

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 916

12 AUGUST 2016

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 (101/1965)

MRF1 M

MRF 15		MRF 15		MRF 15	
Registration number:	09/1.3/18	Registration number:	11/12.2/11	Registration number:	377.1.3/0330
Name of medicine:	DOLOREX	Name of medicine:	LEVANTA 1mg/ml ORAL SOLUTION FOR DOGS	Name of medicine:	ENALAPRIL 5 BIOTECH
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	ORAL SOLUTION	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: BUTORPHANOL TATRATE EQUIVALENT TO BUTORPHANOL 10.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LEVOTHYRONE SODIUM 1.0 mg	Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	INTERVET SA (PTY) LTD	Applicant:	INTERVET SA (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS	Manufacturer:	INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE	Manufacturer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA
Packer:	INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS	Packer:	INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE	Packer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA
Laboratory: FPRC:	INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY INTERVET INTERNATIONAL B.V., BOXMEER, THE NETHERLANDS BIOINDUSTRIAL SERVICES CC, KEMPTON PARK, RSA	Laboratory: FPRC:	INTERVET PRODUCTIONS S.A., IGOVILLE, FRANCE BIOINDUSTRIAL SERVICES CC, KEMPTON PARK, RSA	Laboratory: FPRC:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASSVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA
FPRR:	INTERVET SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	INTERVET SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPARK, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15		MRF 15		5	
Registration number:	377/1.30331	Registration number:	377/1.30332	Registration number:	417/1.30337
Name of medicine:	ENALAPRIL 10 BIOTECH	Name of medicine:	ENALAPRIL 20 BIOTECH	Name of medicine:	OLMETEC PLUS 20/12.5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 10.0 mg	Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20.0 mg HYDROCHLOROTHIAZIDE 12.5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA	Manufacturer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA	Manufacturer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Packer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOPSPARK, CENTURION, RSA	Packer:	LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA WRAPSA MANUFACTURING AND PACKAGING (PTY) LTD, HENNOPSPARK, CENTURION, RSA	Packer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Laboratory:	FPRC : LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SLVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC : LEK PHARMACEUTICAL AND CHEMISTRY COMPANY d.d., LJUBLJANA, VEROVSKOVA, SLOVANIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SLVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15		MRF 15		5	
Registration number:	417.1.3/0338	Registration number:	42/17.1/0180	Registration number:	42/17.1/0181
Name of medicine:	OLMETEC PLUS 20/25	Name of medicine:	SPEC ATACURIUM 25	Name of medicine:	SPEC ATACURIUM 50
Dosage form:	TABLET	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: ATACURIUM BESYLATE 25,0 mg	Active ingredients:	EACH AMPOULE CONTAINS: ATACURIUM BESYLATE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	SPEC PHARM (PTY) LTD	Applicant:	SPEC PHARM (PTY) LTD
Manufacturer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY	Manufacturer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY	Manufacturer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY
Packer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY	Packer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY	Packer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY
Laboratory:	FPRC: SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA	Laboratory:	FPRC: HAMELN PHARMACEUTICALS, HAMELN, GERMANY SPEC PHARMA HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Laboratory:	FPRC: HAMELN PHARMACEUTICALS, HAMELN, GERMANY SPEC PHARMA HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	SPEC PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	SPEC PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15		MRF 15		F 15	
Registration number:	42/26/0744	Registration number:	42/26/0745	Registration number:	42/7.1.3/0769
Name of medicine:	MERCK EPIRUBICIN 10 mg	Name of medicine:	MERCK EPIRUBICIN 50 mg	Name of medicine:	OMESAR PLUS 20/12.5
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 10.0 mg	Active ingredients:	EACH VIAL CONTAINS: EPIRUBICIN HYDROCHLORIDE 50.0 mg	Active ingredients:	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20.0 mg HYDROCHLOROTHIAZIDE 12.5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXI PHARMACEUTICALS (PTY) LTD	Applicant:	XIXI PHARMACEUTICALS (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM	Manufacturer:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM	Manufacturer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Packer:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA MERCK GENERIQUES, LYON CEDEX, FRANCE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA	Packer:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA MERCK GENERIQUES, LYON CEDEX, FRANCE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA	Packer:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY
Laboratory: FPR:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA MERCK GENERIQUES, LYON CEDEX, FRANCE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASSVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPR:	THISSEN LABORATORIES S.A., BRAINE/ALLEUD, BELGIUM PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA MERCK GENERIQUES, LYON CEDEX, FRANCE RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASSVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPR:	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRC:	Shelf-life:	Date of registration:
MRF15	4270.1.1/0859	ACAQUIN 250	TABLET	EACH TABLET CONTAINS: LEVOFLOXACIN 250.0 mg	1, 2, 3, 4, 5, 6, 7, 8	AKACIA HEALTHCARE (PTY) LTD	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE INSTITUTE FOR PHARMACEUTICAL AND CHEMISTRY SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASSVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	24 months (provisional)	18 FEBRUARY 2016
MRF 15	427.1.3/0770	OMESAR PLUS 20/25.0	TABLET	EACH TABLET CONTAINS: OLMESARTAN MEDOXOMIL 20.0 mg HYDROCHLOROTHIAZIDE 25.0 mg	1, 2, 3, 4, 5, 6, 7	ADCOCK INGRAM LIMITED	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY	SANKYO PHARMA GmbH, PFAFFENHOFEN, GERMANY ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD (CLAYVILLE), CLAYVILLE, OLIFANTSFONTEIN, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	36 months	18 FEBRUARY 2016

Registration number: 43/2.5/0267 Name of medicine: VANAPRO SYRUP Dosage form: SYRUP Active ingredients: EACH 5.0 ml SYRUP CONTAINS: SODIUM VALPROATE 200.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ADCOCK INGRAM LIMITED Manufacturer: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA Packer: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA Laboratory: FPRC: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months Date of registration: 18 FEBRUARY 2016	Registration number: 43/20.1.1/0640 Name of medicine: AURO CEFZOLIN 250 mg Dosage form: POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: CEFZOLIN SODIUM EQUIVALENT TO CEFZOLIN 250.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016	Registration number: 43/20.1.1/0641 Name of medicine: AURO CEFZOLIN 500 mg Dosage form: POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: CEFZOLIN SODIUM EQUIVALENT TO CEFZOLIN 500.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016
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MRF 15	MRF15	5
Registration number:	Registration number:	Registration number:
Name of medicine:	Name of medicine:	Name of medicine:
Dosage form:	Dosage form:	Dosage form:
Active ingredients:	Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:	Conditions of registration:
Applicant:	Applicant:	Applicant:
Manufacturer:	Manufacturer:	Manufacturer:
Packer:	Packer:	Packer:
Laboratory: FPRC:	Laboratory: FPRC:	Laboratory: FPRC:
FPRR:	FPRR:	FPRR:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:
43/20.1.1/0642	43/8/0830	44/20.2.8/0009
AURO CEFZOLIN 1 g POWDER FOR INJECTION	SOLUSPIN VC TABLET	COMOZEN TABLET
EACH VIAL CONTAINS: CEFAZOLIN SODIUM EQUIVALENT TO CEFAZOLIN 1.0 g	EACH TABLET CONTAINS: ASPIRIN 100 mg	EACH TABLET CONTAINS: LAMIVUDINE 150.0 mg NEVIRAPINE 200.0 mg ZIDOVUDINE 300.0 mg
1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8
AUROBINDO PHARMA (PTY) LTD	RESMED HEALTHCARE	BLISS PHARMACEUTICALS cc
AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA	HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA
AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA	HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA
AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RS KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA	HETERO DRUGS LIMITED, JEEDIMETLA, HYDRABAD, INDIA
AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA	BLISS PHARMACEUTICALS cc, ORMONDE, JOHANNESBURG, RSA
24 months (provisional)	24 months	24 months (provisional)
18 FEBRUARY 2016	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15		MRF 15		MRF 15	
Registration number:	44/28/0236	Registration number:	44/28/0237	Registration number:	44/28/0238
Name of medicine:	MAGNEGITA 5 ml	Name of medicine:	MAGNEGITA 10 ml	Name of medicine:	MAGNEGITA 15 ml
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	SOLUTION FOR INJECTION	Dosage form:	SOLUTION FOR INJECTION
Active ingredients:	EACH 5.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUKINE EQUIVALENT TO GADOLINIUM 393.15 mg	Active ingredients:	EACH 10.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUKINE EQUIVALENT TO GADOLINIUM 786.30 mg	Active ingredients:	EACH 15.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUKINE EQUIVALENT TO GADOLINIUM 1179.45 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDICINES DEVELOPERS INTERNATIONAL cc	Applicant:	MEDICINES DEVELOPERS INTERNATIONAL cc	Applicant:	MEDICINES DEVELOPERS INTERNATIONAL cc
Manufacturer:	JSC FARMK, KIEV, UKRAINE	Manufacturer:	JSC FARMK, KIEV, UKRAINE	Manufacturer:	JSC FARMK, KIEV, UKRAINE
Packer:	JSC FARMK, KIEV, UKRAINE	Packer:	JSC FARMK, KIEV, UKRAINE	Packer:	JSC FARMK, KIEV, UKRAINE
Laboratory: FPRC:	JSC FARMK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	JSC FARMK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	JSC FARMK, KIEV, UKRAINE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA	FPRC:	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA	FPRC:	MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15
Registration number: 44/28/0239 Name of medicine: MAGNEGITA 20 ml Dosage form: SOLUTION FOR INJECTION Active ingredients: EACH 20.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 1572.60 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc Manufacturer: JSC FARMMAK, KIEV, UKRAINE Packer: JSC FARMMAK, KIEV, UKRAINE Laboratory: FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016	Registration number: 44/28/0240 Name of medicine: MAGNEGITA 30 ml Dosage form: SOLUTION FOR INJECTION Active ingredients: EACH 30.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 2358.90 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc Manufacturer: JSC FARMMAK, KIEV, UKRAINE Packer: JSC FARMMAK, KIEV, UKRAINE Laboratory: FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016	Registration number: 44/28/0241 Name of medicine: MAGNEGITA 100 ml Dosage form: SOLUTION FOR INJECTION Active ingredients: EACH 100.0 ml SOLUTION CONTAINS: GADOPENTETATE DIMEGLUMINE EQUIVALENT TO GADOLINIUM 7863.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: MEDICINES DEVELOPERS INTERNATIONAL cc Manufacturer: JSC FARMMAK, KIEV, UKRAINE Packer: JSC FARMMAK, KIEV, UKRAINE Laboratory: FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: MEDICINES DEVELOPERS INTERNATIONAL cc, MENLO PARK, PRETORIA, RSAA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016

