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CONTENTS • INHOUD*No.**Page
No. Gazette
No.***GENERAL NOTICE****Health, Department of***General Notice*

1137	Health MCC Regulatory Affairs: MRF 15's Registration of Pharmaceutical Products October 2013 (36/20.1.2/0204-46/24/0871)	3	37060
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GENERAL NOTICE

NOTICE 1137 OF 2013

MRF 15	MRF 15	MRF 15
Registration number: 36/20.1.2/0204	Registration number: 36/20.1.2/0205	Registration number: A40/5.4/0439
Name of medicine: ADIPEN 375 (TABLETS)	Name of medicine: ADIPEN 625 (TABLETS)	Name of medicine: DETRUNORM XL
Dosage form: TABLET	Dosage form: TABLET	Dosage form: CAPSULE
Active ingredients: EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125.0 mg	Active ingredients: EACH TABLET CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 500.0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 125.0 mg	Active ingredients: EACH CAPSULE CONTAINS: PROPIVERINE HYDROCHLORIDE 30.0 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: BIOTECH LABORATORIES (PTY) LTD	Applicant: BIOTECH LABORATORIES (PTY) LTD	Applicant: PHARMAFRICA (PTY) LTD
Manufacturer: LEK PHARMACEUTICAL & CHEMICAL, PREVALJE, SLOVENIA	Manufacturer: LEK PHARMACEUTICAL & CHEMICAL, PREVALJE, SLOVENIA	Manufacturer: LOSAN PHARMA GmbH, NEUENBURG, GERMANY
Packer: LEK PHARMACEUTICAL & CHEMICAL, PREVALJE, SLOVENIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer: LEK PHARMACEUTICAL & CHEMICAL, PREVALJE, SLOVENIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Packer: APOGEPHA ARZNEIMITTEL GmbH, DRESDEN, GERMANY PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, JOHANNESBURG, RSA
Laboratory: FPRC: INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: APOGEPHA ARZNEIMITTEL GmbH, DRESDEN, GERMANY SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND	FPRR: BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND	FPRR: PHARMAFRICA (PTY) LTD, NEW CENTRE, JOHANNESBURG, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)	Shelf-life: 36 months
Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013

MRF 15		MRF 15	
Registration number:	42/20.2.2/0085	Registration number:	42/20.2.2/0086
Name of medicine:	ALMATIL 125 mg (TABLETS)	Name of medicine:	ALMATIL 250 mg (TABLETS)
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 125,0 mg	Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
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
Manufacturer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY	Manufacturer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY
Packer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY	Packer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY
Laboratory: FPRC:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15

MRF 15

MRF 15		MRF 15		MRF 15	
Registration number:	42/15.3/0294	Registration number:	42/20.2.2/0382	Registration number:	42/17.1.3/0392
Name of medicine:	EXELON PATCH 10	Name of medicine:	ALMATIL 1 % CREAM	Name of medicine:	NEBICARD-5
Dosage form:	TRANSDERMAL PATCH	Dosage form:	CREAM	Dosage form:	TABLET
Active ingredients:	EACH 10,0 cm ² PATCH CONTAINS: RIVASTIGMINE 18,0 mg	Active ingredients:	EACH 1,0 g CREAM CONTAINS: TERBINAFINE HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: NEBIVOLOL HYDROCHLORIDE EQUIVALENT TO NEBIVOLOL 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:	NOVARTIS SA (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY	Manufacturer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY	Manufacturer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Packer:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Packer:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY	Packer:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA
Laboratory: FPRC:	LTS LOHMANN THERAPIE-SYSTEME AG, ANDERNACH, GERMANY NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND PHARMANALYTICA SA, LOCARNO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	GEDEON RICHTER LTD, BUDAPEST, HUNGARY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, MEHSANA, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRC:	TRINITY PHARMA (PTY) LTD, CNR SLOANE & MEADOWBROOK CLOSE, BRYANSTON, RSA
Shelf-life:	24 months	Shelf-life:	60 months	Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		F 15	
Registration number:	42/20 2.2/0685	Registration number:	43/20 1.1/0012	Registration number:	43/1 2/0097
