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IMPORTANT NOTICE

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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 62 OF 2010

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 62 VAN 2010**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 goedgekeur 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 goedgekeur 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 rakleef tyd 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 rakleef tydperiode dek. Stabiliteitsstoets 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. Bemaking 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 vrystellingstifikaat 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: 38/2.7/0295
Name of medicine: M&P PARACETAMOL SYRUP
Dosage form: SYRUP
Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 8
Applicant: MEDICINE DEVELOPERS
INTERNATIONAL cc
Manufacturer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Packer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
FPRR: MEDICINE DEVELOPERS
INTERNATIONAL cc, MENLO PARK,
PRETORIA, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 38/11.4.1/0298
Name of medicine: M&P MILK OF MAGNESIA
Dosage form: SUSPENSION
Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
MAGNESIUM HYDROXIDE 425,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6
Applicant: MEDICINE DEVELOPERS INTERNATIONAL cc
Manufacturer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Packer: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
Laboratory: FPRC: PHARMANOVA (PVT) LTD, HARARE,
ZIMBABWE
FPRR: MEDICINE DEVELOPERS INTERNATIONAL
cc, MENLO PARK, PRETORIA, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 38/5.3/0311
 Name of medicine: REMINYL CR 8 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 GALANTAMINE HYDROBROMIDE
 EQUIVALENT TO
 GALANTAMINE 8,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
 Manufacturer: JANSSEN PHARMACEUTICA NV, OLEN,
 BELGIUM
 JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 Packer: JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 Laboratory: FPRC: JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 JANSSEN PHARMACEUTICA NV, BEERSE,
 BELGIUM
 FPRR: JANSSEN PHARMACEUTICA,
 WOODMEAD, SANDTON
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 38/5.3/0312
 Name of medicine: REMINYL CR 16 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 GALANTAMINE HYDROBROMIDE
 EQUIVALENT TO
 GALANTAMINE 16,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
 Manufacturer: JANSSEN PHARMACEUTICA NV, OLEN,
 BELGIUM
 JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 Packer: JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 Laboratory: FPRC: JANSSEN-CILAG, BORGO, SAN MICHELLE,
 LATINA, ITALY
 JANSSEN PHARMACEUTICA NV, BEERSE,
 BELGIUM
 FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
 SANDTON
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	38/5.3/0313
Name of medicine:	REMINYL CR 24 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 24,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	JANSSEN PHARMACEUTICA NV, OLEN, BELGIUM JANSSEN-CILAG, BORGO, SAN MICHELLE, LATINA, ITALY
Packer:	JANSSEN-CILAG, BORGO, SAN MICHELLE, LATINA, ITALY
Laboratory:	FPRC: JANSSEN-CILAG, BORGO, SAN MICHELLE, LATINA, ITALY JANSSEN PHARMACEUTICA NV, BEERSE, BELGIUM
	FPRR: JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A38/20.2.2/0697
Name of medicine:	ARROW-TERBINAFINE HCl 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ARROW PHARMA SOUTH AFRICA (PTY) LTD
Manufacturer:	ARROW PHARMA(MALTA) LTD, BIRZEBBUGIA, MALTA
Packer:	ARROW PHARMA(MALTA) LTD, BIRZEBBUGIA, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
Laboratory:	FPRC: ARROW PHARMA(MALTA) LTD, BIRZEBBUGIA, MALTA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM, SEDEK AGRIKEM, KAMEELDRIFT- EAST, PRETORIA, RSA
	FPRR: ARROW PHARMA, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0038
Name of medicine:	EPILIZINE CR 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory:	FPRC: SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR: SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0039
Name of medicine:	EPILIZINE CR 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory:	FPRC: SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
	FPRR: SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0040
Name of medicine:	EPILIZINE CR 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0041
Name of medicine:	VALPIREX CR 200
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0042
Name of medicine:	VALPIREX CR 300
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	A39/2.5/0043
Name of medicine:	VALPIREX CR 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SODIUM VALPROATE 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SANOFI-SYNTHELABO (PTY) LTD
Manufacturer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK
Packer:	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK PHARMACEUTICAL CONTRACTORS, ISANDO
Laboratory: FPRC	SANOFI-SYNTHELABO LTD, FAWDON, NEWCASTLE UPON TYNE, UK M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR	SANOFI-SYNTHELABO, MIDRAND
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: A39/11.9/0104
Name of medicine: DILORAX
Dosage form: DROPS
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LOPERAMIDE HYDROCHLORIDE 2,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Packer: PHARMA-Q, INDUSTRIA, JOHANNESBURG
Laboratory: FPRC: PHARMA-Q, INDUSTRIA, JOHANNESBURG

