30.2/0061
Name of medicine: ERBITUX 2 mg/ml
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 CETUXIMAB 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK (PTY) LTD
Manufacturer: BOEHRINGER INGELHEIM PHARMA GmbH,
 BIBERACH AN DER RISS, GERMANY
Packer: MERCK KgaA, DARMSTADT, GERMANY
Laboratory: FPRC: BOEHRINGER INGELHEIM PHARMA GmbH,
 BIBERACH AN DER RISS, GERMANY
 MERCK KgaA, DARMSTADT, GERMANY
 FPRR: MERCK, MODDERFONTEIN, RSA
Shelf-life: 24 months (provisional)
Date of registration: 08 FEBRUARY 2008

MRF 15

Registration number: A40/2.7/0092
Name of medicine: NUROFEN FOR CHILDREN STRAWBERRY
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
 IBUPROFEN 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RECKITT BENCKISER HEALTHCARE
 (SOUTH AFRICA) (PTY) LTD
Manufacturer: RECKITT BENCKISER HEALTHCARE,
 NOTTINGHAM, UK
Packer: RECKITT BENCKISER HEALTHCARE,
 NOTTINGHAM, UK
Laboratory: FPRC: RECKITT BENCKISER HEALTHCARE,
 NOTTINGHAM, UK
 PHARMA-Q, INDUSTRIA, JOHANNESBURG
 PHARMACEUTICAL CONTRACTORS,
 ISANDO, RSA
 FPRC/FPRR: RECKITT BENCKISER PHARMACEUTICAL,
 ELANDSFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.2/0115
Name of medicine: EXOMAX
Dosage form: INFUSION
Active ingredients: EACH 100,0 ml SOLUTION CONTAINS:
FLUCONAZOLE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: CLARIS LIEFSCIENCES LIMITED, VASANA,
AHMEDABAD, INDIA
Packer: CLARIS LIEFSCIENCES LIMITED, VASANA,
AHMEDABAD, INDIA
Laboratory: FPRC: CLARIS LIEFSCIENCES LIMITED, VASANA,
AHMEDABAD, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0148
Name of medicine: STRIDES-LAMIVUDINE 150 mg &
ZIDOVUDINE 300 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LAMIVUDINE 150,0 mg
ZIDOVUDINE 300,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: STRIDES S.A. 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 PHARMACEUTICALS
SERVICES, SILVERTONDALE
NOVARTIS SA., SPARTAN, KEMPTON PARK
FPRR: STRIDES S.A., ARCADIA, PRETORIA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2/0157
Name of medicine: METRIS
Dosage form: INFUSION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
METRONIDAZOLE 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: CLARIS LIFE SCIENCES LTD, VASANA,
AHMEDABAD, INDIA
Packer: CLARIS LIFE SCIENCES LTD, VASANA,
AHMEDABAD, INDIA
Laboratory: FPRC: CLARIS LIFE SCIENCES LTD, VASANA,
AHMEDABAD, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/2.9/0190
Name of medicine: DOMADOL 50 mg
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
TRAMADOL HYDROCHLORIDE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: UNICHEM S.A. (PTY) LTD
Manufacturer: UNICHEM LABORATORIES LTD, GHZIABAD,
INDIA
Packer: UNICHEM LABORATORIES LTD, GHZIABAD,
INDIA
Laboratory: FPRC: UNICHEM LABORATORIES LTD, GHZIABAD,
INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE, RSA
FPRR: UNICHEM, POTCHEFSTROOM, RSA
Shelf-life: 24 months (provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/2.9/0191
Name of medicine: DOMADOL 100 mg
Dosage form: INJECTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
TRAMADOL HYDROCHLORIDE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: UNICHEM S.A. (PTY) LTD
Manufacturer: UNICHEM LABORATORIES LTD, GHZIABAD, INDIA
Packer: UNICHEM LABORATORIES LTD, GHZIABAD, INDIA
Laboratory: FPRC: UNICHEM LABORATORIES LTD, GHZIABAD, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICALSERVICES,
SILVERTONDALE, RSA
FPRR: UNICHEM, POTCHEFSTROOM, RSA
Shelf-life: 24 months (provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/34/0239
Name of medicine: TAXUS LIBERTE MONORAIL PACLITAXEL-
ELUTING CORONARY STENT SYSTEM
Dosage form: STENT
Active ingredients: EACH mm² CONTAINS:
PACLITAXEL 0,001 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: TRINITY PHARMA (PTY) LTD
Manufacturer: BOSTON SCIENTIFIC IRELAND LTD,
TULLAMORE, OFFALY, IRELAND
BOSTON SCIENTIFIC SCIMED INC,
COVENTRY, USA
Packer: BOSTON SCIENTIFIC IRELAND LTD,
TULLAMORE, OFFALY, IRELAND
BOSTON SCIENTIFIC SCIMED INC,
COVENTRY, USA
Laboratory: FPRC: BOSTON SCIENTIFIC IRELAND LTD,
TULLAMORE, OFFALY, IRELAND
BOSTON SCIENTIFIC SCIMED INC,
COVENTRY, USA
FPRR: TRINITY PHARMA, LYNNWOOD GLEN,
PRETORIA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0277
Name of medicine: BARACLUDE 0,5 mg TABLET
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ENTECAVIR 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer: BRISTOL-MYERS SQUIBB CO, MOUNT VERNON,
 INDIANA, USA
Packer: BRISTOL-MYERS SQUIBB CO, MOUNT VERNON,
 INDIANA, USA
 BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON

Laboratory: FPRC: BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
 MERCK PHARMACEUTICAL MANUFACTURING,
 WADEVILLE, GERMISTON
 BRISTOL-MYERS SQUIBB, EVANSVILLE, INDIANA,
 USA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

 FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0278
Name of medicine: BARACLUDE 1,0 mg TABLET
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ENTECAVIR 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer: BRISTOL-MYERS SQUIBB CO, MOUNT
 VERNON, INDIANA, USA
Packer: BRISTOL-MYERS SQUIBB CO, MOUNT
 VERNON, INDIANA, USA
 BRISTOL-MYERS SQUIBB, EPERNON,
 FRANCE
 MERCK PHARMACEUTICAL
 MANUFACTURING, WADEVILLE,
 GERMISTON

Laboratory: FPRC: BRISTOL-MYERS SQUIBB, EPERNON,
 FRANCE
 MERCK PHARMACEUTICAL
 MANUFACTURING, WADEVILLE,
 GERMISTON
 BRISTOL-MYERS SQUIBB, EVANSVILLE,
 INDIANA, USA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG

 FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW,
 RSA

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0279
Name of medicine: BARACLUDE ORAL SOLUTION 0,05 mg/ml
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ENTECAVIR 0,05 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer: BRISTOL-MYERS SQUIBB CO, MOUNT VERNON,
INDIANA, USA
Packer: BRISTOL-MYERS SQUIBB CO, MOUNT VERNON,
INDIANA, USA
BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Laboratory: FPRC: BRISTOL-MYERS SQUIBB, EPERNON, FRANCE
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
BRISTOL-MYERS SQUIBB, EVANSVILLE, INDIANA,
USA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.1.2/0286
Name of medicine: INDO FLUCLOXACILLIN-250
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
FLUCLOXACILLIN SODIUM EQUIVALENT TO
FLUCLOXACILLIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DEZZO TRADING (392) (PTY) LTD t/a INDO
PHARMA
Manufacturer: KOPRAN LTD, KHALAPUR DISTRICT,
RAIGAD, INDIA
Packer: KOPRAN LTD, KHALAPUR DISTRICT,
RAIGAD, INDIA

Laboratory: FPRC: KOPRAN LTD, KHALAPUR DISTRICT,
RAIGAD, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: DEZZO TRADING (392) t/a INDO PHARMA,
LENASIA, JOHANNESBURG