Name of medicine:	SPEC FLUCONAZOLE 150	Name of medicine:	ORCHID CEFFODOXIME 100 mg	Name of medicine:	MYLAN VENLAFAXINE 75
Dosage form:	CAPSULE	Dosage form:	TABLET	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 150,0 mg	Active ingredients:	CEFFODOXIME PROXETIL EQUIVALENT TO CEFFODOXIME 100,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 75,0 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:	SPECPHARM (PTY) LTD	Applicant:	ORCHID PHARMACEUTICALS SA (PTY) LTD	Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	PHARMATHEN SA, PALLINI, ATTIKIS, GREECE	Manufacturer:	ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), IRUNGATTUKOTAI, SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, INDIA	Manufacturer:	PHARMATHEN SA, PALLINI, GREECE
Packer:	PHARMATHEN SA, PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Packer:	ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), IRUNGATTUKOTAI, SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, INDIA	Packer:	PHARMATHEN SA, PALLINI, GREECE MERCK FARMA QUIMICA SA, BARCELONA, SPAIN MCDERMOTT LABORATORIES LTD, TIA GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPCR: PHARMATHEN SA, PALLINI, ATTIKIS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG RSA	Laboratory:	FPCR: ORCHID HEALTHCARE (A DIVISION OF ORCHID CHEMICALS AND PHARMACEUTICALS LTD), IRUNGATTUKOTAI, SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPCR: PHARMATHEN SA, PALLINI, GREECE MERCK FARMAQUIMICA SA, BARCELONA, SPAIN MCDERMOTT LABORATORIES LTD, TIA GERARD LABORATORIES, DUBLIN, IRELAND GENERIC UK LIMITED, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPCR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPCR:	ORCHID PHARMACEUTICALS SA (PTY) LTD, POTCHEFSTROOM, RSA	FPCR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERPONT, RSA
Shelf-life:	48 months	Shelf-life:	24 months (Provisional)	Shelf-life:	36 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/1.2/0098	Registration number:	43/5.4.1/0119	Registration number:	43/5.4.1/0120
Name of medicine:	MYLAN VENLAFAXINE 150	Name of medicine:	ARROW PRAMIPEXOLE 0,5	Name of medicine:	ARROW PRAMIPEXOLE 0,25
Dosage form:	CAPSULE	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 0,5 mg	Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 0,25 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:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	PHARMATHEN SA, PALLINI, GREECE	Manufacturer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA
Packer:	PHARMATHEN SA, PALLINI, GREECE MERCK FARMAQUIMICA SA, BARCELONA, SPAIN MCDERMOTT LABORATORIES LTD, T/A GERARD LABORATORIES, DUBLIN, IRELAND	Packer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory:	FPRC : PHARMATHEN SA, PALLINI, GREECE MERCK FARMAQUIMICA SA, BARCELONA, SPAIN MCDERMOTT LABORATORIES LTD, T/A GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LIMITED, POTTERSBAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory:	FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA	FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	36 months	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/5.4.1/0121	Registration number:	43/5.4.1/0122	Registration number:	43/5.4.1/0123
Name of medicine:	ARROW PRAMIPEXOLE 1	Name of medicine:	ARROW PRAMIPEXOLE 1,5	Name of medicine:	AROXOLE 0,5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 1,0 mg	Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 1,5 mg	Active ingredients:	EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 0,5 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:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA
Packer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA	Packer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA	Packer:	COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Laboratory:	FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15	MRF 15	MRF 15
Registration number: 43/5.4.1/0124	Registration number: 43/5.4.1/0125	Registration number: 43/5.4.1/0126
Name of medicine: AROXOLE 0,25	Name of medicine: AROXOLE 1	Name of medicine: AROXOLE 1,5
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 0,25 mg	Active ingredients: EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 1,0 mg	Active ingredients: EACH TABLET CONTAINS: PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 1,5 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: ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant: ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA	Manufacturer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA	Manufacturer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA
Packer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA	Packer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: COBALT PHARMACEUTICALS INC., MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC: ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRC: ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRC: ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)	Shelf-life: 24 months (provisional)
Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/15.4/0136	Registration number:	43/15.4/0137	Registration number:	43/20.1.1/0391
Name of medicine:	OCCUMOL 0,5 % (EYE DROP)	Name of medicine:	OCCUMOL 0,25 % (EYE DROP)	Name of medicine:	PIPERACILLIN AND TAZOBACTAM 4 g/0,5 g PROPAN
Dosage form:	EYE DROPS	Dosage form:	EYE DROPS	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH 1,0 ml CONTAINS: TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg	Active ingredients:	EACH 1,0 ml CONTAINS: TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 2,5 mg	Active ingredients:	PIPERACILLIN MONOHYDRATE EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM 0,5 g
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:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA	Manufacturer:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA	Manufacturer:	ORCHID HEALTHCARE, (A DIVISION OF ORCHID CHEMICALS & PHARMACEUTICALS LTD) SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Packer:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA	Packer:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA	Packer:	ORCHID HEALTHCARE, (A DIVISION OF ORCHID CHEMICALS & PHARMACEUTICALS LTD) SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA
Laboratory: FPRC:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, 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	Laboratory: FPRC:	MARCK BIOSCIENCES LIMITED, TALUKA, MATAR, DISTRICT KHEDA, GUJARAT, INDIA SABS COMMERCIAL (PTY) LTD, 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	Laboratory: FPRC:	ORCHID HEALTHCARE, (A DIVISION OF ORCHID CHEMICALS & PHARMACEUTICALS LTD) SRIPERUMBUDUR, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, DURBAN, RSA	FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, DURBAN, RSA	FPRR:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/20.2.2/0560	Registration number:	43/20.2.2/0561	Registration number:	43/20.2.2/0562
Name of medicine:	AURO FLUCONAZOLE 50 mg	Name of medicine:	AURO FLUCONAZOLE 100 mg	Name of medicine:	AURO FLUCONAZOLE 150 mg
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 50,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 100,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 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, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, 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:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15	MRF 15	MRF 15	MRF 15
Registration number:	43/20.2.2/0563	43/20.2.2/0566	43/20.2.2/0567
Name of medicine:	AURO FLUCONAZOLE 200 mg	INSEP 50	INSEP 100
Dosage form:	CAPSULE	CAPSULE	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: FLUCONAZOLE 200,0 mg	EACH CAPSULE CONTAINS: FLUCONAZOLE 50,0 mg	EACH CAPSULE CONTAINS: FLUCONAZOLE 100,0 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, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA KHULLEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA
FPRR:	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:	10 OCTOBER 2013	10 OCTOBER 2013	10 OCTOBER 2013

MRF 15	Registration number: 43/20.2.2/0568 Name of medicine: INSEP 150 Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: FLUCONAZOLE 150.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 10 OCTOBER 2013	MRF 15	Registration number: 43/20.2.2/0569 Name of medicine: INSEP 200 Dosage form: CAPSULE Active ingredients: EACH CAPSULE CONTAINS: FLUCONAZOLE 200.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AUROBINDO PHARMA (PTY) LTD Manufacturer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Laboratory: FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 10 OCTOBER 2013	MRF 15	Registration number: 43/20.1.1/0573 Name of medicine: DYNA TEICOPLANIN 200 mg IV Dosage form: LYOPHILISED STERILE POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: TEICOPLANIN 200.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: PHARMA DYNAMICS (PTY) LTD Manufacturer: SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY Packer: SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY Laboratory: FPRC: SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY FPRC: PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA Shelf-life: 24 months stored at or below 25 °C (Product) 24 hours in-use stored at 2-8 °C (Reconstituted product) Date of registration: 10 OCTOBER 2013	
