REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

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CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1105 OF 2009

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

KENNISGEWING 1105 VAN 2009

MEDISYNEBEHEERRAAD

VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965)

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huidige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 25 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in the voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goekgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening met tussenpose soos deur die Raad bepaal, rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies na goeddunke van die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die produk mag slegs aan die beroepe geadverteer word.
8. Die toegekende voorlopige rakleeftyd moet bevestig word met stabiliteitsdata volgens die Stabiliteitsriglyn op die eerste twee produksielotte (bekende aktiewe bestanddele), of eerste drie produksielotte (nuwe chemiese entiteite), wat die volle rakleeftydperiode dek. Stabiliteitstoetse wat op proeflotte ingedien is, moet ook voltooi word en die verslae ingedien word. Die stabiliteitsverslag moet binne ses maande na voltooiing van die stabiliteitsproef ingedien word. Die Raad moet egter onmiddellik in kennis gestel word indien enige parameter 'n betekenisvolle verandering of buite-spesifikasieresultaat tydens die stabiliteitsproef lewer.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemarking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vullot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15

Registration number:		A05/11.5/08
Name of medicine:		GASTROGARD
Dosage form:		PASTE
Active ingredients:		EACH SYRINGE CONTAINS: OMEPRAZOLE 2,28 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		MERIAL SOUTH AFRICA (PTY) LTD
Manufacturer:		MERCK SHARP & DOHME, BARCENOLETA, PUERTO RICO
Packer:		MERCK SHARP & DOHME, BARCENOLETA, PUERTO RICO
Laboratory:	FPRC:	BIOINDUSTRIAL SERVICES, KEMPTON PARK
	FPRR:	MERIAL S.A., HALFWAY HOUSE
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		A38/20.1.1/0406
Name of medicine:		ORELOX 200
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFPODOXIME PROXETIL EQUIVALENT TO CEFPODOXIME 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD
Manufacturer:		AVENTIS INTERCONTINENTAL, COMPIEGNE, FRANCE
Packer:		AVENTIS INTERCONTINENTAL, COMPIEGNE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	AVENTIS INTERCONTINENTAL, COMPIEGNE, FRANCE WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRR:	SANOFI-AVENTIS SA, MIDRAND, SA WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:		36 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	A39/7.1.3/0580
Name of medicine:	RENICARD 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM SA (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, GHAZIABAD, INDIA
Packer:	UNICHEM LABORATORIES LTD, GHAZIABAD, INDIA
Laboratory: FPRC:	UNICHEM LABORATORIES LTD, GHAZIABAD, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA
FPRR:	UNICHEM SA, NOORDBRUG, POTCHEFSTROOM
Shelf-life:	36 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/21.8.2/0112
Name of medicine:	ESTALIS SEQUI PLUS 50/140
Dosage form:	TRANSDERMAL PATCH
Active ingredients:	EACH PACK CONTAINS: 4 PHASE I PATCHES EACH CONTAINING OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 4,33 mg 4 PHASE II PATCHES EACH CONTAINING OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,620 mg NORETHISTERONE ACETATE 2,70 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA
Packer:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/21.8.2/0113
Name of medicine:	ESTALIS SEQUI PLUS 50/250
Dosage form:	TRANSDERMAL PATCH
Active ingredients:	EACH PACK CONTAINS: 4 PHASE I PATCHES EACH CONTAINING OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 4,33 mg 4 PHASE II PATCHES EACH CONTAINING OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,512 mg NORETHISTERONE ACETATE 4,80 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	NOVARTIS SOUTH AFRICA (PTY) LTD
Manufacturer:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA
Packer:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA NOVARTIS SA, SPARTAN, KEMPTON PARK
Laboratory: FPRC:	NOVEN PHARMACEUTICALS INC, MIAMI, FLORIDA, USA NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	NOVARTIS SA, SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/28/0210
Name of medicine:	ENTERO VU
Dosage form:	POWDER
Active ingredients:	EACH 100,0 g POUCH CONTAINS: BARIUM SULPHATE 81,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AXIM PHARMACEUTICALS (PTY) LTD
Manufacturer:	E-Z-EM INC, WESTBURY, NEW YORK
Packer:	E-Z-EM INC, WESTBURY, NEW YORK
Laboratory: FPRC:	E-Z-EM INC, WESTBURY, NEW YORK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	AXIM PHARMACEUTICALS, MIDRAND, RSA
Shelf-life:	36 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		A40/18.8/0354
Name of medicine:		YASMINELLE