FPRR: EQUITY PHARMACEUTICALS, IRENE,
CENTURION

Shelf-life: 24 months(Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/11.4.3/0154
Name of medicine: PROPAN LANSOPRAZOLE 15
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
LANSOPRAZOLE 15,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: ADCOCK INGRAM LIMITED
Manufacturer: LICONSA S.A., GUADALAJARA, SPAIN
Packer: LICONSA S.A., GUADALAJARA, SPAIN
Laboratory: FPRC: LICONSA S.A., GUADALAJARA, SPAIN

FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON

FPRR: ADCOCK INGRAM LTD, ERAND GARDENS,
MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/11.4.3/0155
 Name of medicine: SABAX LANSOPRAZOLE 15
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 LANSOPRAZOLE 15,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ADCOCK INGRAM LIMITED
 Manufacturer: LICONSA S.A., GUADALAJARA, SPAIN
 Packer: LICONSA S.A., GUADALAJARA, SPAIN
 Laboratory: FPRC: LICONSA S.A., GUADALAJARA, SPAIN

FPRC/FPRR: ADCOCK INGRAM HEALTHCARE,
 WADEVILLE, GERMISTON, RSA

FPRR: ADCOCK INGRAM LTD, ERAND
 GARDENS, MIDRAND

Shelf-life: 24 months (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/21.2/0232
 Name of medicine: METCHEK 500
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 METFORMIN HYDROCHLORIDE 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MEDIVISION (PTY) LTD
 Manufacturer: INDOCO REMEDIES, VERNA, GOA, INDIA
 Packer: INDOCO REMEDIES, VERNA, GOA, INDIA
 Laboratory: FPRC: INDOCO REMEDIES, VERNA, GOA, INDIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

FPRR: MEDIVISION, KRAMERVILLE, SANDTON

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/21.2/0233
Name of medicine: METCHEK 850
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MEDIVISION (PTY) LTD
Manufacturer: INDOCO REMEDIES, VERNA, GOA, INDIA
Packer: INDOCO REMEDIES, VERNA, GOA, INDIA
Laboratory: FPRC: INDOCO REMEDIES, VERNA, GOA, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: MEDIVISION, KRAMERVILLE, SANDTON

Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/18.2/0271
Name of medicine: SPEC-DESMOPRESSIN
Dosage form: NASAL SPRAY
Active ingredients: EACH 1,0 ml SPRAY CONTAINS:
DESMOPRESSIN ACETATE HYDRATE 0,1
mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SPECPHARM (PTY) LTD
Manufacturer: MIPHARM S.p.A., MILAN, ITALY
Packer: MIPHARM S.p.A., MILAN, ITALY
Laboratory: FPRC: MIPHARM S.p.A., MILAN, ITALY
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
SPECPHARM HOLDINGS, HALFWAY
HOUSE, MIDRAND

FPRR: SPECPHARM, HALFWAY HOUSE,
MIDRAND

Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/16.4/0489
 Name of medicine: LISTERINE COOL CITRUS
 Dosage form: SOLUTION
 Active ingredients: EACH 20,0 ml SOLUTION CONTAINS:
 THYMOL 12,78 mg
 ALCOHOL 95 % 4,54 ml

 Conditions of registration: 1, 2, 3, 4, 5, 6
 Applicant: PFIZER LABORATORIES (PTY) LTD
 Manufacturer: PFIZER LABORATORIES, RETREAT, CAPE TOWN
 Packer: PFIZER LABORATORIES, RETREAT, CAPE TOWN
 Laboratory: FPRC: PFIZER LABORATORIES, RETREAT, CAPE TOWN

 FPRR: PFIZER LABORATORIES, SANDTON, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: A40/20.2.8/0778
 Name of medicine: SONKE-ABACLAMIZID
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ABACAVIR SULPHATE EQUIVALENT TO
 ABACAVIR 300,0 mg
 LAMIVUDINE 150,0 mg
 ZIDOVUDINE 300,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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
 CENTRE FOR QUALITY ASSURANCE OF
 MEDICINES, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM

 FPRR: RANBAXY (S.A.), CENTURION, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/11.2/0269

Name of medicine: FRESENIUS-HYOSCINE BUTYLBROMIDE
20 mg/ ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
HYOSCINE BUTYLBROMIDE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BODENE (PTY) LTD t/a INTRAMED

Manufacturer: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH

Packer: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC/FPRR: BODENE t/a INTRAMED, KORSTEN, PORT
ELIZABETH

