

MRF 15	MRF 15
Registration number:	41/8.3/0885
Name of medicine:	ARANESP 15 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,375 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 15,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
FPRC:	CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
FPRR:	OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/8.3/0886
Name of medicine:	ARANESP 20 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 20,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
FPRC:	CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
FPRR:	OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/8.3/0887
Name of medicine:	ARANESP 30 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,3 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 30,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA AMGEN INC, LONGMONT, COLORADO, USA
Packer:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND OCTOPLUS B.V., LEIDEN, THE NETHERLANDS NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRC:	FPRC:
FPRR:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/8.3/0888
Name of medicine:	ARANESP 40 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 40,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA AMGEN INC, LONGMONT, COLORADO, USA
Packer:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND OCTOPLUS B.V., LEIDEN, THE NETHERLANDS NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRC:	FPRC:
FPRR:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/8.3/0889
Name of medicine:	ARANESP 50 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 50,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
FPRC:	CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
FPRR:	OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
FPRR:	NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/8.3/0890
Name of medicine:	ARANESP 60 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0,3 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 60,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
FPRC:	CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
FPRR:	OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
FPRR:	NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	41/8.3/0891	Registration number:	41/8.3/0892
Name of medicine:	ARANESP 80 ug	Name of medicine:	ARANESP 100 ug
Dosage form:	INJECTION	Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 80,0 ug	Active ingredients:	EACH 0,5 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 100,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD	Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA	Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA	Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	FPRC:	Laboratory:	FPRC:
	CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND		CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
	OCTOPLUS B.V., LEIDEN, THE NETHERLANDS		OCTOPLUS B.V., LEIDEN, THE NETHERLANDS
	NIBSC, POTTERS BAR, HERTFORDSHIRE, UK		NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRC:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG	FPRC:	BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/8.3/0893
Name of medicine:	ARANESP 150 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0.3 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 150,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	FPRC: CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/8.3/0894
Name of medicine:	ARANESP 300 ug
Dosage form:	INJECTION
Active ingredients:	EACH 0.6 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 300,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	FPRC: AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/7.1.3/0941
Name of medicine:	ACECYL 2 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory:	SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRR:	FPRR: THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/8.3/0895
Name of medicine:	ARANESP 500 ug
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DARBEPOETIN ALFA 500,0 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	AMGEN INC, THOUSAND OAKS, CALIFORNIA, USA
Packer:	AMGEN INC, LONGMONT, COLORADO, USA
Laboratory:	AMGEN EUROPE B.V., BREDA, THE NETHERLANDS CHARLES RIVERS LABORATORIES, TRANENT, SCOTLAND OCTOPLUS B.V., LEIDEN, THE NETHERLANDS NIBSC, POTTERS BAR, HERTFORDSHIRE, UK
FPRR:	FPRR: BATSWADI PHARMACEUTICALS, BRYANSTON, JOHANNESBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	41/7.1.3/0942	Registration number:	41/7.1.3/0943
Name of medicine:	ACECYL 4 mg	Name of medicine:	ACECYL 8 mg
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 4.0 mg	Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL TERT-BUTYLAMINE 8.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	THEBE MEDICARE (PTY) LTD	Applicant:	THEBE MEDICARE (PTY) LTD
Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE	Manufacturer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE	Packer:	SPECIFAR S.A., VARVARA, ATHENS, GREECE
Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON	Laboratory:	FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG LABORATORY & BIOLOGICAL SERVICES, BRACKENHURST, ALBERTON
FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG	FPRR:	THEBE MEDICARE, NORTHRIDING, RANDBURG
Shelf-life:	24 months	Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15

Registration number: 41/1/2/0944
 Name of medicine: ILLOVEX SR 37,5 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VENLAFAXINE HYDROCHLORIDE EQUIVALENT
 TO VENLAFAXINE 37,5 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 DIVPHARM MANUFACTURING & PACKAGING,
 LONGDALE, JOHANNESBURG
 PHARMACEUTICAL ENTERPRISES, N'DABENI,
 KZN
 Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD, WESTLAKE
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15

Registration number: 41/1/2/0945
 Name of medicine: ILLOVEX SR 75 mg
 Dosage form: TABLET
 Active ingredients: EACH TABLET CONTAINS:
 VENLAFAXINE HYDROCHLORIDE
 EQUIVALENT TO VENLAFAXINE 75,0 mg
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7
 Applicant: PHARMA DYNAMICS (PTY) LTD
 Manufacturer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 Packer: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 DIVPHARM MANUFACTURING &
 PACKAGING, LONGDALE, JOHANNESBURG
 PHARMACEUTICAL ENTERPRISES,
 N'DABENI, KZN
 Laboratory: FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZEJTUN, MALTA
 CONSULTING CHEMICAL LABORATORIES,
 ATLASVILLE, BOKSBURG
 FPRR: PHARMA DYNAMICS, SILVERWOOD,
 WESTLAKE
 Shelf-life: 24 months
 Date of registration: 9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	41/1.2/0946	Registration number:	41/21.5.1/0967
Name of medicine:	ILLOVEX SR 150 mg	Name of medicine:	GENEMIST
Dosage form:	TABLET	Dosage form:	SUSPENSION
Active ingredients:	EACH TABLET CONTAINS: VENLAFAXINE HYDROCHLORIDE EQUIVALENT TO VENLAFAXINE 150,0mg	Active ingredients:	EACH SPRAY CONTAINS: FLUTICASON FUROATE 27,5 ug
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA DYNAMICS (PTY) LTD	Applicant:	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD
Manufacturer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA	Manufacturer:	GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK
Packer:	ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN	Packer:	GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Laboratory:	FPRC: ACTAVIS HF, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZEJTUN, MALTA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	Laboratory:	FPRC: GLAXO OPERATIONS UK LTD, BARNARD CASTLE, COUNTY DURHAM, UK
FPRC:	PHARMA DYNAMICS, SILVERWOOD, WESTLAKE	FPRC/FPRR:	GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN
Shelf-life:	24 months	Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/20.2.8/0988
Name of medicine:	ASPEN ABACAVIR 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:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN PORT ELIZABETH GLAXOSMITHKLINE, EPPING, CAPE TOWN
Packer:	PHARMACARE LTD, KORSTEN PORT ELIZABETH GLAXOSMITHKLINE, EPPING, CAPE TOWN
Laboratory:	FPRC: M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM GLAXOSMITHKLINE, EPPING, CAPE TOWN
FPRC/FPRR:	PHARMACARE LTD, KORSTEN PORT ELIZABETH
FPRR:	PHARMACARE LTD, WOODMEAD, SANDTON
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	41/5.3/1012
Name of medicine:	SANDOZ GALANTAMINE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRR:	SANDOZ S.A., SPARTAN, KEMPTON PARK
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/5.3/1013
Name of medicine:	SANDOZ GALANTAMINE 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 8.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	FPRC: SANDOZ S.A., SPARTAN, KEMPTON PARK 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	41/5.3/1014
Name of medicine:	SANDOZ GALANTAMINE 12
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: GALANTAMINE HYDROBROMIDE EQUIVALENT TO GALANTAMINE 12.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA
Packer:	SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Laboratory:	FPRC: SANDOZ PVT LTD, VILLAGE DIGHE, NAVI MUMBAI, INDIA NOVARTIS S.A., SPARTAN, KEMPTON PARK
Shelf-life:	FPRC: SANDOZ S.A., SPARTAN, KEMPTON PARK 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/20.1.1/1083
Name of medicine:	STRIDES TOBRAMYCIN 1,2 g/30 ml
Dosage form:	INJECTION
Active ingredients:	EACH 30,0 ml SOLUTION CONTAINS: TOBRAMYCIN SULPHATE EQUIVALENT TO TOBRAMYCIN 1,2 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC:	COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG
NOVARTIS S.A., SPARTAN, KEMPTON PARK	NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRC:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/20.1.1/1084
Name of medicine:	STRIDES TOBRAMYCIN 80 mg/2 ml
Dosage form:	INJECTION
Active ingredients:	EACH 2,0 ml SOLUTION CONTAINS: TOBRAMYCIN SULPHATE EQUIVALENT TO TOBRAMYCIN 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
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
FPRC:	COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG
NOVARTIS S.A., SPARTAN, KEMPTON PARK	NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRC:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/2.9/1098
Name of medicine:	OXYCONTIN 5 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 5.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/2.9/1099