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MRF-15		MRF-15		MRF-15	
Registration number:	43/34/0574	Registration number:	43/20.1.1/0575	Registration number:	43/3.2/0636
Name of medicine:	DYNA TEICOPLANIN SOLVENT	Name of medicine:	DYNA TEICOPLANIN 400 mg IV	Name of medicine:	OSTEONEL ONCE A WEEK
Dosage form:	STERILE SOLVENT FOR INJECTION	Dosage form:	LYOPHILISED STERILE POWDER FOR INJECTION	Dosage form:	TABLET
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTION 3,2 ml	Active ingredients:	EACH VIAL CONTAINS: TEICOPLANIN 400,0 mg	Active ingredients:	EACH TABLET CONTAINS: RISEDRONATE SODIUM HEMPENTAHYDRATE EQUIVALENT TO RISEDRONATE SODIUM 35,0 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, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY	Manufacturer:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY	Manufacturer:	PHARMASCIENCE INC., MONTREAL, QUEBEC, CANADA
Packer:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY	Packer:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY	Packer:	PENDOPHARM (DIVISION OF PHARMASCIENCE INC.), MONTREAL, QUEBEC, CANADA ROPACK, MONTREAL, QUEBEC, CANADA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SIRTON PHARMACEUTICALS SPA, VILLA GUARDIA, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMASCIENCE INC., MONTREAL, QUEBEC, CANADA PENDOPHARM (DIVISION OF PHARMASCIENCE INC.), MONTREAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, CAPE TOWN, RSA	FPRR:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional) stored at or below 25 °C	Shelf-life:	24 months stored at or below 25 °C (Product) 24 hours in-use stored at 2-8 °C (Reconstituted product)	Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/8.2/0753	Registration number:	43/20.1.1/0947	Registration number:	43/20.1.1/1058
Name of medicine:	CPD SOLUTION	Name of medicine:	TAVANIC 750	Name of medicine:	LEVOFLOXACIN WINTHROP 750
Dosage form:	SOLUTION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 1 000,0 ml CONTAINS: MONOBASIC SODIUM PHOSPHATE 1,93 g CITRIC ACID 2,99 g DEXTROSE 23,3 g SODIUM CITRATE 23,06 g	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 750,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 750,0 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:	MC PHARMA (PTY) LTD	Applicant:	SANOFLAVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND	Manufacturer:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO	Manufacturer:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO
Packer:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND	Packer:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Packer:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	Laboratory: FPRC:	SANOFLAVENTIS de MEXICO S.A. de C.V., OCOYOACAC, MEXICO WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, RSA	FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA SANOFLAVENTIS SOUTH AFRICA (PTY) LTD, MIDRAND, RSA	FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/34/0097	Registration number:	44/21.12/0154	Registration number:	44/2.5/0402
Name of medicine:	ILARIS 150 mg/ml	Name of medicine:	ROZARA	Name of medicine:	NUREP 100
Dosage form:	POWDER FOR SOLUTION FOR INJECTION	Dosage form:	TABLET	Dosage form:	CAPSULE
Active ingredients:	EACH VIAL CONTAINS: CANAKINUMAB 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: LETROZOLE 2,5 mg	Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 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:	NOVARTIS SA (PTY) LTD	Applicant:	AKACIA HEALTHCARE (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	WEST PHARMA, VENDA NOVA, AMADORA, PORTUGAL	Manufacturer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDORPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA
Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	WEST PHARMA, VENDA NOVA, AMADORA, PORTUGAL	Packer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDORPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA DIVYPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG
Laboratory:	FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA NOVARTIS PHARMA AG, BASEL, SWITZERLAND NOVARTIS PHARMA SAS, HUNINGUE, FRANCE LABOR L+S AG, BAD BOCKLET, GERMANY M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	Laboratory:	FPRC: WEST PHARMA, VENDA NOVA, AMADORA, PORTUGAL SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASHVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASHVILLE, BOKSBURG, RSA
FPRC:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA – FPRC	FPRC:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months stored at 2-8 °C (Product) 24 hours in-use stored at 2-8 °C (Reconstituted product)	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.5/0403	Registration number:	44/2.5/0404	Registration number:	44/5.4.1/0456
Name of medicine:	NUREP 300	Name of medicine:	NUREP 400	Name of medicine:	DUODOPA
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	INTESTINAL GEL
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400,0 mg	Active ingredients:	EACH 1,0 ml CONTAINS: LEVODOPA 20,0 mg CARBIDOPA MONOHYDRATE 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:	LASARA TRADERS (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD	Applicant:	SOLVAY PHARMA (PTY) LTD
Manufacturer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDOPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA	Manufacturer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDOPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA	Manufacturer:	FRESENIUS KABI NORGE AS, HALDEN, NORWAY
Packer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDOPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG	Packer:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA PENDOPHARM, A DIVISION OF PHARMASCIENCE INC, MONTREAL, CANADA CONFAB LABORATORIES INC, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG	Packer:	FRESENIUS KABI NORGE AS, HALDEN, NORWAY SOLVAY PHARMACEUTICALS GmbH, NEUSTADT, GERMANY
Laboratory: FPRC:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	PHARMASCIENCE INC, MONTREAL, QUEBEC, CANADA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	FRESENIUS KABI NORGE AS, HALDEN, NORWAY SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRR:	SOLVAY PHARMA (PTY) LTD, RANDJESPAK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months stored at -20 °C 15 weeks stored at 2-8 °C 16 hours in-use stored at or below 40 °C 4 days in-use stored at or below 25 °C
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/0554	Registration number:	44/7.1.3/0555	Registration number:	44/8.2/0782
Name of medicine:	SANDOZ CANDESARTAN PLUS 16/12,5	Name of medicine:	CANDEPRES PLUS 16/12,5	Name of medicine:	SAG-M SOLUTION
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	SOLUTION
Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH 1 000,0 ml CONTAINS: ADENINE 169,0 mg MANNITOL 5,25 g SODIUM CHLORIDE 8,77 g DEXTROROSE MONOHYDRATE 9,0 g WATER FOR INJECTION 985,0 g
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:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA	Manufacturer:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA	Manufacturer:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND
Packer:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND
Laboratory: FPRC:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	LEK PHARMACEUTICAL, LJUBLJANA, SLOVENIA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	CARDIANBCT NORTHERN IRELAND LIMITED (TRADING AS IVEX PHARMACEUTICALS), MILLBROOK, LARNE, CO. ANTRIM, NORTHERN IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC/FPRC:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	MC PHARMA (PTY) LTD, MNANDI, WIERDAPARK, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/10.2.2/0826	Registration number:	44/10.2.2/0827	Registration number:	44/10.2.2/0828
Name of medicine:	MONTEIL 4 mg	Name of medicine:	MONTEIL 5 mg	Name of medicine:	MONTEIL 10 mg
Dosage form:	CHEWABLE TABLET	Dosage form:	CHEWABLE TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg	Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 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:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA
Packer:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA	Packer:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LIMITED, DISTRICT MEHSANA, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRC:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRC:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/21.8.2/0957	Registration number:	45/32.2/0118	Registration number:	45/32.2/0119
Name of medicine:	ELOINE	Name of medicine:	SILODYX 4	Name of medicine:	SILODYX 8
Dosage form:	TABLET	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH PACK OF TABLETS CONTAINS: 24 TABLETS EACH CONTAINING: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,02 mg PLUS 4 PLACEBO TABLETS	Active ingredients:	EACH CAPSULE CONTAINS: SILODOSIN 4,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: SILODOSIN 8,0 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:	BAYER (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD	Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY	Manufacturer:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY	Manufacturer:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY
Packer:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY	Packer:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY	Packer:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY
Laboratory: FPRC:	SCHERING GmbH UND Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A., MILAN, ITALY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC:	BAYER (PTY) LTD, ISANDO, RSA	FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA	FPRC:	PHARMAPLAN (PTY) LTD, MIDRAND, RSA
Shelf-life:	60 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15	MRF 15	MRF 15
Registration number: 45/20.2.8/0388	Registration number: 45/7.1.3/0394	Registration number: 45/34/0513
Name of medicine: MIVIRDO	Name of medicine: MYLACAND PLUS 16/12.5	Name of medicine: BLAZTERE 5 mg/100 ml
Dosage form: TABLET	Dosage form: TABLET	Dosage form: CONCENTRATED SOLUTION FOR DILUTION FOR IV INFUSION
Active ingredients: EACH TABLET CONTAINS: LAMIVUDINE 150.0 mg NEVIRAPINE 200.0 mg ZIDOVUDINE 300.0 mg	Active ingredients: EACH TABLET CONTAINS: CANDESARTAN CILEXETIL 16.0 mg HYDROCHLOROTHIAZIDE 12.5 mg	Active ingredients: EACH 5.0 ml SOLUTION CONTAINS: ZOLEDRONIC ACID MONOHYDRATE EQUIVALENT TO ZOLEDRONIC ACID 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: MYLAN (PTY) LTD	Applicant: MYLAN (PTY) LTD	Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer: GLAND PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, INDIA
Packer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN, RSA	Packer: GLAND PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, INDIA DRA PHARMACEUTICALS, ROUTE 21, CORPORATE PARK, CENTURION, RSA
Laboratory: FPRC: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: MATRIX LABORATORIES LIMITED, SINNAR, NASHIK, MAHARASHTRA, INDIA CIPLA MEDPRO MANUFACTURING (PTY) LTD, MOBENI, KZN, RSA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: GLAND PHARMA LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC: MYLAN (PTY) LTD, MODDERFONTEIN, RSA	FPRC: MYLAN (PTY) LTD, MODDERFONTEIN, RSA	FPRC: DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA
Shelf-life: 36 months	Shelf-life: 24 months	Shelf-life: 36 months
Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013	Date of registration: 10 OCTOBER 2013

MRF 15		MMRF 15	
Registration number:	45/18.8/0535	Registration number:	45/21.12/0544
Name of medicine:	YASMIN PLUS	Name of medicine:	LETRAZ
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH EVERY-DAY PACK CONTAINS: 21 ORANGE TABLETS CONTAINING: DROSPIRENON 3.0 mg ETHINYLESTRADIOL 0.030 mg LEVOMEFOLATE CALCIUM 0.451 mg 7 LIGHT ORANGE TABLETS CONTAINING: LEVOMEFOLATE CALCIUM 0.451 mg	Active ingredients:	EACH TABLET CONTAINS: LETOZOLE 2.5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BAYER (PTY) LTD	Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	SCHERING GmbH und Co PRODUKTIONS KG, WEIMAR, GERMANY	Manufacturer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND GENEPHARM GROUP, PALLINI, GREECE
Packer:	SCHERING GmbH und Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY BAYER ANIMAL HEALTH, PIETERMARITZBURG, KZN, RSA	Packer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND GENEPHARM GROUP, PALLINI, GREECE
Laboratory: FPRC:	SCHERING GmbH und Co PRODUKTIONS KG, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY INCORPORATING CENQAM, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA BIOCHEMICAL AND SCIENTIFIC CONSULTANTS cc, HILTON, RSA	Laboratory: FPRC:	EIRGEN PHARMA LTD, WATERFORD, IRELAND GENEPHARM GROUP, PALLINI, GREECE CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES (PTY) LTD, SILVERTONDALE, PRETORIA, RSA