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/8.2/0282

Name of medicine: ZYWAR 1

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
WARFARIN SODIUM CLATHRATE
EQUIVALENT TO WARFARIN SODIUM
1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ZYDUS HEALTHCARE SA (PTY) LTD

Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD,
SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
SANAND, AHMEDABAD, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE SA, VAN DER HOFF
PARK, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/8.2/0283
 Name of medicine: ZYWAR 2,5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 WARFARIN SODIUM CLATHRATE
 EQUIVALENT TO WARFARIN SODIUM
 2,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ZYDUS HEALTHCARE SA (PTY) LTD
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 Packer: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE SA, VAN DER HOFF
 PARK, POTCHEFSTROOM
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/8.2/0284
 Name of medicine: ZYWAR 5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 WARFARIN SODIUM CLATHRATE
 EQUIVALENT TO WARFARIN SODIUM
 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: ZYDUS HEALTHCARE SA (PTY) LTD
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 Packer: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,
 SANAND, AHMEDABAD, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ZYDUS HEALTHCARE SA, VAN DER HOFF
 PARK, POTCHEFSTROOM
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0293
 Name of medicine: ARBOTEC 50 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM 50,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS hf, KOPAVOGUR, ICELAND
 Packer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS hf, KOPAVOGUR, ICELAND
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, INDUSTRIA
 TECHNIKON LABORATORIES, ROBERTVILLE,
 FLORIDA
 PHARMACEUTICAL ENTERPRISES, N'DABENI,
 PINELANDS

 Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS hf, KOPAVOGUR, ICELAND
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 TECHNIKON LABORATORIES, ROBERTVILLE,
 FLORIDA

 FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
 Shelf-life: 48 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.1.1/0317
 Name of medicine: SPEC-ZEPILEN 500 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 CEFAZOLIN SODIUM EQUIVALENT TO
 CEFAZOLIN 500,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
 Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