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,02 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		SCHERING GmbH & Co, WEIMAR, GERMANY
Packer:		BAYER SCHERING PHARMA AG, BERLIN, GERMANY
Laboratory:	FPRC:	SCHERING GmbH & Co, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY SOUTH AFRICAN BUREUA OF STANDARDS,GROENKLOOF, PRETORIA
	FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:		60 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		A40/20.1.1/0368
Name of medicine:		BIOTECH CIPROFLOXACIN 250
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BIOTECH LABORATORIES (PTY) LTD
Manufacturer:		UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:		UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING,LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BIOTECH LABORATORIES, MIDRAND
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	A40/20.1.1/0369
Name of medicine:	BIOTECH CIPROFLOXACIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR	BIOTECH LABORATORIES, MIDRAND
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/20.1.1/0370
Name of medicine:	BIOTECH CIPROFLOXACIN 750
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 750,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	BIOTECH LABORATORIES, MIDRAND
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/20.1.1/0371
Name of medicine:	BIOFLOXX 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN **250,0 mg**
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR	BIOTECH LABORATORIES, MIDRAND
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/20.1.1/0372
Name of medicine:	BIOFLOXX 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOTECH LABORATORIES (PTY) LTD
Manufacturer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR	BIOTECH LABORATORIES, MIDRAND
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		A40/20.1.1/0373
Name of medicine:		BIOFLOXX 750
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO CIPROFLOXACIN 750,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BIOTECH LABORATORIES (PTY) LTD
Manufacturer:		UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
Packer:		UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	BIOTECH LABORATORIES, MIDRAND
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		A40/11.10/0481
Name of medicine:		GAVISCON COOLMINT LIQUID
Dosage form:		SUSPENSION
Active ingredients:		EACH 10,0 ml SUSPENSION CONTAINS: SODIUM ALGINATE 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		RECKITT BENCKISER PHARMACEUTICALS (PTY) LTD
Manufacturer:		RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UK
Packer:		RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UK DR REDDY'S LABORATORIES (UK) LTD, BEVERLY, EAST YORKSHIRE, UK PHARMAPACK UK LTD, WIRRAL, MERSEYSIDE, UK
Laboratory:	FPRC:	RECKITT BENCKISER HEALTHCARE (UK) LTD, HULL, EAST YORKSHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
	FPRC/FPRR:	RECKITT BENCKISER PHARMACEUTICALS, ELANDSFONTEIN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		A40/13.4.1/0666
Name of medicine:		MOMETAGEN 0,1 %
Dosage form:		CREAM
Active ingredients:		EACH 1,0 g CREAM CONTAINS: MOMETASONE FUROATE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		MERCK GENERICS RSA (PTY) LTD
Manufacturer:		PACIFIC PHARMACEUTICALS, MT WELLINGTON, AUCKLAND, NEW ZEALAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:		PACIFIC PHARMACEUTICALS, MT WELLINGTON, AUCKLAND, NEW ZEALAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory::	FPRC	PACIFIC PHARMACEUTICALS, MT WELLINGTON, AUCKLAND, NEW ZEALAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR	MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	A40/18.8/0693
Name of medicine:	ORALCON
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVONORGESTREL ..... 0,15 mg ETHINYL ESTRADIOL ..... 0,03 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA
Packer:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA
Laboratory: FPRC:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WETS UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:	36 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/18.8/0743
Name of medicine:	TRIGESTREL
Dosage form:	TABLET
Active ingredients:	EACH PACK CONTAINS: Six light brown tablets each containing: LEVONORGESTREL ..... 50,0 ug ETHINYL ESTRADIOL ..... 30,0 ug Five white tablets each containing: LEVONORGESTREL ..... 75,0 ug ETHINYL ESTRADIOL ..... 40,0 ug Ten yellow tablets each containing: LEVONORGESTREL ..... 125,0 ug ETHINYL ESTRADIOL ..... 30,0 ug Seven inert tablets.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA
Packer:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA
Laboratory: FPRC:	FAMY CARE LTD, UMBERGAON, VALSAD DISTRICT, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WETS UNIVERSITY, POTCHEFSTROOM
FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/18.8/0747
Name of medicine:	HY-AN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVONORGESTREL 0,03 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	FAMY CARE LTD, VALSAD DISTRICT, GUJARAT, INDIA