FPRR:	BAYER (PTY) LTD, ISANDO, RSA	FPRR:	EQUITY PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, PRETORIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1.3/0611	Registration number:	45/1.2/0881	Registration number:	45/1.2/0882
Name of medicine:	TELGEN 80	Name of medicine:	MACLEODS ESCITALOPRAM 10 mg	Name of medicine:	MACLEODS ESCITALOPRAM 20 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TELMISARTAN 80,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 20,0 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:	RANBAXY (S.A.) (PTY) LTD	Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	MACLEODS PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PHASE VIIIA, S.A.S. NAGAR, DISTRICT MOHALI, PUNJAB, INDIA	Manufacturer:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA	Manufacturer:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PHASE VIIIA, S.A.S. NAGAR, DISTRICT MOHALI, PUNJAB, INDIA	Packer:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA	Packer:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PHASE VIIIA, S.A.S. NAGAR, DISTRICT MOHALI, PUNJAB, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	MACLEODS PHARMACEUTICALS LTD, TEHSIL NALAGARH, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA	FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD BUSINESS PARK, WOODMEAD, RSA	FPRR:	MACLEODS PHARMACEUTICALS SA (PTY) LTD, WOODMEAD BUSINESS PARK, WOODMEAD, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/21.12/0908	Registration number:	45/26/1127	Registration number:	45/26/1128
Name of medicine:	EQUISIN	Name of medicine:	RIBOMUSTIN 25 mg	Name of medicine:	RIBOMUSTIN 100 mg
Dosage form:	TABLET	Dosage form:	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: XEMESTANE 25.0 mg	Active ingredients:	EACH VIAL CONTAINS: BENDAMUSTINE HYDROCHLORIDE 25.0 mg	Active ingredients:	EACH VIAL CONTAINS: BENDAMUSTINE HYDROCHLORIDE 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:	EQUITY PHARMACEUTICALS (PTY) LTD	Applicant:	ASTELLAS PHARMA (PTY) LTD	Applicant:	ASTELLAS PHARMA (PTY) LTD
Manufacturer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND	Manufacturer:	THISEN LABORATORIES SA, BRAINE-L'ALLEUD, BELGIUM	Manufacturer:	THISEN LABORATORIES SA, BRAINE-L'ALLEUD, BELGIUM
Packer:	EIRGEN PHARMA LTD, WATERFORD, IRELAND MILLMOUNT HEALTHCARE LTD, STAMULLEN, CO. MEATH, IRELAND MILLMOUNT HEALTHCARE LTD, TRIM ROAD, CO. MEATH, IRELAND	Packer:	THISEN LABORATORIES SA, BRAINE-L'ALLEUD, BELGIUM ONCOTEC PHARMA PRODUKTION GmbH, DESSAU-ROBLAU, GERMANY	Packer:	THISEN LABORATORIES SA, BRAINE-L'ALLEUD, BELGIUM ONCOTEC PHARMA PRODUKTION GmbH, DESSAU-ROBLAU, GERMANY TEMMLER WERKE GmbH, MUNICH, GERMANY DIVPHARM MANUFACTURING & PACKAGING (PTY) LTD, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: EIRGEN PHARMA LTD, WATERFORD, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: TEMMLER WERKE GmbH, MUNICH, GERMANY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: TEMMLER WERKE GmbH, MUNICH, GERMANY CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Product manufactured at Oncotec) 24 months (Provisional) (Product manufactured at Thissen)	Shelf-life:	24 months (Product manufactured at Oncotec) 24 months (Provisional) (Product manufactured at Thissen)
Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013	Date of registration:	10 OCTOBER 2013

MRF 15	MRF 15
Registration number: 46/26/0870	Registration number: 46/26/0871
Name of medicine: XUBIX 150	Name of medicine: XUBIX 500
Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: CAPECITABINE 150,0 mg	Active ingredients: EACH TABLET CONTAINS: CAPECITABINE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7	Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: ROCHE PRODUCTS (PTY) LTD	Applicant: ROCHE PRODUCTS (PTY) LTD
Manufacturer: PRODUCTOS ROCHE S.A. de C.V., TOLUCA, EDO DE MEXICO, MEXICO	Manufacturer: PRODUCTOS ROCHE S.A. de C.V., TOLUCA, EDO DE MEXICO, MEXICO
Packer: PRODUCTOS ROCHE S.A. de C.V., TOLUCA, EDO DE MEXICO, MEXICO F. HOFFMANN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, RSA	Packer: PRODUCTOS ROCHE S.A. de C.V., TOLUCA, EDO DE MEXICO, MEXICO F. HOFFMANN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND AKACIA HEALTH CARE (PTY) LTD, ISANDO, RSA
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