 Laboratory: FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

 FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND
 Shelf-life: 30 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.1.1/0318
 Name of medicine: SPEC-ZEPILLEN 1 g
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 CEFAZOLIN SODIUM EQUIVALENT TO
 CEFAZOLIN 1 000,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: SPECPHARM (PTY) LTD
 Manufacturer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
 Packer: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
 Laboratory: FPRC: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
 FPRC/FPRR: SPECPHARM, HALFWAY HOUSE,
 MIDRAND
 Shelf-life: 30 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0496
 Name of medicine: AUSTELL LOSARTAN 25
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: AUSTELL LABORATORIES (PTY) LTD
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA,
 DADRA & NAGAR HAVELI, INDIA
 Packer: IPCA LABORATORIES LTD, SILVASSA,
 DADRA & NAGAR HAVELI, INDIA
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,
 DADRA & NAGAR HAVELI, INDIA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
 JOHANNESBURG
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0497
Name of medicine: AUSTELL LOSARTAN 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: AUSTELL LABORATORIES (PTY) LTD
Manufacturer: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
M&L LABORATORY SERVICES,
ORMONDE, JOHANNESBURG
FPRR: AUSTELL LABORATORIES,
SPRINGFIELD, JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0498
Name of medicine: AUSTELL LOSARTAN 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUSTELL LABORATORIES (PTY) LTD
Manufacturer: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
Packer: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,
DADRA & NAGAR HAVELI, INDIA
M&L LABORATORY SERVICES, ORMONDE,
JOHANNESBURG
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1/0557
 Name of medicine: CARZIN XL
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DOXAZOSIN MESYLATE EQUIVALENT TO
 DOXAZOSIN 4,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: KRKA dd, NOVO MESTO, SLOVENIA
 Packer: KRKA dd, NOVO MESTO, SLOVENIA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE,
 JOHANNESBURG
 PHARMACEUTICAL ENTERPRISES,
 N'DABENI, PINELANDS, KZN
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 Laboratory: FPRC: KRKA dd, NOVO MESTO, SLOVENIA
 TECHNIKON LABORATORIES,
 ROBERTVILLE, FLORIDA
 CONSULTING CHEMICAL
 LABORATORIES, ATLASVILLE,
 BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD,
 WESTLAKE
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.1.1/0571
 Name of medicine: MYLAN VANCOMYCIN 500 mg
 Dosage form: INFUSION
 Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:
 VANCOMYCIN HYDROCHLORIDE
 EQUIVALENT TO VANCOMYCIN 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: MERCK GENERICS RSA (PTY) LTD
 Manufacturer: BIOLOGICAL ITALIA LABORATORIOS S.r.L,
 MASATE, MILANO, ITALY
 Packer: BIOLOGICAL ITALIA LABORATORIOS S.r.L,
 MASATE, MILANO, ITALY
 VIANEX SA, PALLINI ATTICA, GREECE
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 Laboratory: FPRC: BIOLOGICAL ITALIA LABORATORIOS S.r.L,
 MASATE, MILANO, ITALY
 VIANEX SA, PALLINI ATTICA, GREECE
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: MERCK GENERICS RSA, MODDERFONTEIN,
 RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.1.1/0572
Name of medicine: MYLAN VANCOMYCIN 1 g
Dosage form: INFUSION
Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:
VANCOMYCIN HYDROCHLORIDE
EQUIVALENT TO VANCOMYCIN 1,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: MERCK GENERICS RSA (PTY) LTD
Manufacturer: BIOLOGICAL ITALIA LABORATORIOS
S.r.L, MASATE, MILANO, ITALY
Packer: BIOLOGICAL ITALIA LABORATORIOS
S.r.L, MASATE, MILANO, ITALY
VIANEX SA, PALLINI ATTICA, GREECE
DIVPHARM MANUFACTURING &
PACKAGING, LONGDALE,
JOHANNESBURG
Laboratory: FPRC: BIOLOGICAL ITALIA LABORATORIOS
S.r.L, MASATE, MILANO, ITALY
VIANEX SA, PALLINI ATTICA, GREECE
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
CONSULTING CHEMICAL
LABORATORIES, ATLASVILLE,
BOKSBURG
FPRR: MERCK GENERICS RSA,
MODDERFONTEIN, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/2.5/0622
Name of medicine: TOPALEX 25 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TOPIRAMATE 25,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
Packer: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
IVERS-LEE LTD, BURGDORF,
SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY
HOUSE, MIDRAND
Laboratory: FPRC: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY
HOUSE, MIDRAND
FPRR: JANSSEN PHARMACEUTICA,
WOODMEAD, SANDTON
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/2.5/0623
Name of medicine: TOPALEX 50 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TOPIRAMATE 50,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: CILAG AG, SCHAFFHAUSEN, SWITZERLAND
Packer: CILAG AG, SCHAFFHAUSEN, SWITZERLAND
IVERS-LEE LTD, BURGDORF, SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY HOUSE,
MIDRAND
Laboratory: FPRC: CILAG AG, SCHAFFHAUSEN, SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY HOUSE,
MIDRAND
FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/2.5/0624
Name of medicine: TOPALEX 100 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TOPIRAMATE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
Packer: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
IVERS-LEE LTD, BURGDORF,
SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY
HOUSE, MIDRAND
Laboratory: FPRC: CILAG AG, SCHAFFHAUSEN,
SWITZERLAND
SPECPHARM HOLDINGS, HALFWAY
HOUSE, MIDRAND
FPRR: JANSSEN PHARMACEUTICA, WOODMEAD,
SANDTON
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/21.2/0639
Name of medicine: ACCORD METFORMIN 500
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 500,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: 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: 36 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/21.2/0640
Name of medicine: ACCORD METFORMIN 850
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: 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: 36 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0743
 Name of medicine: CO-TAREG 160
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VALSARTAN 160,0 mg
 HYDROCHLOROTHIAZIDE 12,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 Packer: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 NOVARTIS PHARMA PRODUKTIONS
 GmbH, WEHR/BADEN, GERMANY
 Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 M&L LABORATORY SERVICES,
 ORMONDE, JOHANNESBURG
 FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0744
 Name of medicine: CO-TAREG 160 PLUS
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VALSARTAN 160,0 mg
 HYDROCHLOROTHIAZIDE 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 Packer: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 NOVARTIS PHARMA PRODUKTIONS GmbH,
 WEHR/BADEN, GERMANY
 Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	41/20.1.1/0777
Name of medicine:	RAN-MOXIFLOXACIN 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (PTY)
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:	4 DECEMBER 2009

MRF 15

Registration number:	41/20.1.1/0778
Name of medicine:	AVEBACT 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (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:	4 DECEMBER 2009

MRF 15

Registration number: 41/5.7.1/0779
 Name of medicine: DESODENE
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DESLORATADINE 5,0 mg

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.1.1/0829
 Name of medicine: ZOPERCIN
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 PIPERACILLIN 4,0 g
 TAZOBACTAM 0,5 g

 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: ORCHID PHARMACEUTICALS SA (PTY) LTD
 Manufacturer: ORCHID HEALTHCARE, SRIPERUMBUDUR,
 KANCHEEPURAM DISTRICT, TAMIL NADU,
 INDIA
 Packer: ORCHID HEALTHCARE, SRIPERUMBUDUR,
 KANCHEEPURAM DISTRICT, TAMIL NADU,
 INDIA
 Laboratory: FPRC: ORCHID HEALTHCARE, SRIPERUMBUDUR,
 KANCHEEPURAM DISTRICT, TAMIL NADU,
 INDIA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: ORCHID PHARMACEUTICALS S.A.,
 NOORDBRUG, POTCHEFSTROOM
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/5.3/0835
Name of medicine: ARIKNOW 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: RANBAXY S.A. (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, PAONTA
SAHIB, HIMACHAL PRADESH
Packer: RANBAXY LABORATORIES LTD, PAONTA
SAHIB, HIMACHAL PRADESH
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 (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/5.3/0836
Name of medicine: ARIKNOW 10
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DONEPEZIL HYDROCHLORIDE 10,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: RANBAXY S.A. (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, PAONTA
SAHIB, HIMACHAL PRADESH
Packer: RANBAXY LABORATORIES LTD, PAONTA
SAHIB, HIMACHAL PRADESH
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 (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/5.3/0837
 Name of medicine: RAN DONEPEZIL 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: 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 (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/5.3/0838
 Name of medicine: RAN DONEPEZIL 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DONEPEZIL HYDROCHLORIDE 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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 (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	41/20.2.8/0957
Name of medicine:	AURO-DIDANOSINE TABLETS 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DIDANOSINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	41/20.2.8/0958
Name of medicine:	AURO-DIDANOSINE TABLETS 150 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DIDANOSINE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Laboratory:	FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
	FPRR: AUROBINDO PHARMA, MEYERSDAL, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 41/20.2.8/0959
Name of medicine: AURO-DIDANOSINE TABLETS 200 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 DIDANOSINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
Packer: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.2.8/0960
Name of medicine: NADACINE TABLETS 100 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
 DIDANOSINE 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
 MANDAL, RANGA REDDY DISTRICT, ANDHRA
 PRADESH, INDIA
 FPRR: AUROBINDO PHARMA, MEYERSDAL,
 JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.2.8/0961
Name of medicine: NADACINE TABLETS 150 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DIDANOSINE 150,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/20.2.8/0962
Name of medicine: NADACINE TABLETS 200 mg
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
DIDANOSINE 200,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Packer: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/26/0973
 Name of medicine: TASIGNA 200 mg
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 NILOTINIB HYDROCHLORIDE EQUIVALENT
 TO NILOTINIB 200,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD
 Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 Packer: IVERS-LEE AG, BURGDORF, SWITZERLAND
 NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
 SWITZERLAND
 NOVARTIS PHARMA ANALYTICA SA,
 LOCARNO, SWITZERLAND
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0982
 Name of medicine: RAN-LOSARTAN 25
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 LOSARTAN POTASSIUM 25,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: RANBAXY (S.A.) (PTY) LTD
 Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Packer: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
 MADHYA PRADESH, INDIA
 KHULULEKANI LABORATORY SERVICES,
 COVENTRY PARK, MIDRAND
 CENTRE FOR QUALITY ASSURANCE OF
 MEDICINES, NO NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: RANBAXY (S.A.), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0983
Name of medicine: RAN-LOSARTAN 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: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
COVENTRY PARK, MIDRAND
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, NO NORTH-WEST
UNIVERSITY, POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0984
Name of medicine: RAN-LOSARTAN 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
KHULULEKANI LABORATORY SERVICES,
COVENTRY PARK, MIDRAND
CENTRE FOR QUALITY ASSURANCE OF
MEDICINES, NO NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: RANBAXY (S.A.), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	41/7.1.3/0985
Name of medicine:	LOHYPE 25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LOSARTAN POTASSIUM 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA 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:	4 DECEMBER 2009

MRF 15

Registration number:	41/7.1.3/0986
Name of medicine:	LOHYPE 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:	RANBAXY (S.A.) (PTY) LTD
Manufacturer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Packer:	RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA
Laboratory:	FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA 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:	4 DECEMBER 2009

MRF 15

Registration number: 41/7.1.3/0987
Name of medicine: LOHYPE 100
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
LOSARTAN POTASSIUM 100,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: RANBAXY (S.A.) (PTY) LTD
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Packer: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA PRADESH, INDIA
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS,
MADHYA 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: 4 DECEMBER 2009

MRF 15

Registration number: 41/3.1/1061
Name of medicine: ORENCIA 250 mg
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
ABATACEPT 250,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: BRISTOL MYERS SQUIBB (PTY) LTD
Manufacturer: BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD,
MANATI, PUERTO RICO
Packer: BRISTOL-MYERS SQUIBB S.r.l., ANAGNI-FT, ITALY
Laboratory: FPRC: BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD,
MANATI, PUERTO RICO
BRISTOL-MYERS SQUIBB CO, EAST SYRACUSE,
NEW YORK
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
FPRR: BRISTOL MYERS SQUIBB, BEDFORDVIEW,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	42/26/0006
Name of medicine:	ERIOX 20
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: DOCETAXEL 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Packer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Laboratory:	FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	42/34/0007
Name of medicine:	ERIOX 20 DILUENT
Dosage form:	INFUSION
Active ingredients:	EACH VIAL CONTAINS: WATER FOR INJECTION 1,5 ml
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Packer:	ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA
Laboratory:	FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS, ARGENTINA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 42/26/0008
Name of medicine: ERIX 80
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
DOCETAXEL 80,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
Packer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
Laboratory: FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/34/0009
Name of medicine: ERIX 80 DILUENT
Dosage form: INFUSION
Active ingredients: EACH VIAL CONTAINS:
WATER FOR INJECTION 6,0 ml
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: PHARMAPLAN (PTY) LTD
Manufacturer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
Packer: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
Laboratory: FPRC: ERIOCHEM S.A., PARANA, ENTRE RIOS,
ARGENTINA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG
FPRR: PHARMAPLAN, MIDRAND, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.2.8/0032
Name of medicine: AURO-DIDANOSINE ORAL SOLUTION 2 g
Dosage form: SOLUTION
Active ingredients: EACH 100,0 ml SOLUTION CONTAINS:
DIDANOSINE 2,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.2.8/0033
Name of medicine: AURO-DIDANOSINE ORAL SOLUTION 4 g
Dosage form: SOLUTION
Active ingredients: EACH 100,0 ml SOLUTION CONTAINS:
DIDANOSINE 4,0 g
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: AUROBINDO PHARMA (PTY) LTD
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR
MANDAL, RANGA REDDY DISTRICT, ANDHRA
PRADESH, INDIA
FPRR: AUROBINDO PHARMA, MEYERSDAL,
JOHANNESBURG
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	42/6.2/0036
Name of medicine:	AMIDAJECT 50 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml AMPOULE CONTAINS: AMIODARONE HYDROCHLORIDE 150,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory:	FPRC: STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS S.A., SPARTAN, KEMPTON PARK
	FPRR: STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	42/8.2/0128
Name of medicine:	PHARMA DYNAMICS CLOPIDOGREL 75 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CLOPIDOGREL HYDROGEN SULPHATE EQUIVALENT TO CLOPIDOGREL 75,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMA DYNAMICS (PTY) LTD
Manufacturer:	KRKA d.d., NOVO MESTO, SLOVENIA KRKA POLSKA Sp., WARSAW, POLAND KRKA FAMA, CVETKOVICI, CROATIA INDOCO REMEDIES LTD, VERNA, GOA, INDIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Packer:	KRKA d.d., NOVO MESTO, SLOVENIA KRKA POLSKA Sp., WARSAW, POLAND KRKA FAMA, CVETKOVICI, CROATIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA PHARMACEUTICAL ENTERPRISES, N'DABENI, PINELANDS, KZN
Laboratory:	FPRC: KRKA d.d., NOVO MESTO, SLOVENIA KRKA POLSKA Sp., WARSAW, POLAND KRKA FAMA, CVETKOVICI, CROATIA TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
Shelf-life:	36 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 42/20.1.1/0142
 Name of medicine: LITARES
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 MOXIFLOXACIN HYDROCHLORIDE
 EQUIVALENT TO MOXIFLOXACIN 400,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0155
 Name of medicine: RISPACOR 0,5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 RISPERIDONE 0,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 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: 36 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0160
Name of medicine: ACCORD RISPERIDONE 0,5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
RISPERIDONE 0,5 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
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: 36 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/1.2/0199
Name of medicine: DRL ESCITALOPRAM 5
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
ESCITALOPRAM OXALATE EQUIVALENT TO
ESCITALOPRAM 5,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
Applicant: DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
Packer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, CENTURION, RSA
Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM
FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/1.2/0200
 Name of medicine: DRL ESCITALOPRAM 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ESCITALOPRAM OXALATE EQUIVALENT TO
 ESCITALOPRAM 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, CENTURION, RSA
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/1.2/0201
 Name of medicine: DRL ESCITALOPRAM 20
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ESCITALOPRAM OXALATE EQUIVALENT TO
 ESCITALOPRAM 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, CENTURION,
 RSA
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	42/1.2/0282
Name of medicine:	CONCERTA 27 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METHYLPHENIDATE HYDROCHLORIDE 27,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	JANSSEN PHARMACEUTICA (PTY) LTD
Manufacturer:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA
Packer:	ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA CARDINAL HEALTH, PHILADELPHIA, PENNSYLVANIA, USA ORTHO MC NEIL PHARMACEUTICAL, RARITAN, NEW JERSEY, USA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND
Laboratory:	FPRC: ALZA CORPORATION, VACAVILLE, CALIFORNIA, USA ALZA CORPORATION, MOUNTAIN VIEW, CALIFORNIA, USA SPECPHARM HOLDINGS, HALFWAY HOUSE, MIDRAND
	FPRR: JANSSEN PHARMACEUTICA, WOODMEAD, SANDTON
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	42/20.1.1/0442
Name of medicine:	DRL MOXIFLOXACIN
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA
Packer:	DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES LTD, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 42/34/0478
Name of medicine: SANDOZ TAMSULOSIN 0,4
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
LJUBLJANA, SLOVENIA
Packer: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
LJUBLJANA, SLOVENIA
Laboratory: FPRC: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
LJUBLJANA, SLOVENIA

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

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/34/0479
Name of medicine: UROFLO
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
TAMSULOSIN HYDROCHLORIDE 0,4 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7
Applicant: SANDOZ S.A. (PTY) LTD
Manufacturer: LEK PHARMACEUTICALS d.d.,
VEROVSKOVA, LJUBLJANA, SLOVENIA
Packer: LEK PHARMACEUTICALS d.d.,
VEROVSKOVA, LJUBLJANA, SLOVENIA
Laboratory: FPRC: LEK PHARMACEUTICALS d.d.,
VEROVSKOVA, LJUBLJANA, SLOVENIA

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

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0544

Name of medicine: DRL OLANZAPINE 2,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 2,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0545

Name of medicine: DRL OLANZAPINE 5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA

Packer: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	42/2.6.5/0546
Name of medicine:	DRL OLANZAPINE 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Packer:	DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	42/2.6.5/0547
Name of medicine:	DRL OLANZAPINE 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OLANZAPINE 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	DR REDDY'S LABORATORIES (PTY) LTD
Manufacturer:	DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Packer:	DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA DRA PHARMACEUTICALS, IRENE, CENTURION
Laboratory:	FPRC: DR REDDY'S LABORATORIES, QUTHUBULLAPUR MANDAL, RANGA REDDY DISTRICT, ANDHRA PRADESH, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
	FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0548
Name of medicine: RAN ATORVASTATIN 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
Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0549
Name of medicine: RAN ATORVASTATIN 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
Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0550
 Name of medicine: RAN ATORVASTATIN 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
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0551
 Name of medicine: RAN ATORVASTATIN 80
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ATORVASTATIN CALCIUM EQUIVALENT TO
 ATORVASTATIN 80,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0552
 Name of medicine: ATOLIP 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
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0553
 Name of medicine: ATOLIP 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
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	42/7.5/0554
Name of medicine:	ATOLIP 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
Applicant:	RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number:	42/7.5/0555
Name of medicine:	ATOLIP 80
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ATORVASTATIN CALCIUM EQUIVALENT TO ATORVASTATIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0556
Name of medicine: LIPOGEN 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
Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0557
Name of medicine: LIPOGEN 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
Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
Shelf-life: 24 months
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0558
 Name of medicine: LIPOGEN 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
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0559
 Name of medicine: LIPOGEN 80
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 ATORVASTATIN CALCIUM EQUIVALENT TO
 ATORVASTATIN 80,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: RANBAXY (SA) (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 (SA), CENTURION, RSA
 Shelf-life: 24 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.2.8/0560
Name of medicine: MEDPRO TENOFOVIR 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TENOFIVIR DISOPROXIL FUMARATE 300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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 (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.2.8/0561
Name of medicine: CIPLA TENOFOVIR 300
Dosage form: TABLET
Active ingredients: EACH TABLET CONTAINS:
TENOFIVIR DISOPROXIL FUMARATE
300,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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 (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/5.7.1/0635
 Name of medicine: DESAWAY
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 DESLORATADINE 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0653
 Name of medicine: LESCOGEN 20
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 FLUVASTATIN SODIUM EQUIVALENT TO
 FLUVASTATIN 20,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0654
Name of medicine: LESCOGEN 40
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
FLUVASTATIN SODIUM EQUIVALENT TO
FLUVASTATIN 40,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0655
Name of medicine: RAN-FLUVASTATIN 20
Dosage form: CAPSULE
Active ingredients: EACH CAPSULE CONTAINS:
FLUVASTATIN SODIUM EQUIVALENT TO
FLUVASTATIN 20,0 mg
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
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, RSA
Shelf-life: 24 months (Provisional)
Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/7.5/0656
 Name of medicine: RAN-FLUVASTATIN 40
 Dosage form: CAPSULE
 Active ingredients: EACH CAPSULE CONTAINS:
 FLUVASTATIN SODIUM EQUIVALENT TO
 FLUVASTATIN 40,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 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, RSA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.1.1/0697
 Name of medicine: ASPEN MEROPENEM 500 mg
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 MEROPENEM TRIHYDRATE EQUIVALENT TO
 MEROPENEM 500,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMACARE LIMITED
 Manufacturer: DEMO S.A., KRYONERI, ATHENS, GREECE
 Packer: DEMO S.A., KRYONERI, ATHENS, GREECE
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 DEMO S.A., KRYONERI, ATHENS, GREECE
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 36 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/20.1.1/0698
 Name of medicine: ASPEN MEROPENEM 1 g
 Dosage form: INJECTION
 Active ingredients: EACH VIAL CONTAINS:
 MEROPENEM TRIHYDRATE EQUIVALENT TO
 MEROPENEM 1 000,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMACARE LIMITED
 Manufacturer: DEMO S.A., KRYONERI, ATHENS, GREECE
 Packer: DEMO S.A., KRYONERI, ATHENS, GREECE
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Laboratory: FPRC: PHARMATHEN S.A., PALLINI, ATTIKIS, GREECE
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 DEMO S.A., KRYONERI, ATHENS, GREECE
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 36 months
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0814
 Name of medicine: REDILANZ 2,5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 OLANZAPINE 2,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0815
 Name of medicine: REDILANZ 5
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 OLANZAPINE 5,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 DRA PHARMACEUTICALS, IRENE, CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA REDDY
 DISTRICT, ANDHRA PRADESH, INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
 PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0816
 Name of medicine: REDILANZ 10
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 OLANZAPINE 10,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8
 Applicant: DR REDDY'S LABORATORIES (PTY) LTD
 Manufacturer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 Packer: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 DRA PHARMACEUTICALS, IRENE,
 CENTURION
 Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
 QUTHUBULLAPUR MANDAL, RANGA
 REDDY DISTRICT, ANDHRA PRADESH,
 INDIA
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRR: DR REDDY'S LABORATORIES,
 MURRAYFIELD, PRETORIA
 Shelf-life: 24 months (Provisional)
 Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 42/2.6.5/0817

Name of medicine: REDILANZ 15

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OLANZAPINE 15,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA

Packer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
DRA PHARMACEUTICALS, IRENE, CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA REDDY
DISTRICT, ANDHRA PRADESH, INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S LABORATORIES, MURRAYFIELD,
PRETORIA

Shelf-life: 24 months (Provisional)

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number: 43/20.1.1/0428

Name of medicine: REDIMOX

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MOXIFLOXACIN HYDROCHLORIDE
EQUIVALENT TO MOXIFLOXACIN 400,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: DR REDDY'S LABORATORIES (PTY) LTD

Manufacturer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA

Packer: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
DRA PHARMACEUTICALS, IRENE,
CENTURION

Laboratory: FPRC: DR REDDY'S LABORATORIES LTD,
QUTHUBULLAPUR MANDAL, RANGA
REDDY DISTRICT, ANDHRA PRADESH,
INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, NORTH-WEST UNIVERSITY,
POTCHEFSTROOM

FPRR: DR REDDY'S LABORATORIES,
MURRAYFIELD, PRETORIA

Shelf-life: 24 months

Date of registration: 4 DECEMBER 2009

MRF 15

Registration number:	43/2.9/0539
Name of medicine:	EQUITY-METHADONE
Dosage form:	SOLUTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: METHADONE HYDROCHLORIDE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EQUITY PHARMACEUTICALS (PTY) LTD
Manufacturer:	MARTINDALE PHARMACEUTICALS, HAROLD HILL, U.K.
Packer:	MARTINDALE PHARMACEUTICALS, HAROLD HILL, U.K.
Laboratory:	FPRC: MARTINDALE PHARMACEUTICALS, HAROLD HILL, U.K. CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
	FPRR: EQUITY PHARMACEUTICALS, IRENE, CENTURION
Shelf-life:	24 months
Date of registration:	4 DECEMBER 2009