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/21.2/0464
Name of medicine: DIAMIN-500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DEZZO TRADING (392) (PTY) LTD t/a INDO PHARMA
Manufacturer: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Packer: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Laboratory: FPRC: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: DEZZO TRADING (392) t/a INDO PHARMA, LENASIA, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/21.2/0465
Name of medicine: DIAMIN-850
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DEZZO TRADING (392) (PTY) LTD t/a INDO PHARMA
Manufacturer: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Packer: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
Laboratory: FPRC: RUSAN PHARMA LTD, GANDHIDHAM-KUTCH, INDIA
 CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
 FPRR: DEZZO TRADING (392) t/a INDO PHARMA, LENASIA, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0490
Name of medicine: AURO-NEVIRAPINE ORAL SUSPENSION
50 mg/5 ml
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
NEVIRAPINE HEMIHYDRATE EQUIVALENT TO
NEVIRAPINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.3/0543
Name of medicine: RIFIZID 300/150
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RIFAMPICIN 300,0 mg
ISONIAZID 150,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: DEZZO TRADING (392) (PTY) LTD t/a INDO
PHARMA
Manufacturer: RUSAN PHARMA LTD, GANDHIDHAM-
KUTCH, INDIA
Packer: RUSAN PHARMA LTD, GANDHIDHAM-
KUTCH, INDIA
Laboratory: FPRC: RUSAN PHARMA LTD, GANDHIDHAM-
KUTCH, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: DEZZO TRADING (392) t/a INDO PHARMA,
LENASIA, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/20.2.8/0561
Name of medicine: AURO-LAMIVUDINE ORAL SOLUTION 10 mg/ml
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: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
 REDDY DISTRICT, ANDHRA PRADESH, INDIA

FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG
Shelf-life: 24 months (provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/5.10/0572
Name of medicine: SABAX ONDANSETRON INJECTION
 4 mg/2 ml
Dosage form: INJECTION
Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
 ONDANSETRON 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY)
 LTD
Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG

FPRR: ADCOCK INGRAM CRITICAL CARE,
 AEROTON, JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/5.10/0573
Name of medicine: SABAX ONDANSETRON INJECTION 8 mg/4 ml
Dosage form: INJECTION
Active ingredients: EACH 4,0 ml SOLUTION CONTAINS:
ONDANSETRON 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/5.7.1/0590
Name of medicine: SANDOZ FEXOFENADINE 120
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
FEXOFENADINE HYDROCHLORIDE 120,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
INDIA
Packer: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
INDIA
Laboratory: FPRC: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
INDIA
NOVARTIS S.A., SPARTAN, KEMPTON PARK
ANALYTICON, TERENURE, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/5.7.1/0591
Name of medicine: SANDOZ FEXOFENADINE 180
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 FEXOFENADINE HYDROCHLORIDE 180,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
 INDIA
Packer: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
 INDIA
Laboratory: FPRC: SANDOZ PRIVATE LTD, DIGHE, NAVI MUMBAI,
 INDIA
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 ANALYTICON, TERENURE, KEMPTON PARK
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: A40/28/0679
Name of medicine: FLUORESCITE 10 %
Dosage form: INJECTION
Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
 FLUORESCIN 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: ALCON LABORATORIES (SA) (PTY) LTD
Manufacturer: INTERNATIONAL MEDICATION SYSTEMS,
 SOUTH EL MONTE, CALIFORNIA, USA
Packer: INTERNATIONAL MEDICATION SYSTEMS,
 SOUTH EL MONTE, CALIFORNIA, USA
Laboratory: FPRC: INTERNATIONAL MEDICATION SYSTEMS,
 SOUTH EL MONTE, CALIFORNIA, USA
 ALCON MANUFACTURING LTD, FORT
 WORTH, TEXAS, USA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ALCON LABORATORIES, BRYANSTON,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/21.8.2/0021
Name of medicine: ESCAPELLE
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LEVONORGESTREL 1,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: GEDEON RICHTER LTD, BUDAPEST, HUNGARY
Packer: GEDEON RICHTER LTD, BUDAPEST, HUNGARY
Laboratory: FPRC: GEDEON RICHTER LTD, BUDAPEST, HUNGARY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/5.7.1/0086
Name of medicine: TEXA SYRUP
Dosage form: SYRUP
Active ingredients: EACH 1,0 ml SYRUP CONTAINS:
CETIRIZINE DIHYDROCHLORIDE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMA DYNAMICS (PTY) LTD
Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS hf, KOPAVOGUR, ICELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
Packer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS hf, KOPAVOGUR, ICELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG
PHARMACEUTICAL ENTERPRISES, N'DABENI,
PINELANDS, KZN
Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND
ACTAVIS hf, KOPAVOGUR, ICELAND
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life: 36 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/30.1/0145
Name of medicine: GARDASIL
Dosage form: INJECTION
Active ingredients: EACH 0,5 ml DOSE CONTAINS:
 HUMAN PAPILOMAVIRUS:
 TYPE 6 L 1 PROTEIN 20,0 ug
 TYPE 11 L 1 PROTEIN 40,0 ug
 TYPE 16 L 1 PROTEIN 40,0 ug
 TYPE 18 L 1 PROTEIN 20,0 ug
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
Laboratory: FPRC: MERCK & CO INC, WEST POINT,
 PENNSYLVANIA, USA
 MERCK SHARP & DOHME BV, HAARLEM,
 THE NETHERLANDS
 FPRR: MSD, HALFWAY HOUSE, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/26/0195
Name of medicine: SUTENT 25 mg CAPSULE
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 SUNITINIB MALEATE EQUIVALENT TO
 SUNITINIB 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES (PTY) LTD
Manufacturer: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
Packer: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
Laboratory: FPRC: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
 FPRC/FPRR: PFIZER GLOBAL MANUFACTURING, RETREAT,
 CAPE TOWN
 FPRR: PFIZER LABORATORIES, SANDTON,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/26/0196
Name of medicine: SUTENT 50 mg CAPSULE
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SUNITINIB MALEATE EQUIVALENT TO
SUNITINIB 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES (PTY) LTD
Manufacturer: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
Packer: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
Laboratory: FPRC: PFIZER ITALIA S.r.L., ASCOLI PICENO, ITALY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: PFIZER GLOBAL MANUFACTURING, RETREAT,
CAPE TOWN
FPRR PFIZER LABORATORIES, SANDTON,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/26/0197
Name of medicine: SUTENT 12,5 mg CAPSULE
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
SUNITINIB MALEATE EQUIVALENT TO
SUNITINIB 12,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PFIZER LABORATORIES (PTY) LTD
Manufacturer: PFIZER ITALIA S.r.L., ASCOLI PICENO,
ITALY
Packer: PFIZER ITALIA S.r.L., ASCOLI PICENO,
ITALY
Laboratory: FPRC: PFIZER ITALIA S.r.L., ASCOLI PICENO,
ITALY
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF,
PRETORIA
FPRC/FPRR: PFIZER GLOBAL MANUFACTURING,
RETREAT, CAPE TOWN
FPRR PFIZER LABORATORIES, SANDTON,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/21.12/0200
Name of medicine: SANDOZ BICALUTAMIDE 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 BICALUTAMIDE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON
Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/21.12/0201
Name of medicine: BICADEX 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 BICALUTAMIDE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ S.A., BUENOS AIRES,
 ARGENTINA
 SANDOZ S.A., BUENOS AIRES,
 ARGENTINA
 NOVARTIS S.A., SPARTAN, KEMPTON
 PARK
Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES,
 ARGENTINA
 SOUTH AFRICAN BUREAU OF
 STANDARDS, GROENKLOOF, PRETORIA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON
 PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON
 PARK
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.2.8/0217
Name of medicine: ALUVIA
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOPINAVIR 200,0 mg
RITONAVIR 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ABBOTT LABORATORIES S.A. (PTY) LTD
Manufacturer: ABBOTT GmbH & CO KG, LUDWIGSHAFEN,
GERMANY
Packer: ABBOTT GmbH & CO KG, LUDWIGSHAFEN,
GERMANY
ABBOTT LABORATORIES LTD,
QUEENSBOROUGH, KENT, UK
Laboratory: FPRC: ABBOTT GmbH & CO KG, LUDWIGSHAFEN,
GERMANY
ABBOTT LABORATORIES LTD,
QUEENSBOROUGH, KENT, UK
FPRR: ABBOTT LABORATORIES S.A., CONSTANTIA
KLOOF, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/21.12/0222
Name of medicine: CIPLA-FINASTERIDE 1 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
FINASTERIDE 1,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, VIRGONAGAR, BANGALORE,
INDIA
Packer: CIPLA LTD, VIRGONAGAR, BANGALORE,
INDIA
Laboratory: FPRC: CIPLA LTD, VIRGONAGAR, BANGALORE,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPAK,
BELLVILLE
Shelf-life: 24 Months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/30.1/0366
Name of medicine: CERVARIX
Dosage form: INJECTION
Active ingredients: EACH 0,5 ml DOSE CONTAINS:
 HUMAN PAPILLOMAVIRUS:
 TYPE 16 L 1 PROTEIN 20,0 ug
 TYPE 18 L 1 PROTEIN 20,0 ug
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer: GLAXOSMITHKLINE BIOLOGICALS S.A.,
 RIXENSART, BELGIUM
 GLAXOSMITHKLINE BIOLOGICALS
 S.A.,WAVRE, BELGIUM
Packer: GLAXOSMITHKLINE BIOLOGICALS S.A.,
 WAVRE, BELGIUM
 GLAXOSMITHKLINE SOUTH AFRICA, EPPING,
 CAPE TOWN
Laboratory: FPRC: GLAXOSMITHKLINE BIOLOGICALS S.A.,
 RIXENSART, BELGIUM
 GLAXOSMITHKLINE BIOLOGICALS S.A.,
 WAVRE, BELGIUM
FPRC/FPRR: GLAXOSMITHKLINE SOUTH AFRICA, EPPING,
 CAPE TOWN
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/1.2/0401
Name of medicine: CIPLA-ESCITALOPRAM 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 ESCITALOPRAM 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
 INDIA
Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
 INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
 INDIA
FPRR: CIPLA LIFE SCIENCES, ROSEN PARK,
 BELLVILLE
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/1.2/0402
Name of medicine: CIPLA-ESCITALOPRAM 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPAK,
BELLVILLE
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/1.2/0403
Name of medicine: CIPLA-ESCITALOPRAM 20
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,
INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPAK,
BELLVILLE
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/3/0404
Name of medicine: DISCOVISC
Dosage form: SOLUTION
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
 SODIUM HYALURONATE 16,5 mg
 SODIUM CHONDROITIN SULPHATE
 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: ALCON LABORATORIES (SA) (PTY) LTD
Manufacturer: S.A. ALCON-COUVREUR NV, PUURS, BELGIUM