MRF 15		MRF 15		MRF 15	
Registration number:	44/5.7.1/0843	Registration number:	44/24/0896	Registration number:	44/5.3/0933
Name of medicine:	GLENCET 5	Name of medicine:	HYDRASSIST ORS	Name of medicine:	CURLOVON 5
Dosage form:	TABLET	Dosage form:	POWDER	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOCETIRIZINE DIHYDROCHLORIDE 5.0 mg	Active ingredients:	EACH SACHET CONTAINS: GLUCOSE ANHYDROUS 2 700.0 mg TRISODIUM CITRATE DIHYDRATE 580.0 mg SODIUM CHLORIDE 520.0 mg POTASSIUM CHLORIDE 300.0 mg	Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD	Applicant:	TRINITY PHARMA (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA	Manufacturer:	PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA	Packer:	PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA TEHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	GLENMARK PHARMACEUTICALS LIMITED, BARDEZ, GOA, INDIA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	PT. NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, VORNA VALLEY, MIDRAND, RSA	FPRR:	TRINITY PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA	FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	24 months (provisional)	Shelf-life:	24 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

Registration number: 44/5/3/0934	Registration number: 45/7.1/0150	Registration number: 45/7.1/0151
Name of medicine: CURLOVON 10	Name of medicine: URODOXA 1 mg	Name of medicine: URODOXA 2 mg
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg	Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 10 mg	Active ingredients: EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DR REDDY'S LABORATORIES (PTY) LTD	Applicant: AUROBINDO PHARMA (PTY) LTD	Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS (PTY) LTD, IRENE, CENTURION, RSA TEHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC: AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA
FPRR: DR REDDY'S LABORATORIES (PTY) LTD, SANDTON, JOHANNESBURG, RSA	FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life: 24 months	Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)
Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016	Date of registration: 18 FEBRUARY 2016

MRF 15	Registration number:	45/7.1/0152	Registration number:	45/7.1/0153	Registration number:	45/7.1/0154
	Name of medicine:	URODOXA 4 mg	Name of medicine:	URODOXA 8 mg	Name of medicine:	FLOCARD 1 mg
	Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
	Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4.0 mg	Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8.0 mg	Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1.0 mg
	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
	Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
	Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
	Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA
	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	45/7.1/0155	45/7.1/0156	45/7.1/0157
Name of medicine:	FLOCARD 2 mg	FLOCARD 4 mg	FLOCARD 8 mg
Dosage form:	TABLET	TABLET	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 2,0 mg	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4,0 mg	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	24 months (provisional)	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRR:	Shelf-life:	Date of registration:
MRF 15	457.1/0158	DUROCARD 1 mg	TABLET	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1,0 mg	1, 2, 3, 4, 5, 6, 7, 8	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	24 months (provisional)	18 FEBRUARY 2016
MRF 15	457.1/0159	DUROCARD 2 mg	TABLET	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 1,0 mg	1, 2, 3, 4, 5, 6, 7, 8	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	24 months (provisional)	18 FEBRUARY 2016
MRF 15	457.1/0160	DUROCARD 4 mg	TABLET	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 4,0 mg	1, 2, 3, 4, 5, 6, 7, 8	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	24 months (provisional)	18 FEBRUARY 2016

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1.0161	Registration number:	45/8.2/0288	Registration number:	45/7.1.5/0470
Name of medicine:	DUROCARD 8 mg	Name of medicine:	OGRAVIA 75 mg	Name of medicine:	ROVETA 25
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOXAZOSIN EQUIVALENT TO DOXAZOSIN 8.0 mg	Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75.0 mg	Active ingredients:	EACH TABLET CONTAINS: SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA	Manufacturer:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA
Packer:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA	Packer:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA
Laboratory: FPRC:	AUROBINDO PHARMA, UNIT III, BACHUPALLY VILLAGE, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, TALUKA-KADDI, DISTRICT MEHSANA, INDRAD, GUJARAT, INDIA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ARROW LABORATORIES LTD, CRYODON SOUTH, VICTORIA, AUSTRALIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRIKEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	FPRC:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

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MRF 15		MRF 15		MRF 15	
Registration number:	45/6.2/0594	Registration number:	45/2.9/0658	Registration number:	45/2.9/0659
Name of medicine:	MYLAN CLOPIDOGREL 75 mg	Name of medicine:	MYLAN REMIFENTANIL 1 mg	Name of medicine:	MYLAN REMIFENTANIL 2 mg
Dosage form:	TABLET	Dosage form:	POWDER CONCENTRATE FOR INFUSION	Dosage form:	POWDER CONCENTRATE FOR SOLUTION FOR INJECTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL 75.0 mg	Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 1.0 mg	Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE EQUIVALENT TO REMIFENTANIL 2.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN	Manufacturer:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN
Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN	Packer:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN
Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN LABORATORIES (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN MYLAN S.A.S., SIAINT-PIERRE, FRANCE ACORN LABORATORIES (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE S.A., SANT JOAN DESPI, BARCELONA, SPAIN MYLAN S.A.S., SIAINT-PIERRE, FRANCE ACORN LABORATORIES (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	18 months	Shelf-life:	36 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	MRF 15	MRF 15
Registration number:	Registration number:	Registration number:
Name of medicine:	Name of medicine:	Name of medicine:
Dosage form:	Dosage form:	Dosage form:
Active ingredients:	Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:	Conditions of registration:
Applicant:	Applicant:	Applicant:
Manufacturer:	Manufacturer:	Manufacturer:
Packer:	Packer:	Packer:
Laboratory:	Laboratory:	Laboratory:
FPR:	FPR:	FPR:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:

MRF 15	Registration number: 45/20.1.1/0799 Name of medicine: CIPROFLOXACIN FRESENIUS 2 mg/ml 250 ml Dosage form: SOLUTION FOR INFUSION Active ingredients: EACH 50.0 ml SOLUTION CONTAINS: CIPROFLOXACIN HYDROGEN SULPHATE EQUIVALENT TO CIPROFLOXACIN 500.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: FRESENIUS KABI (PTY) LTD Manufacturer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND Packer: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND Laboratory: FPRC: FRESENIUS KABI NORGE AS, HALDEN, NORWAY FRESENIUS KABI PLSKA Sp. z o.o., KUTNO, SIENKIEWICZA, POLAND BODENE (PTY) LIMITED TRADING AS INTRAMED, KORSTEN, PORT ELIZABETH, RSA KHULULEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA FPRR: FRESENIUS KABI SOUTH AFRICA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Shelf-life: 24 months (Poland/kabipack bottles) 36 months (Norway/free flex bags) Date of registration: 18 FEBRUARY 2016	MRF15	Registration number: 457.1.3/0800 Name of medicine: RAPHEX 8 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 8.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ASTRA ZENECA PHARMACEUTICALS (PTY) LTD Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA FPRR: ASTRAZENECA PHARMACEUTICALS (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016	Registration number: 4577.1.3/0801 Name of medicine: RAPHEX 16 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ASTRA ZENECA PHARMACEUTICALS (PTY) LTD Manufacturer: ASTRAZENECA AB, SODERTALJE, SWEDEN Packer: ASTRAZENECA AB, SODERTALJE, SWEDEN Laboratory: FPRC: ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA FPRR: ASTRAZENECA PHARMACEUTICALS (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016
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MRF-15		MRF-15		MRF-15	
Registration number:	45/20.2.2/0904	Registration number:	4577.1.3/0802	Registration number:	4577.1.3/0802
Name of medicine:	ARICON 50	Name of medicine:	RAPHEX 32 mg	Name of medicine:	RAPHEX 32 mg
Dosage form:	CAPSULE	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 50.0 mg	Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16.0 mg HYDROCHLOROTHAZIDE 12.5 mg	Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 32.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ASTRA ZENECA PHARMACEUTICALS (PTY) LTD	Applicant:	ASTRA ZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN	Manufacturer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN	Packer:	ASTRAZENECA AB, SODERTALJE, SWEDEN
Laboratory, FPRC:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA	Laboratory, FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory, FPRC:	ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTOND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	48 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15		MRF15	
Registration number:	45/20.2.2/0905	Registration number:	45/20.2.2/0906
Name of medicine:	ARICON 150	Name of medicine:	ARICON 200
Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 150.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 200.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE FAMAR SA, ANTHOUSA, ATTIKI, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, ATHENS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA
Shelf-life:	48 months	Shelf-life:	48 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016
Registration number:	45/2.9/1111	Registration number:	45/2.9/1111
Name of medicine:	FERTINAC 2 mg	Name of medicine:	FERTINAC 2 mg
Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2.0 mg	Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	RANBAXY SA (PTY) LTD	Applicant:	RANBAXY SA (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	Manufacturer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN
Packer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	Packer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN
Laboratory:	FPRC: LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN KHULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN KHULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	<table> <tr> <td>Registration number:</td><td>45/2.9/1111</td></tr> <tr> <td>Name of medicine:</td><td>FERTINAC 2 mg</td></tr> <tr> <td>Dosage form:</td><td>INJECTION</td></tr> <tr> <td>Active ingredients:</td><td>EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2,0 mg</td></tr> <tr> <td>Conditions of registration:</td><td>1, 2, 3, 4, 5, 6, 7, 8</td></tr> <tr> <td>Applicant:</td><td>RANBAXY SA (PTY) LTD</td></tr> <tr> <td>Manufacturer:</td><td>LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN</td></tr> <tr> <td>Packer:</td><td>LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN</td></tr> <tr> <td>Laboratory:</td><td>LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN</td></tr> <tr> <td>FPRR:</td><td>LABORATORY REIG JOFRE S.A, SANT JOAN KHULULEKANI LABORATORY SERVICES cc, HALEWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</td></tr> <tr> <td>Shelf-life:</td><td>RANBAXY SA (PTY) LTD, CENTURION, RSA</td></tr> <tr> <td>Date of registration:</td><td>24 months (provisional) 18 FEBRUARY 2016</td></tr> </table>	Registration number:	45/2.9/1111	Name of medicine:	FERTINAC 2 mg	Dosage form:	INJECTION	Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2,0 mg	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Applicant:	RANBAXY SA (PTY) LTD	Manufacturer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	Packer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	Laboratory:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN	FPRR:	LABORATORY REIG JOFRE S.A, SANT JOAN KHULULEKANI LABORATORY SERVICES cc, HALEWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Shelf-life:	RANBAXY SA (PTY) LTD, CENTURION, RSA	Date of registration:	24 months (provisional) 18 FEBRUARY 2016
Registration number:	45/2.9/1111																								
Name of medicine:	FERTINAC 2 mg																								
Dosage form:	INJECTION																								
Active ingredients:	EACH VIAL CONTAINS: REMIFENTANIL HYDROCHLORIDE 2,0 mg																								
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8																								
Applicant:	RANBAXY SA (PTY) LTD																								
Manufacturer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN																								
Packer:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN																								
Laboratory:	LABORATORY REIG JOFRE S.A, SANT JOAN DESPI, BARCELONA, SPAIN																								
FPRR:	LABORATORY REIG JOFRE S.A, SANT JOAN KHULULEKANI LABORATORY SERVICES cc, HALEWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA																								
Shelf-life:	RANBAXY SA (PTY) LTD, CENTURION, RSA																								
Date of registration:	24 months (provisional) 18 FEBRUARY 2016																								
MRF15	<table> <tr> <td>Registration number:</td><td>45/3.1/150</td></tr> <tr> <td>Name of medicine:</td><td>MOTIFINE</td></tr> <tr> <td>Dosage form:</td><td>CAPSULE</td></tr> <tr> <td>Active ingredients:</td><td>EACH CAPSULE CONTAINS: DICLOFENAC SODIUM 75,0 mg</td></tr> <tr> <td>Conditions of registration:</td><td>1, 2, 3, 4, 5, 6, 7</td></tr> <tr> <td>Applicant:</td><td>BIOTECH LABORATORIES (PTY) LTD</td></tr> <tr> <td>Manufacturer:</td><td>TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY</td></tr> <tr> <td>Packer:</td><td>TEMMLER WERKE GmbH, MUNCHEN, GERMANY</td></tr> <tr> <td>Laboratory:</td><td>TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY LABOR L'S AG, BAD BOCKLET, GERMANY SAB'S PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA</td></tr> <tr> <td>FPRR:</td><td>BIOTECH LABORATORIES (PTY) LTD, RANDESAPARK, MIDRAND, RSA</td></tr> <tr> <td>Shelf-life:</td><td>48 months</td></tr> <tr> <td>Date of registration:</td><td>18 FEBRUARY 2016</td></tr> </table>	Registration number:	45/3.1/150	Name of medicine:	MOTIFINE	Dosage form:	CAPSULE	Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC SODIUM 75,0 mg	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Applicant:	BIOTECH LABORATORIES (PTY) LTD	Manufacturer:	TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY	Packer:	TEMMLER WERKE GmbH, MUNCHEN, GERMANY	Laboratory:	TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY LABOR L'S AG, BAD BOCKLET, GERMANY SAB'S PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDESAPARK, MIDRAND, RSA	Shelf-life:	48 months	Date of registration:	18 FEBRUARY 2016
Registration number:	45/3.1/150																								
Name of medicine:	MOTIFINE																								
Dosage form:	CAPSULE																								
Active ingredients:	EACH CAPSULE CONTAINS: DICLOFENAC SODIUM 75,0 mg																								
Conditions of registration:	1, 2, 3, 4, 5, 6, 7																								
Applicant:	BIOTECH LABORATORIES (PTY) LTD																								
Manufacturer:	TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY																								
Packer:	TEMMLER WERKE GmbH, MUNCHEN, GERMANY																								
Laboratory:	TEMMLER IRELAND LTD, KERRY, BANSHAGH, IRELAND TEMMLER WERKE GmbH, MUNCHEN, GERMANY LABOR L'S AG, BAD BOCKLET, GERMANY SAB'S PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA																								
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDESAPARK, MIDRAND, RSA																								
Shelf-life:	48 months																								
Date of registration:	18 FEBRUARY 2016																								
	<table> <tr> <td>Registration number:</td><td>45/20.1.1/1200</td></tr> <tr> <td>Name of medicine:</td><td>DYNAFLOC IV 100 ml</td></tr> <tr> <td>Dosage form:</td><td>SOLUTION FOR INFUSION</td></tr> <tr> <td>Active ingredients:</td><td>EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg</td></tr> <tr> <td>Conditions of registration:</td><td>1, 2, 3, 4, 5, 6, 7</td></tr> <tr> <td>Applicant:</td><td>PHARMA DYNAMICS (PTY) LTD</td></tr> <tr> <td>Manufacturer:</td><td>CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA</td></tr> <tr> <td>Packer:</td><td>CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA</td></tr> <tr> <td>Laboratory:</td><td>CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA</td></tr> <tr> <td>FPRR:</td><td>PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA</td></tr> <tr> <td>Shelf-life:</td><td>24 months</td></tr> <tr> <td>Date of registration:</td><td>18 FEBRUARY 2016</td></tr> </table>	Registration number:	45/20.1.1/1200	Name of medicine:	DYNAFLOC IV 100 ml	Dosage form:	SOLUTION FOR INFUSION	Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Applicant:	PHARMA DYNAMICS (PTY) LTD	Manufacturer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA	Packer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA	Laboratory:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	Shelf-life:	24 months	Date of registration:	18 FEBRUARY 2016
Registration number:	45/20.1.1/1200																								
Name of medicine:	DYNAFLOC IV 100 ml																								
Dosage form:	SOLUTION FOR INFUSION																								
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 200,0 mg																								
Conditions of registration:	1, 2, 3, 4, 5, 6, 7																								
Applicant:	PHARMA DYNAMICS (PTY) LTD																								
Manufacturer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA																								
Packer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA																								
Laboratory:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA																								
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA																								
Shelf-life:	24 months																								
Date of registration:	18 FEBRUARY 2016																								