Packer:	FAMY CARE LTD, VALSAD DISTRICT, GUJARAT, INDIA
Laboratory: FPRC:	FAMY CARE LTD, VALSAD DISTRICT, GUJARAT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:	36 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	A40/20.2.8/0777
Name of medicine:	SONKE-ABACAVIR 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA
Laboratory: FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, DIST. SIRMOUR, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	RANBAXY (S.A.), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	41/20.1.1/0043
Name of medicine:	AUROPROZIL 250 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CEFPROZIL MONOHYDRATE EQUIVALENT TO CEFPROZIL 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		41/20.1.1/0044
Name of medicine:		AUROPROZIL 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFPROZIL MONOHYDRATE EQUIVALENT TO CEFPROZIL 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/25.2/0060
Name of medicine:		SMOFlipid 20 %
Dosage form:		INFUSION
Active ingredients:		EACH 1000,0 ml SUSPENSION CONTAINS: SOY OIL 60,0 g OLIVE OIL 50,0 g FISH OIL 30,0 g MEDIUM CHAIN TRIGLYCERIDES 60,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6
Applicant:		FRESENIUS KABI SOUTH AFRICA (PTY) LTD
Manufacturer:		FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, UPPSALA, SWEDEN
Packer:		FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, UPPSALA, SWEDEN
Laboratory:	FPRC:	FRESENIUS KABI AUSTRIA GmbH, GRAZ, AUSTRIA FRESENIUS KABI AB, UPPSALA, SWEDEN KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND BODENE t/a INTRAMED, KORSTEN, PORT ELIZABETH
	FPRR:	FRESENIUS KABI, HALFWAY HOUSE, RSA
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/20.2.2/0107
Name of medicine:		GULF FLUCONAZOLE 200
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: FLUCONAZOLE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK SWIFT MICRO LABORATORIES, CONSTANTIA, MIDRAND
	FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMB, KZN
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/20.2.2/0124
Name of medicine:		GULF FLUCONAZOLE 150
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: FLUCONAZOLE 150,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK SWIFT MICRO LABORATORIES, CONSTANTIA, MIDRAND
	FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMB, KZN
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/11.3/0153
Name of medicine:		GLENMARK-SIBUTRAMINE CAPSULES 15 mg
Dosage form:		CAPSULES
Active ingredients:		EACH CAPSULE CONTAINS: SIBUTRAMINE HYDROCHLORIDE MONOHYDRATE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/7.1.3/0175
Name of medicine:		GLENMARK-PERINDOPRIL TABLETS 4 mg
Dosage form:		TABLETS
Active ingredients:		EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/11.3/0180
Name of medicine:		GLENMARK-SIBUTRAMINE CAPSULES 10 mg
Dosage form:		CAPSULES
Active ingredients:		EACH CAPSULE CONTAINS: SIBUTRAMINE HYDROCHLORIDE MONOHYDRATE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		BOUWER BARTLETT (PTY) LTD
Manufacturer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Packer:		GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
Laboratory:	FPRC:	GLENMARK PHARMACEUTICALS LTD, BARDEZ, GOA, INDIA
	FPRR:	BOUWER BARTLETT, VORNA VALLEY, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/20.2.2/0240
Name of medicine:		GULF FLUCONAZOLE 50
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: FLUCONAZOLE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		GULF DRUG COMPANY (PTY) LTD
Manufacturer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Packer:		ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA
Laboratory:	FPRC:	ALEMBIC LTD, TAL-HALOL, DISTRICT PANCHMAHALS, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA CONSULTING MICROBIOLOGICAL LABORATORY, MOREWILL, BEYERSPARK SWIFT MICRO LABORATORIES, CONSTANTIA, MIDRAND
	FPRR:	GULF DRUG COMPANY, MOUNT EDGECOMB, KZN
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	41/20.2.8/0248
Name of medicine:	AURO-ABACAVIR TABLETS 300 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	41/21.1/0362
Name of medicine:	INSULIN GLARGINE-WINTHROP
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: INSULIN GLARGINE 3,64 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory: FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY
FPRC/FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
FPRR:	SANOFI-SYNTHELABO, MIDRAND, RSA
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		41/21.1/0363
Name of medicine:		INSULIN GLARGINE-SANOFI-AVENTIS
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: INSULIN GLARGINE 3,64 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:		SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY
Packer:		SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Laboratory:	FPRC:	SANOFI-AVENTIS DEUTSCHLAND GmbH, FRANKFURT, GERMANY
	FPRR:	WINTHROP PHARMACEUTICALS, WALTLOO, PRETORIA
Shelf-life:		SANOFI-SYNTHELABO, MIDRAND, RSA
Date of registration:		24 months 12 JUNE 2009