Packer: S.A. ALCON-COUVREUR NV, PUURS, BELGIUM

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

 FPRR: ALCON LABORATORIES, BRYANSTON,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.2.8/0541
Name of medicine: AURO-EFAVIRENZ CAPSULES 50 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
 EFAVIRENZ 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA

Packer: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA

Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III,
 RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA

 FPRR: AUROBINDO PHARMA, ROSEBANK,
 JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.2.8/0542
Name of medicine: AURO-EFAVIRENZ CAPSULES 100 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
EFAVIRENZ 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.2.8/0543
Name of medicine: AURO-EFAVIRENZ CAPSULES 200 mg
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
EFAVIRENZ 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, RANGA
REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.5/0666
 Name of medicine: ZYSIM 10 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SIMVASTATIN 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
 POTCHEFSTROOM
 Shelf-life: 24 months
 Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.5/0667
 Name of medicine: ZYSIM 20 mg TABLETS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 SIMVASTATIN 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
 AHMEDABAD, INDIA
 INSTITUTE FOR PHARMACEUTICAL
 SERVICES, SILVERTONDALE
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
 POTCHEFSTROOM
 Shelf-life: 24 months
 Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.5/0668
Name of medicine: ZYSIM 40 mg TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.5/0669
Name of medicine: ZYSIM 80 mg TABLETS
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 80,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL
SERVICES, SILVERTONDALE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.1.3/0694
Name of medicine: PERISTAR 2
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: LUPIN LTD, VERNA, SALCETTE, INDIA
Packer: LUPIN LTD, VERNA, SALCETTE, INDIA
Laboratory: FPRC: LUPIN LTD, VERNA, SALCETTE, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.1.3/0695
Name of medicine: PERISTAR 4
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 4,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: LUPIN LTD, VERNA, SALCETTE, INDIA
Packer: LUPIN LTD, VERNA, SALCETTE, INDIA
Laboratory: FPRC: LUPIN LTD, VERNA, SALCETTE, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG

FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/7.1.3/0696
Name of medicine: PERISTAR 8
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL TERT-BUTYLAMINE 8,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: LUPIN LTD, VERNA, SALCETTE, INDIA
Packer: LUPIN LTD, VERNA, SALCETTE, INDIA
Laboratory: FPRC: LUPIN LTD, VERNA, SALCETTE, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/5.2/0740
Name of medicine: ALFUZOSIN-WINTHROP 10 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ALFUZOSIN HYDROCHLORIDE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANOFI-SYNTHELABO (PTY) LTD
Manufacturer: SANOFI WINTHROP INDUSTRIE, TOURS,
FRANCE
Packer: SANOFI WINTHROP INDUSTRIE, TOURS,
FRANCE
WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
Laboratory: FPRC: SANOFI WINTHROP INDUSTRIE, TOURS,
FRANCE
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO,
PRETORIA
FPRR: SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life: 36 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0918
Name of medicine: KEFTAZ 0,5 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 CEFTAZIDIME PENTAHYDRATE EQUIVALENT
 TO
 CEFTAZIDIME 0,5 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
 NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0919
Name of medicine: KEFTAZ 1,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 CEFTAZIDIME PENTAHYDRATE EQUIVALENT
 TO
 CEFTAZIDIME 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
 NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0920
Name of medicine: KEFTAZ 2,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFTAZIDIME PENTAHYDRATE
EQUIVALENT TO
CEFTAZIDIME 2,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0921
Name of medicine: SANDOZ CEFTAZIDIME 0,5 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
CEFTAZIDIME PENTAHYDRATE
EQUIVALENT TO
CEFTAZIDIME 0,5 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0922
Name of medicine: SANDOZ CEFTAZIDIME 1,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 CEFTAZIDIME PENTAHYDRATE
 EQUIVALENT TO
 CEFTAZIDIME 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
 NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 41/20.1.1/0923
Name of medicine: SANDOZ CEFTAZIDIME 2,0 g
Dosage form: INJECTION
Active ingredients: EACH VIAL CONTAINS:
 CEFTAZIDIME PENTAHYDRATE
 EQUIVALENT TO
 CEFTAZIDIME 2,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA
Packer: SANDOZ GmbH, KUNDL, AUSTRIA
 NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC: SANDOZ GmbH, KUNDL, AUSTRIA
 SOUTH AFRICAN BUREAU OF STANDARDS,
 GROENKLOOF, PRETORIA

FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life: 24 months
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 42/20.2.8/0014
Name of medicine: SONKE-DIDANOSINE 25
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DIDANOSINE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: 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
FPRR: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 42/20.2.8/0015
Name of medicine: SONKE-DIDANOSINE 50
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DIDANOSINE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: 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
FPRR: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 42/20.2.8/0016
Name of medicine: SONKE-DIDANOSINE 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 DIDANOSINE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: 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

 FPRR RANBAXY (S.A.), CENTURION, RSA

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008

MRF 15

Registration number: 42/20.2.8/0026
Name of medicine: ASPEN 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: PHARMACARE LIMITED
Manufacturer: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH

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

Laboratory: FPRC: STRIDES ARCOLAB LTD, ANEKAL TALUK, BANGALORE, INDIA
 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

Shelf-life: 24 months (Provisional)
Date of registration: 8 FEBRUARY 2008