Name of medicine:	OXYCONTIN 10 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 10.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/2.9/1100
Name of medicine:	OXYCONTIN 20 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Registration number:	41/2.9/1101
Name of medicine:	OXYCONTIN 40 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	41/2.9/1102
Name of medicine:	OXYCONTIN 80 mg PROLONGED RELEASE TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXYCODONE HYDROCHLORIDE 80,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MEDWICH PHARMA (PTY) LTD
Manufacturer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Packer:	BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK
Laboratory:	FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Registration number:	41/2.5/1106
Name of medicine:	MYLAN OXCARBAZEPINE 600
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: OXCARBAZEPINE 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	Registration number:
42/5.7.2/0010	42/5.7.2/0011
Name of medicine:	Name of medicine:
SANDOZ GRANISETRON 1 mg/1 ml IVI	GRANJECT 3 mg/3 ml IVI
Dosage form:	INJECTION
INJECTION	INJECTION
Active ingredients:	Active ingredients:
EACH 1,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 1,0 mg	EACH 3,0 ml SOLUTION CONTAINS: GRANISETRON HYDROCHLORIDE EQUIVALENT TO GRANISETRON 3,0 mg
Conditions of registration:	Conditions of registration:
1, 2, 3, 4, 5, 6, 7, 8	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	Applicant:
SANDOZ S.A. (PTY) LTD	SANDOZ S.A. (PTY) LTD
Manufacturer:	Manufacturer:
SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	Packer:
SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	Laboratory:
FPRC:	FPRC:
SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	FPRR:
SANDOZ SA, SPARTAN, KEMPTON PARK	SANDOZ SA, SPARTAN, KEMPTON PARK
Shelf-life:	Shelf-life:
24 months (Provisional)	24 months (Provisional)
Date of registration:	Date of registration:
9 OCTOBER 2009	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/5.7.2/0012
Name of medicine:	SANDOZ GRANISETRON 3 mg/3 ml IVI
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:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Registration number:	42/5.7.2/0013
Name of medicine:	GRANJECT 1 mg/1 ml IVI
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:	SANDOZ S.A. (PTY) LTD
Manufacturer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY
Packer:	SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA
Laboratory:	FPRC: SANDOZ CANADA Inc, BOUCHERVILLE, CANADA HAMELN PHARMACEUTICALS GmbH, HAMELN, GERMANY SALUTAS PHARMA GmbH, BARLEBEN, GERMANY LEK PHARMACEUTICALS d.d., VEROVSKOVA, LJUBLJANA, SLOVENIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/21.5.1/0042
Name of medicine:	ADROJECT 120 mg/30 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXAMETHASONE PHOSPHATE 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	STRIDES SA PHARMACEUTICALS (PTY) LTD
Manufacturer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Packer:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA
Laboratory:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS S.A., SPARTAN, KEMPTON PARK
FPRC:	FPRC:
FPRR:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/10.2.1/0043
Name of medicine:	MERCK-SALBUTAMOL K HALER
Dosage form:	INHALER
Active ingredients:	EACH DOSE CONTAINS: SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 0,1 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	INXX PHARMA, RANCORN, CHESHIRE, UK
Packer:	INXX PHARMA, RANCORN, CHESHIRE, UK
Laboratory:	INXX PHARMA, RANCORN, CHESHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC:	FPRC:
FPRR:	XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/32/0055
Name of medicine:	HELICAP
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: UREA 37,0 kBq
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	LEBASI PHARMACEUTICALS CC
Manufacturer:	INSTITUTE OF ISOTOPES CO LTD, BUDAPEST, HUNGARY
Packer:	INSTITUTE OF ISOTOPES CO LTD, BUDAPEST, HUNGARY
Laboratory:	FPRC: INSTITUTE OF ISOTOPES CO LTD, BUDAPEST, HUNGARY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	12 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/3.1/0058
Name of medicine:	AUSTIFEN – 200 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/3.1/0058
Name of medicine:	AUSTIFEN – 200 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/3.1/0059
Name of medicine:	AUSTIFEN – 400 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/3.1/0060
Name of medicine:	AUSTIFEN – 600 TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	FPRC: IPCA LABORATORIES, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	42/3.1/0061	Registration number:	42/3.1/0062
Name of medicine:	IBUCARE-200	Name of medicine:	IBUCARE-400
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD	Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA	Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	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	Laboratory:	FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG	FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:	24 months (Provisional)	Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/3.1/0063