MRF 15

Registration number:		41/20.2.8/0386
Name of medicine:		AURO-ABACAVIR ORAL SOLUTION 20 mg/ml
Dosage form:		SOLUTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: ABACAVIR SULPHATE EQUIVALENT TO ABACAVIR 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT III, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/0397
Name of medicine:		GRANICIP 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VERNA SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/0398
Name of medicine:		GRANICIP 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA MEDPRO (PTY) LTD
Manufacturer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VERNA SALCETTE, GOA, INDIA
	FPRR:	CIPLA MEDPRO, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/0399
Name of medicine:		CIPLA GRANISETRON 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VERNA SALCETTE, GOA, INDIA
	FPRR	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/0400
Name of medicine:		CIPLA GRANISETRON 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Packer:		CIPLA LTD, VERNA SALCETTE, GOA, INDIA
Laboratory:	FPRC:	CIPLA LTD, VERNA SALCETTE, GOA, INDIA
	FPRR:	CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/8.4/0602
Name of medicine:		VITAHES
Dosage form:		INFUSION SOLUTION
Active ingredients:		EACH 1 000 ml SOLUTION CONTAINS: HYDROXYETHYL STARCH 130/0,42 60.0 g SODIUM CHLORIDE 9,0 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		SERUMWERK BERNBURG AG, BERNBURG, GERMANY
Packer:		SERUMWERK BERNBURG AG, BERNBURG, GERMANY
Laboratory:	FPRC:	SERUMWERK BERNBURG AG, BERNBURG, GERMANY ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, R.S.A.
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, S.A
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/8.4/0603
Name of medicine:		VITAFUSAL
Dosage form:		INFUSION SOLUTION
Active ingredients:		EACH 1 000 ml SOLUTION CONTAINS: HYDROXYETHYL STARCH 130/0,42 60,0 g SODIUM CHLORIDE 6,0 g POTASSIUM CHLORIDE 0,4 g CALCIUM CHLORIDE DIHYDRATE 0,134 g MAGNESIUM CHLORIDE HEXAHYDRATE 0,2 g SODIUM ACETATE TRIHYDRATE 3,7 g
Conditions of registration:		1, 2, 3, 4, 5, 6, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		SERUMWERK BERNBURG AG, BERNBURG, GERMANY
Packer:		SERUMWERK BERNBURG AG, BERNBURG, GERMANY
Laboratory:	FPRC:	SERUMWERK BERNBURG AG, BERNBURG, GERMANY ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, R.S.A
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, S.A
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/2.5/0705
Name of medicine:		TRINITY LAMOTRIGINE 25
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		TRINITY PHARMA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA
Packer:		TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/2.5/0706
Name of medicine:		TRINITY LAMOTRIGINE 50
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LAMOTRIGINE 50,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		TRINITY PHARMA (PTY) LTD
Manufacturer:		TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA
Packer:		TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	41/2.5/0707
Name of medicine:	TRINITY LAMOTRIGINE 100
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	41/2.5/0708
Name of medicine:	TRINITY LAMOTRIGINE 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	TRINITY PHARMA (PTY) LTD
Manufacturer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA
Packer:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory: FPRC:	TORRENT PHARMACEUTICALS LTD, INDRAD, MEHSANA DISTRICT, INDIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	TRINITY PHARMA, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		A40/21.8.2/0842
Name of medicine:		YAZ
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,02 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		BAYER (PTY) LTD
Manufacturer:		SCHERING GmbH & Co, WEIMAR, GERMANY
Packer:		SCHERING GmbH & Co, WEIMAR, GERMANY
Laboratory:	FPRC:	SCHERING GmbH & Co, WEIMAR, GERMANY BAYER SCHERING PHARMA AG, BERLIN, GERMANY SOUTH AFRICAN BUREUA OF STANDARDS,GROENKLOOF, PRETORIA
	FPRR:	BAYER, ISANDO, KEMPTON PARK
Shelf-life:		60 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/21.5.1/0968
Name of medicine:		AVAMYS
Dosage form:		SUSPENSION
Active ingredients:		EACH SPRAY CONTAINS: FLUTICASONE FUROATE 27,5 ug
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:		GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK
Packer:		GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory:	FPRC:	GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK
	FPRC/FPRR:	GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	41/7.1.3/1070
Name of medicine:	NATRAZONE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	41/7.1.3/1071
Name of medicine:	NATRAZONE 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SPECPHARM (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory: FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		41/7.1.3/1072
Name of medicine:		NATRAZONE 100
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/7.1.3/1073
Name of medicine:		NATRAZONE 12,5
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LOSARTAN POTASSIUM 12,5 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		SPECPHARM (PTY) LTD
Manufacturer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:		SPECIFAR S.A., VARVARA, ATHENS, GREECE SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:	FPRC:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
	FPRR:	SPECPHARM, HALFWAY HOUSE, MIDRAND
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/1079
Name of medicine:		ADCO-GRANISETRON 1 mg/1 ml
Dosage form:		INJECTION
Active ingredients:		EACH 1,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/5.7.2/1080
Name of medicine:		ADCO-GRANISETRON 3 mg/3 ml
Dosage form:		INJECTION
Active ingredients:		EACH 3,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer:		PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	PHARMA-Q, INDUSTRIA, JOHANNESBURG
	FPRR:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0204
Name of medicine:		AURO-CEFALEXIN TABLETS 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALEXIN 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0205
Name of medicine:		AURO-CEFALEXIN TABLETS 750 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFALEXIN MONOHYDRATE EQUIVALENT TO CEFALEXIN 750,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0509
Name of medicine:		ASPEN LEVOFLOXACIN 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0510
Name of medicine:		ASPEN LEVOFLOXACIN 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		PHARMACARE LIMITED
Manufacturer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:		ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:		PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:		24 months (Provisional) 12 JUNE 2009

