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GENERAL NOTICE

NOTICE 765 OF 2013
DEPARTMENT OF HEALTH

MRF 15	MRF15	MRF 15
Registration number: 09/8, 3/07 Name of medicine: CERENIA INJECTION Dosage form: INJECTION Active ingredients: EACH 1,0 ml SOLUTION CONTAINS: MAROPITANT CITRATE EQUIVALENT TO MAROPITANT 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: PFIZER LABORATORIES (PTY) LTD Manufacturer: PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE Packer: PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE Laboratory: FPRC: PFIZER GLOBAL MANUFACTURING, POCE SURE CISSE, FRANCE M & L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA FPRR: PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA Shelf-life: 24 months (Provisional) Date of registration: 01 MARCH 2013	Registration number: 07/21, 1/28 Name of medicine: COBACTAN IV 4,5 % (Solvent for solution for IV and IM injection) Dosage form: INJECTION Active ingredients: EACH 300,0 ml VIAL CONTAINS: DISODIUM HYDROGEN PHOSPHATE 1,491 g WATER FOR INJECTION qs Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: INTERVET S.A. (PTY) LTD Manufacturer: FACTA FARMACEUTICI SpA, TERAMO, ITALY Packer: FACTA FARMACEUTICI SpA, TERAMO, ITALY INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY Laboratory: FPRC: FACTA FARMACEUTICI SpA, TERAMO, ITALY BIOINDUSTRIAL SERVICES, KEMPTON PARK, RSA FPRR: INTERVET S.A., SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months Date of registration: 01 MARCH 2013	Registration number: 07/21, 1/27 Name of medicine: COBACTAN IV 4,5 % (Powder for Solution for IV and IM Injection) Dosage form: INJECTION Active ingredients: EACH 100,0 ml VIAL CONTAINS: CEQUINOME SULPHATE EQUIVALENT TO CEQUINOME 4,5 g Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: INTERVET S.A. (PTY) LTD Manufacturer: FACTA FARMACEUTICI SpA, TERAMO, ITALY Packer: FACTA FARMACEUTICI SpA, TERAMO, ITALY INTERVET INTERNATIONAL GmbH, UNTERSCHLEISSHEIM, GERMANY Laboratory: FPRC: FACTA FARMACEUTICI SpA, TERAMO, ITALY BIOINDUSTRIAL SERVICES, KEMPTON PARK, RSA FPRR: INTERVET S.A., SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months Date of registration: 01 MARCH 2013

MRF 15		MRF 15	
Registration number:	10/21.1/01	Registration number:	33/3.1/0091
Name of medicine:	EXCEDE	Name of medicine:	VOLTAREN PATCH
Dosage form:	INJECTION	Dosage form:	PLASTER
Active ingredients:	EACH 1.0 ml SUSPENSION CONTAINS: Ceftiofur 200,0 mg	Active ingredients:	EACH PLASTER CONTAINS: Diclofenac hydroxyethylpyrrolidine equivalent to 0,140 g Diclofenac
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:	NOVARTIS SA (PTY) LTD
Manufacturer:	PHARMACIA & UPJOHN, KALAMAZOO, MICHIGAN, USA	Manufacturer:	ALTERGON ITALIA S.r.L, MORRA de SANCTIS, ITALY IBSA INSTITUT BIOCHIMIQUE SA, PAMBIO-NORANCO, SWITZERLAND
Packer:	PHARMACIA & UPJOHN, KALAMAZOO, MICHIGAN, USA	Packer:	ALTERGON ITALIA S.r.L, MORRA de SANCTIS, ITALY IBSA INSTITUT BIOCHIMIQUE SA, PAMBIO-NORANCO, SWITZERLAND MIRREN (PTY) LTD, MOREHILL, BENONI, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:
	PHARMACIA & UPJOHN, KALAMAZOO, MICHIGAN, USA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA		ALTERGON ITALIA S.r.L, MORRA de SANCTIS, ITALY IBSA INSTITUT BIOCHIMIQUE SA, PAMBIO-NORANCO, SWITZERLAND M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA	FPRR:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	36 months 6 weeks (in-use)	Shelf-life:	36 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15

MRF 15

MRF 15

MRF 15

MRF 15

MRF 15

MRF 15		MRF 15		MRF 15	
Registration number:	38/10.2.1/0122	Registration number:	38/7.1.3/0221	Registration number:	38/7.1.3/0222
Name of medicine:	CYCLOVENT	Name of medicine:	ARROW BISOPROLOL 5	Name of medicine:	ARROW BISOPROLOL 10
Dosage form:	INHALATION POWDER IN HARD CAPSULES	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: IPRATROPIUM BROMIDE 40.0 µg	Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 5.0 mg	Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10.0 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:	PHARMACHEMIE (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS	Manufacturer:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND	Manufacturer:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND
Packer:	PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	PHARMACHEMIE BV, HAARLEM, THE NETHERLANDS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, WEST UNIVERSITY, POTCHEFSTROOM, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	ROTTENDORG PHARMA GmbH, ENNIGERLOH, GERMANY RIVOPHARM, MANN, SWITZERLAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	PHARMACHEMIE (PTY) LTD, MIDRAND, RSA	FPRR:	ARROW PHARMA S.A., NORWICH CLOSE, SANDTON, RSA	FPRR:	ARROW PHARMA S.A., NORWICH CLOSE, SANDTON, RSA
Shelf-life:	18 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	A40/18.1/0138	Registration number:	41/2.1/1121	Registration number:	41/2.1/1122
Name of medicine:	JADELLE	Name of medicine:	FRESENIUS PROPOVEN 1 % (20 ml)	Name of medicine:	FRESENIUS PROPOVEN 1 % (50 ml)
Dosage form:	IMPLANT	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH IMPLANT CONTAINS: LEVONORGESTREL 75,0 mg	Active ingredients:	EACH 20,0 ml AMPOULE/VIAL CONTAINS: PROPOFOL 200,0 mg	Active ingredients:	EACH 50,0 ml VIAL CONTAINS: PROPOFOL 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
Applicant:	BAYER (PTY) LTD	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD	Applicant:	FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:	SCHERING Oy, TURKU, FINLAND	Manufacturer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN	Manufacturer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN
Packer:	SCHERING Oy, TURKU, FINLAND	Packer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN EBEWE PHARMA, GmbH, UNTERACH AM ATTERSEE, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA	Packer:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN EBEWE PHARMA, GmbH, UNTERACH AM ATTERSEE, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA
Laboratory: FPRC:	SCHERING Oy, TURKU, FINLAND SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA	Laboratory: FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN KHULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN KHULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	BAYER, ISANDO, KEMPTON PARK	FPRR:	FRESENIUS KABI, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	FRESENIUS KABI, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	60 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		F 15	
Registration number: 41/2.1/1123 Name of medicine: FRESENIUS PROPOVEN 1 % (100 ml) Dosage form: INJECTION Active ingredients: EACH 100.0 ml EMULSION CONTAINS: PROPOFOL 1 000.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: FRESENIUS KABI SOUTH AFRICA (PTY) LTD Manufacturer: FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN Packer: FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN EBEWE PHARMA, GmbH, UNTERACH AMATTERSEE, AUSTRIA FRESENIUS KABI AUSTRIA GmbH, LINZ, AUSTRIA Laboratory: FPRC : FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, RAPSGATAN, UPPSALA, SWEDEN KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA FPRR: FRESENIUS KABI, HALFWAY HOUSE, MIDRAND, RSA Shelf-life: 24 months Date of registration: 01 MARCH 2013	Registration number: 42/8.2/0187 Name of medicine: ENOXAPARIN SODIUM 20 SANOFI-AVENTIS Dosage form: INJECTION Active ingredients: EACH 0.2 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 20.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD Manufacturer: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE Packer: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA Laboratory: FPRC: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA Shelf-life: 24 months Date of registration: 01 MARCH 2013	Registration number: 42/8.2/0188 Name of medicine: ENOXAPARIN SODIUM 40 SANOFI-AVENTIS Dosage form: INJECTION Active ingredients: EACH 0.4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD Manufacturer: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE Packer: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA Laboratory: FPRC: AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE FPRC/FPRR: WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA Shelf-life: 24 months Date of registration: 1 MARCH 2013	

MRF 15		MRF 15		MRF 15	
Registration number:	42/8.2/0189	Registration number:	42/8.2/0190	Registration number:	42/8.2/0191
Name of medicine:	ENOXAPARIN SODIUM 60 SANOFI-AVENTIS	Name of medicine:	ENOXAPARIN SODIUM 80 SANOFI-AVENTIS	Name of medicine:	ENOXAPARIN SODIUM 100 SANOFI-AVENTIS
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH 0.6 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 60.0 mg	Active ingredients:	EACH 0.8 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 80.0 mg	Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 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
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA	FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA	FPRR:	SANOFI-AVENTIS S.A., MIDRAND, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	1 MARCH 2013	Date of registration:	1 MARCH 2013	Date of registration:	1 MARCH 2013