Name of medicine:	IBUCARE-600
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: IBUPROFEN 600,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA
Laboratory:	IPCA LABORATORIES LTD, SILVASSA, DADRA & NAGAR HAVELI, INDIA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	AUSTELL LABORATORIES, SPRINGFIELD, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0075
Name of medicine:	HALOJECT 5 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: HALOPERIDOL 5,0 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:	STRIDES ARCOLAB LTD, BILEKAHALLI, BANGALORE, INDIA COLUMBIA PHARMACEUTICALS, BARDENE, BOKSBURG NOVARTIS SA, SPARTAN, KEMPTON PARK
FPRR:	STRIDES SA PHARMACEUTICALS, ARCADIA, PRETORIA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/26/0083
Name of medicine:	CIPLA VINORELBINE 10
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory:	FPRC: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSEN PARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/26/0084
Name of medicine:	CIPLA VINORELBINE 50
Dosage form:	INJECTION
Active ingredients:	EACH 5,0 ml SOLUTION CONTAINS: VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Packer:	CIPLA LTD, UNIT V, VERNA, GOA, INDIA
Laboratory:	FPRC: CIPLA LTD, UNIT V, VERNA, GOA, INDIA
FPRR:	CIPLA MEDPRO, ROSEN PARK, BELLVILLE
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/26/0088
Name of medicine:	ACCORD GEMCITABINE 200 mg
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 200,0 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
Shelf-life:	FPRC: 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/26/0089
Name of medicine:	WINTHROP GEMCITABINE 200 mg
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 200,0 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
Shelf-life:	FPRC: 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/21.12/0121
Name of medicine:	SENSIPAR 30 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CINACALCET HYDROCHLORIDE RQUIVALENT TO CINACALCET 30,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA BUDELPACK HAMONT N.V., HAMONT, BELGIUM BRECON PHARMACEUTICALS LTD, HAY ON WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, WYE VALLEY, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BUILTH WELLS, POWYS, WALES CARDINAL HEALTH UK, GREAT OAKLY, CORBY, NORTHAMPTONSHIRE, UK CARDINAL HEALTH UK, WESTHOUGHTON, BOLTON, LANCASHIRE, UK CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UK AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	PATHEON INC, BURLINGTON, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
FPRC:	FPRC:
FPRR:	FPRR:
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/21.12/0122
Name of medicine:	SENSIPAR 60 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CINACALCET HYDROCHLORIDE RQUIVALENT TO CINACALCET 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	BATSWADI PHARMACEUTICALS (PTY) LTD
Manufacturer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA
Packer:	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA BUDELPACK HAMONT N.V., HAMONT, BELGIUM BRECON PHARMACEUTICALS LTD, HAY ON WYE, HEREFORD, UK BRECON PHARMACEUTICALS LTD, WYE VALLEY, HEREFORD, UK BRECON PHARMACEUTICALS LTD, BUILTH WELLS, POWYS, WALES CARDINAL HEALTH UK, GREAT OAKLY, CORBY, NORTHAMPTONSHIRE, UK CARDINAL HEALTH UK, WESTHOUGHTON, BOLTON, LANCASHIRE, UK CARDINAL HEALTH UK, SWINDON, WILTSHIRE, UK AMGEN EUROPE B.V., BREDA, THE NETHERLANDS
Laboratory:	PATHEON INC, BURLINGTON, ONTARIO, CANADA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG COSI PHARMACEUTICALS, INDUSTRIA WEST, JOHANNESBURG
FPRC:	FPRC:
FPRR:	FPRR:
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/1.2/0137
Name of medicine:	XIXIA 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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/1.2/0138
Name of medicine:	XIXIA 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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCCK FARMA Y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/1.2/0139
Name of medicine:	XIXIA ESCITALOPRAM 15
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ESCITALOPRAM OXALATE EQUIVALENT TO ESCITALOPRAM 15,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH- WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRC: XIXIA PHARMACEUTICALS, MODDERFONTEIN 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/1.2/0140
Name of medicine:	XIXIA 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:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GENERICS UK, POTTERS BAR, HERTFORDSHIRE, UK GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: ALPHAPHARM, BRISBANE, QUEENSLAND AUSTRALIA MERCK FARMA y QUIMICA S.A., MOLLET DEL VALLES, BARCELONA, SPAIN MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON GERARD LABORATORIES, DUBLIN, IRELAND RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRC: XIXIA PHARMACEUTICALS, MODDERFONTEIN 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/2.6.5/0156