MRF 15	Registration number: 45/20.1.1/1201 Name of medicine: DYNAFLOC IV 200 ml Dosage form: SOLUTION FOR INFUSION Active ingredients: EACH 100.0 ml SOLUTION CONTAINS: CIPROFLOXACIN LACTATE MONOHYDRATE EQUIVALENT TO CIPROFLOXACIN 400.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA Packer: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA Laboratory: FPRC: CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA FPRC: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA Shelf-life: 24 months Date of registration: 18 FEBRUARY 2016
MRF15	Registration number: 46/18.1/0015 Name of medicine: FUROSIX Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMADYNE HEALTHCARE (PTY) LTD Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016
	Registration number: 46/18.1/0016 Name of medicine: RENOSIX 40 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: FRUSEMIDE 40.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMADYNE HEALTHCARE (PTY) LTD Manufacturer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA Packer: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA Laboratory: FPRC: INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA FPRC: CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016

MRF 15	MRF15	
Registration number:	46/18.1/0017	46/26/0211
Name of medicine:	FRUSEMIDE PHARMADYNE 40	INTAPLAT 100 mg
Dosage form:	TABLET	CONCENTRATE FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: FRUSEMIDE 40,0 mg	EACH VIAL CONTAINS: OXALIPLATIN 100, 0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMADYNE HEALTHCARE (PTY) LTD	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA	INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA
Packer:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA	INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC:	INDOCO REMEDIES LIMITED, VERNA, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACTAVIS PHARMA (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA	INTAS PHARMACEUTICALS LIMITED, MATODA SANAD, DISTRICT AHMEDABAD, GUJARAT, INDIA
Shelf-life:	24 months (provisional)	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA
Date of registration:	18 FEBRUARY 2016	24 months (provisional)
		Date of registration: 18 FEBRUARY 2016

MRF 15	Registration number: 46/2.5/0338 Name of medicine: LEVETIRACETAM UNICORN 250 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 250.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: UNICORN PHARMACEUTICALS (PTY) LTD Manufacturer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA Packer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA Laboratory: FPRR: UNICORN PHARMCEUTICALS (PTY) LTD, WOODSTOCK, CAPE TOWN, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016
MRF15	Registration number: 46/2.5/0339 Name of medicine: LEVETIRACETAM UNICORN 750 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: LEVETIRACETAM 750.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: UNICORN PHARMACEUTICALS (PTY) LTD Manufacturer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA Packer: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA Laboratory: FPRC: JUBILANT ORGANOSYS LIMITED, BHAGWANPUR, ROORKEE, DISTRICT HARIDWAR, UTTRAKHAND, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICALSERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA FPRR: UNICORN PHARMCEUTICALS (PTY) LTD, WOODSTOCK, CAPE TOWN, RSA Shelf-life: 24 months (provisional) Date of registration: 18 FEBRUARY 2016
	Registration number: 46/5.2/0390 Name of medicine: BISOLPROLOL UNICHEM 5 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 5.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: UNICHEM SA (PTY) LTD Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICALSERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA FPRR: UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA Shelf-life: 24 months Date of registration: 18 FEBRUARY 2016

MRF 15	Registration number: 46/5.2/0391 Name of medicine: BISOLPROLOL UNICHEM 10 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: UNICHEM SA (PTY) LTD Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA Shelf-life: 24 months Date of registration: 18 FEBRUARY 2016
MRF15	Registration number: 46/5.11/0416 Name of medicine: MEMANTINE UNICHEM 10 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: UNICHEM SA (PTY) LTD Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016
	Registration number: 46/5.11/0427 Name of medicine: MEMINIST 10 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: BISOLPROLOL FUMARATE 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: UNICHEM SA (PTY) LTD Manufacturer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Packer: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA Laboratory: FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016