MRF 15

Registration number:		42/26/0528
Name of medicine:		ASPEN EPIRUBICIN 10 mg/5 ml
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
	FPRR	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/26/0529
Name of medicine:		ASPEN EPIRUBICIN 20 mg/10 ml
Dosage form:		INJECTION
Active ingredients:		EACH 10,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:		PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:		24 months 12 JUNE 2009

MRF 15

Registration number:	42/26/0530
Name of medicine:	ASPEN EPIRUBICIN 50 mg/25 ml
Dosage form:	INJECTION
Active ingredients:	EACH 25,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:	24 months 12 JUNE 2009

MRF 15

Registration number:	42/26/0531
Name of medicine:	ASPEN EPIRUBICIN 100 mg/50 ml
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:	24 months 12 JUNE 2009

MRF 15

Registration number:		42/26/0532
Name of medicine:		ASPEN EPIRUBICIN 200 mg/100 ml
Dosage form:		INJECTION
Active ingredients:		EACH 100,0 ml SOLUTION CONTAINS: EPIRUBICIN HYDROCHLORIDE 200,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		PHARMACARE LIMITED
Manufacturer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA
Packer:		S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:	FPRC:	S.C. SINDAN-PHARMA S.R.L., BUCHAREST, ROMANIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:		PHARMACARE LTD, WOODMEAD, SANDTON
Date of registration:		24 months 12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0601
Name of medicine:		AURO CEFOTAXIME 250 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 250,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	42/20.1.1/0602
Name of medicine:	AURO CEFOTAXIME 500 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRC/FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	42/20.1.1/0603
Name of medicine:	AURO CEFOTAXIME 1 000 mg
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1 000,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory: FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
FPRC/FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		42/20.1.1/0604
Name of medicine:		AURO CEFOTAXIME 2 000 mg
Dosage form:		INJECTION
Active ingredients:		EACH VIAL CONTAINS: CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 2 000,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		AUROBINDO PHARMA (PTY) LTD
Manufacturer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Packer:		AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC:	AUROBINDO PHARMA LTD, UNIT VI, PATANCHERU MANDAL, MEDAK DISTRICT, ANDHRA PRADESH, INDIA
	FPRC/FPRR:	AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/11.3/0628
Name of medicine:		RAN-SIBUTRAMINE 10
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: SIBUTRAMINE HYDROCHLORIDE MONOHYDRATE 10,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (S.A.), CENTURION
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/11.3/0629
Name of medicine:		RAN-SIBUTRAMINE 15
Dosage form:		CAPSULE
Active ingredients:		EACH CAPSULE CONTAINS: SIBUTRAMINE HYDROCHLORIDE MONOHYDRATE 15,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		RANBAXY (S.A.) (PTY) LTD
Manufacturer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Packer:		RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA
Laboratory:	FPRC:	RANBAXY LABORATORIES LTD, PAONTA SAHIB, HIMACHAL PRADESH, INDIA KHULULEKANI LABORATORY SERVICES, COVENTRY PARK, MIDRAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	RANBAXY (S.A.), CENTURION
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0702
Name of medicine:		AROGLIM 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0703
Name of medicine:		AROGLIM 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0704