Name of medicine:	RISPACOR 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 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
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0157
Name of medicine:	RISPACOR 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 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
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/2.6.5/0158
Name of medicine:	RISPACOR 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 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:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
FPRC:	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0159
Name of medicine:	RISPACOR 5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 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:	INTAS PHARMACEUTICALS LTD, MATODA, SANAND, AHMEDABAD, INDIA
FPRC:	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC:	ACCORD HEALTHCARE, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/2.6.5/0161
Name of medicine:	ACCORD RISPERIDONE 1
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 1,0 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
FPRC:	FPRC:
FRR:	FRR:
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0162
Name of medicine:	ACCORD RISPERIDONE 2
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 2,0 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
FPRC:	FPRC:
FRR:	FRR:
Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/2.6.5/0163
Name of medicine:	ACCORD RISPERIDONE 3
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 3,0 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
Shelf-life:	FPRC: ACCORD HEALTHCARE, RIVONIA, RSA 36 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0164
Name of medicine:	ACCORD RISPERIDONE 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: RISPERIDONE 4,0 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
Shelf-life:	FPRC: ACCORD HEALTHCARE, RIVONIA, RSA 36 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/21.10/0184
Name of medicine:	42/34/0185 FOSTIMON 75 IU POWDER FOR SOLUTION FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: UROFOLLITROPIN 75.0 IU
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	DELFRAN PHARMACEUTICALS (PTY) LTD
Manufacturer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND
Packer:	IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND
Laboratory:	FPRC: IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC:	FPRC:
FPRC:	FPRC: IBSA INSTITUT BIOCHIMIQUE SA, LAMONE, SWITZERLAND CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
FPRC:	FPRC: DELFRAN PHARMACEUTICALS, EL DORAIGNE, CENTURION
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/26/0227
Name of medicine:	TORISEL 25 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1.0 ml SOLUTION CONTAINS: TEMSIROLIMUS 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
Packer:	PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WYETH LEADERLE S.p.A, CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE WYETH LEADERLE S.p.A, CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG WYETH RESEARCH, GOSPORT, UK WYETH LEADERLE RESEARCH, PEARL RIVER, NEW YORK, USA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	FPRC: WYETH S.A., VORNA VALLEY, MIDRAND 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/34/0228
Name of medicine:	DILUENT FOR TORISEL 25 mg/ml CONCENTRATE FOR INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH 1.8 ml VIAL CONTAINS: DEHYDRATED ALCOHOL 438,0 mg POLYETHYLENE GLYCOL 400 941,0 mg POLYSORBATE 80 880,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 8
Applicant:	WYETH SOUTH AFRICA (PTY) LTD
Manufacturer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA
Packer:	BEN VENUE LABORATORIES, BEDFORD, OHIO, USA WYETH LEADERLE S.p.A., CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	FPRC: BEN VENUE LABORATORIES, BEDFORD, OHIO, USA WYETH LEADERLE S.p.A., CATANIA, ITALY PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Shelf-life:	FPRC: WYETH S.A., VORNA VALLEY, MIDRAND 24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/20.2.8/0565
Name of medicine:	PHARMA-Q LAMIVUDINE SYRUP
Dosage form:	SYRUP
Active ingredients:	EACH 1.0 ml SYRUP CONTAINS: LAMIVUDINE 10.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMA-Q (PTY) LTD
Manufacturer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Packer:	PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Laboratory:	CENTRE FOR QUALITY ASSURANCE OF MEDICINES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	FPRC/FPRR: PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/2.6.5/0573
Name of medicine:	SEROQUEL XR 50
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 50.0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRC/FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15		
Registration number:	42/2.6.5/0574	Registration number:	42/2.6.5/0575
Name of medicine:	SEROQUEL XR 200	Name of medicine:	SEROQUEL XR 300
Dosage form:	TABLET	Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg	Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8	Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK	Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK	Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG	Laboratory:	FPRC: ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
Shelf-life:	36 months	Shelf-life:	36 months
Date of registration:	9 OCTOBER 2009	Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/2.6.5/0576
Name of medicine:	SEROQUEL XR 400
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 400,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Packer:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK
Laboratory:	ASTRAZENECA PHARMACEUTICALS, NEWARK, DELAWARE, USA ASTRAZENECA UK LTD, MACCLESFIELD, CHESHIRE, UK CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	ASTRAZENECA PHARMACEUTICALS, SUNNINGHILL, JOHANNESBURG
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/11.3/0630
Name of medicine:	RANBUTE 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:	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
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/11.3/0631
Name of medicine:	RANBUTE 15
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: SIBUTRAMINE HYDROCHLORIDE 15,0 mg MONOHYDRATE
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
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009
Registration number:	42/21.5.1/0638
Name of medicine:	ADROJECT 4 mg/ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXAMETHASONE PHOSPHATE 4,0 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
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
FRR:	FRR:
FRR:	FRR:
FRR:	FRR:

MRF 15	MRF 15
Registration number:	42/21.5.1/0639
Name of medicine:	ADROJECT 20 mg/5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: DEXAMETHASONE PHOSPHATE 4,0 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:	9 OCTOBER 2009
Registration number:	42/5.10/0662
Name of medicine:	ZOFER RAPITAB 4
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Laboratory:	FPRC: SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/5.10/0663
Name of medicine:	ZOFER RAPITAB 8
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Packer:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
Laboratory:	SUN PHARMACEUTICAL INDUSTRIES, HALOL, PAMCHMAHAL, GUJARAT, INDIA
FPRC:	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/20.2.2/0683
Name of medicine:	BIO-FLUCONAZOLE IV
Dosage form:	INFUSION
Active ingredients:	EACH 100,0 ml SOLUTION CONTAINS: FLUCONAZOLE 200,0 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
Laboratory:	UNIQUE PHARMACEUTICAL LABORATORIES, PANOLI, GUJARAT, INDIA
FPRC:	M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG
FPRR:	CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG
FPRR:	RESEARCH INSTITUTE FOR INDUSTRIAL SERVICES, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
FPRR:	BIOTECH LABORATORIES, RANDJESPAK, MIDRAND
Shelf-life:	24 months
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/26/0902
Name of medicine:	WINTHROP GEMCITABINE 1 g
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 1,0 g
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
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/26/0903
Name of medicine:	ACCORD GEMCITABINE 1 g
Dosage form:	INJECTION
Active ingredients:	EACH 50,0 ml VIAL CONTAINS: GEMCITABINE HYDROCHLORIDE EQUIVALENT TO GEMCITABINE 1,0 g
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
Shelf-life:	24 months (Provisional)
Date of registration:	9 OCTOBER 2009

MRF 15	MRF 15
Registration number:	42/20.2.8/0978
Name of medicine:	REFAVIN 200 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: EFAVIRENZ 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7, 8
Applicant:	ADCOCK INGRAM LIMITED
Manufacturer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Packer:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON
Laboratory: FPRC/FPRR:	ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON ADCOCK INGRAM LTD, AEROTON, JOHANNESBURG
Shelf-life:	FPRR: 24 months (Provisional)
Date of registration:	9 OCTOBER 2009
Registration number:	42/5.7.2/1007
Name of medicine:	ASPEN 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:	PHARMACARE LIMITED
Manufacturer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	ACTAVIS hf, HAFNARFJORDUR, ICELAND ACTAVIS LTD, ZETJUN, MALTA M&L LABORATORY SERVICES, ORMONDE, JOHANNESBURG RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM
Shelf-life:	FPRC/FPRR: 36 months
Date of registration:	FPRR: 9 OCTOBER 2009

MRF 15

Registration number: 42/5.7.2/1008
 Name of medicine: ASPEN 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: PHARMACARE LIMITED
 Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZETJUN, MALTA
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Packer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZETJUN, MALTA
 PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 Laboratory: FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND
 ACTAVIS LTD, ZETJUN, MALTA
 M&L LABORATORY SERVICES, ORMONDE,
 JOHANNESBURG
 RESEARCH INSTITUTE FOR INDUSTRIAL
 PHARMACY, NORTH-WEST UNIVERSITY,
 POTCHEFSTROOM
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON
 Shelf-life: 36 months
 Date of registration: 9 OCTOBER 2009

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