MRF 15	MRF15	
Registration number:	46/20.1.2/0492	46/20.1.2/0492
Name of medicine:	APEX-DESCLORATADINE 5 mg	46/20.1.2/0493
Dosage form:	TABLET	AERZIT 5 mg
Active ingredients:	EACH TABLET CONTAINS: DESCLORATADINE 5.0 mg	EACH TABLET CONTAINS: DESCLORATADINE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE
Packer:	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE
Laboratory: FPRC:	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	GENEPHARM S.A., PALLINI, ATTIKI, GREECE BOEHRINGER HELLAS S.A., KOROPI ATTIKIS, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
Shelf-life:	36 months	36 months
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016
Registration number:	46/15.4/0918	46/15.4/0918
Name of medicine:	SPERSATAN	SPERSATAN
Dosage form:	EYE DROPS	EYE DROPS
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LATANOPROST 50.0 µg	EACH 1.0 ml SOLUTION CONTAINS: LATANOPROST 50.0 µg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED	ADCOCK INGRAM LIMITED
Manufacturer:	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE
Packer:	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE
Laboratory: FPRC:	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD, (WADEVILLE), WADEVILLE, GERMISTON, RSA	VIANEX S.A., PLANTA, METAMORPHOSI ATTICA, GREECE ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA ADCOCK INGRAM HEALTHCARE (PTY) LTD, (WADEVILLE), WADEVILLE, GERMISTON, RSA
Shelf-life:	36 months (stored at 2-8°C) 28 days (in-use stored at 25°C)	36 months (stored at 2-8°C) 28 days (in-use stored at 25°C)
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	Registration number: 47/21.1/0165 Name of medicine: RYZODEG Dosage form: SOLUTION FOR INJECTION Active ingredients: EACH 1.0 ml SOLUTION CONTAINS: INSULIN DEGLUDEC 70.0 units INSULIN ASPART 30.0 units Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: NOVO NORDISK (PTY) LTD Manufacturer: NOVO NORDISK A/S, BAGSVAERD, DENMARK Packer: NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK NOVO NORDISK A/S, KALUNDBORG, DENMARK NOVO NORDISK PRODUCTION SAS, CHERTRES, FRANCE Laboratory: FPRC: NOVO NORDISK A/S, BAGSVAERD, DENMARK NOVO NORDISK A/S, HILLEROD, DENMARK Shelf-life: 30 months (stored at 2-8°C) 28 days (in-use, stored at or below 30°C) Date of registration: 18 FEBRUARY 2016	MRF15	Registration number: 47/32/0507 Name of medicine: REVLIMID 5 mg Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: LENALIDOMIDE 5.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: KEY ONCOLOGICS (PTY) LTD Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016	Registration number: 47/32/0508 Name of medicine: REVLIMID 10 mg Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: LENALIDOMIDE 10.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: KEY ONCOLOGICS (PTY) LTD Manufacturer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND Packer: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND Laboratory: FPRC: PEN PHARMACEUTICAL SERVICES LTD, TREDEGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND CELGENE CORPORATION, SUMMIT, NEW JERSEY, USA CELSIS LABORATORIES, EDISON, NEW JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA Shelf-life: 36 months Date of registration: 18 FEBRUARY 2016
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MRF 15		MRF 15		MRF 15	
Registration number:	47/32/0509	Registration number:	47/32/0510	Registration number:	47/15-4/0526
Name of medicine:	REVLIMID 15 mg	Name of medicine:	REVLIMID 25 mg	Name of medicine:	LOXOPTIC
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	OPHTHALMIC SOLUTION
Active ingredients:	EACH CAPSULE CONTAINS: LENALIDOMIDE 15.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: LENALIDOMIDE 25.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: BETAXOLOL HYDROCHLORIDE EQUIVALENT TO BETAZOLOL 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7,	Conditions of registration:	1, 2, 3, 4, 5, 6, 7,	Conditions of registration:	1, 2, 3, 4, 5, 6, 7,
Applicant:	KEY ONCOLOGICS (PTY) LTD	Applicant:	KEY ONCOLOGICS (PTY) LTD	Applicant:	ACTOR PHARMA (PTY) LTD
Manufacturer:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND	Manufacturer:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND	Manufacturer:	FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA
Packer:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND	Packer:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND ACINO PHARM AG, LIESBERG, SWITZERLAND ACINO PHARM AG, AESCH, SWITZERLAND	Packer:	FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
Laboratory: FPRC:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND JERSEY, USA JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PEN PHARMACEUTICAL SERVICES LTD, TREDGAR, GWENT, UNITED KINGDOM CELGENE INTERNATIONAL SARL, BOUDRY, SWITZERLAND SOLVIA AG, KAISERAUGST, SWITZERLAND JERSEY, USA JERSEY, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	FDC LIMITED, WALUJ, AURANGABAD, MAHARASHTRA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE INDUSTRIA, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA	FPRR:	KEY ONCOLOGICS (PTY) LTD, HOUGHTON, JOHANNESBURG, RSA	FPRR:	ACTOR PHARMA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15	MRF15	
Registration number:	47/18.1/0948	48/20.2.8/0028
Name of medicine:	LIXETIC 10 mg/ml	NEVIRAPINE LITHA
Dosage form:	SOLUTION FOR INJECTION	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: FRUSEMIDE 10.0 mg	EACH TABLET CONTAINS: NEVIRAPINE 200.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	LITHA PHARMA (PTY) LTD
Manufacturer:	CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA	MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA
Packer:	CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA	MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CLARIS LIFESCIENCES LIMITED, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	MICRO LABS LIMITED, VERNA, SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM CC, SILVERTONDALE, PRETORIA, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	LITHA PHARMA (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016

MRF 15	4877.J0037	4877.J0039	MRF15
Registration number:	4877.J0037	4877.J0039	Registration number:
Name of medicine:	AMLODIPINE DEZZO 5	VASCOLOK 5 mg	Name of medicine:
Dosage form:	TABLET	TABLET	Dosage form:
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5.0 mg	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5.0 mg	Active ingredients:
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	Conditions of registration:
Applicant:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant:
Manufacturer:	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:
Packer:	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Packer:
Laboratory: FPRC:	CADILA PHARMACEUTICALS LIMITED, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA	Laboratory: FPRC:
FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR:
Shelf-life:	24 months	24 months	Shelf-life:
Date of registration:	18 FEBRUARY 2016	18 FEBRUARY 2016	Date of registration:

MRF 15				MRF15			
Registration number:	48/7.J0040	Registration number:	48/20.2.80403	Registration number:	48/7.1/0584		
Name of medicine:	VASCOLOK 10 mg	Name of medicine:	TIVICAY 50 mg	Name of medicine:	AMLODIPINE HETERO 5		
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET		
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10.0 mg	Active ingredients:	EACH TABLET CONTAINS: DOLUTEGRAVIR 50.0 mg	Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5.0 mg		
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8		
Applicant:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	HETERO DRUGS SA		
Manufacturer:	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM	Manufacturer:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA		
Packer:	CADILA PHARMACEUTICALS LIMITED, DHOLKA, AHMEDABAD, GUJARAT, INDIA	Packer:	GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM	Packer:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA		
Laboratory: FPRC:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	Laboratory: FPRC:	GLAXO OPERATIONS UK LTD T/A GLAXO WELLCOME OPERATIONS, WARE, HERTFORDSHIRE, UNITED KINGDOM	Laboratory: FPRC:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOBNAGAR DISTRICT, ANDHRA PRADESH, INDIA		
FPRC:		FPRC:	GLAXO WELLCOME S.A., ARANDA DE DUERO, BURGOS, SPAIN	FPRC:	CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA		
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (provisional)		
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016		

MRF 15		MRF15	
Registration number:	48/7.10585	Registration number:	48/20.1.2/1122
Name of medicine:	AMLODIPINE HETERO 10	Name of medicine:	CAMOX CO-AMOXICLAV ES 600
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10.0 mg	Active ingredients:	EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	HETERO DRUGS SA	Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY
Packer:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA	Packer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY
Laboratory: FPCR:	HETERO LABS LIMITED, UNIT V, POLEPALY VILLAGE, JADCHERLA MANDAL, MAHABOONAGAR DISTRICT, ANDHRA PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICAL (PTY) LTD, NORTH- RIDING, RANDBURG, RSA	Laboratory: FPCR:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA
FPRR:	HETERO DRUGS SA, CENTURION, RSA	FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXT 3, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	18 FEBRUARY 2016	Date of registration:	18 FEBRUARY 2016

MRF 15		MRF15	
Registration number:	48/20.1.2/1123	Registration number:	48/20.1.2/1124
Name of medicine:	AUSTELL CO-AMOXICLAV ES 600	Name of medicine:	APEX CO-AMOXICLAV ES 600
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg	Active ingredients:	EACH 5.0 ml SUSPENSION CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 600.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 42.9 mg
Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8	Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD	Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY	Manufacturer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY
Packer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY	Packer:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY
Laboratory: FPRC:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA	Laboratory: FPRC:	DEVA HOLDINGS A.S., TEKIRDAG, TURKEY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA
Shelf-life:	24 months (provisional)	FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN EXT 3, JOHANNESBURG, RSA
Date of registration:	18 FEBRUARY 2016	Shelf-life:	24 months (provisional)
		Date of registration:	18 FEBRUARY 2016

Registration number:	48/20.1.1/1047	Registration number:	48/20.1.1/1047
Name of medicine:	AKLIV IV	Name of medicine:	AKLIV IV
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg
Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8	Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8
Applicant:	AKACIA HEALTHCARE (PTY) LTD	Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA
Packer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	Packer:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA PHARMADOX HEALTHCARE LTD, PAOLA, MALTA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	CLARIS LIFESCIENCES LIMITED, AHMEDABAD, GUJARAT, INDIA AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA PHARMADOX HEALTHCARE LTD, PAOLA, MALTA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Date of registration:	18 FEBRUARY 2016	Shelf-life:	24 months (provisional)
		Date of registration:	18 FEBRUARY 2016

MRF 15		MRF 15		MRF 15	
Registration number:	13/3.1.204	Registration number:	13/3.1.209	Registration number:	09/17.1.15
Name of medicine:	EQUICAM INJECTION 2 %	Name of medicine:	VETCAM INJECTION 2 %	Name of medicine:	AQUAFLO 50 %
Dosage form:	SOLUTIO FOR INJECTION	Dosage form:	SOLUTIO FOR INJECTION	Dosage form:	ORAL PREMIX POWDER
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MELOXICAM 20.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: MELOXICAM 20.0 mg	Active ingredients:	EACH 1.0 kg POWDER CONTAINS: FLORFENICOL 500.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 16, 17
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	INTERVET SOUTH AFRICA (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Manufacturer:	SCHERING-PLOUGH ANIMAL HEALTH CORPORATION, BARON ROUGE, LOS ANGELES, USA
Packer:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Packer:	SCHERING-PLOUGH ANIMAL HEALTH CORPORATION, BARON ROUGE, LOS ANGELES, USA
Laboratory, FPRC:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Laboratory, FPRC:	CIPLA LTD, UNIT IX, VERNA SALCETTE, GOA, INDIA	Laboratory, FPRC:	KHULILEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INTERVET SOUTH AFRICA (PTY) LTD, SPARTAN, ISANDO, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	INTERVET SOUTH AFRICA (PTY) LTD, SPARTAN, ISANDO, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15		MRF15		RF 15	
Registration number:	41/7.1.3/1112	Registration number:	41/7.1.3/1113	Registration number:	42/7.1.3/0640
Name of medicine:	ASPEN VALSARTAN 80 mg	Name of medicine:	ASPEN VALSARTAN 160 mg	Name of medicine:	ASPEN VALSARTAN 40 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80,0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Manufacturer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Manufacturer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Packer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Packer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Packer:	ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Laboratory:	FPRC : ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Laboratory:	FPRC: ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Laboratory:	FPRC ACTAVIS LTD, BULEBEL INDUSTRIAL ESTATE, ZEJTUN, MALTA PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
FPR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	FPR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	FPR:	PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA PHARMACARE LIMITED, WOODMEAD, JOHANNESBURG, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15		MRF15		RF 15	
Registration number:	43/7.1.3/0521	Registration number:	43/7.1.3/0522	Registration number:	43/7.1.3/0523
Name of medicine:	RINTEZEX 320	Name of medicine:	ZOMEVEK 320 TABLET	Name of medicine:	MIGROBEN 320 TABLET
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 320.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 320.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 320.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD	Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD	Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND	Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND	Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND ALLPACK AG, REINACH, SWITZERLAND KONAPHARMA AG, PRATTELN, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND
Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	NOVARTIS SOUTH AFRICA (PTY) LTD, LTD, WATERFALL CITY, MIDRAND, RSA	FPRR:	NOVARTIS SOUTH AFRICA (PTY) LTD, LTD, WATERFALL CITY, MIDRAND, RSA	FPRR:	NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF15	F 15
Registration number: 43/7.1.3/0547 Name of medicine: DYNAVAL 40 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: VALSARTAN 40,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA; TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA; SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA Shelf-life: 24 months (provisional) Date of registration: 21 APRIL 2016	Registration number: 43/7.1.3/0548 Name of medicine: DYNAVAL 80 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: VALSARTAN 80,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA; TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA; SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA Shelf-life: 24 months (provisional) Date of registration: 21 APRIL 2016	Registration number: 43/7.1.3/0549 Name of medicine: DYNAVAL 160 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: VALSARTAN 160,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN Packer: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA; TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA; SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN; CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA Shelf-life: 24 months (provisional) Date of registration: 21 APRIL 2016