Name of medicine:		AROGLIM 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0705
Name of medicine:		AROGLIM 4 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0702
Name of medicine:		ARROW GLIMEPIRIDE 1 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 1,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0707
Name of medicine:		ARROW GLIMEPIRIDE 2 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 2,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		42/21.2/0708
Name of medicine:		ARROW GLIMEPIRIDE 3 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: GLIMEPIRIDE 3,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:	42/21.2/0709
Name of medicine:	ARROW GLIMEPIRIDE 4 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GLIMEPIRIDE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory: FPRC:	ARROW PHARMACEUTICALS, CROYDON SOUTH, VICTORIA, AUSTRALIA COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
FPRC/FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	12 JUNE 2009

MRF 15

Registration number:	42/1.2/0718
Name of medicine:	ARROW CITALOPRAM 40 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:	COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC:	COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA PHARMA-Q, INDUSTRIA, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	12 JUNE 2009

MRF 15

Registration number:		42/1.2/0719
Name of medicine:		ARROW CITALOPRAM 20 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM 20,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7
Applicant:		ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:		COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA
Packer:		COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory:	FPRC:	COLBALT PHARMACEUTICALS, MISSISSAUGA, ONTARIO, CANADA PHARMA-Q, INDUSTRIA, JOHANNESBURG CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR:	ARROW PHARMA S.A., WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		44/26/0024
Name of medicine:		IRINOTAS 100
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml VIAL CONTAINS: IRINOTECAN HYDROCHLORIDE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		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
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		44/26/0025
Name of medicine:		ACCORD IRINOTECAN 100
Dosage form:		INJECTION
Active ingredients:		EACH 5,0 ml VIAL CONTAINS: IRINOTECAN HYDROCHLORIDE 100,0 mg
Conditions of registration:		1, 2, 3, 4, 5, 6, 7, 8
Applicant:		ACCORD HEALTHCARE (PTY) LTD
Manufacturer:		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
	FPRR:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:		24 months (Provisional)
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/20.1.1/0721
Name of medicine:		ZEFURIME 250 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg
Conditions of registration:		1,2,3,4,5,6,7
Applicant:		PHARMACARE LIMITED
Manufacturer:		LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA
Packer:		LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA
Laboratory:	FPRC:	LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		12 JUNE 2009

MRF 15

Registration number:		41/20.1.1/0722
Name of medicine:		ZEFURIME 500 mg
Dosage form:		TABLET
Active ingredients:		EACH TABLET CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg
Conditions of registration:		1,2,3,4,5,6,7
Applicant:		PHARMACARE LIMITED
Manufacturer:		LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA
Packer:		LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA
Laboratory:	FPRC:	LUPIN LTD, MANDIDEEP, RAISEN DISTRICT, MADHYA PRADESH, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:		24 months
Date of registration:		12 JUNE 2009