MRF 15		MRF 15		F 15	
Registration number:	42/8.2/0192	Registration number:	42/13.11/0441	Registration number:	42/20.2.8/0941
Name of medicine:	ENOXAPARIN SODIUM 300 SANOFI-AVENTIS	Name of medicine:	CLINDOXYL GEL	Name of medicine:	CELESTRI 150 mg
Dosage form:	INJECTION	Dosage form:	GEL	Dosage form:	TABLET
Active ingredients:	EACH 3.0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 300.0 mg	Active ingredients:	EACH 100.0 g GEL CONTAINS: Benzoyl peroxide hydrous equivalent to anhydrous Benzoyl peroxide 5.0 g Clindamycin phosphate equivalent to Clindamycin 1.0 g	Active ingredients:	EACH TABLET CONTAINS: MARAVIROC 150.0 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:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	GLAXOSMITHKLINE (SA) (PTY) LTD	Applicant:	PFIZER LABORATORIES (PTY) LTD
Manufacturer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Manufacturer:	STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND	Manufacturer:	GODECKE GmbH, FREIBURG, GERMANY
Packer:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Packer:	STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND	Packer:	GODECKE GmbH, FREIBURG, GERMANY
Laboratory: FPRC:	AVENTIS INTERNATIONAL, MAISONS-ALFORT-CEDEX, FRANCE AVENTIS PHARMA LE TRAIT, LE TRAIT, FRANCE	Laboratory: FPRC:	STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	FPRR:	GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA	FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)	Shelf-life:	60 months
Date of registration:	1 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		F 15	
Registration number:	42/20.2.8/0942	Registration number:	42/21.5.1/0954
Name of medicine:	CELSENTRI 300 mg	Name of medicine:	BUDONEB 0,5 mg/ml
Dosage form:	TABLET	Dosage form:	SUSPENSION
Active ingredients:	EACH TABLET CONTAINS: MARAVIROC 300,0 mg	Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: BUDESONIDE 0,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PFIZER LABORATORIES (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	GODECKE GmbH, FREIBURG, GERMANY	Manufacturer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA
Packer:	GODECKE GmbH, FREIBURG, GERMANY	Packer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA
Laboratory: FPRC:	GODECKE GmbH, FREIBURG, GERMANY JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SEDEK AGRIKEM, DEKGRAS ROAD, SILVERTONDALE, PRETORIA, RSA
FPRR:	PFIZER LABORATORIES (PTY) LTD, SANDTON, RSA	FPRR:	ARROW PHARMA S.A., NORWICH CLOSE, SANDTON, RSA
Shelf-life:	60 months	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	42/21.5.1/0955	Registration number:	42/21.5.1/0956	Registration number:	42/7.1.3/0963
Name of medicine:	ARROW BUDESONIDE 0,25 mg/ml	Name of medicine:	ARROW BUDESONIDE 0,5 mg/ml	Name of medicine:	SARGEN 50/12,5
Dosage form:	SUSPENSION	Dosage form:	SUSPENSION	Dosage form:	TABLET
Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: BUDESONIDE 0,25 mg	Active ingredients:	EACH 1,0 ml SUSPENSION CONTAINS: BUDESONIDE 0,5 mg	Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA	Manufacturer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA	Manufacturer:	LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN
Packer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN MCDERMOTT LABORATORIES LTD T/A GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SEDEK AGRIKEM, DEKGRAS ROAD, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	CATALENT PHARMACEUTICAL SOLUTIONS, WOODSTOCK, ILLINOIS, USA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA SEDEK AGRIKEM, DEKGRAS ROAD, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN MCDERMOTT LABORATORIES LTD T/A GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA
FPRR:	ARROW PHARMA S.A., NORWICH CLOSE, SANDTON, RSA	FPRR:	ARROW PHARMA S.A., NORWICH CLOSE, SANDTON, RSA	FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF15		MRF 15	
Registration number:	42/7.1.3/0964	Registration number:	43/21.5.1/0008	Registration number:	43/13.4.1/0250
Name of medicine:	SARGEN 100/25	Name of medicine:	OMNAIR	Name of medicine:	MOMATE 0,1 % CREAM
Dosage form:	TABLET	Dosage form:	NASAL SPRAY	Dosage form:	CREAM
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH ACTUATION DELIVERS: CICLESONIDE 50,0 ug	Active ingredients:	EACH 1,0 g CREAM CONTAINS: MOMETASONE FURAOATE 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:	XIXIA PHARMACEUTICALS (PTY) LTD	Applicant:	NYCOMED (PTY) LTD	Applicant:	GLENMARK PHARMACEUTICALS SA (PTY) LTD
Manufacturer:	LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN	Manufacturer:	NYCOMED GmbH, SINGEN, GERMANY	Manufacturer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Packer:	LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN MCDERMOTT LABORATORIES LTD T/A GERARD LABORATORIES, DUBLIN, IRELAND	Packer:	NYCOMED GmbH, SINGEN, GERMANY	Packer:	GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: LABORATORIOS LICONSA SA, AZUQUECA DE HENARES (GUADALAJARA) SPAIN MCDERMOTT LABORATORIES LTD T/A GERARD LABORATORIES, DUBLIN, IRELAND GENERICS (UK) LTD, POTTERS BAR, HERTFORDSHIRE, UNITED KINGDOM SABS PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM MERCK PHARMACEUTICAL MANUFACTURING (PTY) LTD, WADEVILLE, GERMISTON, RSA	Laboratory:	FPRC: NYCOMED GmbH, SINGEN, GERMANY WEST MONARCH ANALYTICAL LABORATORIES, MAUMEE, OHIO, USA LABOR L & S AG, BAD BOCKLET, GROSSENBRACH, GERMANY NEXTBREATH LLC, BALTIMORE, MARYLAND, USA	Laboratory:	FPRC: GLENMARK PHARMACEUTICALS LIMITED, DISTRICT SOLAN, BADDI, HIMACHAL PRADESH, INDIA
FPRR:	XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, GAUTENG, RSA	FPRR:	NYCOMED (PTY) LTD, BRYANSTON, RSA	FPRR:	GLENMARK PHARMACEUTICALS SA (PTY) LTD, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/1.2/0364	Registration number:	43/1.2/0365	Registration number:	43/1.2/0366
Name of medicine:	ARROW ESCITALOPRAM 5	Name of medicine:	ARROW ESCITALOPRAM 10	Name of medicine:	ARROW ESCITALOPRAM 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO 20,0 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:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA	Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA
Laboratory:	FPRC: ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIAL, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA	FPRC/FPRR:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA	FPRR:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/1.2/0367	Registration number:	43/1.2/0368	Registration number:	43/1.2/0369
Name of medicine:	ZITOLEX 5	Name of medicine:	ZITOLEX 10	Name of medicine:	ZITOLEX 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 5.0 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, 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:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA
Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA	Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
	ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA		ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA		ARROW LABORATORIES LTD, SOUTH CROYDON, AUSTRALIA COBALT PHARMACEUTICALS, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTSVILLE, FLORIDA, RSA SEDEK AGRIKEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA	FPRC:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA	FPRC:	ARROW PHARMA SA (PTY) LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15	MRF 15	MRF 15
Registration number: 43/21.12/0402 Name of medicine: SPEC BICALUTAMIDE 50 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SPECPHARM (PTY) LTD Manufacturer: GENEPHARM S.A, PALLINI ATTIKIS, GREECE Packer: GENEPHARM S.A, PALLINI ATTIKIS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: GENEPHARM S.A, PALLINI ATTIKIS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA Shelf-life: 36 months Date of registration: 01 MARCH 2013	Registration number: 43/13.9.1/0524 Name of medicine: SEBIPROX 1,5 % SHAMPOO Dosage form: LIQUID Active ingredients: EACH 100,0 g CONTAINS: CICLOPIROX OLAMINE 150,0 g Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: GLAXOSMITHKLINE SA (PTY) LTD Manufacturer: STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND Packer: STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND Laboratory: FPRC: STIEFEL LABORATORIES IRELAND LTD, SLIGO, IRELAND CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: GLAXOSMITHKLINE SA (PTY) LTD, EPPING, CAPE TOWN, RSA Shelf-life: 36 months Date of registration: 01 MARCH 2013	Registration number: 43/26/0557 Name of medicine: YONDELIS 1 mg Dosage form: INJECTION Active ingredients: EACH VIAL CONTAINS: TRABACTEDIN 1,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: JANSSEN PHARMACEUTICA (PTY) LTD Manufacturer: BAXTER ONCOLOGY GmbH, HALLE/WESFALEN, KUNSEBECK, GERMANY Packer: BAXTER ONCOLOGY GmbH, HALLE/WESFALEN, KUNSEBECK, GERMANY JANSSEN PHARMACEUTICA N.V. BEERSE, BELGIUM JANSSEN PHARMACEUTICA, WOODMEAD, RSA Laboratory: FPRC: BAXTER ONCOLOGY GmbH, HALLE/WESFALEN, KUNSEBECK, GERMANY JANSSEN PHARMACEUTICA N.V. BEERSE, BELGIUM JANSSEN PHARMACEUTICA, WOODMEAD, RSA FPRR: JANSSEN PHARMACEUTICA (PTY) LTD, WOODMEAD, RSA Shelf-life: 36 months Date of registration: 01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/20.1.1/0948	Registration number:	43/20.1.1/1059	Registration number:	44/34/0133
Name of medicine:	TAVANIC I.V. 750	Name of medicine:	LEVOFLOXACIN WINTHROP I.V. 750	Name of medicine:	WATER FOR INJECTION GULF
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: Levofloxacin 750,0 mg	Active ingredients:	EACH VIAL CONTAINS: Levofloxacin 750,0 mg	Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION 5,0 or 10,0 ml
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:	SANOFL-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Manufacturer:	SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Manufacturer:	MARCK BIOSCIENCES LIMITED, TALUKA MATAR, DISTRICT KHEDA, GUJARAT, INDIA
Packer:	SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Packer:	SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Packer:	MARCK BIOSCIENCES LIMITED, TALUKA MATAR, DISTRICT KHEDA, GUJARAT, INDIA
Laboratory:	FPRC: SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Laboratory:	FPRC: SANOFL-AVENTIS DEUTSCHLAND GmbH, FRANKFURT am MAIN, GERMANY	Laboratory:	FPRC: MARCK BIOSCIENCES LIMITED, TALUKA MATAR, DISTRICT KHEDA, GUJARAT, INDIA
FPRC:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	FPRC:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA	FPRC:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/21.8.2/0159	Registration number:	44/34/0264	Registration number:	44/2.5/0368
Name of medicine:	VISANNE	Name of medicine:	REFRAT 250 mg	Name of medicine:	DYNA LEVETIRACETAM 250 mg
Dosage form:	TABLET	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DIENOGEST 2,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 250,0 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:	BAYER (PTY) LTD	Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	SCHERING GmbH und CO. PRODUKTIONS KG, WEIMAR, GERMANY	Manufacturer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA	Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	SCHERING GmbH und CO. PRODUKTIONS KG, WEIMAR, GERMANY	Packer:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA	Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, CAPE TOWN, RSA
Laboratory: FPRC:	SCHERING GmbH und CO. PRODUKTIONS KG, WEIMAR, GERMANY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	STRIDES ARCOLAB LIMITED, ANEKAL TALUK, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA
FPRR:	BAYER (PTY) LTD, ISANDO JOHANNESBURG, RSA	FPRR:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA
Shelf-life:	60 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF15		MRF 15	
Registration number:	44/2.5/0369	Registration number:	44/2.5/0370	Registration number:	44/2.5/0371
Name of medicine:	DYNA LEVETIRACETAM 500 mg	Name of medicine:	DYNA LEVETIRACETAM 750 mg	Name of medicine:	DYNA LEVETIRACETAM 1 000 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 750,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVETIRACETAM 1 000,0 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:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA	Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA	Manufacturer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA
Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, CAPE TOWN, RSA	Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, CAPE TOWN, RSA	Packer:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, PINELANDS, CAPE TOWN, RSA
Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	LUPIN LIMITED, VERNA-SALCETTE, GOA, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRC/FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA	FPRR:	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:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.1.1/0372	Registration number:	44/20.1.1/0373	Registration number:	44/20.1.1/0492
Name of medicine:	ZOCEF 750 mg	Name of medicine:	ZOCEF 1,5 g	Name of medicine:	AZITHROMYCIN 500 mg TABLETS ZYDUS
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	TABLET
Active ingredients:	EACH 15,0 ml VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg	Active ingredients:	EACH 20,0 ml VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,5 g	Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN 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, 8
Applicant:	ALKEM LABORATORIES (PTY) LTD	Applicant:	ALKEM LABORATORIES (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA	Manufacturer:	ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA	Packer:	ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: ALKEM LABORATORIES LTD, DABHEL DAMAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC:	ALKEM LABORATORIES, NOORDBRUG, POTCHEFSTROOM, RSA	FPRC:	ALKEM LABORATORIES, NOORDBRUG, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MMRF 15	
Registration number:	44/14.3/0645	Registration number:	44/11.4.3/0840	Registration number:	44/2.6.5/0865
Name of medicine:	VICRYL PLUS	Name of medicine:	PANTOPRAZOLE SPECPHARM 40	Name of medicine:	XEPLION 25 mg/0,25 ml
Dosage form:	SUTURE	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH 1,0 m SUTURE CONTAINS: TRICLOSAN 270,0 µg	Active ingredients:	EACH VIAL CONTAINS: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 40,0 mg	Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: PALIPERIDONE 25,0 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:	JOHNSON & JOHNSON MEDICAL (PTY) LTD	Applicant:	SPECPHARM (PTY) LTD	Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	ETHICON GmbH & CO KG, NORDERSTEDT, GERMANY	Manufacturer:	FARMA MEDITERRANIA S.L., SANT JUST DESVERN, BARCELONA, SPAIN	Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Packer:	ETHICON GmbH & CO KG, NORDERSTEDT, GERMANY JOHNSON & JOHNSON MEDICAL (PTY) LTD, MIDRAND, RSA	Packer:	FARMA MEDITERRANIA S.L., SANT JUST DESVERN, BARCELONA, SPAIN SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Packer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
	ETHICON GmbH & CO KG, NORDERSTEDT, GERMANY JOHNSON & JOHNSON MEDICAL (PTY) LTD, MIDRAND, RSA		SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA BIOMENDI S.A., BERNEDO, ALAVA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA		JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
FPRC:	JOHNSON & JOHNSON MEDICAL (PTY) LTD, MIDRAND, RSA	FPRC:	SPECPHARM, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.6.5/0866	Registration number:	44/2.6.5/0867	Registration number:	44/2.6.5/0868
Name of medicine:	XEPLION 50 mg/0,50 ml	Name of medicine:	XEPLION 75 mg/0,75 ml	Name of medicine:	XEPLION 100 mg/1,0 ml
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: PALIPERIDONE 50,0 mg	Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: PALIPERIDONE 75,0 mg	Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: PALIPERIDONE 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:	JANSSEN PHARMACEUTICA (PTY) LTD	Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD	Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Packer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Packer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Packer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
Laboratory: FPRC:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON, RSA	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON, RSA	FPRR:	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MMRF 15	
Registration number:	44/2.6.5/0870	Registration number:	44/2.6.5/0916
Name of medicine:	XEPLION 150 mg/1,50 ml	Name of medicine:	PREXOLAN ODT 10
Dosage form:	INJECTION	Dosage form:	TABLET
Active ingredients:	EACH PRE-FILLED SYRINGE CONTAINS: PALIPERIDONE 150.0 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 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
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
Packer:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., SCHIMATARI, ATHENS, GREECE
Laboratory: FPRC:	JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRC	JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON, RSA	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.6.5/0917	Registration number:	44/2.6.5/0918	Registration number:	44/20.1.1/1030
Name of medicine:	PREXOLAN ODT 15	Name of medicine:	PREXOLAN ODT 20	Name of medicine:	GDC CEFTRIAXONE 1 g
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 15,0 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 20,0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE 1,0 g
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:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE	Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN
Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., SCHIMATARI, ATHENS, GREECE	Packer:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA FAMAR S.A., ANTHOUSA, ATTIKIS, GREECE PHARMANEL PHARMACEUTICALS S.A., SCHIMATARI, ATHENS, GREECE	Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE M&L LABORATORY SERVICES ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE M&L LABORATORY SERVICES ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN 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, SILVERTONDALE, PRETORIA, RSA
FPRC/FPFR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA	FPRC/FPFR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA	FPFR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	36 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.1.1/1031	Registration number:	44/20.1.1/1032	Registration number:	44/20.1.1/1035
Name of medicine:	GDC CEFUROXIME 750 mg	Name of medicine:	GDC CEFUROXIME 1,5 g	Name of medicine:	GDC CEFOTAXIME 1 g
Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg	Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,5 g	Active ingredients:	EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1,0 g
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:	GULF DRUG COMPANY (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN
Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA	FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA	FPRR:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGEcombe, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	48 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.1.1/1036	Registration number:	44/20.1.1/1037	Registration number:	44/20.1.1/1038
Name of medicine:	GDC CEFOTAXIME 2 g	Name of medicine:	GDC VANCOMYCIN 0.5 g	Name of medicine:	GDC VANCOMYCIN 1 g
Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 2.0 g	Active ingredients:	EACH VIAL CONTAINS: VANCOMYCIN HCl EQUIVALENT TO VANCOMYCIN 0.5 g	Active ingredients:	EACH VIAL CONTAINS: VANCOMYCIN HCl EQUIVALENT TO VANCOMYCIN 1.0 g
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:	GULF DRUG COMPANY (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD	Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Manufacturer:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN	Manufacturer:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN
Packer:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN	Packer:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN	Packer:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORIO REIG JOFRE, TOLEDO, SPAIN 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, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN 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, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	LABORATORIO REIG JOFRE, BARCELONA, SPAIN 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, SILVERTONDALE, PRETORIA, RSA
FPRC:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA	FPRC:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA	FPRC:	GULF DRUG COMPANY (PTY) LTD, MOUNT EDGECOMBE, RSA
Shelf-life:	48 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15	MRF 15	MRF 15	MRF 15
Registration number: 4417.5/1054 Name of medicine: ASTOR 10 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: LASARA TRADERS (PTY) LTD Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: LASARA TRADERS, MORELETA PARK, PRETORIA, RSA Shelf-life: 24 months (Provisional) Date of registration: 01 MARCH 2013	Registration number: 4417.5/1055 Name of medicine: ASTOR 20 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: LASARA TRADERS (PTY) LTD Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: LASARA TRADERS, MORELETA PARK, PRETORIA, RSA Shelf-life: 24 months (Provisional) Date of registration: 01 MARCH 2013	Registration number: 4417.5/1056 Name of medicine: ASTOR 40 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: LASARA TRADERS (PTY) LTD Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: LASARA TRADERS, MORELETA PARK, PRETORIA, RSA Shelf-life: 24 months (Provisional) Date of registration: 01 MARCH 2013	Registration number: 4417.5/1056 Name of medicine: ASTOR 40 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: LASARA TRADERS (PTY) LTD Manufacturer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE Packer: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: LASARA TRADERS, MORELETA PARK, PRETORIA, RSA Shelf-life: 24 months (Provisional) Date of registration: 01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.5/1057	Registration number:	44/7.5/1058	Registration number:	44/7.5/1059
Name of medicine:	ASTOR 80	Name of medicine:	LESTAVOR 10	Name of medicine:	LESTAVOR 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 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:	LASARA TRADERS (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Laboratory: FPRC:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
FPRC:	LASARA TRADERS, MORELETA PARK, PRETORIA, RSA	FPRC:	LASARA TRADERS, MORELETA PARK, PRETORIA, RSA	FPRC:	LASARA TRADERS, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15	
Registration number:	44/7.5/1060	Registration number:	44/7.5/1061
Name of medicine:	LESTAVOR 40	Name of medicine:	LESTAVOR 80
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	LASARA TRADERS (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE	Manufacturer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE
Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA	Packer:	PHARMATHEN S.A., PALLINI, ATTIKI, GREECE PHARMATHEN INTERNATIONAL, RODOPI, ELLAS, GREECE DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA
Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: PHARMATHEN S.A., PALLINI, ATTIKI, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	LASARA TRADERS, MORELETA PARK, PRETORIA, RSA	FPRR:	LASARA TRADERS, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

Registration number:	45/7.1.3/0073	Registration number:	45/7.1.3/0073
Name of medicine:	ISART CO 150	Name of medicine:	ISART CO 150
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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
Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRR:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1.3/0074	Registration number:	45/7.1.3/0075	Registration number:	45/7.1.3/0076
Name of medicine:	ISART CO 300	Name of medicine:	IRBESARTAN HYDROCHLOROTHIAZIDE ZYDUS 150/12,5 mg	Name of medicine:	IRBESARTAN HYDROCHLOROTHIAZIDE ZYDUS 300/12,5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 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:	ZYDUS HEALTHCARE S.A. (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD	Applicant:	ZYDUS HEALTHCARE S.A. (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE SA, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.5/0091	Registration number:	45/2.5/0092	Registration number:	45/20.1.1/0198
Name of medicine:	NAVALPRO CR 300	Name of medicine:	NAVALPRO CR 500	Name of medicine:	FLOPRO 250 mg TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 199,8 mg VALPROIC ACID 87,0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 333,0 mg VALPROIC ACID 145,0 mg	Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 250,0 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:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY	Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRC:	BRIMPARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRC:	BRIMPARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRC:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0199	Registration number:	45/20.1.1/0200	Registration number:	45/20.1.1/0201
Name of medicine:	FLOPRO 500 mg TABLETS	Name of medicine:	FLOPRO 750 mg TABLETS	Name of medicine:	COLIPRID 250 mg TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 750,0 mg	Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 250,0 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 LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0202	Registration number:	45/20.1.1/0203	Registration number:	45/6.2/0350
Name of medicine:	COLIPRID 500 mg TABLETS	Name of medicine:	COLIPRID 750 mg TABLETS	Name of medicine:	BRINAVESS 200 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to 500,0 mg Ciprofloxacin	Active ingredients:	EACH TABLET CONTAINS: Ciprofloxacin hydrochloride equivalent to 750,0 mg Ciprofloxacin	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: VERNAKALANT HCl 20,0 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	MSD (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY MERCK SHARP & DOHME, HAARLEM, NETHERLANDS
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA	Laboratory: FPRC:	HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY MERCK SHARP & DOHME, HAARLEM, NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	36 months (10 ml vials) 24 months (30 ml vials)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/6.2/0351	Registration number:	45/26/0410	Registration number:	45/2.5/0411
Name of medicine:	BRINAVESS 500 mg	Name of medicine:	TASIGNA 150 mg	Name of medicine:	NAVALPRO CR 200
Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: VERNAKALANT HCl 20.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: Nilotinib 150.0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 133.2 mg VALPROIC ACID 58.0 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:	MSD (PTY) LTD	Applicant:	NOVARTIS SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD
Manufacturer:	HAMELIN PHARMACEUTICALS GmbH, HAMELIN, GERMANY	Manufacturer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND	Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY
Packer:	HAMELIN PHARMACEUTICALS GmbH, HAMELIN, GERMANY MERCK SHARP & DOHME, HAARLEM, NETHERLANDS	Packer:	NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, INDUSTRIAL, JOHANNESBURG, RSA DRA PHARMACEUTICALS CC, IRENE, PRETORIA, RSA	Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: HAMELIN PHARMACEUTICALS GmbH, HAMELIN, GERMANY MERCK SHARP & DOHME, HAARLEM, NETHERLANDS MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Laboratory:	FPRC: NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND PHARMANALYTICA SA, LOCARNO, SWITZERLAND SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA M&L LABORATORY SERVICES (PTY) LTD, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: DRAGENOPHARM APOTHEKER PUSCHL GmbH, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	MSD (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRC:	NOVARTIS SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRC:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	36 months (10 ml vials) 24 months (30 ml vials)	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/3.2/0580	Registration number:	45/3.2/0581	Registration number:	45/20.2.8/0516
Name of medicine:	DENSATE 10 mg	Name of medicine:	DENSATE 70 mg	Name of medicine:	PREZISTA 600 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM EQUIVALENT TO ALENDRONIC ACID 70,0 mg	Active ingredients:	EACH TABLET CONTAINS: DARUNAVIR ETHANOLATE EQUIVALENT TO DARUNAVIR 600,0 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	PHARMACARE LIMITED
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	JANSSEN CILAG SpA, BORGO SAN MICHELE, LATINA, ITALY ASPEN PORT ELIZABETH, KORSTEN, PORT ELIZABETH, RSA
Laboratory FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory FPRC:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO JANSSEN CILAG SpA, BORGO SAN MICHELE, LATINA, ITALY ASPEN PORT ELIZABETH, KORSTEN, PORT ELIZABETH, RSA
FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

MRF 15		MRF15		MRF 15	
Registration number:	45/7.5/0955	Registration number:	45/7.5/0956	Registration number:	45/7.5/0957
Name of medicine:	ROSVATOR 5	Name of medicine:	ROSVATOR 10	Name of medicine:	ROSVATOR 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 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:	RANBAXY (S.A.) (PTY) LTD	Applicant:	RANBAXY (S.A.) (PTY) LTD	Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Manufacturer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Manufacturer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Packer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Packer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013

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MRF 15		MRF 15		MRF 15	
Registration number:	45/7.5/0961	Registration number:	45/7.5/0962	Registration number:	45/2.7/1020
Name of medicine:	ROSUVASTATIN RAN 20	Name of medicine:	ROSUVASTATIN RAN 40	Name of medicine:	DOLIPRANE 500 EFFERVESCENT TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	EFFERVESCENT TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 mg	Active ingredients:	EACH EFFERVESCENT TABLET CONTAINS: PARACETAMOL 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:	RANBAXY (S.A.) (PTY) LTD	Applicant:	RANBAXY (S.A.) (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Manufacturer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Manufacturer:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY
Packer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Packer:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA	Packer:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY
Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	RANBAXY LABORATORIES LIMITED, DISTRICT SIRMOUR, HIMACHAL PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
FPRC:	RANBAXY SA (PTY) LTD, CENTURION, RSA	FPRC:	RANBAXY SA (PTY) LTD, CENTURION, RSA	FPRC:	WINTHROP PHARMACEUTICALS, MIDRAND, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Date of registration:	01 MARCH 2013	Date of registration:	01 MARCH 2013	Date of registration:	24 months (Provisional) 01 MARCH 2013

MRF 15	
Registration number:	46/20.2.8/0464
Name of medicine:	EFAVIRENZ KETLA
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Packer:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
Laboratory: FPRC:	JOHNSON & JOHNSON (PTY) LTD, RETREAT, CAPE TOWN, RSA
FPRR:	MC PHARMA (PTY) LTD, WIERDA PARK, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013

MRF 15	
Registration number:	45/2.7/1021
Name of medicine:	DOLIPRANE 1 000 EFFERVESCENT TABLETS
Dosage form:	EFFERVESCENT TABLET
Active ingredients:	EACH EFFERVESCENT TABLET CONTAINS: PARACETAMOL 1 000.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY
Packer:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY
Laboratory: FPRC:	A. NATTERMAN & CIE GmbH, KOLN, GERMANY
FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	01 MARCH 2013

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRC:	Shelf-life:	Date of registration:
MRF 15	35/24/0370	ULTIPOT	TABLET	EACH TABLET CONTAINS: POTASSIUM CHLORIDE 600,0 mg	1, 2, 3, 4, 5, 6, 7, 8	MIRREN (PTY) LTD	MIRREN (PTY) LTD, BENONI, RSA	MIRREN (PTY) LTD, BENONI, RSA	MIRREN (PTY) LTD, BENONI, RSA	MIRREN (PTY) LTD, BENONI, CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA	24 months (Provisional)	19 APRIL 2013
MRF 15	A40/5.4/0044	FRESENIUS GLYCOPYRRROLATE 0,4 mg/2 ml	INJECTION	EACH 2,0 ml SOLUTION CONTAINS: GLYCOPYRRROLATE 0,4 mg	1, 2, 3, 4, 5, 6, 7	BODENE (PTY) LTD t/a INTRAMED	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	24 months	19 APRIL 2013
F 15	A40/5.4/0101	FRESENIUS GLYCOPYRRROLATE 0,2 mg/1 ml	INJECTION	EACH 1,0 ml SOLUTION CONTAINS: GLYCOPYRRROLATE 0,2 mg	1, 2, 3, 4, 5, 6, 7	BODENE (PTY) LTD t/a INTRAMED	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	BODENE (PTY) LTD t/a INTRAMED, KORSTEN, PORT ELIZABETH, RSA	24 months	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	41/7.1.3/0073	Registration number:	41/7.1.3/0074	Registration number:	41/26/0158
Name of medicine:	CIPLATEC 20	Name of medicine:	CIPLA ENALAPRIL 20	Name of medicine:	DOCELEX 20
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 20,0 mg	Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL (ANHYDROUS) 20,0 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:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPAK, CAPE TOWN, RSA	FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPAK, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPAK, CAPE TOWN, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		F 15	
Registration number:	Name of medicine:	Registration number:	Name of medicine:
41/26/0159	DOCELEX 80	42/3/20221	FEMAX 70
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL TRIHYDRATE EQUIVALENT TO DOCETAXEL (ANHYDROUS) 80.0 mg	Active ingredients:	EACH TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70.0 mg
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:	ARROW PHARMA SA (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Manufacturer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, BIRZEBBUGIA, MALTA
Packer:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Packer:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA	Laboratory: FPRC:	ARROW LABORATORIES LTD, CROYDON SOUTH, VICTORIA, AUSTRALIA ARROW PHARMA (MALTA) LIMITED, BIRZEBBUGIA, MALTA SELAMINE LTD, 1/a ARROW GENERICS LIMITED, CLONSNAUGH, DUBLIN, IRELAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA
FPRC/FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, CAPE TOWN, RSA	FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15	MRF 15	F 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:
42/20 1.1/0387	42/20 2.8/0667	42/20 2.8/0668
ASPEN CEFPODOXIME 40 mg/5 ml (ORALSUSPENSION)	CIPLAFLAM 125	CIPLAFLAM 250
POWDER FOR ORAL SUSPENSION	TABLET	TABLET
EACH 5.0 ml SUSPENSION CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 40.0 mg	EACH TABLET CONTAINS: FAMCICLOVIR 125.0 mg	EACH TABLET CONTAINS: FAMCICLOVIR 250.0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
PHARMACARE LIMITED	CIPLA MEDPRO (PTY) LTD	CIPLA MEDPRO (PTY) LTD
LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
PORT ELIZABETH, KORSTEN, PHARMACARE LIMITED, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
LUPIN LIMITED, MANDIDEEP, DISTRICT RAISEN, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
PHARMACARE LIMITED, KORSTEN, PORT ELIZABETH, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA	CIPLA LTD, UNIT IV, VERNA, SALCETTE, GOA, INDIA
24 months for the powder when packed in translucent HDPE bottles 10 days at 2-8 °C when reconstituted	24 months (Provisional)	24 months (Provisional)
19 APRIL 2013	19 APRIL 2013	19 APRIL 2013

MRF 15	MRF 15	MRF 15
Registration number: 42/8.4/0993 Name of medicine: TETRASPAN 6 % Dosage form: SOLUTION FOR INFUSION Active ingredients: EACH 1 000.0 ml SOLUTION CONTAINS: HYDROXYETHYL STARCH 60.00 g SODIUM CHLORIDE 6.252 g POTASSIUM CHLORIDE 0.2984 g CALCIUM CHLORIDE DIHYDRATE 0.3675 g MAGNESIUM CHLORIDE 0.2033g HEXAHYDRATE 3.266 g SODIUM ACETATE TRIHYDRATE 3.266 g L-MALIC ACID 0.671 g Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: B BRAUN MEDICAL (PTY) LTD Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND Packer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRC: B BRAUN MEDICAL (PTY) LTD, HONEYDEW, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013	Registration number: 42/8.4/0994 Name of medicine: TETRASPAN 10 % Dosage form: SOLUTION FOR INFUSION Active ingredients: EACH 1 000.0 ml SOLUTION CONTAINS: HYDROXYETHYL STARCH 100.00 g SODIUM CHLORIDE 6.252 g POTASSIUM CHLORIDE 0.2984 g CALCIUM CHLORIDE DIHYDRATE 0.3675 g MAGNESIUM CHLORIDE 0.2033g HEXAHYDRATE 3.266 g SODIUM ACETATE TRIHYDRATE 3.266 g L-MALIC ACID 0.671 g Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: B BRAUN MEDICAL (PTY) LTD Manufacturer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND Packer: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND Laboratory: FPRC: B BRAUN MELSUNGEN AG, MELSUNGEN, GERMANY B BRAUN MEDICAL S.A., CRISSIER, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRC: B BRAUN MEDICAL (PTY) LTD, HONEYDEW, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013	Registration number: 43/5.3/0435 Name of medicine: ZELMERON 5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: AKACIA HEALTHCARE (PTY) LTD Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA LABORATORY AND BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA FPRC: AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 19 APRIL 2013

MRF 15		F 15		MRF 15	
Registration number:	43/5.3/0436	Registration number:	43/1.5/0619	Registration number:	43/21.4/0836
Name of medicine:	ZELMERON 10	Name of medicine:	ASPEN GABAPENTIN 400 mg	Name of medicine:	PREOTACT
Dosage form:	TABLET	Dosage form:	CAPSULE	Dosage form:	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 10.0 mg	Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 400.0 mg	Active ingredients:	EACH DOSE CONTAINS: PARATHYROID HORMONE 100.0 µg
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:	AKACIA HEALTHCARE (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	NYCOMED (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE	Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN	Manufacturer:	VETTER PHARMA-FERTIGUNG GmbH & Co KG, SCHUTZENSTRASSE, RAVENSBURG, GERMANY
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE	Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN MPF B.V. (MANUFACTURING PACKAGING FARMACIA), OUDEHASKE, THE NETHERLANDS SOFARMEX INDUSTRIA QUIMICA E FARMACEUTICA Lda, ALTO DE COLARIDE, AGUALVA, CACEM	Packer:	VETTER PHARMA-FERTIGUNG GmbH & Co KG, SCHUTZENSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co KG, HOLBEINSTRASSE, RAVENSBURG, GERMANY NYCOMED DANMARK ApS, ROSKILDE, DENMARK
Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA LABORATORY AND BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: VETTER PHARMA-FERTIGUNG GmbH & Co KG, SCHUTZENSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co KG, HOLBEINSTRASSE, RAVENSBURG, GERMANY VETTER PHARMA-FERTIGUNG GmbH & Co KG, EISENBAHNSTRASSE, LANGENARGEN, GERMANY SGS CANADA INC/NPS ALLELIX CORP., MISSISSAUGA, ONTARIO, CANADA NUCRO-TECHNICS INCORPORATED, SCARBOROUGH, ONTARIO, CANADA NYCOMED DANMARK ApS, ROSKILDE, DENMARK
FPRC:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, JOHANNESBURG, RSA	FPRC:	PHARMACARE LIMITED, WOODMEAD, SANDTON RSA	FPRC:	NYCOMED (PTY) LTD, BRYANSTON, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	36 months	Shelf-life:	24 months (Provisional) 28 days at 2-8 °C (In-use)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		F 15	
Registration number:	43/15.4/1134	Registration number:	44/7.1.3/0018
Name of medicine:	CROMAL	Name of medicine:	DYNAVAL CO 80/12.5 mg
Dosage form:	EYE DROPS	Dosage form:	TABLET
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: CROMOLYN SODIUM 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 80.0 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
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT 1, VERNA, GOA, INDIA	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN
Packer:	CIPLA LTD, UNIT 1, VERNA, GOA, INDIA	Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA
Laboratory: FPRC:	CIPLA LTD, UNIT 1, VERNA, GOA, INDIA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSEN PARK, CAPE TOWN, RSA	FPRR:	PHARMA DYNAMICS (PTY) LTD, WESTLAKE, RSA
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15	Registration number:	Name of medicine:	Dosage form:	Active ingredients:	Conditions of registration:	Applicant:	Manufacturer:	Packer:	Laboratory:	FPRC:	Shelf-life:	Date of registration:
MRF 15	44/7.1.3/0020	DYNAVAL CO 160/25 mg	TABLET	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	1, 2, 3, 4, 5, 6, 7	PHARMA DYNAMICS (PTY) LTD	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	FPRC:	24 months	19 APRIL 2013
MRF 15	44/7.1.3/0021	DIZARTAN CO 80/12,5	TABLET	EACH TABLET CONTAINS: VALSARTAN 80,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	1, 2, 3, 4, 5, 6, 7	PHARMA DYNAMICS (PTY) LTD	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	FPRC:	24 months	19 APRIL 2013
MRF 15	44/7.1.3/0022	DIZARTAN CO 160/12,5	TABLET	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	1, 2, 3, 4, 5, 6, 7	PHARMA DYNAMICS (PTY) LTD	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	FPRC:	24 months	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/0023	Registration number:	44/20.1.1/0249	Registration number:	44/20.1.1/0250
Name of medicine:	DIZARTAN CO 160/25	Name of medicine:	ZYBACT 250 mg	Name of medicine:	ZYBACT 500 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 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
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN PHARMACEUTICAL ENTERPRISES (PTY) LTD, N'DABENI, CAPE TOWN, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC	Laboratory:	FPRC	Laboratory:	FPRC
					ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMA DYNAMICS (PTY) LTD, SILVERWOOD CLOSE, WESTLAKE, RSA – FPRR	FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:		Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.1.1/0251	Registration number:	44/20.1.1/0252	Registration number:	44/30.3/0263
Name of medicine:	LEVOFLOXACIN ZYDUS 250 mg	Name of medicine:	LEVOFLOXACIN ZYDUS 500 mg	Name of medicine:	TISSEEL
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	SOLUTION FOR TISSUE SEALANT
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 250,0 mg	Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN 500,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: HUMAN FIBRINOGEN 72,0 – 110,0 mg HUMAN FACTOR XIII ≤10,0 I.U. APROTININ 3 000 KIU ² HUMAN THROMBIN 500 I.U. ³ CALCIUM CHLORIDE 40,0 µmol
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:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	BAXTER AG, INDUSTRIESTRASSE, VIENNA, AUSTRIA BAXTER AG, ORTH/DONAU, AUSTRIA BAXTER AG, ALLEE, VIENNA, AUSTRIA
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	BAXTER AG, ALLEE, VIENNA, AUSTRIA
Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: BAXTER AG, ORTH/DONAU, AUSTRIA BAXTER AG, ALLEE, VIENNA, AUSTRIA
FPRC:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months stored at or below -20 °C 72 hours in-use shelf life stored at or below 25 °C
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15	Registration number: 44/20.1.1/0310 Name of medicine: ERAZEF 1 g INJECTION Dosage form: POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 1,0 g 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 FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 19 APRIL 2013
MRF 15	Registration number: 44/20.1.1/0311 Name of medicine: ERAZEF 2 g INJECTION Dosage form: POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 2,0 g 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 FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (provisional) Date of registration: 19 APRIL 2013
MRF 15	Registration number: 44/20.1.1/0312 Name of medicine: MEDAZIN 1 g INJECTION Dosage form: POWDER FOR INJECTION Active ingredients: EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 1,0 g 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 FPRC: AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA Shelf-life: 24 months (Provisional) Date of registration: 19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.1.1/0313	Registration number:	44/20.1.1/0314	Registration number:	44/20.1.1/0315
Name of medicine:	MEDAZIN 2 g INJECTION	Name of medicine:	FELDRET 1 g INJECTION	Name of medicine:	FELDRET 2 g INJECTION
Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION	Dosage form:	POWDER FOR INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 2.0 g	Active ingredients:	EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 1.0 g	Active ingredients:	EACH VIAL CONTAINS: CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN 2.0 g
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, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA	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	Packer:	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:	Laboratory:	FPRC:	Laboratory:	FPRC
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:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15	MRF 15	MRF 15
Registration number: 44/7.1/0342 Name of medicine: GITSALAT 60 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: NIFEDIPINE 60,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BAYER (PTY) LTD Manufacturer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY Packer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA Laboratory: FPRC FPFR: BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA Shelf-life: 48 months (packed in PP/Al and PA/Alu/PVC blisters.) 60 months (packed in PVC/PVDC blisters) Date of registration: 19 APRIL 2013	Registration number: 44/7.1/0341 Name of medicine: GITSALAT 30 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: NIFEDIPINE 30,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BAYER (PTY) LTD Manufacturer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY Packer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA Laboratory: FPRC FPFR: BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA Shelf-life: 48 months (packed in PP/Al and PA/Alu/PVC blisters.) 60 months (packed in PVC/PVDC blisters) Date of registration: 19 APRIL 2013	Registration number: 44/7.1/0340 Name of medicine: GITSALAT 20 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: NIFEDIPINE 20,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: BAYER (PTY) LTD Manufacturer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY Packer: BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA PHARMACEUTICAL CONTRACTORS (PTY) LTD, ISANDO, RSA Laboratory: FPRC FPFR: BAYER (PTY) LTD, ISANDO, JOHANNESBURG, RSA Shelf-life: 48 months (packed in PP/Al and PA/Alu/PVC blisters.) 60 months (packed in PVC/PVDC blisters) Date of registration: 19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/20.2.2/0481	Registration number:	44/2.9/0496	Registration number:	44/2.9/0497
Name of medicine:	FLUCORIC INFUSION	Name of medicine:	TRAMADOL SR 100 TABLETS ZYDUS	Name of medicine:	TRAMADOL SR 150 TABLETS ZYDUS
Dosage form:	SOLUTION FOR INFUSION	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: FLUCONAZOLE 2,0 mg	Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 150,0 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:	RANBAXY (S.A.) (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	LABORATORY REIG JOFRE S.A., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES cc, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPR:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA	FPR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPR:	ZYDUS HEALTHCARE SA (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.9/0498	Registration number:	44/7.1.3/0511	Registration number:	44/7.1.3/0512
Name of medicine:	TRAMADOL SR 200 TABLETS ZYDUS	Name of medicine:	APRESAR 75	Name of medicine:	APRESAR 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	447.1.3/0513	Registration number:	447.1.3/0526	Registration number:	447.1.3/0527
Name of medicine:	APRESAR 300	Name of medicine:	IRBEVEL 75	Name of medicine:	IRBEVEL 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE-PAMPLONA, SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, RESEARCH AND DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF15		MRF 15	
Registration number:	44/7.1.3/0528	Registration number:	44/7.1.3/0529	Registration number:	44/7.1.3/0530
Name of medicine:	IRBEVEL 300	Name of medicine:	ADCO IRBESARTAN 75	Name of medicine:	ADCO IRBESARTAN 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF15		MMRF 15	
Registration number:	44/7.1.3/0531	Registration number:	44/7.1.3/0532	Registration number:	44/7.1.3/0533
Name of medicine:	ADCO IRBESARTAN 300	Name of medicine:	PROPAN IRBESARTAN 75	Name of medicine:	PROPAN IRBESARTAN 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA
FPRC:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRC:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRC:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15	
Registration number:	44/7.1.3/0534	Registration number:	44/7.1.3/0536
Name of medicine:	PROPAN IRBESARTAN 300	Name of medicine:	COVAN IRBESARTAN 150
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300.0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN
Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD. (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD. (RESEARCH & DEVELOPMENT), AEROTON, RSA
FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD. (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD. (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MMRF 15	
Registration number:	44/7.1.3/0537	Registration number:	44/2.9/0754
Name of medicine:	COVAN IRBESARTAN 300	Name of medicine:	FENTANYL SANDOZ 50 µg/h
Dosage form:	TABLET	Dosage form:	PATCH
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300.0 mg	Active ingredients:	EACH PATCH DELIVERS: FENTANYL 50.0 µg/h
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN	Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA
Laboratory: FPRC:	LABORATORIOS CINFA S.A., HUARTE (PAMPLONA), SPAIN LABORATORIOS LICONSA S.A., AZUQUECA DE HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, RSA	Laboratory: FPRC:	HEXAL AG, HOLZKIRCHEN, GERMANY SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRC:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD (RESEARCH & DEVELOPMENT), AEROTON, RSA ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRC:	SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.9/0755	Registration number:	44/2.9/0756	Registration number:	44/2.9/0757
Name of medicine:	FENTANYL SANDOZ 75 µg/h	Name of medicine:	FENTANYL SANDOZ 100 µg/h	Name of medicine:	FENDERMAL 25 µg/h
Dosage form:	PATCH	Dosage form:	PATCH	Dosage form:	PATCH
Active ingredients:	EACH PATCH DELIVERS: FENTANYL 75,0 µg/h	Active ingredients:	EACH PATCH DELIVERS: FENTANYL 100,0 µg/h	Active ingredients:	EACH TRANSDERMAL PATCH DELIVERS: FENTANYL 25,0 µg/h
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:	HEXAL AG, HOLZKIRCHEN, GERMANY	Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY	Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY	Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY	Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Laboratory:	FPRC: SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA	Laboratory:	FPRC: SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA	Laboratory:	FPRC: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA		CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA		CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
	SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA		SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA		SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA
FPRC/FPRR:	SANDOZ SA (PTY) LTD, KEMPTON PARK, RSA	FPRC/FPRR:	SANDOZ SA (PTY) LTD, 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:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/2.9/0758	Registration number:	44/2.9/0759	Registration number:	44/2.9/0760
Name of medicine:	FENDERMAL 50 µg/h	Name of medicine:	FENDERMAL 75 µg/h	Name of medicine:	FENDERMAL 100 µg/h
Dosage form:	PATCH	Dosage form:	PATCH	Dosage form:	PATCH
Active ingredients:	EACH TRANSDERMAL PATCH DELIVERS: FENTANYL 50.0 µg/h	Active ingredients:	EACH TRANSDERMAL PATCH DELIVERS: FENTANYL 75.0 µg/h	Active ingredients:	EACH TRANSDERMAL PATCH DELIVERS: FENTANYL 100.0 µg/h
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:	HEXAL AG, HOLZKIRCHEN, GERMANY	Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY	Manufacturer:	HEXAL AG, HOLZKIRCHEN, GERMANY
Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	HEXAL AG, HOLZKIRCHEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	HEXAL AG, HOLZKIRCHEN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA 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	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:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/21.2/0771	Registration number:	44/21.2/0772	Registration number:	44/21.2/0773
Name of medicine:	DIAPHAGE 500	Name of medicine:	DIAPHAGE 850	Name of medicine:	DIAPHAGE 1 000
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 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:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Manufacturer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Manufacturer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Packer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Packer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Packer:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, CAPE TOWN, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, CAPE TOWN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF-15	XF 15	
	Registration number:	Registration number:
44/21.2/0774	44/21.2/0774	44/21.2/0774
CIPLA METFORMIN 500	CIPLA METFORMIN 850	CIPLA METFORMIN 1 000
TABLET	TABLET	TABLET
EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 500,0 mg	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000,0 mg
1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
CIPLA LIFE SCIENCES (PTY) LTD	CIPLA LIFE SCIENCES (PTY) LTD	CIPLA LIFE SCIENCES (PTY) LTD
CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA	CIPLA LTD, UNIT I, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, INDIA
CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, CAPE TOWN, RSA
24 months	24 months	24 months
19 APRIL 2013	19 APRIL 2013	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/21.2/1022	Registration number:	44/21.2/1023	Registration number:	45/34/0033
Name of medicine:	TASDIAM 50	Name of medicine:	TASDIAM 150	Name of medicine:	ZOLAPOR
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	CONCENTRATED SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 50,0 mg	Active ingredients:	EACH TABLET CONTAINS: BICALUTAMIDE 150,0 mg	Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: 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:	RANBAXY (S.A.) (PTY) LTD	Applicant:	RANBAXY (S.A.) (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD
Manufacturer:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE	Manufacturer:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE	Manufacturer:	DELPHARM TOURS, CHAMBRAY-LES-TOURS, FRANCE
Packer:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE	Packer:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE	Packer:	DELPHARM TOURS, CHAMBRAY-LES-TOURS, FRANCE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	GENEPHARM S.A., PALLINI ATTIKIS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	DELPHARM TOURS, CHAMBRAY-LES-TOURS, FRANCE SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRC:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA	FPRC:	RANBAXY (S.A.) (PTY) LTD, CENTURION, RSA	FPRC:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.5/0093	Registration number:	45/2.5/0094	Registration number:	45/5.2/0128
Name of medicine:	VALPROATE BRIMPARM CR 300	Name of medicine:	VALPROATE BRIMPARM CR 500	Name of medicine:	BISLO 5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 199,8 mg VALPROIC ACID 87,0 mg	Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 333,0 mg VALPROIC ACID 145,0 mg	Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 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, 8
Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY	Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY	Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA
Laboratory:	FPRC: DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	UNICHEM SA (PTY) LTD, POTCHEFSTROOM, RSA
Shelf-life:	24 months packed in (OPA/)/PVC/Al Blister strips	Shelf-life:	24 months packed in (OPA/)/PVC/Al Blister strips	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/5.2/0129	Registration number:	45/2.6.5/0166	Registration number:	45/2.6.5/0167
Name of medicine:	BISLO 10	Name of medicine:	MYLAN OLANZAPINE 2,5 mg	Name of medicine:	MYLAN OLANZAPINE 5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 5,0 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:	UNICHEM SA (PTY) LTD	Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA	Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA MCDERMOTT LABORATORIES LTD, 1/a GERARD LABORATORIES, DUBLIN, IRELAND CIPLA MEDPRO MANUFACTURING (PTY) LIMITED, MOBENI, RSA	Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA MCDERMOTT LABORATORIES LTD, 1/a GERARD LABORATORIES, DUBLIN, IRELAND CIPLA MEDPRO MANUFACTURING (PTY) LIMITED, MOBENI, RSA
Laboratory:	FPRC: UNICHEM LABORATORIES LIMITED, PILERNE, BARDEZ, GOA, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory:	FPRC: ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDSBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDAL, RANDSBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	UNICHEM SA (PTY) LTD, POTCHEFSTROOM, RSA	FPRC:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA	FPRC:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.6.5/0168	Registration number:	45/3.1/0179	Registration number:	45/21.2/0204
Name of medicine:	MYLAN OLANZAPINE 10 mg	Name of medicine:	VIMOVO 500/20	Name of medicine:	REDORFIN 500 mg TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: NAPROXEN 500,0 mg ESOMEPRAZOLE MAGNESIUM TRIHYDRATE EQUIVALENT TO ESOMEPRAZOLE 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 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, 8
Applicant:	MYLAN (PTY) LTD	Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA MCDERMOTT LABORATORIES LTD, 1/a GERARD LABORATORIES, DUBLIN, IRELAND CIPLA MEDPRO MANUFACTURING (PTY) LIMITED, MOBENI, RSA	Packer:	PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA ASTRAZENECA AB, SODERTALJE, SWEDEN ASTRAZENECA AG, UMEA, SWEDEN ASTRAZENECA PHARMACEUTICALS LP, NEWARK, DELAWARE, USA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: ALPHAPHARM (PTY) LTD, CAROLE PARK, QUEENSLAND, AUSTRALIA MATRIX LABORATORIES LTD, MALEGON SINNAR, NASHIK, MAHARASHTRA, INDIA ACORN PHARMACEUTICALS (PTY) LTD, NORTH RIDING, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA ASTRAZENECA AB, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA	FPRR:	ASTRAZENECA PHARMACEUTICAL (PTY) LTD, SUNNINGHILL, RSA	FPRR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	36 months (packed in HDPE bottles 24 months (packed in aluminium blisters)	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/21.2/0205	Registration number:	45/21.2/0206	Registration number:	45/21.2/0207
Name of medicine:	REDORFIN 850 mg TABLETS	Name of medicine:	REDORFIN 1 000 mg TABLETS	Name of medicine:	ROMIDAB 500 mg TABLETS
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000,0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA
Laboratory:	FPRC	Laboratory:	FPRC	Laboratory:	FPRC
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:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/21.2/0208	Registration number:	45/21.2/0209	Registration number:	45/7.5/0314
Name of medicine:	ROMIDAB 850 mg TABLETS	Name of medicine:	ROMIDAB 1 000 mg TABLETS	Name of medicine:	ARROW ROSUVASTATIN 5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850.0 mg	Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 1 000.0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 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, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	ARROW PHARMA SA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Laboratory: FPCR:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPCR:	AUROBINDO PHARMA LIMITED, UNIT III, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, HYDERABAD, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPCR:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
FPCR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPCR:	AUROBINDO PHARMA (PTY) LTD, MEYERSDAL, JOHANNESBURG, RSA	FPCR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.5/0315	Registration number:	45/7.5/0316	Registration number:	45/7.5/0317
Name of medicine:	ARROW ROSUVASTATIN 10	Name of medicine:	ARROW ROSUVASTATIN 20	Name of medicine:	ARROW ROSUVASTATIN 40
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 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:	ARROW PHARMA SA (PTY) LTD	Applicant:	ARROW PHARMA SA (PTY) LTD	Applicant:	ARROW PHARMA SA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS INC, MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRR:	ARROW PHARMA SA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15	MRF 15	MRF 15	MRF 15
Registration number: 45/2.6.5/0323 Name of medicine: REDILANZ ODT 5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 5,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: DR REDDY'S LABORATORIES (PTY) LTD Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA DRA PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA FPRR: DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013	Registration number: 45/2.6.5/0324 Name of medicine: REDILANZ ODT 10 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: DR REDDY'S LABORATORIES (PTY) LTD Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA DRA PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA FPRR: DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013	Registration number: 45/2.6.5/0325 Name of medicine: DRL OLANZAPINE ODT 5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 5,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: DR REDDY'S LABORATORIES (PTY) LTD Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA DRA PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA FPRR: DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013	Registration number: 45/2.6.5/0326 Name of medicine: REDILANZ ODT 5 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 5,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: DR REDDY'S LABORATORIES (PTY) LTD Manufacturer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA Packer: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA DRA PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA Laboratory: FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA FPRR: DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA Shelf-life: 24 months Date of registration: 19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2 6 5/0326	Registration number:	45/2 7/0374	Registration number:	45/2 7/0375
Name of medicine:	DRL OLANZAPINE ODT 10	Name of medicine:	ASPEN PARACETAMOL 1 g IV	Name of medicine:	PARASPEN 1 g
Dosage form:	TABLET	Dosage form:	SOLUTION FOR INFUSION	Dosage form:	SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg	Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: PARACETAMOL 1,0 g	Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: PARACETAMOL 1,0 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:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY	Manufacturer:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG/HESSEN, GERMANY
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA DRA PHARMACEUTICALS (PTY) LTD, CORPORATE PARK, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY CDM L'AVOISIER, LABORATOIRES CHAIX DU MARAIS, BLOIS, FRANCE	Packer:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG/HESSEN, GERMANY CDM L'AVOISIER, LABORATOIRES CHAIX ET DU MARAIS, BLOIS, FRANCE
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG, GERMANY CDM L'AVOISIER, LABORATOIRES CHAIX DU MARAIS, BLOIS, FRANCE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	FREZENIUS KABI DEUTSCHLAND GmbH, FRIEDBERG/HESSEN, GERMANY CDM L'AVOISIER, LABORATOIRES CHAIX ET DU MARAIS, BLOIS, FRANCE SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SOUTH WING, SANDTON, RSA	FPRR:	ASPEN PORT ELIZABETH LIMITED, KORSTON, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA	FPRR:	ASPEN PORT ELIZABETH LIMITED, KORSTON, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON, WILSONIA, EAST LONDON, RSA PHARMACARE LIMITED, WOODMEAD, SANDTON, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2/50412	Registration number:	45/34/0435	Registration number:	45/10/2/20475
Name of medicine:	VALPROATE BRIMPARM CR 200	Name of medicine:	ZOMABON	Name of medicine:	MONTELUKAST CHEW BIOTECH 4
Dosage form:	TABLET	Dosage form:	INFUSION	Dosage form:	CHEWABLE TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 133.2 mg VALPROIC ACID 58.0 mg	Active ingredients:	EACH 5.0 ml CONTAINS: ZOLEDRONIC ACID 4.0 mg	Active ingredients:	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4.0 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:	BRIMPARM SA (PTY) LTD	Applicant:	LASARA TRADERS (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY	Manufacturer:	B BRAUN MEDICAL SA, LOS OLIVARES, JAEN, SPAIN	Manufacturer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN
Packer:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY DRAGENOPHARM APOTHEKER PUSCHL GmbH, BERLIN, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	B BRAUN MEDICAL SA, LOS OLIVARES, JAEN, SPAIN SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN
Laboratory:	DRAGENOPHARM APOTHEKER PUSCHL GmbH & Co KG, TITTMONING, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: B BRAUN MEDICAL SA, LOS OLIVARES, JAEN, SPAIN COMBINO PHARM S.L., BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SPECPHARM HOLDINGS (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	Laboratory:	FPRC: LABORATORIOS LESVI S.L., BARCELONA, SPAIN LABORATORIOS MICRO-BIOS S.L., (PYROGENS AND MICROBIAL CONTAMINATION), BARCELONA, SPAIN BIO-CHIC (PYROGENS AND MICROBIAL CONTAMINATION), WARSAW, POLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA AFRIKA BIOPHARMA ANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	LASARA TRADERS (PTY) LTD, MORELETA PARK, PRETORIA, RSA	FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDESPARK, MIDRAND, RSA
Shelf-life:	24 months packed in (OPA)/PVC/Al Blister strips	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/10.2.2/0476	Registration number:	45/10.2.2/0477	Registration number:	45/7.1.3/0505
Name of medicine:	MONTELUKAST CHEW BIOTECH 5	Name of medicine:	MONTELUKAST BIOTECH 10	Name of medicine:	CO IRBESARTAN BRIMPARM 150/12,5
Dosage form:	CHEWABLE TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH CHEWABLE TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 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
Applicant:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BIOTECH LABORATORIES (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD
Manufacturer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN	Manufacturer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN	Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Packer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN	Packer:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN	Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Laboratory: FPRC:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN LABORATORIOS MICRO-BIOS S.L., (PYROGENS AND MICROBIAL CONTAMINATION), BARCELONA, SPAIN BIO-CHIC (PYROGENS AND MICROBIAL CONTAMINATION), WARSAW, POLAND CONSULTING CHEMICAL LABORATORIES, ATLASSVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	LABORATORIOS LESVI S.L., BARCELONA, SPAIN LABORATORIOS MICRO-BIOS S.L., (PYROGENS AND MICROBIAL CONTAMINATION), BARCELONA, SPAIN BIO-CHIC (PYROGENS AND MICROBIAL CONTAMINATION), WARSAW, POLAND CONSULTING CHEMICAL LABORATORIES, ATLASSVILLE, BOKSBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA	Laboratory: FPRC:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASSVILLE, BOKSBURG, RSA
FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPRR:	BIOTECH LABORATORIES (PTY) LTD, RANDJESPAK, MIDRAND, RSA	FPRR:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1.3/0506	Registration number:	45/7.1.3/0508	Registration number:	45/7.1.3/0509
Name of medicine:	CO IRBESARTAN BRIMPARM 300/12,5	Name of medicine:	CO IRTANEL 150/12,5	Name of medicine:	CO IRTANEL 300/12,5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 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:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD
Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN	Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN	Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN
Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN NOVAFARM MANIPULACIONES GENERALES S.A., BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN NOVAFARM MANIPULACIONES GENERALES S.A., BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN NOVAFARM MANIPULACIONES GENERALES S.A., BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRC:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRC:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRC:	BRIMPARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.1.3/0510	Registration number:	45/8.3/0539	Registration number:	45/8.3/0550
Name of medicine:	CO IRTANEL 300/25	Name of medicine:	IRON SUCROSE ZYDUS 20 mg	Name of medicine:	ZYPIRON 20
Dosage form:	TABLET	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH 1,0 ml CONTAINS: IRON SUCROSE EQUIVALENT TO ELEMENTAL IRON 20,0 mg	Active ingredients:	EACH 1,0 ml CONTAINS: IRON SUCROSE EQUIVALENT TO ELEMENTAL IRON 20,0 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:	BRIMPHARM SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD	Applicant:	ZYDUS HEALTHCARE SA (PTY) LTD
Manufacturer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN NOVAFARM MANIPULACIONES GENERALES S.A., BARCELONA, SPAIN DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	KERN PHARMA S.L., TERRASSA, BARCELONA, SPAIN CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	BRIMPHARM SA (PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA	FPRR:	ZYDUS CADILA HEALTHCARE LIMITED, MORAIYA, SANAND, AHMEDABAD, INDIA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.2.8/0888	Registration number:	47/20.2.8/0328	Registration number:	47/20.2.8/0328
Name of medicine:	MACLEODS LAMIVUDINE 150/STAVUDINE 30/NEVIRAPINE 200	Name of medicine:	TRIPLOCO	Name of medicine:	TRIVENZ
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMIVUDINE 150,0 mg STAVUDINE 30,0 mg NEVIRAPINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: EFVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFIVIR 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: EFVIRENZ 600,0 mg EMTRICITABINE 200,0 mg TENOFIVIR 300,0 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:	MACLEODS PHARMACEUTICALS SA (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Manufacturer:	HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA	Manufacturer:	HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Packer:	MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA	Packer:	HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA	Packer:	HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: MACLEODS PHARMACEUTICALS LTD, KACHIGAM, DAMAN, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SEDEK AGRICHEM, SILVERTONDALE, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA ADCOCK INGRAM HEALTHCARE (PTY) LTD WADEVILLE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: HETERO LABS LIMITED, UNIT V, JADCHERIA MANDAL, MAHABOOB NAGAR, ANDHRA PRADESH, INDIA ADCOCK INGRAM HEALTHCARE (PTY) LTD WADEVILLE, WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED (RESEARCH AND DEVELOPMENT), AEROTON, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013	Date of registration:	19 APRIL 2013

MRF 15

Registration number:	47/20.2.8/0607
Name of medicine:	EFAVIRENZ AUSTELL 600
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Packer:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA
Laboratory FPRC:	EMCURE PHARMACEUTICALS LIMITED, HINJWADI, PUNE, INDIA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, RANDBURG, RSA
FPRR:	CAMOX PHARMACEUTICALS (PTY) LTD, CROWN X3, JOHANNESBURG, RSA
Shelf-life:	36 months
Date of registration:	19 APRIL 2013

MRF 15		MRF 15		5	
Registration number:	09/21 9/21	Registration number:	A39/3.2/0645	Registration number:	41/20 1.2/0102
Name of medicine:	ZACTRAN	Name of medicine:	ASPEN PAMIDRONATE IV	Name of medicine:	SANDOZ CO-AMOXYCLAV 625
Dosage form:	INJECTION	Dosage form:	CONCENTRATE FOR INTRAVENOUS INFUSION	Dosage form:	DISPERSIBLE TABLET
Active ingredients:	EACH 1.0 ml CONTAINS: GAMITHROMYCIN 150.0 mg	Active ingredients:	EACH 1.0 ml CONTAINS: DISODIUM PAMIDRONATE 15.0 mg	Active ingredients:	EACH DISPERSIBLE TABLET CONTAINS: Amoxycillin trihydrate equivalent to 250.0 mg Clavulanic acid equivalent to Clavulanic acid 125.0 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:	MERIAL SOUTH AFRICA (PTY) LTD	Applicant:	PHARMACARE LIMITED	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	MERIAL SAS, TOULOUSE, CEDEX, FRANCE	Manufacturer:	WULFING PHARMA GmbH, GRONAU, GERMANY KORSTEN, GERMANY ABTSGMUND-INTERGRONINGEN, GERMANY HOLPACK VERPACKUNGSTECHNIK GmbH, SULZBACH-LAUFEN, GERMANY PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Manufacturer:	LEK PHARMACEUTICALS d.d. PREVALJE, SLOVENIA
Packer:	MERIAL SAS, TOULOUSE, CEDEX, FRANCE	Packer:	WULFING PHARMA GmbH, GRONAU, GERMANY HOLPACK VERPACKUNGSTECHNIK GmbH, ABTSGMUND-INTERGRONINGEN, GERMANY HOLPACK VERPACKUNGSTECHNIK GmbH, SULZBACH-LAUFEN, GERMANY PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Packer:	LEK PHARMACEUTICALS d.d. PREVALJE, SLOVENIA TECHNICON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	BIOINDUSTRIAL SERVICES cc, KEMPTON PARK, RSA	Laboratory: FPRC:	WULFING PHARMA GmbH, GRONAU, GERMANY HOLPACK VERPACKUNGSTECHNIK GmbH, ABTSGMUND-INTERGRONINGEN, GERMANY HOLPACK VERPACKUNGSTECHNIK GmbH, SULZBACH-LAUFEN, GERMANY PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA	Laboratory: FPRC:	LEK PHARMACEUTICALS d.d. PREVALJE, SLOVENIA LEK PHARMACEUTICALS d.d. LJUBLJANA, SLOVENIA NOVARTIS SA (PTY), SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA
FPRC:	MERIAL SOUTH AFRICA (PTY) LTD, MIDRAND, RSA	FPRC:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA	FPRC/FPRC:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	36 months	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15	MRF 15	MRF 15
Registration number: 41/20.1.2/0103 Name of medicine: SANDOZ CO-AMOXICYCLAV 1 000 Dosage form: DISPERSIBLE TABLET Active ingredients: EACH DISPERSIBLE TABLET CONTAINS: Amoxicillin trihydrate equivalent to 875,0 mg Amoxicillin Potassium clavulanate equivalent to Clavulanic acid 125,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SANDOZ SA (PTY) LTD Manufacturer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA Packer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA LEK PHARMACEUTICALS d.d., LJUBLJANA, SLOVENIA NOVARTIS SA (PTY), SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months Date of registration: 20 JUNE 2013	Registration number: 41/20.1.2/0104 Name of medicine: CURAM 625 Dosage form: DISPERSIBLE TABLET Active ingredients: EACH DISPERSIBLE TABLET CONTAINS: Amoxicillin trihydrate equivalent to 500,0 mg Amoxicillin Clavulanic acid 125,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SANDOZ SA (PTY) LTD Manufacturer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA Packer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA LEK PHARMACEUTICALS d.d., LJUBLJANA, SLOVENIA NOVARTIS SA (PTY), SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months Date of registration: 20 JUNE 2013	Registration number: 41/20.1.2/0105 Name of medicine: CURAM 1 000 Dosage form: DISPERSIBLE TABLET Active ingredients: EACH DISPERSIBLE TABLET CONTAINS: Amoxicillin trihydrate equivalent to 875,0 mg Amoxicillin Potassium clavulanate equivalent to Clavulanic acid 125,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: SANDOZ SA (PTY) LTD Manufacturer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA Packer: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: LEK PHARMACEUTICALS d.d., PREVALJE, SLOVENIA LEK PHARMACEUTICALS d.d., LJUBLJANA, SLOVENIA NOVARTIS SA (PTY), SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months Date of registration: 20 JUNE 2013

MRF 15		MRF 15		F 15	
Registration number:	41/15.1/0926	Registration number:	41/20.2/1114	Registration number:	42/20.1/0176
Name of medicine:	SPEC DOBUTAMINE 12.5 mg/ml	Name of medicine:	ADCO TERBINAFINE 250	Name of medicine:	AP MEROPENEM 1 g
Dosage form:	SOLUTION FOR INJECTION	Dosage form:	TABLET	Dosage form:	INJECTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: DOBUTAMINE 12.5 mg	Active ingredients:	TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250.0 mg	Active ingredients:	EACH VIAL CONTAINS: MEROPENEM TRIHYDRATE EQUIVALENT TO MEROPENEM ANHYDROUS 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:	SPECPHARM (PTY) LTD	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	PHARMACARE LIMITED
Manufacturer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY	Manufacturer:	LABORATORIOS LICONSA S.A., AZUQUECA de HENARES, GUADALAJARA, SPAIN	Manufacturer:	STRIDES ARCOLAB LIMITED (BETA LACTAM DIVISION), BILEKAHALLI, BANGALORE, INDIA
Packer:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY	Packer:	LABORATORIOS LICONSA S.A., AZUQUECA de HENARES, GUADALAJARA, SPAIN	Packer:	STRIDES ARCOLAB LIMITED (BETA LACTAM DIVISION), BILEKAHALLI, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA
Laboratory: FPRC:	HAMELN PHARMACEUTICALS, HAMELN, GERMANY	Laboratory: FPRC:	LABORATORIOS LICONSA S.A., AZUQUECA de HENARES, GUADALAJARA, SPAIN ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA	Laboratory: FPRC:	STRIDES ARCOLAB LIMITED (BETA LACTAM DIVISION), BILEKAHALLI, BANGALORE, INDIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA ASPEN PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA SABS COMMERCIAL (PTY) LTD, PHARMACEUTICAL CHEMISTRY LABORATORY, GROENKLOOF, PRETORIA, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	SPECPHARM (PTY) LTD, HALFWAY HOUSE, MIDRAND, RSA	FPRR:	ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND, RSA	FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH, RSA PHARMACARE EAST LONDON (PTY) LTD, WILSONIA, EAST LONDON, RSA PHARMACARE LTD, WOODMEAD, SANDTON, RSA
Shelf-life:	36 months at or below 25 °C (Product) 24 hours at 2-8 °C (Reconstituted product)	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

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MRF-15	MRF-15	MRF-15
Registration number: 42/20.1.1/0695 Name of medicine: CAPLIN 4 g/500 mg Dosage form: POWDER FOR SOLUTION FOR INFUSION Active ingredients: EACH VIAL CONTAINS: Piperacillin sodium equivalent to Piperacillin 4.0 g Tazobactam sodium equivalent to Tazobactam 500.0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: XIXIA PHARMACEUTICALS (PTY) LTD Manufacturer: LABORATORIO FARMACEUTICO C.T. S.r.l, SANREMO, ITALY Packer: LABORATORIO FARMACEUTICO C.T. S.r.l, SANREMO, ITALY Laboratory: FPRC: G.E.T. S.r.l, SANREMO, ITALY SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA PHARMA-Q (PTY) LTD, INDUSTRIA WEST, JOHANNESBURG, RSA FPRR: XIXIA PHARMACEUTICALS (PTY) LTD, MODDERFONTEIN, RSA Shelf-life: 24 months at or below 25 °C (Product) 24 hours at 2-8 °C (Reconstituted product) Date of registration: 20 JUNE 2013	Registration number: 42/5.7.1/0821 Name of medicine: CETICIT Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: MEDREICH SA (PTY) LTD Manufacturer: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA Packer: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA Laboratory: FPRC: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: MEDREICH SA (PTY) LTD, ROBERTSHAM, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 20 JUNE 2013	Registration number: 42/5.7.1/0822 Name of medicine: SENSAHIST Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: CETIRIZINE DIHYDROCHLORIDE 10,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: MEDREICH SA (PTY) LTD Manufacturer: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA Packer: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA Laboratory: FPRC: ADCOCK INGRAM LIMITED, UNIT IV, ANEKAL TALUK, BOMMASANDRA, BANGALORE, INDIA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA FPRR: MEDREICH SA (PTY) LTD, ROBERTSHAM, JOHANNESBURG, RSA Shelf-life: 36 months Date of registration: 20 JUNE 2013

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MRF 15		MRF 15		MRF 15	
Registration number:	42/21.12/1004	Registration number:	43/7.1.3/0289	Registration number:	43/7.1.3/0283
Name of medicine:	BREDEX 1 mg	Name of medicine:	ISART 75	Name of medicine:	ISART 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ANASTROZOLE 1,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 150,0 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:	AKACIA HEALTHCARE (PTY) LTD	Applicant:	ZYDUS HEALTHCARE (PTY) LTD	Applicant:	ZYDUS HEALTHCARE (PTY) LTD
Manufacturer:	REMEDICA LTD, LIMASSOL, CYPRUS	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Packer:	REMEDICA LTD, LIMASSOL, CYPRUS	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA
Laboratory:	FPRC: REMEDICA LTD, LIMASSOL, CYPRUS CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA CONSULTING MICROBIOLOGICAL LABORATORY, MOREHILL, BENONI SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT, GROENKLOOF, PRETORIA, RSA	Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory:	FPRC: ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRC:	AKACIA HEALTHCARE (PTY) LTD, ISANDO, RSA	FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		F 15	
Registration number:	43/7.1.3/0291	Registration number:	43/11.4.3/0696	Registration number:	43/11.4.3/0697
Name of medicine:	ISART 300	Name of medicine:	PANTOR 20	Name of medicine:	PANTOR 40
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300,0 mg	Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 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:	ZYDUS HEALTHCARE (PTY) LTD	Applicant:	TRINITY PHARMA (PTY) LTD	Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA	Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA
FPRR:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA, RSA	FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA, RSA
Shelf-life:	36 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.3/0863	Registration number:	43/7.1.3/0864	Registration number:	43/7.1.3/0867
Name of medicine:	SANDOZ LOSARTAN COMP 50/12,5 mg	Name of medicine:	SANDOZ LOSARTAN COMP 100/25 mg	Name of medicine:	LOS-ARB COMP 50/12,5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 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:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD	Applicant:	SANDOZ SA (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA	Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA	Manufacturer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA
Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) SPARTAN, KEMPTON PARK, RSA	Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) SPARTAN, KEMPTON PARK, RSA	Packer:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) SPARTAN, KEMPTON PARK, RSA
Laboratory: FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory: FPRC:	LEK PHARMACEUTICALS D.D, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA 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	FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/7.1.3/0868	Registration number:	43/21.12/0918	Registration number:	43/32.4/0919
Name of medicine:	LOS-ARB COMP 100/25 mg	Name of medicine:	FIRMAGON 80 mg	Name of medicine:	FIRMAGON SOLVENT
Dosage form:	TABLET	Dosage form:	POWDER FOR SUSPENSION FOR INJECTION	Dosage form:	SOLVENT FOR SUSPENSION FOR INJECTION
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Active ingredients:	EACH VIAL CONTAINS: DEGARELIX ACETATE EQUIVALENT TO DEGARELIX 80,0 mg	Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION 6,0 ml
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:	FERRING (PTY) LTD	Applicant:	FERRING (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS D.D., LJUBLJANA, SLOVENIA	Manufacturer:	RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY	Manufacturer:	HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	LEK PHARMACEUTICALS D.D., LJUBLJANA, SLOVENIA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA SANDOZ SA (PTY) SPARTAN, KEMPTON PARK, RSA	Packer:	RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY FERRING INTERNATIONAL CENTER SA, ST PREX, SWITZERLAND	Packer:	HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Laboratory:	FPRC: LEK PHARMACEUTICALS D.D., LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Laboratory:	FPRC: RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY FERRING GmbH, KIEL, GERMANY FERRING INTERNATIONAL CENTER SA, ST PREX, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	FERRING (PTY) LIMITED, CORPORATE PARK, IRENE, RSA	FPRR:	FERRING (PTY) LIMITED, CORPORATE PARK, IRENE, RSA
Shelf-life:	24 months	Shelf-life:	36 months	Shelf-life:	48 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15	Registration number: 43/21.12/0920 Name of medicine: FIRMAGON 120 mg Dosage form: POWDER FOR SUSPENSION FOR INJECTION Active ingredients: EACH VIAL CONTAINS: DEGARELIX ACETATE EQUIVALENT TO 120,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7 Applicant: FERRING (PTY) LTD Manufacturer: RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY Packer: RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY FERRING INTERNATIONAL CENTER SA, ST PREX, SWITZERLAND Laboratory, FPRC: RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM GERMANY FERRING GmbH, KIEL, GERMANY FERRING INTERNATIONAL CENTER SA, ST PREX, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA FPRR: FERRING (PTY) LIMITED, CORPORATE PARK, IRENE, RSA Shelf-life: 36 months Date of registration: 20 JUNE 2013
MRF 15	Registration number: 43/3.2/1158 Name of medicine: RISACTO 35 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: RISEDRONATE SODIUM 35,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY Packer: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Laboratory, FPRC: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY SANDOZ SA (PTY) LTD SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013
MRF 15	Registration number: 43/3.2/1159 Name of medicine: SANDOZ RISEDRONATE 35 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: RISEDRONATE SODIUM 35,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY Packer: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Laboratory, FPRC: SANDOZ IAC SANAYI ve TICARET A.S., ATATURK BULVARI, GEBZE-KOCAELI, TURKEY SANDOZ SA (PTY) LTD SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	43/2.5/1176	Registration number:	43/2.5/1177	Registration number:	43/2.5/1178
Name of medicine:	GABACOR 600	Name of medicine:	GABACOR 800	Name of medicine:	ACCORD GABAPENTIN 600
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 600,0 mg	Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 800,0 mg	Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 600,0 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:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	ACCORD HEALTHCARE (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, JOHANNESBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, JOHANNESBURG, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, JOHANNESBURG, RSA
FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPRR:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	4312 5/1179	Registration number:	44/7 1 3/0055	Registration number:	44/7 1 3/0056
Name of medicine:	ACCORD GABAPENTIN 800	Name of medicine:	VASPEC 75	Name of medicine:	VASPEC 150
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GABAPENTIN 800.0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 75.0 mg	Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 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:	ACCORD HEALTHCARE (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASPEC CONSULTING LABORATORIES, FERNDALE, JOHANNESBURG, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA	Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA
FPRC:	ACCORD HEALTHCARE (PTY) LTD, RIVONIA, JOHANNESBURG, RSA	FPRC:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, JOHANNESBURG, RSA	FPRC:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	447.1.30057	Registration number:	44/34/0269	Registration number:	44/34/0270
Name of medicine:	VASPEC 300	Name of medicine:	MEMATEX 5	Name of medicine:	MEMATEX 10
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IRBESARTAN 300.0 mg	Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 5.0 mg	Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 10.0 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:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Packer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA	Packer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA
Laboratory: FPRC:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR, MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Laboratory: FPRC:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA	Laboratory: FPRC:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA
FPRC:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, JOHANNESBURG, 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	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

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MRF 15		MRF 15		MRF 15	
Registration number:	44/34/0271	Registration number:	44/34/0272	Registration number:	44/34/0329
Name of medicine:	ARROW MEMANTINE 5	Name of medicine:	ARROW MEMANTINE 10	Name of medicine:	PARADOTE
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	CONCENTRATE FOR SOLUTION FOR INFUSION
Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 5,0 mg	Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: ACETYLCYSTEINE 200,0 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:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA	Manufacturer:	ROTEXMEDICA GmbH ARZNEIMITTELWERK, TRITTAU, GERMANY
Packer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) ROBBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) ROBBERTVILLE, FLORIDA, RSA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDUSTRIA, RSA	Packer:	ROTEXMEDICA GmbH ARZNEIMITTELWERK, TRITTAU, GERMANY
Laboratory: FPRC:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) ROBBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA	Laboratory: FPRC:	COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA TECHNIKON LABORATORIES (PTY) ROBBERTVILLE, FLORIDA, RSA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA	Laboratory: FPRC:	ROTEXMEDICA GmbH ARZNEIMITTELWERK, TRITTAU, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA EQUITY PHARMACEUTICALS (PTY) LTD, CORPORATE PARK IRENE, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15	MRF 15	MRF 15
Registration number: 44/11.4.3/0335 Name of medicine: NEXMEZOL 20 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Esomeprazole magnesium dihydrate equivalent to 20,0 mg Esomeprazole Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/11.4.3/0336 Name of medicine: NEXMEZOL 40 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Esomeprazole magnesium dihydrate equivalent to 40,0 mg Esomeprazole Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA FPRC/FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/11.4.3/0337 Name of medicine: SANDOZ ESOMEPRAZOLE 20 Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Esomeprazole magnesium dihydrate equivalent to 20,0 mg Esomeprazole Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: SANDOZ SA (PTY) LTD Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Laboratory: FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA FPRR: SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/11.4.3/0338	Registration number:	44/2.6.5/0572	Registration number:	44/2.6.5/0573
Name of medicine:	SANDOZ ESOMEPRAZOLE 40	Name of medicine:	LANAZYP 2,5	Name of medicine:	LANAZYP 5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Esomeprazole magnesium dihydrate equivalent to Esomeprazole 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 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, 8
Applicant:	SANDOZ SA (PTY) LTD	Applicant:	BRIMPHARM SA (PTY) LTD	Applicant:	BRIMPHARM SA (PTY) LTD
Manufacturer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY	Manufacturer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA	Manufacturer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	Packer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory: FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA SABS COMMERCIAL (PTY) LTD PHARMACEUTICAL CHEMISTRY DEPARTMENT; GROENKLOOF, PRETORIA, RSA	Laboratory: FPRC:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SWITZERLAND CONFARMA FRANCE S.A.R.L. HOMBURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SIEGFRIED LTD, ZOFINGEN, SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	SANDOZ SA (PTY) LTD, SPARTAN, KEMPTON PARK, RSA	FPRR:	BRIMPHARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	BRIMPHARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF15		MMRF 15	
Registration number:	44/2.6.5/0574	Registration number:	44/2.6.5/0575	Registration number:	44/2.6.5/0576
Name of medicine:	LANAZYP 10	Name of medicine:	OLANZAPINE BRIMPARM 2,5	Name of medicine:	OLANZAPINE BRIMPARM 5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 2,5 mg	Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 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, 8
Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD	Applicant:	BRIMPARM SA (PTY) LTD
Manufacturer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA	Manufacturer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA	Manufacturer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA
Packer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer:	SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory:	FPRC: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	BRIMPARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	BRIMPARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRR:	BRIMPARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15	MRF 15	MRF 15
Registration number: 44/2.6.5/0577	Registration number: 44/5.3/0942	Registration number: 44/5.3/0943
Name of medicine: OLANZAPINE BRIMPHARM 10	Name of medicine: NELOPT 5 mg TABLETS	Name of medicine: NELOPT 10 mg TABLETS
Dosage form: TABLET	Dosage form: TABLET	Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS: OLANZAPINE 10,0 mg	Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 5,0 mg	Active ingredients: EACH TABLET CONTAINS: DONEPEZIL HYDROCHLORIDE 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: BRIMPHARM SA (PTY) LTD	Applicant: AUROBINDO PHARMA (PTY) LTD	Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA	Manufacturer: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA	Packer: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory: FPRC: SIEGFRIED GENERICS (MALTA) LTD, HAL FAR, MALTA SIEGFRIED LTD, ZOFINGEN, SWITZERLAND CONFARMA FRANCE S.A.R.L., HOMBOURG, FRANCE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA	Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRC: BRIMPHARM S.A.(PTY) LTD, CLAREMONT, CAPE TOWN, RSA	FPRC: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRC: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)	Shelf-life: 24 months (Provisional)
Date of registration: 20 JUNE 2013	Date of registration: 20 JUNE 2013	Date of registration: 20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/5.3/0946	Registration number:	44/5.3/0947	Registration number:	44/5.4.1/0983
Name of medicine:	PRIFET 5 mg TABLETS	Name of medicine:	PRIFET 10 mg TABLETS	Name of medicine:	RESTAN PRAMIPEXOLE 0,125 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: Pranipexole dihydrochloride monohydrate 0,125 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:	ADCOCK INGRAM LIMITED
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	SYNTHON HISPANIA S.L. SAINT BOI de LIOREGAT, SPAIN
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	SYNTHON HISPANIA S.L. SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLL PHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	SYNTHON HISPANIA S.L. SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET- GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE) WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRC:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRC:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/5.4.1/0984	Registration number:	44/5.4.1/0985	Registration number:	44/5.4.1/0983
Name of medicine:	RESTAN PRAMIPEXOLE 0,25 mg	Name of medicine:	RESTAN PRAMIPEXOLE 0,5 mg	Name of medicine:	RESTAN PRAMIPEXOLE 1,0 mg
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 0,5 mg	Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN
Packer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID, SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID, SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID, SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY
Laboratory:	FPRC: SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory:	FPRC: SYNTHON HISPANIA S.L. SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/5.4.1/0987	Registration number:	44/5.4.1/0988	Registration number:	44/5.4.1/0989
Name of medicine:	PRAMIDAS 0,125 mg	Name of medicine:	PRAMIDAS 0,25 mg	Name of medicine:	PRAMIDAS 0,5 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,125 mg	Active ingredients:	EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,25 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN
Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY
Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET - GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET - GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET - GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15	MRF 15	MRF 15
Registration number: 44/5.4.1/0991 Name of medicine: ADCO PRAMIPEXOLE 0.125 mg Dosage form: TABLET Active ingredients: Each TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0.125 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/5.4.1/0992 Name of medicine: ADCO PRAMIPEXOLE 0.25 mg Dosage form: TABLET Active ingredients: Each TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0.25 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/5.4.1/0993 Name of medicine: ADCO PRAMIPEXOLE 0.5 mg Dosage form: TABLET Active ingredients: Each TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0.5 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L, SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRC: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/5.4.1/0994	Registration number:	44/5.4.1/0995	Registration number:	44/5.4.1/0996
Name of medicine:	ADCO PRAMIPEXOLE 1,0 mg	Name of medicine:	PROPAN PRAMIPEXOLE 0,125 mg	Name of medicine:	PROPAN PRAMIPEXOLE 0,25 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Pranipexole dihydrochloride monohydrate 1,0 mg	Active ingredients:	EACH TABLET CONTAINS: Pranipexole dihydrochloride monohydrate 0,125 mg	Active ingredients:	EACH TABLET CONTAINS: Pranipexole dihydrochloride monohydrate 0,25 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:	ADCOCK INGRAM LIMITED	Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN	Manufacturer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN
Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY	Packer:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A, TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY
Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET- GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET- GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA	Laboratory: FPRC:	SYNTHON HISPANIA S.L, SAINT BOI de LIOREGAT, SPAIN QUINTA ANALYTICA s.r.o. PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET- GROBENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA
FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA	FPRR:	ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

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MRF 15	MRF 15	MRF 15
Registration number: 44/5.4.1/1000 Name of medicine: COVAN PRAMIPEXOLE 0,25 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,25 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/5.4.1/1001 Name of medicine: COVAN PRAMIPEXOLE 0,5 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 0,5 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013	Registration number: 44/5.4.1/1002 Name of medicine: COVAN PRAMIPEXOLE 1,0 mg Dosage form: TABLET Active ingredients: EACH TABLET CONTAINS: Pramipexole dihydrochloride monohydrate 1,0 mg Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8 Applicant: ADCOCK INGRAM LIMITED Manufacturer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN Packer: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN ROTTENDORF PHARMA GmbH, ENNIGERLOH, GERMANY LABORATORIOS MEDICAMENTOS INTERNACIONALES S.A. TORREJON de ARDOZ, MADRID, SPAIN TOLLPHARMA, ALCOBENDAS, MADRID SPAIN ARTESAN PHARMA GmbH & Co KG, LUCHOW, WENDLAND, GERMANY Laboratory: FPRC: SYNTHON HISPANIA S.L., SAINT BOI de LOREGAT, SPAIN QUINTA ANALYTICA s.r.o, PRAGUE, CZECH REPUBLIC LABOR L + S AG, BAD BOCKLET-GROENBRACH, GERMANY SYNTHON BV, NIJMEGEN, THE NETHERLANDS ADCOCK INGRAM HEALTHCARE (PTY) LTD (WADEVILLE), WADEVILLE, GERMISTON, RSA ADCOCK INGRAM LIMITED RESEARCH & DEVELOPMENT, AEROTON, JOHANNESBURG, RSA FPRR: ADCOCK INGRAM LIMITED, ERAND GARDENS, MIDRAND, RSA Shelf-life: 24 months (Provisional) Date of registration: 20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/34/1013	Registration number:	44/34/1014	Registration number:	44/7.1.3/1069
Name of medicine:	MEMANTINE ZYDUS 10 mg	Name of medicine:	MEMOR 10 mg	Name of medicine:	VANICON 1,25 mg CAPSULES
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	CAPSULE
Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: MEMANTINE HYDROCHLORIDE 10,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 1,25 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:	ZYDUS HEALTHCARE (PTY)	Applicant:	ZYDUS HEALTHCARE (PTY)	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/1069	Registration number:	44/7.1.3/1070	Registration number:	44/7.1.3/1071
Name of medicine:	VANICON 1,25 mg CAPSULES	Name of medicine:	VANICON 2,5 mg CAPSULES	Name of medicine:	VANICON 5 mg CAPSULES
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 1,25 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 2,5 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 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, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/1072	Registration number:	44/7.1.3/1077	Registration number:	44/7.1.3/1078
Name of medicine:	VANICON 10 mg CAPSULES	Name of medicine:	RUMILE 1,25 mg CAPSULES	Name of medicine:	RUMILE 2,5 mg CAPSULES
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 10,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 1,25 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 2,5 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory:	FPRC: AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	44/7.1.3/1079	Registration number:	44/7.1.3/1080	Registration number:	45/3.1/0120
Name of medicine:	RUMILE 5 mg CAPSULES	Name of medicine:	RUMILE 10 mg CAPSULES	Name of medicine:	RARZULITE 500/20
Dosage form:	CAPSULE	Dosage form:	CAPSULE	Dosage form:	TABLET
Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 5,0 mg	Active ingredients:	EACH CAPSULE CONTAINS: RAMIPRIL 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: NAPROXEN 500,0 mg ESOMEPRAZOLE 20,0 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:	AUROBINDO PHARMA (PTY) LTD	Applicant:	AUROBINDO PHARMA (PTY) LTD	Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Manufacturer:	PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA
Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA	Packer:	PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN ASTRAZENECA AB, UMEA, SWEDEN ASTRAZENECA PHARMACEUTICALS LP, NEWARK, DELAWARE, USA AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, QUTHUBULLAPUR MANDAL, ANDHRA PRADESH, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA	Laboratory: FPRC:	PATHEON PHARMACEUTICALS INC, CINCINNATI, OHIO, USA ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE, SWEDEN AFRIKA BIOPHARMA MANUFACTURING (PTY) LTD, ALRODE, ALBERTON, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG, RSA	FPRR:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD, SUNNINGHILL, JOHANNESBURG, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	36 months (HDPE Bottles) 24 months (Aluminium Blisters)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0186	Registration number:	45/20.1.1/0187	Registration number:	45/20.1.1/0188
Name of medicine:	CIPLA AMIKACIN 100	Name of medicine:	CIPLA AMIKACIN 250	Name of medicine:	CIPLA AMIKACIN 500
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 100,0 mg	Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 250,0 mg	Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 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
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD	Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA LIFE SCIENCES (PTY) LTD, ROSENPARK, BELVILLE, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/20.1.1/0189	Registration number:	45/20.1.1/0190	Registration number:	45/20.1.1/0191
Name of medicine:	MEDPRO AMIKACIN 100	Name of medicine:	MEDPRO AMIKACIN 250	Name of medicine:	MEDPRO AMIKACIN 500
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 100,0 mg	Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 250,0 mg	Active ingredients:	EACH VIAL CONTAINS: AMIKACIN SULPHATE EQUIVALENT TO AMIKACIN 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
Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD	Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Manufacturer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Packer:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA	Laboratory: FPRC:	CIPLA LTD, UNIT IX, SALCETTE, GOA, INDIA
FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELVILLE, RSA	FPRR:	CIPLA MEDPRO (PTY) LTD, ROSENPARK, BELVILLE, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/2.9/0303	Registration number:	45/2.9/0304	Registration number:	45/7.5/0310
Name of medicine:	TRAMAZAC Co 37,5	Name of medicine:	TRAMADOL PARACETAMOL ZYDUS 37,5/325 mg	Name of medicine:	VUSOR 5
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 37,5 mg PARACETAMOL 325,0 mg	Active ingredients:	EACH TABLET CONTAINS: TRAMADOL HYDROCHLORIDE 37,5 mg PARACETAMOL 325,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 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:	ZYDUS HEALTHCARE (PTY) LTD	Applicant:	ZYDUS HEALTHCARE (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
Laboratory, FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory, FPRC:	ZYDUS CADILA HEALTHCARE LTD, MORAIYA, SANAND, AHMEDABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA	Laboratory, FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc, MISSISSAUGA, ONTARIO, CANADA SEDEK AGRICHEM, KAMEELDRIET- EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA
FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ZYDUS HEALTHCARE (PTY) LTD, VAN DER HOFF PARK, POTCHEFSTROOM, RSA	FPRC:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.5/0311	Registration number:	45/7.5/0312	Registration number:	45/7.5/0313
Name of medicine:	VUSOR 10	Name of medicine:	VUSOR 20	Name of medicine:	VUSOR 40
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 10,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 40,0 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:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA	Manufacturer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA
Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES LTD, ROBBERTVILLE, FLORIDA, RSA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBBERTVILLE, FLORIDA, RSA	Packer:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD LONGDALE, INDUSTRIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBBERTVILLE, FLORIDA, RSA
Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBBERTVILLE, FLORIDA, RSA	Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBBERTVILLE, FLORIDA, RSA	Laboratory: FPRC:	ARROW LABORATORIES LIMITED, CROYDON, VICTORIA, AUSTRALIA COBALT PHARMACEUTICALS Inc. MISSISSAUGA, ONTARIO, CANADA SEDEK AGRICHEM, KAMEELDRIFT-EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBBERTVILLE, FLORIDA, RSA
FPRR:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, 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:	24 months (Provisional)	Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

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MRF 15		MRF 15		MRF 15	
Registration number:	45/25/0468	Registration number:	45/26/0469	Registration number:	45/7-5/0527
Name of medicine:	OXACHEM 50	Name of medicine:	OXACHEM 100	Name of medicine:	VASTOR 10 mg
Dosage form:	INJECTION	Dosage form:	INJECTION	Dosage form:	TABLET
Active ingredients:	EACH VIAL CONTAINS: OXALIPLATIN 50,0 mg	Active ingredients:	EACH VIAL CONTAINS: OXALIPLATIN 100,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 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, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA	Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA DIVPHARM MANUFACTURING AND PACKAGING (PTY) LTD, LONGDALE, INDIA, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA SEDEK AGRICHEM, KAMEELDRIET- EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Laboratory: FPRC:	INTAS PHARMACEUTICALS LIMITED, SANAND, AHMEDABAD, GUJARAT, INDIA SEDEK AGRICHEM, KAMEELDRIET-EAST, PRETORIA, RSA CONSULTING CHEMICAL LABORATORIES (PTY) LTD, ATLASVILLE, BOKSBURG, RSA TECHNIKON LABORATORIES (PTY) LTD, ROBERTVILLE, FLORIDA, RSA	Laboratory: FPRC:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA PHARMASPEC LABORATORIES, FERNDAL, JOHANNESBURG, RSA ACORN PHARMACEUTICALS, NORTH RIDING, JOHANNESBURG, RSA
FPRC:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRC:	ARROW PHARMA SOUTH AFRICA (PTY) LTD, NORWICH CLOSE, SANDOWN, RSA	FPRC:	MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months	Shelf-life:	24 months	Shelf-life:	24 months (provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/7.5/0528	Registration number:	45/7.5/0529	Registration number:	45/7.5/0530
Name of medicine:	VASTOR 20 mg	Name of medicine:	VASTOR 40 mg	Name of medicine:	VASTOR 80 mg
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 20,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 40,0 mg	Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 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:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD	Applicant:	MYLAN (PTY) LTD
Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA	Manufacturer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA	Packer:	MATRIX LABORATORIES LTD, SINNAR, NASHIK, MAHARASHTRA, INDIA
Laboratory:	FPRC:	Laboratory:	FPRC:	Laboratory:	FPRC
					CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
					PHARMASPEC LABORATORIES, FERNDAL, JOHANNESBURG, RSA
					ACORN PHARMACEUTICALS, NORTH RIDING, JOHANNESBURG, RSA
					ACORN PHARMACEUTICALS, NORTH RIDING, JOHANNESBURG, RSA
					MYLAN (PTY) LTD, MODDERFONTEIN, RSA
					MYLAN (PTY) LTD, MODDERFONTEIN, RSA
Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)	Shelf-life:	24 months (provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	45/11.4.3/0592	Registration number:	45/11.4.3/0593	Registration number:	45/2.7/1018
Name of medicine:	PENTONZ OTC	Name of medicine:	DRL PANTOPRAZOLE OTC 20 mg	Name of medicine:	DOLIPRANE 500
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20.0 mg	Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 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
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	DR REDDY'S LABORATORIES (PTY) LTD	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Manufacturer:	SANOFI WINTHROP INDUSTRIE, EDOUARD BRANLY, FRANCE
Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Packer:	DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Packer:	SANOFI WINTHROP INDUSTRIE, EDOUARD BRANLY, FRANCE
Laboratory:	FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Laboratory:	FPRC: DR REDDY'S LABORATORIES LIMITED, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA	Laboratory:	FPRC: SANOFI WINTHROP INDUSTRIE, EDOUARD BRANLY, FRANCE
FPR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, JOHANNESBURG, RSA	FPR:	DR REDDY'S LABORATORIES (PTY) LTD, THE PLACE, SANDTON, JOHANNESBURG, RSA	FPR:	WINTHROP PHARMACEUTICALS, MIDRAND, JOHANNESBURG, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15	
Registration number:	45/2.7/1019	Registration number:	46/20.2.8/0018
Name of medicine:	DOLIPRANE 1 000	Name of medicine:	HETFAZ 600
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PARACETAMOL 1 000,0 mg	Active ingredients:	EACH TABLET CONTAINS: EFAVIRENZ 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD	Applicant:	HETERO DRUGS SA
Manufacturer:	SANOFI WINTHROP INDUSTRIE, EDOUARD BRANLY, FRANCE	Manufacturer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	SANOFI WINTHROP INDUSTRIE, EDOUARD BRANLY, FRANCE	Packer:	HETERO DRUGS LIMITED, UNIT III, JEEDIMETLA, HYDERABAD, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory:	FPRC:	Laboratory:	FPRC:
FPRC:	WINTHROP PHARMACEUTICALS, MIDRAND, JOHANNESBURG, RSA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA, RSA	FPRC:	HETERO DRUGS SA, JEAN PARK CHAMBERS, CENTURION, RSA
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

Registration number:	46/30.1/0447	Registration number:	46/30.1/0447
Name of medicine:	HEXAXIM	Name of medicine:	HEXAXIM
Dosage form:	SUSPENSION FOR INJECTION	Dosage form:	SUSPENSION FOR INJECTION
Active ingredients:	EACH 0,5 ml DOSE CONTAINS: Diphtheria toxoid $\geq 20,0$ IU Tetanus toxoid $\geq 40,0$ IU Hepatitis b surface antigen 10,0 µg Haemophilus influenza type b 12,0 µg Bordetella Pertussis antigens: Pertussis Toxoid 25,0 µg Filamentous Haemagglutinin 25,0 µg Poliovirus virus (Inactivated) Type 1 (Mahoney) 40 D antigen units Type 2 (MEF-1) 8 D antigen units Type 3 (Saukett) 32 D antigen units	Active ingredients:	EACH 0,5 ml DOSE CONTAINS: Diphtheria toxoid $\geq 20,0$ IU Tetanus toxoid $\geq 40,0$ IU Hepatitis b surface antigen 10,0 µg Haemophilus influenza type b 12,0 µg Bordetella Pertussis antigens: Pertussis Toxoid 25,0 µg Filamentous Haemagglutinin 25,0 µg Poliovirus virus (Inactivated) Type 1 (Mahoney) 40 D antigen units Type 2 (MEF-1) 8 D antigen units Type 3 (Saukett) 32 D antigen units
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD	Applicant:	SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE GRUPPO LEPETIT S.R.L., ANAGNI, ITALY	Manufacturer:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE GRUPPO LEPETIT S.R.L., ANAGNI, ITALY
Packer:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE GRUPPO LEPETIT S.R.L., ANAGNI, ITALY THE BIOVAC INSTITUTE, PINELANDS, CAPE TOWN, RSA	Packer:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE GRUPPO LEPETIT S.R.L., ANAGNI, ITALY THE BIOVAC INSTITUTE, PINELANDS, CAPE TOWN, RSA
Laboratory:	FPRC	Laboratory:	FPRC
FPRC:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE	FPRC:	SANOFI PASTEUR MARCY I'ETOILE, MARCY I'ETOILE, FRANCE SANOFI PASTEUR VAL de REUIL (VDR), VAL de REUIL, FRANCE
Shelf-life:	36 months (2-8 °C)	Shelf-life:	36 months (2-8 °C)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15		MRF 15		MRF 15	
Registration number:	46/20.2.8/0850	Registration number:	46/20.2.8/0851	Registration number:	47/20.2.8/0035
Name of medicine:	PREZISTA 75 mg	Name of medicine:	PREZISTA 150 mg	Name of medicine:	ATRESLAWIN
Dosage form:	TABLET	Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DARUNAVIR 75,0 mg	Active ingredients:	EACH TABLET CONTAINS: DARUNAVIR 150,0 mg	Active ingredients:	EACH TABLET CONTAINS: Efavirenz 600,0 mg Emtricitabine 200,0 mg Tenofovir disoproxil fumarate 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, 8
Applicant:	PHARMACARE LIMITED	Applicant:	PHARMACARE LIMITED	Applicant:	WINTHROP PHARMACEUTICALS (PTY) LTD
Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA	Manufacturer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA	Manufacturer:	HETERO DRUGS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOONAGAR, ANDHRA PRADESH, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Packer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA JANSSEN CILAG SpA, LATINA, ITALY	Packer:	JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA JANSSEN CILAG SpA, LATINA, ITALY	Packer:	HETERO DRUGS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOONAGAR, ANDHRA PRADESH, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
Laboratory:	FPRC: JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA	Laboratory:	FPRC: JANSSEN ORTHO LLC, GURABO, PUERTO RICO, USA ASPEN PORT ELIZABETH (PTY) LTD, KORSTEN, PORT ELIZABETH, RSA	Laboratory:	FPRC: HETERO DRUGS LIMITED, UNIT V, JADCHERLA MANDAL, MAHABOONAGAR, ANDHRA PRADESH, INDIA WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON, RSA	FPRR:	WINTHROP PHARMACEUTICALS (PTY) LTD, WALTLOO, PRETORIA, RSA WINTHROP PHARMACEUTICALS (PTY) LTD, MIDRAND, RSA
Shelf-life:	36 months	Shelf-life:	36 months	Shelf-life:	24 months (Provisional)
Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013	Date of registration:	20 JUNE 2013

MRF 15

Registration number:	47/20.2.8/00504
Name of medicine:	CITENVIR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: Efavirenz 600,0 mg Emtricitabine 200,0 mg Tenofovir disoproxil fumarate 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	NOVAGEN PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LIMITED, UNIT VII, JADCHERLA MANDAL, MAHABOONNAGAR DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LIMITED, UNIT VII, JADCHERLA MANDAL, MAHABOONNAGAR DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LIMITED, UNIT VII, JADCHERLA MANDAL, MAHABOONNAGAR DISTRICT, ANDHRA PRADESH, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA KHULLEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND, RSA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG, RSA
FPRR:	NOVAGEN PHARMA (PTY) LTD, IRENE, PRETORIA, RSA
Shelf-life:	24 months
Date of registration:	20 JUNE 2013

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