MRF 15		MRF 15		MRF 15	
Registration number:	437.1.3/0550	Registration number:	437.1.3/0551	Registration number:	437.1.3/0552
Name of medicine:	DYNA VALSARTAN 40 mg	Name of medicine:	DYNA VALSARTAN 80 mg	Name of medicine:	DYNA VALSARTAN 160 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 40.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, JOHANNESBURG, RSA HALFWAY HOUSE, MIDRAND, RSA	Packer:	LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Packer:	LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory:	FPRC: LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A., HUARTE- PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA 24 months (provisional)	Shelf-life:	FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA 24 months (provisional)	Shelf-life:	FPRR: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA 24 months (provisional)
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15

Registration number:	437.1.3/0949	Registration number:	43/20.1.1/1180
Name of medicine:	PHARMA DYNAMICS VALSARTAN 80 mg	Name of medicine:	CRITPEME 500 mg
Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INJECTION OR INFUSION
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80.0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 500.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LUPIN LTD, VERNA SALCETTE, GOA, INDIA	Manufacturer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA
Packer:	LUPIN LTD, VERNA SALCETTE, GOA, INDIA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Packer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory: FPRC	LUPIN LTD, VERNA SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (provisional)		24 months (provisional)
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	5	MRF15
Registration number:	43/20.1.1/1181	43/20.1.1/1182
Name of medicine:	CRITPEME 1 000 mg	CRITPEME 2 000 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	POWDER FOR SOLUTION FOR INJECTION OR INFUSION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 2 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY
Packer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY
Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA	SANDOZ GmbH, KUNDL, AUSTRIA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (provisional)	24 months (provisional)
Date of registration:	21 APRIL 2016	21 APRIL 2016
Registration number:	43/20.1.1/1183	43/20.1.1/1183
Name of medicine:	SANDOZ CEFEPIME 500 mg	SANDOZ CEFEPIME 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	POWDER FOR SOLUTION FOR INJECTION OR INFUSION
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY
Packer:	SANDOZ GmbH, KUNDL, AUSTRIA	SANDOZ GmbH, KUNDL, AUSTRIA
Laboratory: FPRC:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY
FPRR:	SANDOZ GmbH, KUNDL, AUSTRIA	SANDOZ GmbH, KUNDL, AUSTRIA
Shelf-life:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Date of registration:	24 months (provisional)	24 months (provisional)
Date of registration:	21 APRIL 2016	21 APRIL 2016

MRF 15		MRF 15		MRF 15	
Registration number:	43/20.1.1/1184	Registration number:	43/20.1.1/1185	Registration number:	44/18.2/0283
Name of medicine:	SANDOZ CEFEPIME 1 000 mg	Name of medicine:	SANDOZ CEFEPIME 2 000 mg	Name of medicine:	SANDOZ CLOPIDOGREL 75
Dosage form:	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 1 000,0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFEPIME DIHYDROCHLORIDE EQUIVALENT TO CEFEPIME 2 000,0 mg	Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	Manufacturer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	Manufacturer:	SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA
Packer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	Packer:	SANDOZ INDUSTRIAL PRODUCTS GmbH, FRANKFURT, GERMANY SANDOZ GmbH, KUNDL, AUSTRIA	Packer:	SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15		MRF 15		MRF 15	
Registration number:	44/8.2/0284	Registration number:	44/2.6.5/0673	Registration number:	44/2.6.5/0674
Name of medicine:	PLAHIP	Name of medicine:	RISPIDE 0.5	Name of medicine:	RISPIDE 1
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BISULPHATE EQUIVALENT TO CLOPIDOGREL 75.0 mg	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 0.5 mg	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD	Applicant:	ABEX PHARMACEUTICA (PTY) LTD	Applicant:	ABEX PHARMACEUTICA (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA
Laboratory:	FPRC: SANDOZ PRIVATE LIMITED, KALWE BLOCK, VILLAGE-DIGHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.6.5/0675	Registration number:	44/2.6.5/0676	Registration number:	44/2.6.5/0677
Name of medicine:	RISPIDE 2	Name of medicine:	RISPIDE 3	Name of medicine:	RISPIDE 4
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2.0 mg	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3.0 mg	Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ABEX PHARMACEUTICA (PTY) LTD	Applicant:	ABEX PHARMACEUTICA (PTY) LTD	Applicant:	ABEX PHARMACEUTICA (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA
Laboratory, FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory, FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory, FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	ABEX PHARMACEUTICA (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRR:	ABEX PHARMACEUTICA (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRR:	ABEX PHARMACEUTICA (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

Registration number:	44/2.6.5/0678	Registration number:	44/21.12/0850	Registration number:	44/20.2.8/1050
Name of medicine:	RISPIDE 6	Name of medicine:	DUODART	Name of medicine:	TENOLAM
Dosage form:	TABLET	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 6.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: DUTASTERID 0.5 mg TAMSULOSIN HYDROCHLORIDE 0.4 mg	Active ingredients:	EACH TABLET CONTAINS: TENOFIVIR DISPROXIL FUMARATE 300.0 mg LAMIVUDINE 300.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ABEX PHARMACEUTICA (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE (DUTASTERIDE INTERMEDIATE) ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY (TAMSULOSIN HCI INTERMEDIATE)	Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., LAMIA HIGHWAY, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY GLAXOSMITHKLINE SA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: CATALENT GERMANY SCHORNDORF GmbH, SCHORNDORF, GERMANY CATALENT FRANCE BEINHEIM SA, BEINHEIM, FRANCE ROTTENDORF PHARMA GmbH, ENNINGERLOH, GERMANY QUINTA-ANALYTICA s.r.o., PRAGUE HOSTIVAR, CZECH REPUBLIC SYNTHON HIPANIA S.L., SAINT BOI DE LOBREGAT, SPAIN GLAXOSMITHKLINE SA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	Laboratory:	FPRC: MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA ASPEN OSD (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

Registration number:	45/20.2.8/0098	Registration number:	45/20.2.8/0099	Registration number:	45/7.1.3/0106
Name of medicine:	CIPLA LOPINAVIR & RITONAVIR 80/20 mg/ml	Name of medicine:	MEDPRO LOPINAVIR & RITONAVIR 80/20 mg/ml	Name of medicine:	VOLIBRIS 5 mg
Dosage form:	ORAL SOLUTION	Dosage form:	ORAL SOLUTION	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LOPINAVIR 80.0 mg RITONAVIR 20.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LOPINAVIR 80.0 mg RITONAVIR 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: AMBRISANTAN 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Manufacturer:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA
Packer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Packer:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, INDUSTRIA, CAPE TOWN, RSA
Laboratory: FPRC:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT 1, VERNA SALCETTE, GOA, INDIA	Laboratory: FPRC:	PATHEON INC. MISSISSAUGA, ONTARIO, CANADA GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, INDUSTRIA, CAPE TOWN, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA	FPRR:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING, INDUSTRIA, CAPE TOWN, RSA
Shelf-life:	48 months	Shelf-life:	48 months	Shelf-life:	48 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0417	Registration number:	45/20.1.1/0418	Registration number:	45/20.1.1/0419
Name of medicine:	MERTIC 500 mg	Name of medicine:	MERTIC 1 g	Name of medicine:	MEROPENEM SANDOZ 500 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION OF INFUSION
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 500.0 mg	Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1.0 g	Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 500.0 mg
Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8	Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8	Conditions of registration:	1. 2. 3. 4. 5. 6. 7. 8
Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA	Manufacturer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA	Manufacturer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA
Packer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA	Packer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA	Packer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC/FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF15	3F 15	
Registration number:	45/20.1.1/0420	Registration number:	45/10.2.2/0668
Name of medicine:	MEROPENEM SANDOZ 1 g	Name of medicine:	LUCAN CHEW 5 mg
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM 1,0 g	Active ingredients:	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Applicant:	MYLAN (PTY) LTD
Manufacturer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA	Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA	Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	SANDOZ PRIVATE LIMITED, TURBHE, NAVI MUMBAI, MAHARASHTRA, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RANDBURG, JOHANNESBURG, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF15	MRF 15
Registration number: 45/20.2.6/0828	Registration number: 45/20.2.6/0829	Registration number: 45/20.2.6/0830
Name of medicine: METRONIDAZOLE DEZZO 200	Name of medicine: METRONIDAZOLE DEZZO 400	Name of medicine: FLAMET 200
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 200.0 mg	Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 400.0 mg	Active ingredients: EACH TABLET CONTAINS: METRONIDAZOLE 200.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA
Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA	Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA	Manufacturer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA
Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA	Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA	Packer: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA
Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDSBURG, RSA	Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDSBURG, RSA	Laboratory: FPRC: KOPRAN LIMITED, TALUKA KHALAPUR, RAIGAD, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDSBURG, RSA
FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR: DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA
Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)
Date of registration: 21 APRIL 2016	Date of registration: 21 APRIL 2016	Date of registration: 21 APRIL 2016

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MRF 15		MRF 15		MRF 15	
Registration number:	45/8.3/0166	Registration number:	45/8.3/0167	Registration number:	45/8.3/0168
Name of medicine:	MonoFer 100 mg	Name of medicine:	MonoFer 500 mg	Name of medicine:	MonoFer 1 000 mg
Dosage form:	SOLUTION FOR INJECTION OR INFUSION	Dosage form:	SOLUTION FOR INJECTION OR INFUSION	Dosage form:	SOLUTION FOR INJECTION OR INFUSION
Active ingredients:	EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSIDE 1 000 EQUIVALENT TO IRON 100.0 mg	Active ingredients:	EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSIDE 1 000 EQUIVALENT TO IRON 500.0 mg	Active ingredients:	EACH VIAL OF AMPOULE CONTAINS: IRON (III) ISOMALTOSIDE 1 000 EQUIVALENT TO IRON 1 000.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY	Manufacturer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY	Manufacturer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY
Packer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØD, DENMARK	Packer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØD, DENMARK	Packer:	SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GmbH, MELSUNGEN, GERMANY WASSERBURGER ARZNEIMITTELWERK GmbH, WASSERBURGER, GERMANY SCANPHARM A/S, BIRKERØD, DENMARK
Laboratory:	FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: PHARMACOSMOS A/S, HOLBAEK, DENMARK CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	MRF15	
Registration number:	47/3.J0467	48/20.1.1/0434
Name of medicine:	ORENCIA 125 mg	LINEZOLID FRESENIUS 600 mg/300 ml
Dosage form:	SOLUTION FOR INJECTION	SOLUTION FOR INFUSION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: ABATACEPT 125.0 mg	EACH 300.0 ml SOLUTION CONTAINS: LINEZOLID 600.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 18
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO	FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA
Packer:	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO	FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY
Laboratory: FPRC:	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, MANATI, PUERTO RICO BRISTOL-MYERS SQUIBB COMPANY, EAST SYRACUSE NEW YORK, USA COVANCE LABORATORIES LTD, HARROGATE, NORTH YORKSHIRE, UNITED KINGDOM	FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY
FPRC:	BRISTOL-MYERS SQUIBB (PTY) LTD, BEDFORDVIEW, JOHANNESBURG, RSA	FRESENIUS KABI MANUFACTURING SA (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA FRESENIUS KABI NORGE AS, OSTOFOLD, NORWAY KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months	24 months
Date of registration:	21 APRIL 2016	21 APRIL 2016

MPF 15		MPF 15		MPF 15	
Registration number:	49/20.2.8/0097	Registration number:	49/20.2.8/0374	Registration number:	49/20.2.8/0503
Name of medicine:	TRELAVUE	Name of medicine:	LAMIVUDINE SANDOZ	Name of medicine:	ZIDOVUDINE SANDOZ 300 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50.0 mg ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 600.0 mg LAMIVUDINE 300.0 mg	Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 300.0 mg	Active ingredients:	EACH TABLET CONTAINS: ZIDOVUDINE 300.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD (T/A GLAXO WELLCOME OPERATIONS), WARE, HERTFORDSHIRE, UNITED KINGDOM	Manufacturer:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	GLAXO OPERATIONS UK LTD (T/A GLAXO WELLCOME OPERATIONS), WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOWELLCOME S.A., ARANDA DE DUERO, BURGOS, SPAIN GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	Packer:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD (T/A GLAXO WELLCOME OPERATIONS), WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOWELLCOME S.A., ARANDA DE DUERO, BURGOS, SPAIN GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	Laboratory: FPRC:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	HETERO LABS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, ANDHRA PRADESH, INDIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

MRF 15	Registration number:	49/21.1.0708	Registration number:	A40/1.2/0477
	Name of medicine:	BASAGLAR	Name of medicine:	ROXET 10 mg
	Dosage form:	SOLUTION FOR INJECTION	Dosage form:	TABLET
	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: INSULIN GLARGINE 3.64 mg	Active ingredients:	EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 10.0 mg
	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
	Applicant:	ELI LILLY (S.A.) (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
	Manufacturer:	ELI LILLY FRANCE, FEGERSHEIM, FRANCE	Manufacturer:	ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA
	Packer:	ELI LILLY FRANCE, FEGERSHEIM, FRANCE ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA, USA	Packer:	ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
	Laboratory: FPRC:	SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
	FPRR:	ELI LILLY (S.A.) (PTY) LTD, BRYANSTON, JOHANNESBURG, RSA	FPRR:	M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
	Shelf-life:	24 months	Shelf-life:	36 months
	Date of registration:	21 APRIL 2016	Date of registration:	21 APRIL 2016

Registration number:	A40/21.10/0263
Name of medicine:	LEUPROLIDE HEXAL 5
Dosage form:	IMPLANT
Active ingredients:	EACH IMPLANT CONTAINS: LEUPROLIDE ACETATE EQUIVALENT TO LEUPROLIDE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	JENAHEXAL PHARMA GmbH, JENA, GERMANY REUSCH STERILISATION SERVICE GmbH, KERNEN, GERMANY GAMMA-SERVICE PRODUKTBESTRAHLUNG GmbH, RADEBERG, GERMANY
Packer:	JENAHEXAL PHARMA GmbH, JENA, GERMANY SALUTAS PHARM GmbH, BARLEBEN, GERMANY DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA
Laboratory: FPRC:	JENAHEXAL PHARMA GmbH, JENA, GERMANY SALUTAS PHARM GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	48 months
Date of registration:	21 APRIL 2016

MRF 15	MRF 15
Registration number: A40/1.2/0478 Name of medicine: ROXET 20 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD Manufacturer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA Packer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA Laboratory: FPRC: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 21 APRIL 2016	Registration number: A40/1.2/0479 Name of medicine: ROXET 30 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 30.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD Manufacturer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA Packer: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA Laboratory: FPRC: ARROW PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA FPRR: ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 21 APRIL 2016

MRF 15	MRF15	F 15
Registration number: 07/3.1/13 Name of medicine: TOLFEDINE 6 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 60 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016	Registration number: 07/3.1/14 Name of medicine: TOLFEDINE 20 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 20.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016	Registration number: 07/3.1/15 Name of medicine: TOLFEDINE 60 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: TOLFENAMIC ACID 60.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: AFRIVET BUSINESS MANAGEMENT (PTY) LTD Manufacturer: VETOQUINOL SA, LURE, CEDEX, FRANCE Packer: VETOQUINOL SA, LURE, CEDEX, FRANCE Laboratory: FPRC: BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA FPRR: AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016

MRF 15		.5	
Registration number:	07/3.1/16	Registration number:	10/17.1.6/16
Name of medicine:	TOLFEDINE 120 mg	Name of medicine:	BAXIN 100 mg/ml
Dosage form:	TABLET	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: TOLFENAMIC ACID 120,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ENROLFLOXACIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	VETOQUINOL SA, LURE, CEDEX, FRANCE	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA
Packer:	VETOQUINOL SA, LURE, CEDEX, FRANCE	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA
Laboratory: FPRC :	BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA	Laboratory: FPRC	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	A08/3.1/08	Registration number:	41/7.1/0661	Registration number:	41/7.1/0662
Name of medicine:	TOLFEDINE INJECTABLE	Name of medicine:	ACCORD AMLODIPINE 5	Name of medicine:	ACCORD AMLODIPINE 10
Dosage form:	INJECTION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 100.0 ml SOLUTION CONTAINS: TOLFENAMIC ACID 4.0 g	Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATETE EQUIVALENT TO AMLODIPINE 5.0 mg	Active ingredients:	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	VETOQUINOL SA, LURE, CEDEX, FRANCE	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA
Packer:	VETOQUINOL SA, LURE, CEDEX, FRANCE	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA
Laboratory:	BIO-INDUSTRIAL SERVICES (PTY) LTD, SUNNYRIDGE, GERMISTON, RSA	Laboratory:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	INTAS PHARMACEUTICALS LTD, MATODA, TALUKA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPR:	AFRIVET BUSINESS MANAGEMENT (PTY) LTD, HAZELDEAN, PRETORIA, RSA	FPR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA
Shelf-life:	36 months 28 days (in-use)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	Registration number:	41/3.2/0408	Registration number:	41/26/0910	Registration number:	41/26/1129
	Name of medicine:	ALOVELL	Name of medicine:	OXALIPLATIN EBEWE 50 mg	Name of medicine:	OXALIPLATIN EBEWE 100 mg
	Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INFUSION	Dosage form:	POWDER FOR SOLUTION FOR INFUSION
	Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONATE 10.0 mg	Active ingredients:	EACH VIAL CONTAINS: OXALIPLATIN 50.0 mg	Active ingredients:	EACH VIAL CONTAINS: OXALIPLATIN 100.0 mg
	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
	Applicant:	GULF DRUG COMPANY (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
	Manufacturer:	PT NOVELL PHARMACEUTICAL LABORATORIES, SENAYAN, JAKARTA, INDONESIA	Manufacturer:	ONCOTEC PHARMA PRODUCTION GmbH, RÖDLEBEN, GERMANY	Manufacturer:	ONCOTEC PHARMA PRODUCTION GmbH, RÖDLEBEN, GERMANY
	Packer:	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	Packer:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
	Laboratory:	PT NOVELL PHARMACEUTICAL LABORATORIES, GUNUNG PUTRI, BOGOR, INDONESIA	Laboratory:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA	Laboratory:	EBEWE PHARMA GmbH, UNTERACH, AUSTRIA
	FPRC:	WRAPSA (PTY) LTD, HENNOPSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+S AG, BAD BOCKLET, GERMANY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	MIKROBIOLOGISCHES PRUFLABOR, INNSBRUCK, AUSTRIA LABOR L+S AG, BAD BOCKLET, GERMANY SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

Registration number:	42/5.8/0223	Registration number:	42/20.1.2/0225	Registration number:	42/20.1.2/0226
Name of medicine:	SINUPHEN SINUS PAIN	Name of medicine:	CLAVAM SR	Name of medicine:	GSK AMOXICILLIN/CLAVULANATE SR
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PHENYLEPHRINE HYDROCHLORIDE 5,0 mg PARACETAMOL 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 1 000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg	Active ingredients:	EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 1 000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 62,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JOHNSON & JOHNSON (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	Manufacturer:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE	Manufacturer:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE
Packer:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	Packer:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	Packer:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA
Laboratory: FPRC	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	GLAXO WELLCOME PRODUCTION, MAYENNE, FRANCE GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA KHULULEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	FPRR:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA	FPRR:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIA, CAPE TOWN, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months		24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	MRF15	5
Registration number:	Registration number:	Registration number:
Name of medicine:	Name of medicine:	Name of medicine:
Dosage form:	Dosage form:	Dosage form:
Active ingredients:	Active ingredients:	Active ingredients:
Conditions of registration:	Conditions of registration:	Conditions of registration:
Applicant:	Applicant:	Applicant:
Manufacturer:	Manufacturer:	Manufacturer:
Packer:	Packer:	Packer:
Laboratory:	Laboratory:	Laboratory:
FPRR:	FPRR:	FPRR:
Shelf-life:	Shelf-life:	Shelf-life:
Date of registration:	Date of registration:	Date of registration:
42/11.5/0412	42/11.5/0413	43/2.1/0392
PURGOLENE	PURGOPED	TORRANE
POWDER FOR ORAL SOLUTION	POWDER FOR ORAL SOLUTION	LIQUID FOR INHALATION
EACH SACHET CONTAINS: MACROGOL (PEG) 3350 13.125 g SODIUM BICARBONATE 178.5 mg SODIUM CHLORIDE 350.7 mg POTASSIUM CHLORIDE 46.6 mg	EACH SACHET CONTAINS: MACROGOL (PEG) 3350 6.563 g SODIUM BICARBONATE 89.3 mg SODIUM CHLORIDE 175.4 mg POTASSIUM CHLORIDE 23.3 mg	EACH BOTTLE CONTAINS: DESFLURANE 250.0 ml
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8
ANMARATE (PTY) LTD	ANMARATE (PTY) LTD	SAFE LINE PHARMACEUTICALS (PTY) LTD
DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA
DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA
INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	MINRAD INC, BETHLEHEM, PENNSYLVANIA, USA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA
ANMARATE (PTY) LTD, GEORGE, RSA	ANMARATE (PTY) LTD, GEORGE, RSA	SAFE LINE PHARMACEUTICALS (PTY) LTD, WELTEVREDEN PARK, JOHANNESBURG, RSA
48 months	48 months	24 months (provisional)
09 JUNE 2016	09 JUNE 2016	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	43/13.1/1057	Registration number:	43/21.13/0829	Registration number:	43/8.2/0763
Name of medicine:	BARRS MERCUROCHROME 1 % SOLUTION	Name of medicine:	GLYPRESSIN	Name of medicine:	VASPID
Dosage form:	SOLUTION	Dosage form:	SOLUTION FOR INJECTION	Dosage form:	TABLET
Active ingredients:	EACH 20.0 ml SOLUTION CONTAINS: MERCUROCHROME 0.20 g	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: TERLIPRESSIN ACETATE EQUIVALENT TO TERLIPRESSIN 0.1 mg	Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL BESYLATE EQUIVALENT TO CLOPIDOGREL 75.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BARRS PHARMACEUTICAL INDUSTRIES cc	Applicant:	FERRING (PTY) LTD	Applicant:	AKACIA HEALTHCARE (PTY) LTD
Manufacturer:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA	Manufacturer:	ZENTIVA A.S., PRAGUE, CZECH REPUBLIC	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE
Packer:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA	Packer:	ZENTIVA A.S., PRAGUE, CZECH REPUBLIC	Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE
Laboratory:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA	Laboratory:	FPRC: ZENTIVA A.S., PRAGUE, CZECH REPUBLIC FERRING-LECIVA A.S., JESENICE U PRAHY, CZECH REPUBLIC ITEST PLUS S.R.O., HRADEC KRALOVE, CZECH REPUBLIC FRESENIUS HEMOCARE CZ S.R.O., ZVERINEK, CZECH REPUBLIC CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA	Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	BARRS PHARMACEUTICAL INDUSTRIES cc, NDABENI, CAPE TOWN, RSA	FPRR:	FERRING (PTY) LTD, IRENE, PRETORIA, RSA	FPRR:	AKACIA HEALTHCARE (PTY) LTD, ISANDO JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months (provisional)
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	43/26/1067	Registration number:	43/21.5/1143	Registration number:	44/21.12/0190
Name of medicine:	CAMPTO CSV 300 mg/15 ml	Name of medicine:	MACLEODS HYDROCORTISONE INJECTION	Name of medicine:	ZETRA
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: IRINOTECAN HYDROCHLORIDE TRIHYDRATE 300.0 mg	Active ingredients:	EACH VIAL CONTAINS: HYDROCORTISONE SODIUM SUCCINATE EQUIVALENT TO HYDROCORTISONE 100.0 mg	Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2.5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	Pfizer Laboratories (PTY) LTD	Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	Pfizer Perth (PTY) Limited, Bentley, Australia	Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Manufacturer:	DOUGLAS PHARMACEUTICALS LTD, NADI, FIJI
Packer:	Pfizer Perth (PTY) LTD, Bentley, Australia	Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Packer:	DOUGLAS PHARMACEUTICALS LTD, NADI, FIJI DOUGLAS MANUFACTURING LIMITED, LINCOLN, AUCKLAND, NEW ZEALAND
Laboratory:	FPRC: Pfizer Perth (PTY) LTD, Bentley, Australia KHULILEKANI LABORATORY CC, HALFWAY HOUSE, MIDRAND, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA	Laboratory:	FPRC: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory:	FPRC: DOUGLAS PHARMACEUTICALS LTD, MARTINAR, NADI, FIJI CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	Pfizer Laboratories (PTY) LTD, SANDTON, RSA	FPRC:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	MRF15	3F 15	
		44/20.1.2/0471	44/20.1.2/0472
Registration number:	44/20.1.2/0471	44/20.1.2/0472	44/20.1.2/0472
Name of medicine:	LICAX 250 mg INJECTION	LICAX 500 mg INJECTION	LICAX 500 mg INJECTION
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	POWDER FOR SOLUTION FOR INJECTION	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CLOXACILLIN 250.0 mg	EACH VIAL CONTAINS: CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 500.0 mg	EACH VIAL CONTAINS: CLOXACILLIN SODIUM EQUIVALENT TO CLOXACILLIN 500.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA (PTY) LTD	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA	AUROBINDO PHARMA LIMITED, UNIT XII, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULILEKANI LABORATORY SERVICES cc, HALFWAY HOUSE, MIDRAND, RSA
FPRC:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	24 months (provisional)	24 months (provisional)
Date of registration:	09 JUNE 2016	09 JUNE 2016	09 JUNE 2016
Registration number:	44/26/0548	44/26/0548	44/26/0548
Name of medicine:	REVOLADE 25 mg	REVOLADE 25 mg	REVOLADE 25 mg
Dosage form:	TABLET	TABLET	TABLET
Active ingredients:	EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 25.0 mg	EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 25.0 mg	EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 25.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM
Packer:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA
Laboratory: FPRC:	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA	GLAXO OPERATIONS UK LTD, WARE, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA
FPRC:	NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA	NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA	NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA
Shelf-life:	48 months	48 months	48 months
Date of registration:	09 JUNE 2016	09 JUNE 2016	09 JUNE 2016

Registration number: 44/20.1.2/0970	Registration number: 44/20.1.2/0969	Registration number: 44/26/0549
Name of medicine: GDC CO AMOXICLAV 1 000/200	Name of medicine: GDC CO AMOXICLAV 500/100	Name of medicine: REVOLADE 50 mg
Dosage form: INJECTION	Dosage form: INJECTION	Dosage form: TABLET
Active ingredients: EACH VIAL CONTAINS: AMOXICILLIN 1 000.0 mg CLAVULANIC ACID 200.0 mg	Active ingredients: EACH VIAL CONTAINS: AMOXICILLIN 500.0 mg CLAVULANIC ACID 100.0 mg	Active ingredients: EACH TABLET CONTAINS: ELTROMBOPAG OLAMINE EQUIVALENT TO ELTROMBOPAG 50.0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: GULF DRUG COMPANY (PTY) LTD	Applicant: GULF DRUG COMPANY (PTY) LTD	Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer: LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Manufacturer: LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Manufacturer: GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM
Packer: LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer: LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer: GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM
Laboratory: LABORATORIO REIG JOFRE, TOLEDO, SPAIN WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA	Laboratory: LABORATORIO REIG JOFRE, TOLEDO, SPAIN WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA	Laboratory: GLAXO OPERATIONS UK LTD, HERTFORDSHIRE, UNITED KINGDOM GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA
FPRR: GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	FPRR: GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA	FPRR: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD, EPPING INDUSTRIAL, CAPE TOWN, RSA
Shelf-life: 36 months	Shelf-life: 36 months	Shelf-life: 48 months
Date of registration: 09 JUNE 2016	Date of registration: 09 JUNE 2016	Date of registration: 09 JUNE 2016

MRF 15	Registration number:	44/18.8/1033	Registration number:	4515.4/0142
	Name of medicine:	GDC CLOMIFENE 50	Name of medicine:	DORZOTIM
	Dosage form:	TABLET	Dosage form:	EYE DROPS
	Active ingredients:	EACH TABLET CONTAINS: CLOMIPHENE CITRATE EQUIVALENT TO CLOMIPHENE 50.0 mg	Active ingredients:	EACH SOLUTION CONTAINS: DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20.0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5.0 mg
	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
	Applicant:	GULF DRUG COMPANY (PTY) LTD	Applicant:	LITHA PHARMA (PTY) LTD
	Manufacturer:	OMAN	Manufacturer:	FAMAR S.A., ALIMOS, ATHENS, GREECE
	Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer:	FAMAR S.A., ALIMOS, ATHENS, GREECE PHARMATEN S.A., PALLINI, ATTIKIS, GREECE
	Laboratory:	FPRR:	Laboratory:	FPRC
		LABORATORIO REIG JOFRE, TOLEDO, SPAIN WRAPSA (PTY) LTD, HENNOSPARK, CENTURION, RSA SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SWIFT MICRO LABORATORIES (PTY) LTD, CONSTANTIA, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY (PTY) LTD, MOREHILL, BENONI, RSA		FAMAR S.A., ALIMOS, ATHENS, GREECE PHARMATEN S.A., PALLINI, ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
	Shelf-life:	24 months (provisional)	Shelf-life:	LITHA PHARMA (PTY) LTD, MIDRAND, JOHANNESBURG, RSA
	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	MRF15	3F 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRR:	Shelf-life:	Date of registration:
MRF 15	45/26/0268	HEMADAUN	INJECTION	EACH VIAL CONTAINS: DAUNORUBICIN HYDROCHLORIDE EQUIVALENT TO DAUNORUBICIN 20,0 mg	1, 2, 3, 4, 5, 6, 7	CIPLA MEDPRO (PTY) LTD GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	24 months	09 JUNE 2016
MRF15	45/26/0269	CIPLA DAUNORUBICIN 20	INJECTION	EACH VIAL CONTAINS: DAUNORUBICIN HYDROCHLORIDE EQUIVALENT TO DAUNORUBICIN 20,0 mg	1, 2, 3, 4, 5, 6, 7	CIPLA LIFE SCIENCES (PTY) LTD INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	CIPLA LIFE SCIENCES (PTY) LTD, ROSEN PARK, BELLVILLE, CAPE TOWN, RSA	24 months	09 JUNE 2016
3F 15	45/71.3/0608	MICATEL 40	TABLET	EACH TABLET CONTAINS: TELMISARTAN 40,0 mg	1, 2, 3, 4, 5, 6, 7, 8	RANBAXY (SA) (PTY) LTD INDIA	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	24 months (provisional)	09 JUNE 2016

MRF 15	MRF15		3F 15	
	Registration number:	45/10.2.2/0661	Registration number:	45/10.2.2/0662
Name of medicine:	MICATEL 80	WATSON MONTELUKAST 4	Name of medicine:	WATSON MONTELUKAST 5
Dosage form:	TABLET	CHEWABLE TABLET	Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80.0 mg	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 40 mg	Active ingredients:	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY) LTD	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	SPECIFAR SA, VARVARA, ATHENS, GREECE	Manufacturer:	SPECIFAR SA, VARVARA, ATHENS, GREECE
Packer:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA	SPECIFAR SA, VARVARA, ATHENS, GREECE	Packer:	SPECIFAR SA, VARVARA, ATHENS, GREECE
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, NAGAR DISTRICT, MOHALI, PUNJAB, INDIA KHULLEKANI LABORATORY SERVICES CC, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, BOKSBURG, RSA	SPECIFAR SA, VARVARA, ATHENS, GREECE TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, JOHANNESBURG, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Laboratory: FPRC:	SPECIFAR SA, VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (SA) (PTY) LTD, CENTURION, RSA	FPRR:	FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, SANDOWN, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	24 months	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.5/0698	Registration number:	45/2.5/0699	Registration number:	45/2.5/0700
Name of medicine:	GABAPENTIN TEVA 100	Name of medicine:	GABAPENTIN TEVA 300	Name of medicine:	GABAPENTIN TEVA 400
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TEVA PHARMACEUTICALS (PTY) LTD	Applicant:	TEVA PHARMACEUTICALS (PTY) LTD	Applicant:	TEVA PHARMACEUTICALS (PTY) LTD
Manufacturer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel	Manufacturer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel	Manufacturer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel
Packer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA	Packer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA	Packer:	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PRIVATE LIMITED COMPANY, PALLAFI UT, DEBRECEN DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC:
	TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA		TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA		TEVA PHARMAC EUTICALS INDUSTRIES LTD, Kfar Saba, Israel PHARMACHEMIE B.V., SWENSWEG, HAARLEM SABS PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUMSIG, ROODEPOORT, RSA	FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUMSIG, ROODEPOORT, RSA	FPRR:	TEVA PHARMACEUTICALS (PTY) LTD, RUMSIG, ROODEPOORT, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	Registration number: 45/16.4/0808 Name of medicine: SEPTOLETE CHERRY LOZENGES Dosage form: LOZENGE Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BLISS PHARMACEUTICALS cc Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA Packer: KRKA d.d., NOVO MESTO, SLOVENIA Laboratory: FPRC: M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: BLISS PHARMACEUTICALS c, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016
MRF15	Registration number: 45/16.4/0809 Name of medicine: SEPTOLETE LEMON LOZENGES Dosage form: LOZENGE Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BLISS PHARMACEUTICALS cc Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA Packer: KRKA d.d., NOVO MESTO, SLOVENIA Laboratory: FPRC: M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: BLISS PHARMACEUTICALS c, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016
MRF15	Registration number: 45/16.4/0810 Name of medicine: SEPTOLETE APPLE LOZENGES Dosage form: LOZENGE Active ingredients: EACH CAPSULE CONTAINS: CETYLPRYRIDINIUM 1,2 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BLISS PHARMACEUTICALS cc Manufacturer: KRKA d.d., NOVO MESTO, SLOVENIA Packer: KRKA d.d., NOVO MESTO, SLOVENIA Laboratory: FPRC: M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: BLISS PHARMACEUTICALS c, WOODMEAD, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 09 JUNE 2016

MRF15		MRF15		MRF15	
Registration number:	45/34/1025	Registration number:	45/34/1026	Registration number:	45/15 4/1080
Name of medicine:	REBIF 22 MULTIDOSE	Name of medicine:	REBIF 44 MULTIDOSE	Name of medicine:	GOZOPT
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	SOLUTION FOR INJECTION	Dosage form:	EYE DROPS
Active ingredients:	EACH PRE FILLED CONTAINS: INTERFERON BETA-1 a 1.5 mg	Active ingredients:	EACH PRE FILLED CONTAINS: INTERFERON BETA-1 a 1.5 mg	Active ingredients:	EACH DROP CONTAINS: DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK (PTY) LTD	Applicant:	MERCK (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Manufacturer:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Manufacturer:	CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Packer:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Packer:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Packer:	CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Laboratory: FPRC:	MERCK SERONO S.p.A., MODUGNO, ITALY MERCK SERONO S.A., AUBONNE, SWITZERLAND	Laboratory: FPRC:	CIPLA LTD, UNIT I, VERNA, SALCETTE, GOA, INDIA
FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	MERCK (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELLVILLE, CAPE TOWN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	45/26/0212	Registration number:	45/26/0213	Registration number:	46/7.30217
Name of medicine:	OPLAXIN 50 mg	Name of medicine:	OPLAXIN 100 mg	Name of medicine:	RIZATRIPTAN MYLAN ODT 5 mg
Dosage form:	CONCENTRATE SOLUTION FOR INFUSION	Dosage form:	CONCENTRATE SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH 50 mg SOLUTION CONTAINS: OXALIPLATIN 50,0 mg	Active ingredients:	EACH 50 mg SOLUTION CONTAINS: OXALIPLATIN 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Manufacturer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA	Packer:	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA SANAND, DISTRICT AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	Laboratory:	FPRC: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15	MRF 15		MRF 15
	Registration number:	Registration number:	Registration number:
467.3/0218	467.3/0218	46/5.3/0404	46/5.3/0405
RIZATRIPTAN MYLAN ODT 10 mg	RIZATRIPTAN MYLAN ODT 10 mg	NEPIZEL 5	NEPIZEL 10
Tablet	Tablet	Tablet	Tablet
Each tablet contains: RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 10.0 mg	Each tablet contains: RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 10.0 mg	Each tablet contains: DONEPEZIL HYDROCHLORIDE 5.0 mg	Each tablet contains: DONEPEZIL HYDROCHLORIDE 10.0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
MYLAN (PTY) LTD	MYLAN (PTY) LTD	UNICHEM SA (PTY) LTD	UNICHEM SA (PTY) LTD
MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH-RIDING, RANDBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA
MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	MYLAN (PTY) LTD, MODDERFONTEIN, JOHANNESBURG, RSA	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
24 months	24 months	36 months	36 months
09 JUNE 2016	09 JUNE 2016	09 JUNE 2016	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	46/5.3/0406	Registration number:	46/5.3/0407	Registration number:	46/34/0696
Name of medicine:	DONEPEZIL UNICHEM 5 mg	Name of medicine:	DONEPEZIL UNICHEM 10 mg	Name of medicine:	AFINITOR 2.5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: EVEROLIMUS 2.5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	UNICHEM SA (PTY) LTD	Applicant:	UNICHEM SA (PTY) LTD	Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Manufacturer:	NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Packer:	NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND KONAPHARMA AG, PRATTEN, SWITZERLAND ALLPACK GROUP AG, REINACH, SWITZERLAND IVERS-LEE AG, BURGDORF, SWITZERLAND PROMLOG AG, PRATTEN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA DRA PHARMACEUTICALS cc, IRENE, CENTURION, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA NOVARTIS PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA
FPRR:	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRR:	UNICHEM SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRR:	NOVARTIS SOUTH AFRICA (PTY) LTD, WATERFALL CITY, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months (provisional)
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	48/20.1.1/0814	Registration number:	48/20.1.1/0815	Registration number:	48/32.2/1152
Name of medicine:	CEFALEXIN ASCENDIS 250	Name of medicine:	CEFALEXIN ASCENDIS 500	Name of medicine:	IMUGRAFT 500
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALIN 250.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALIN 500.0 mg	Active ingredients:	EACH TABLET CONTAINS: MYCOPHENOLATE MOFETIL 500.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA	Applicant:	INGWE LIFESCIENCE (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA	Manufacturer:	ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA
Packer:	ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA	Packer:	ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA	Packer:	INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA
Laboratory:	FPRC: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA	Laboratory:	FPRC: ALKEM LABORATORIES LIMITED, DABHEL, AMALIYA, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA	Laboratory:	FPRC: INTAS PHARMACEUTICALS LIMITED, MATODA, GUJARAT, INDIA INTAS PHARMA LTD, VILLAGE MATODA, AHMEDABAD, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDSBURG, RSA
FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR:	INGWE LIFESCIENCE (PTY) LTD, MOOI RIVER, KWAZULU NATAL, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	36 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	49/20.1.10899	Registration number:	49/20.1.10899	Registration number:	49/26/1045
Name of medicine:	LINZAI IV	Name of medicine:	LINZAI IV	Name of medicine:	CAPECITABINE SPECPHARM 150
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: LINEZOLID 2.0 mg	Active ingredients:	EACH TABLET CONTAINS: CAPECITABINE 150.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA	Manufacturer:	CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA	Manufacturer:	REMEDICA LTD, LIMASSOL, CYPRUS
Packer:	CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA	Packer:	CLARIS INJECTABLES LIMITED, CHACHARWADI-VASANA, AHMEDABAD, INDIA PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, NDABENI, CAPE TOWN, RSA	Packer:	REMEDICA LTD, LIMASSOL, CYPRUS SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR:	DEZZO TRADING 392 (PTY) LTD T/A INDO PHARMA, ANCHORVILLE, LENASIA, RSA	FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months (provisional)	Shelf-life:	36 months
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		MRF 15		MRF 15	
Registration number:	49/26/1046	Registration number:	A39/20.1.1/0166	Registration number:	A39/20.1.1/0167
Name of medicine:	CAPECITABINE SPECIPHARM 500	Name of medicine:	CEFUROXIME FRESENIUS 750 mg	Name of medicine:	CEFUROXIME FRESENIUS 1 500 mg
Dosage form:	TABLET	Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	POWDER FOR SOLUTION FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: CAPECITABINE 500.0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM 750.0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM 1 500.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECIPHARM (PTY) LTD	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	REMEDICA LTD, LIMASSOL, CYPRUS	Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA	Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA
Packer:	REMEDICA LTD, LIMASSOL, CYPRUS SPECIPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Packer:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Packer:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA
Laboratory: FPRC:	REMEDICA LTD, LIMASSOL, CYPRUS SPECIPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA
FPRC:	SPECIPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016	Date of registration:	09 JUNE 2016

MRF 15		
Registration number:	A39/20.1.1/0175	Registration number:
Name of medicine:	CEFUXIME FRESENIUS 250 mg	Name of medicine:
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:
Active ingredients:	EACH VIAL CONTAINS: CEFUXIME SODIUM 250.0 mg	Active ingredients:
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:
Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	Applicant:
Manufacturer:	SANDOZ GmbH, KUNDL, AUSTRIA	Manufacturer:
Packer:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Packer:
Laboratory: FPRC:	SANDOZ GmbH, KUNDL, AUSTRIA BODENE (PTY) LTD T/A INTRAMED, KORSTEN, PORT ELIZABETH, RSA	Laboratory: FPRC:
FPRR:	FRESENIUS KABI SOUTH (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:
Shelf-life:	24 months (provisional)	Shelf-life:
Date of registration:	09 JUNE 2016	Date of registration: