

WHO List of Prequalified Medicinal Products

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For information about the listing of prequalified products and the alternative approval procedure, please see "General information" at http://www.who.int/prequal/info_general/notes_registry.htm.

Legend:

"+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product (i.e. co-blisters)

[A+B] + C means A and B are in a fixed-dose formulation and C is co-packaged

"**" refers to products approved by both WHO Prequalification Programme and US FDA

USFDA1 - approved by USFDA; USFDA2 - tentatively approved by USFDA; EMEA Art 58 - approved by EMEA according to Article 58

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
DI	Zinc (as sulfate monohydrate)	Dispersible tablets 20mg	Laboratoires Pharmaceutiques Rodael, France	Route de Socx, Bierne, France	Alu/PVDC/PVC blister 10 x 10	DI002	2012-Dec-04	
DI	Zinc (as sulfate monohydrate)	Dispersible tablets 20mg	Alkem Laboratories Ltd	Amaliya, Daman, India	Al/PVC/PVDC blister 1x10, 10x10	DI004	2014-Feb-19	
HIV	[Emtricitabine + Tenofovir disoproxil fumarate] + Nevirapine	Tablets [200mg + 300mg] + 200mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Alu/Alu blister 1 + 2 combipack	HA564	2014-Nov-17	
HIV	[Lamivudine + Tenofovir disoproxil fumarate] + Nevirapine	Tablets [300mg + 300mg] + 200mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Alu/Alu blister, one carton contains one blister of one lamivudine/TDF tablet and one blister of two nevirapine tablets	HA522	2014-Apr-10	
HIV	[Tenofovir disoproxil fumarate + Lamivudine] + Atazanavir (as sulfate) + Ritonavir	Tablets + Capsules + Tablets [300mg + 300mg] + 300mg + 100mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	Alu/Alu blister (1+1+1) per co-packed blister, 3 blisters in a carton	HA512	2011-Nov-28	
HIV	[Tenofovir disoproxil fumarate + Lamivudine] + Nevirapine	Tablets (co-packaged) [300mg + 300mg] + 200mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra; Inda	Alu/Alu blister: (1+2) per blister, 3, 10 blisters in a carton	HA501*	2011-Mar-31	
HIV	Abacavir	Tablets 300mg	ViiV HealthCare	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	Blister 60	HA106 (a)	2002-Mar-20	
HIV	Abacavir	Oral solution 20mg/ml	ViiV HealthCare	Mississauga, Ontario, Canada	HDPE bottle 240ml	HA107 (a)	2002-Mar-20	
HIV	Abacavir	Tablets 300mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60; Blister 6 x 10	HA322	2008-Jul-25	
HIV	Abacavir	Tablets 300mg	Cipla Ltd	Patalganga, India	HDPE bottle 60	HA371*	2008-Apr-23	
HIV	Abacavir	Tablets 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister 6 x 10	HA393*	2008-Jul-25	
HIV	Abacavir (as sulfate)	Oral solution 20mg/ml	Cipla Ltd	Verna, Goa, India	HDPE bottle 100ml, 240ml	HA382	2009-Nov-11	
HIV	Abacavir (as sulfate)	Tablets 60mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA435*	2009-Oct-26	
HIV	Abacavir (as sulfate)	Oral solution 20mg/ml	Meditab Specialities Pvt Ltd	Satara, Maharashtra, India	PET 100ml	HA453	2012-May-02	
HIV	Abacavir (as sulfate)	Dispersible tablets 60mg	Cipla Ltd	Patalganga, India	HDPE bottle 60	HA488	2010-Aug-20	
HIV	Abacavir (as sulfate)	Oral solution 20mg/ml	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India	HDPE bottle 240ml	HA493	2012-Nov-01	
HIV	Abacavir (as sulfate)	Tablets 300mg	Strides Arcolab Limited	Bangalore, India	Alu/PVC blister 6x10; HDPE bottle 60	HA494*	2011-Dec-22	
HIV	Abacavir (as sulfate) + Lamivudine	Tablets 60mg + 30mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30, 60; Triple laminated bag, 7000 (USFDA)	HA456*	2009-Oct-26	
HIV	Abacavir (as sulfate) + Lamivudine	Dispersible tablets 60mg + 30mg	Cipla Ltd	Patalganga, India	HDPE bottle 60, 120; Blister 6 x 10 (USFDA)	HA518*	2014-Jan-08	
HIV	Abacavir (as sulfate) + Lamivudine + Zidovudine	Tablets 60mg + 30mg + 60mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA436	2009-May-25	
HIV	Abacavir (as sulfate) + Lamivudine + Zidovudine	Tablets 300mg + 150mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA505*	2011-Nov-28	

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HIV	Abacavir + Lamivudine + Zidovudine	Tablets 300mg + 150mg + 300mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA324	2008-Mar-07	
HIV	Abacavir + Lamivudine + Zidovudine	Tablets 300mg + 150mg + 300mg	ViiV HealthCare	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	Blister 40, 60; HDPE bottle 60	HA111 (a)	2002-Mar-20	
HIV	Aciclovir	Tablets 200mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA542 (a)	2013-Jun-24	
HIV	Aciclovir	Tablets 400mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA543 (a)	2013-Jun-24	
HIV	Aciclovir	Lyophilisate for solution for injection 250mg	DEMO SA	Krioneri, Attica, Greece	Glass vial 250mg	HA602 (a)	2014-Jan-08	
HIV	Amoxicillin (as trihydrate) + Clavulanic acid (as potassium salt)	Tablets 500mg + 125mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA577 (a)	2013-Jun-24	
HIV	Atazanavir	Capsules 150mg	Bristol-Myers Squibb	Evansville, Indiana, USA; Mount Vernon, Indiana (primary packaging), USA	HDPE bottle 60	HA421 (a)	2008-Mar-07	
HIV	Atazanavir (as sulfate)	Capsules 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 30, 100	HA477*	2010-Oct-25	
HIV	Atazanavir (as sulfate)	Capsules 150mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 30, 100	HA478*	2010-Oct-25	
HIV	Atazanavir (as sulfate) + Ritonavir	Tablets 300mg + 100mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30; HDPE bottle 90, 120 (USFDA)	HA507*	2011-Nov-28	
HIV	Azithromycin	Film-coated tablets 500mg	HEC Pharm GmbH	Sunshine Lake Pharma Co Ltd, Dongguan, Guangdong, China	Al/PVC/PVDC blister 3	HA556 (a)	2012-Nov-02	
HIV	Azithromycin	Tablets 250mg	HEC Pharm GmbH, Germany	Sunshine Lake Pharma Co, Ltd, Guangdong (manufacturer), China; Formula Pharmazeutische und chemische Entwicklungs GmbH, Berlin (batch release within EEA), Germany	PVC/PVDC/Alu blister 1 x 6	HA571 (a)	2014-Oct-06	
HIV	Ceftriaxone	Powder for injection 500mg	Roche	Basel, Switzerland	Glass vials 5ml	HA137 (a)	2002-May-29	
HIV	Ceftriaxone	Powder for injection 250mg	Roche	Basel, Switzerland	Glass vials 5ml	HA138 (a)	2002-May-29	
HIV	Ceftriaxone (as sodium)	Powder for injection 1g	Egyptian International Pharmaceutical Industries Co (EIPICO)	Tenth of Ramadan City, Egypt	Glass vial 1g	HA479	2014-May-16	
HIV	Ceftriaxone (as sodium)	Powder for injection 0.5g	Egyptian International Pharmaceutical Industries Co (EIPICO)	Tenth of Ramadan City, Egypt	Glass vial 0.5g	HA480	2014-May-16	
HIV	Ciprofloxacin	Tablets 750mg	Laboratorios Cinfa S.A.	Navarra, Spain	Blister 10	HA001 (a)	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 500mg	Laboratorios Cinfa S.A.	Navarra, Spain	Blister 10, 20	HA002 (a)	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 250mg	Laboratorios Cinfa S.A.	Navarra, Spain	Blister 10, 20	HA003 (a)	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 100mg	Cipla Ltd	Kurkumbh, India; Goa, India	Blister 10	HA056	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 250mg	Cipla Ltd	Kurkumbh, India; Goa, India	Blister 10	HA057	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 500mg	Cipla Ltd	Kurkumbh, India; Goa, India	Blister 10	HA058	2002-Mar-20	
HIV	Ciprofloxacin	Tablets 750mg	Cipla Ltd	Kurkumbh, India; Goa, India	Blister 10	HA059	2002-Mar-20	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Ciprofloxacin (as hydrochloride monohydrate)	Tablets 500mg	DEMO SA	Boehringer Ingelheim Hellas SA, Paiania, Greece	Al/PVC/PVDC blister 1 x 10, 10 x 10	HA605 (a)	2013-Nov-04	
HIV	Ciprofloxacin (as hydrochloride)	Tablets 250mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA579 (a)	2013-Jun-24	
HIV	Ciprofloxacin (as hydrochloride)	Tablets 500mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA580 (a)	2013-Jun-24	
HIV	Dapsone	Tablets 100mg	Jacobus Pharmaceutical Company, Inc	Plainsboro, NJ (Manufacturing and release testing), USA; Future Pak, Ltd, Wixom, MI (Primary packaging), USA	PVC/TE/Pvdc/Alu blister 2 x 15	HA645 (a)	2015-Jan-13	
HIV	Darunavir (as ethanolate)	Film-coated tablets 75mg	Janssen-Cilag International NV, Belgium	Janssen Ortho LLC, Gurabo, Puerto Rico, United States (Manufacturing and release testing); Janssen-Cilag SpA, Latina, Italy (Testing and final QC release and packaging)	HDPE bottle 480	HA529 (a)	2012-Sep-11	
HIV	Darunavir (as ethanolate)	Film-coated tablets 150mg	Janssen-Cilag International NV, Belgium	Janssen Ortho LLC, Gurabo, Puerto Rico, United States (Manufacturing and release testing); Janssen-Cilag SpA, Latina, Italy (Testing and final QC release and packaging)	HDPE bottle 240	HA530 (a)	2012-Sep-11	
HIV	Darunavir (as ethanolate)	Film-coated tablets 600mg	Janssen-Cilag International NV, Belgium	Janssen Ortho LLC, Gurabo, Puerto Rico, USA (manufacturing and release testing); Janssen-Cilag SpA, Latina, Italy (packaging, testing and QC release); Pharmicare Limited, Korsten, Port Elizabeth, South Africa (QC release)	HDPE bottle 60	HA531	2012-Dec-04	
HIV	Dexamethasone phosphate (as sodium salt)	Solution for injection 4mg/ml	Kern Pharma S.L.	Terrassa (Barcelona), Spain	Glass ampoule 1ml (3 or 100 ampoules per carton)	HA618 (a)	2014-Aug-13	
HIV	Diazepam	Tablets 2mg	Apotex Inc.	Toronto, Ontario, Canada	HDPE bottle 100, 1000	HA559 (a)	2012-Nov-16	
HIV	Diazepam	Tablets 5mg	Apotex Inc.	Toronto, Ontario, Canada	HDPE bottle 100, 1000	HA560 (a)	2012-Nov-16	
HIV	Didanosine	Tablets 25mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey, USA (Manufacturing and primary packaging); Bristol-Myers Squibb, Anagni (Frosinone), Italy (Secondary packaging, testing and batch release)	HDPE bottle 60	HA065 (a)	2002-Mar-20	
HIV	Didanosine	Tablets 50mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey, USA (Manufacturing and primary packaging); Bristol-Myers Squibb, Anagni (Frosinone), Italy (Secondary packaging, testing and batch release)	HDPE bottle 60	HA066 (a)	2002-Mar-20	
HIV	Didanosine	Tablets 100mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey, USA (Manufacturing and primary packaging); Bristol-Myers Squibb, Anagni (Frosinone), Italy (Secondary packaging, testing and batch release)	HDPE bottle 60	HA067 (a)	2002-Mar-20	
HIV	Didanosine	Tablets 150mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey, USA (Manufacturing and primary packaging); Bristol-Myers Squibb, Anagni (Frosinone), Italy (Secondary packaging, testing and batch release)	HDPE bottle 60	HA068 (a)	2002-Mar-20	
HIV	Didanosine	Capsules 250mg	Bristol-Myers Squibb	Mount Vernon, Indiana, USA; Anagni (Primary and secondary packaging and batch release), Italy; Aesica Queenborough Ltd (Primary and secondary packaging and batch release), UK	Blister 30	HA330 (a)	2006-May-23	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Didanosine	Capsules 400mg	Bristol-Myers Squibb	Mount Vernon, Indiana, USA; Anagni (Primary and secondary packaging and batch release), Italy; Aesica Queenborough Ltd (Primary and secondary packaging and batch release), UK	Blister 30	HA331 (a)	2006-May-23	
HIV	Didanosine	Powder for oral solution 2g	Bristol-Myers Squibb	Mount Vernon, Indiana, USA; Anagni (Secondary packaging and batch release), Italy	Glass bottle 2g	HA332 (a)	2006-May-23	
HIV	Didanosine	Delayed release capsules 125mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30	HA471*	2011-Sep-01	
HIV	Didanosine	Delayed release capsules 200mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30	HA472*	2011-Sep-01	
HIV	Didanosine	Delayed release capsules 250mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30	HA473*	2011-Sep-01	
HIV	Didanosine	Delayed release capsules 400mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30	HA474*	2011-Sep-01	
HIV	Dolutegravir (as sodium salt)	Tablets 50mg	ViiV Healthcare UK Limited	Glaxo Operations UK Ltd, Hertfordshire (manufacturing and quality control), UK; Glaxo Wellcome S.A., Burgos (primary and secondary packaging, batch release), Spain	HDPE bottle 30	HA634 (a)	2014-Oct-14	
HIV	Efavirenz	Tablets 200mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	HDPE bottle 90	HA389*	2009-Feb-24	
HIV	Efavirenz	Tablets 600mg	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India; Mahaboob Nagar, Andhra Pradesh, India	HDPE bottle 30, 250	HA399*	2009-Jul-01	
HIV	Efavirenz	Tablets 600mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 30; Blister packs 10	HA403*	2008-Jul-25	
HIV	Efavirenz	Tablets 50mg	Merck Sharp & Dohme Limited	South Granville, NSW - Australia; BN Haarlem (packager, responsible for batch release in the EU) - Netherlands	HDPE bottle 30	HA427 (a)	2008-May-14	
HIV	Efavirenz	Tablets 200mg	Merck Sharp & Dohme Limited	South Granville, NSW - Australia; BN Haarlem (packager, responsible for batch release in the EU) - Netherlands	HDPE bottle 90	HA428 (a)	2008-May-14	
HIV	Efavirenz	Capsules 200mg	Cipla Ltd	Goa, India	HDPE bottle 90; 1000(USFDA)	HA438*	2010-Dec-14	
HIV	Efavirenz	Tablets 600mg	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	HDPE bottle 30	HA506*	2012-Dec-04	
HIV	Efavirenz	Dispersible tablets 100mg	Ranbaxy Laboratories Ltd	S.A.S. Nagar (Mohali), Punjab, India	HDPE bottle 30	HA509	2012-May-02	
HIV	Efavirenz	Capsules 200mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 90; HDPE bottle 90	HA305	2006-May-23	
HIV	Efavirenz	Tablets 600mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 30; HDPE bottle 30	HA306	2006-May-23	
HIV	Efavirenz	Capsules 50mg	Merck Sharp & Dohme	Manati, Puerto Rico; Haarlem, The Netherlands	HDPE bottle 30	HA335 (a)	2006-Mar-01	
HIV	Efavirenz	Capsules 200mg	Merck Sharp & Dohme	Manati, Puerto Rico; Haarlem, The Netherlands	HDPE bottle 90	HA336 (a)	2006-Mar-01	
HIV	Efavirenz	Tablets 600mg	Merck Sharp & Dohme	Bristol-Myers Squibb Pharma, Manati, Puerto Rico; Merck Sharp & Dohme Australia Pty. Ltd, South Granville, Australia; Merck Sharp & Dohme, BV Haarlem, The Netherlands; Zhejiang Huahai Pharmaceutical Co., Ltd, Zhejiang, China	HDPE bottle 30	HA337 (a)	2006-May-23	
HIV	Efavirenz	Oral solution 30mg/ml	Merck Sharp & Dohme	Patheon, Ontario, Canada; Haarlem, The Netherlands	HDPE bottle 180ml	HA338 (a)	2006-May-23	

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HIV	Efavirenz	Tablets 600mg	Cipla Ltd	Goa, India; Himachal Pradesh, India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda; Meditab Specialities Pvt Ltd, Kundaim, Goa, India	HDPE bottle 30; HDPE bottle 500 (USFDA)	HA352*	2008-Dec-16	
HIV	Efavirenz	Tablets 600mg	Strides Arcolab Limited	Bangalore, India	HDPE bottle 30	HA390*	2009-Feb-24	
HIV	Efavirenz + [Lamivudine + Zidovudine]	Tablets 600mg + Tablets [150mg + 300mg]	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Alu/Alu blister 2+1; Cardboard box 30+15	HA356	2007-Aug-30	
HIV	Efavirenz + Emtricitabine + Tenofovir	Tablets 600mg + 200mg + 300mg	Merck Sharp & Dohme	Patheon Inc., Mississauga, Ontario, Canada; Merck Sharp & Dohme, BV Haarlem, (Packaging & batch release site), The Netherlands	HDPE bottle 30	HA413 (a)	2007-Dec-21	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Cipla Ltd	Goa, India	HDPE bottle 30	HA500	2011-Dec-08	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Ranbaxy Laboratories Ltd, India	Shasun Pharmaceuticals Ltd, Periyakalpet, Pondicherry, India	HDPE bottle 30	HA527	2014-Oct-24	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Hetero Labs Limited	Mahaboob Nagar, Andhra Pradesh, India	HDPE bottle 30, 500	HA538	2014-Feb-19	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	HDPE bottle 30	HA553	2014-Dec-12	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 30	HA562	2014-Nov-17	
HIV	Efavirenz + Emtricitabine + Tenofovir disoproxil fumarate	Tablets 600mg + 200mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India; Dhar, Madhya Pradesh, India	HDPE bottle 30; HDPE bottle 100 (USFDA)	HA444*	2010-Oct-25	
HIV	Efavirenz + Lamivudine + Tenofovir disoproxil fumarate	Tablets 600mg + 300mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India; Dhar, Madhya Pradesh, India	HDPE bottle 30; HDPE bottle 100 (USFDA)	HA466*	2010-Oct-25	
HIV	Emtricitabine	Capsules 200mg	Cipla Ltd	Goa, India	HDPE bottle 30	HA418	2011-Sep-01	
HIV	Emtricitabine	Capsules 200mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30; HDPE bottle 100; (USFDA) Blister 2 X 10, 3 X 10 (USFDA)	HA451*	2010-Apr-29	
HIV	Emtricitabine + Tenofovir	Tablets 200mg + 300mg	Gilead Sciences, Inc.	Altana Pharma, Oranienburg GmbH, Germany; Patheon Inc., Mississauga, Ontario, Canada; Aspen Pharmacare, OSD Facility, Korsten, Port Elizabeth, South Africa	HDPE bottle 30	HA343 (a)	2006-May-23	
HIV	Emtricitabine + Tenofovir disoproxil fumarate	Tablets 200mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 30, 100; Blister 3 x 10; Blister 10 (USFDA)	HA417*	2010-Aug-20	
HIV	Emtricitabine + Tenofovir disoproxil fumarate	Tablets 200mg + 300mg	Cipla Ltd	Goa, India	HDPE bottle 30	HA439	2011-Oct-05	
HIV	Emtricitabine + Tenofovir disoproxil fumarate	Tablets 200mg + 300mg	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India	HDPE bottle 30, 60	HA498	2013-Jun-24	
HIV	Emtricitabine + Tenofovir disoproxil fumarate	Tablets 200mg + 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 30; Alu/Alu blister 10 x 10	HA561	2014-Apr-08	
HIV	Etravirine	Tablets 100mg	Janssen-Cilag International NV, Belgium	Janssen-Cilag SpA, Latina, Italy (Manufacturing, packaging, release testing and final QC release)	HDPE bottle 120	HA532 (a)	2012-Sep-11	
HIV	Etravirine	Tablets 25mg	Janssen-Cilag International NV, Belgium	Janssen-Cilag SpA, Latina, Italy	HDPE bottle 120	HA600 (a)	2013-Oct-21	
HIV	Fluconazole	Capsules 50mg	Cipla Ltd	Kurkumbh, India	Blister 10	HA207	2004-Jul-13	
HIV	Fluconazole	Capsules 150mg	Cipla Ltd	Kurkumbh, India	Blister 10	HA208	2004-Jul-13	
HIV	Fluconazole	Capsules 200mg	Cipla Ltd	Kurkumbh, India	Blister 10x10	HA209	2004-Jul-13	

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HIV	Fluconazole	Tablets 50mg	Apotex Inc.	Toronto, Ontario (Manufacturing), Canada; Weston, Ontario (Packaging), Canada	HDPE bottle 50	HA548 (a)	2013-Aug-26	
HIV	Fluoxetine (as hydrochloride)	Capsules 20mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA583 (a)	2013-Jun-24	
HIV	Ganciclovir	Powder for injection 500mg	F.Hoffman-La Roche	Basel, Switzerland	Vials, glass, 10ml	HA134 (a)	2002-May-29	
HIV	Ganciclovir (as sodium salt)	Powder for injection 500mg	Hainan Poly Pharm Co Ltd	Haikou, Hainan, China	Glass vial 10ml	HA515	2012-Dec-20	
HIV	Indinavir	Capsules 400mg	Merck Sharp & Dohme	Elkton, Virginia, USA;	HDPE bottle 180	HA334 (a)	2006-May-23	
HIV	Indinavir (as sulfate)	Capsules 400mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 90, 180	HA363	2009-Nov-10	
HIV	Lamivudine	Oral solution 10mg/ml	Cipla Ltd	Goa, India; Indore, SEZ, Pithampur, Dist Dhar (M.P.), India	PET bottle 100ml; HDPE bottle 240ml (USFDA)	HA053*	2002-Mar-20	
HIV	Lamivudine	Tablets 150mg	ViiV HealthCare	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	HDPE bottle 60	HA117 (a)	2002-Mar-20	
HIV	Lamivudine	Oral solution 10mg/ml	ViiV HealthCare	Mississauga, Ontario, Canada	HDPE bottle 240ml	HA128 (a)	2002-Mar-20	
HIV	Lamivudine	Film-coated tablets 150mg	Hetero Labs Limited	Hetero Labs Limited, Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; STADA-VN Joint Venture Co, Ltd, Duong Province, Vietnam	PVC/Alu Blisters 10 x 10; HDPE bottle 60; HDPE bottle 600 (USFDA)	HA153*	2007-May-29	
HIV	Lamivudine	Tablets 150mg	Strides Arcolab Ltd	Anekal Taluk, Bangalore, India	Blister 10; HDPE bottle 60	HA203*	2004-Jul-13	
HIV	Lamivudine	Tablets 150mg	Aspen Port Elizabeth (Pty) Ltd	Port Elizabeth, South Africa	Metallised lay flat pack, PP bottle 60	HA282	2005-Dec-01	
HIV	Lamivudine	Tablets 150mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 10; HDPE bottle 60	HA290*	2005-Aug-11	
HIV	Lamivudine	Tablets 150mg	Cipla Ltd	Cipla Ltd, Goa, India; Meditab Specialties Pvt Ltd, Kundaim, Goa, India	HDPE bottle 30, 60	HA353	2010-Sep-29	
HIV	Lamivudine	Tablets 300mg	Cipla Ltd	Goa, India	HDPE bottle 30, 60	HA354	2010-Sep-29	
HIV	Lamivudine	Film-coated tablets 150mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister (PVdC/PVC/Alu) 10	HA391*	2008-Mar-07	
HIV	Lamivudine	Tablets 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	PVdC/PVC/Alu blister 6 x 10; HDPE bottle 60	HA420*	2008-Dec-16	
HIV	Lamivudine	Tablets 150mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Solan, Himachal Pradesh, India	HDPE bottle 60; PVC/PVdC/Alu Blister 6 X 10	HA424*	2010-Dec-14	
HIV	Lamivudine	Tablets 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 30; PVC/PVdC/Alu Blister 3 x 10	HA425*	2010-Dec-14	
HIV	Lamivudine	Tablets 30mg	Cipla Ltd	Goa, India	HDPE bottle 60	HA502	2012-Jul-04	
HIV	Lamivudine	Oral solution 10mg/ml	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	HDPE bottle 240ml	HA523	2013-Feb-05	
HIV	Lamivudine	Dispersible tablets 30mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA533	2012-Sep-14	
HIV	Lamivudine	Tablets 30mg	Micro Labs Limited	Verna, Goa, India	PVC/PVdC/Alu blister 10 x 10; HDPE bottle 60, 100, 500, 1000	HA536	2013-Feb-18	
HIV	Lamivudine + Nevirapine + Stavudine	Dispersible tablets 30mg + 50mg + 6mg	Cipla Ltd	Goa, India	HDPE bottle 60; HDPE bottle 1000 (USFDA)	HA375*	2008-Apr-23	
HIV	Lamivudine + Nevirapine + Stavudine	Dispersible tablets 60mg + 100mg + 12mg	Cipla Ltd	Goa, India	HDPE bottle 60; HDPE bottle 1000 (USFDA)	HA376*	2008-Apr-23	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 30mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA407	2008-Jul-25	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 40mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA408	2008-Jul-25	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 30mg	Varichem Pharmaceuticals (Pvt) Ltd	Harare, Zimbabwe	HDPE bottle 60	HA482	2010-Dec-14	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 30mg	Cipla Ltd	Patalganga, India; Goa, India; Himachal Pradesh, India; Cipla Ltd Indore, SEZ, Pithampur, Dist Dhar (M.P.), India	HDPE bottle 60; HDPE bottle 30, 1000 (USFDA)	HA267*	2004-Aug-09	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 40mg	Hetero Labs Limited	Jeedimetla, Hyderabad, Andhra Pradesh, India	Blister 10; HDPE bottle 60	HA276	2005-Sep-29	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 30mg	Hetero Labs Limited	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; Unit-V, Mahaboob Nagar, Andhra Pradesh, India	HDPE bottle 60, 100, 500	HA277*	2005-Dec-21	
HIV	Lamivudine + Nevirapine + Stavudine	Tablets 150mg + 200mg + 30mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA300	2005-Aug-11	
HIV	Lamivudine + Nevirapine + Zidovudine	Tablets 150mg + 200mg + 300mg	Ranbaxy Laboratories Ltd	Ranbaxy Laboratories Ltd, Paonta Sahib, Himachal Pradesh, India; Shasun Pharmaceutical Ltd, Puducherry, India	HDPE bottle, 60;	HA323	2008-Mar-07	
HIV	Lamivudine + Nevirapine + Zidovudine	Film-coated tablets 150mg + 200mg + 300mg	Cipla Ltd	Cipla Ltd, Goa, India; Cipla Ltd, Indore, SEZ, Pithampur, Dist Dhar (M.P.), India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda; Cipla Ltd Baddi, Himachal Pradesh, India; Meditab Specialities Pvt Ltd, Kundaim, Goa, India	HDPE bottle 30, 60; HDPE bottle 500 (USFDA)	HA365*	2009-Mar-10	
HIV	Lamivudine + Nevirapine + Zidovudine	Tablets 150mg + 200mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India; Shasun Pharmaceutical Ltd, Periyakalpet, Puducherry, India	PVC/PVdC/Alu blister 6 X 10; HDPE bottle 60	HA426*	2009-Feb-24	
HIV	Lamivudine + Nevirapine + Zidovudine	Dispersible tablets 30mg + 50mg + 60mg	Mylan Laboratories Ltd	Mylan Laboratories Ltd, Sinnar, Nashik District, Maharashtra, India; Mylan Laboratories Ltd, Waluj, Aurangabad, Maharashtra, India; Shasun Pharmaceutical Ltd, Puducherry, India; Mylan Laboratories Ltd, Pithampur, Dhar, Madhya Pradesh, India	HDPE bottle 60	HA433*	2009-Oct-26	
HIV	Lamivudine + Nevirapine + Zidovudine	Tablets 150mg + 200mg + 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Solan, Himachal Pradesh, India	HDPE bottle 60	HA513*	2012-May-24	
HIV	Lamivudine + Nevirapine + Zidovudine	Tablets 150mg + 200mg + 300mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	HDPE bottle 60	HA524*	2014-Jun-13	
HIV	Lamivudine + Nevirapine + Zidovudine	Dispersible tablets 30mg + 50mg + 60mg	Strides Arcolab Limited	Bangalore, India	HDPE bottle 60	HA557	2014-Oct-24	
HIV	Lamivudine + Nevirapine + Zidovudine	Tablets 150mg + 200mg + 300mg	Hetero Labs Limited	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; Unit-V, Mahaboob Nagar, Andhra Pradesh, India	Blister 10; HDPE bottle 60	HA275	2006-May-23	
HIV	Lamivudine + Stavudine	Tablets 150mg + 30mg	Cipla Ltd	Goa, India; Patalganga; India	HDPE bottle 60; HDPE bottle 30, 1000 (USFDA)	HA303*	2007-Aug-30	
HIV	Lamivudine + Stavudine	Tablets 150mg + 30mg	Strides Arcolab Ltd	Bangalore, India	HDPE bottle 60	HA313	2007-Dec-21	
HIV	Lamivudine + Stavudine	Dispersible tablets 30mg + 6mg	Cipla Ltd	Goa, India	Alu/Alu strip 14, HDPE bottle 30, 60; Blister 14 (USFDA), HDPE bottle 1000 (USFDA)	HA454*	2011-Feb-08	
HIV	Lamivudine + Stavudine	Dispersible tablets 60mg + 12mg	Cipla Ltd	Goa, India	Alu/Alu strip 14, HDPE bottle 30, 60; Blister 14, (USFDA) HDPE bottle 1000 (USFDA);	HA455*	2011-Feb-08	
HIV	Lamivudine + Stavudine	Tablets 150mg + 30mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 10; HDPE bottle 60	HA302	2005-Aug-11	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra; India	HDPE bottle 30, 100	HA414	2010-Jun-30	
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Hetero Labs Limited	Jeedimetla, Hyderabad, Andhra Pradesh, India	HDPE bottle 30, 60; HDPE bottle 100, 500 (USFDA)	HA448*	2011-Sep-01	
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Cipla Ltd	Cipla Ltd, Kurkumbh, India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda	HDPE bottle 30; Alu/PVC/PE/PVDC blister 3 x 10; HDPE bottle 500(USFDA)	HA489*	2011-Oct-05	
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Solan, Himachal Pradesh, India (USFDA)	HDPE bottle 30; Alu/Alu blister 10 x 10	HA514*	2014-Apr-10	
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Ranbaxy Laboratories Ltd	Shasun Pharmaceutical Limited, Periyakalpet, Puducherry, India	HDPE bottle 30	HA525	2012-Sep-11	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Strides Arcolab Ltd	Bangalore, India	HDPE bottle 60	HA291*	2006-Jun-30	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 60, Blister 60; Blister 10 (USFDA)	HA392*	2008-Apr-23	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Varichem Pharmaceuticals (Pvt) Ltd	Harare, Zimbabwe	HDPE bottle 60	HA402	2010-Sep-29	
HIV	Lamivudine + Zidovudine	Tablets 30mg + 60mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA437*	2009-May-25	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Solan, Himachal Pradesh, India	HDPE bottle 60; PVC/PVdC/Alu blister 6 x 10; 12 x 10(USFDA)	HA459*	2011-Oct-18	
HIV	Lamivudine + Zidovudine	Dispersible tablets 30mg + 60mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA463	2011-Sep-29	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Micro Labs Limited	Verna, Goa, India	HDPE bottle 30, 60, 90; PVDC/PVC/Alu blister 10x10	HA485	2010-Oct-25	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Universal Corporation Ltd	Kikuyu, Kenya	HDPE bottle 60	HA490	2011-Oct-21	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India; Mahaboob Nagar, Andhra Pradesh, India	HDPE bottle 60; HDPE bottle 60, 500 (USFDA)	HA521*	2013-Jun-14	
HIV	Lamivudine + Zidovudine	Tablets 30mg + 60mg	Micro Labs Limited	Verna, Goa, India	PVC/PVdC/Alu blister 6 x 10; HDPE 60, 100, 1000	HA555	2015-Jan-13	
HIV	Lamivudine + Zidovudine	Dispersible tablets 30mg + 60mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	HDPE bottle 60	HA572*	2014-Apr-10	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Cipla Ltd	Goa, India; Indore, SEZ, Pithampur, Dist Dhar (M.P.), India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda; Cipla Ltd Baddi, Himachal Pradesh, India; Meditab Specialities Pvt Ltd, Kundaim, Goa, India	Blister 10, 14; HDPE bottle 60; HDPE bottle 1000 (USFDA)	HA060*	2004-Nov-30	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	ViiV HealthCare	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	Blister 60; HDPE bottle 60	HA110 (a)	2002-Mar-20	
HIV	Lamivudine + Zidovudine	Tablets 150mg + 300mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60; Alu/PA/PVC blister 10; PVdC/PVC blister 10	HA286	2005-Aug-11	
HIV	Lopinavir + Ritonavir	Capsules 133,3mg + 33,3mg	Abbott Laboratories	RP Scherer, Florida, USA	HDPE bottle 90	HA097 (a)	2002-Mar-20	
HIV	Lopinavir + Ritonavir	Tablets 200mg + 50mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	Alu/Alu blister 10 X 12; HDPE bottle 120; Blister 6 (USFDA)	HA411*	2009-Feb-19	
HIV	Lopinavir + Ritonavir	Tablets 100mg + 25mg	Mylan Laboratories Ltd	Unit-8, Andhra Pradesh (for premix), India Sinnar, Nashik District, Maharashtra (for tablets), India	HDPE bottle 120	HA429	2009-May-25	
HIV	Lopinavir + Ritonavir	Tablets 200mg + 50mg	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India	HDPE bottle 60, 120; Alu/Alu blister 10; Alu/PVC/PVdC blister 10	HA492	2013-Jan-11	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Lopinavir + Ritonavir (Aluvia)	Film-coated tablets 200mg + 50mg (red)	AbbVie Ltd	AbbVie Deutschland GmbH & Co KG Ludwigshafen, Germany; Aesica Queenborough Ltd (packaging and batch release), UK	HDPE bottle 120	HA412 (a)	2007-Jun-06	
HIV	Lopinavir + Ritonavir (Aluvia)	Film-coated tablets 100mg + 25mg	AbbVie Ltd	AbbVie Deutschland GmbH & Co KG Ludwigshafen, Germany; Aesica Queenborough Ltd (packaging and batch release), UK	HDPE bottle 60	HA434 (a)	2008-Jul-25	
HIV	Lopinavir + Ritonavir (Kaletra)	Oral solution (80mg + 20mg)/ml	AbbVie Ltd	Aesica Queenborough Ltd, UK	PET bottle 60ml	HA098 (a)	2002-Mar-20	
HIV	Lopinavir + Ritonavir (Kaletra)	Film-coated tablets 200mg + 50mg	AbbVie Ltd	AbbVie Deutschland GmbH & Co KG Ludwigshafen, Germany; Fournier Laboratories Ireland Ltd, Co, Cork, Ireland; AbbVie LTD, Barceloneta (manufacturing only), Puerto Rico; Aesica Queenborough Ltd (packaging and batch release), UK	HDPE bottle 120	HA381 (a)	2006-Oct-30	
HIV	Morphine hydrochloride	Prolonged-release tablets 10mg	G.L. Pharma GmbH	Lannach, Austria; Vienna (secondary packaging and batch control/testing), Austria	PVC/Alu blister 1x10, 2x10, 3x10, 5x10, 6x10, 10x10	HA636 (a)	2014-Dec-12	
HIV	Morphine hydrochloride	Prolonged-release tablets 30mg	G.L. Pharma GmbH	Lannach, Austria; Vienna (secondary packaging and batch control/testing only), Austria	PVC/Alu blister 1x10, 2x10, 3x10, 5x10, 6x10, 10x10	HA637 (a)	2014-Dec-12	
HIV	Morphine hydrochloride	Prolonged-release tablets 60mg	G.L. Pharma GmbH	Lannach, Austria; Vienna (secondary packaging and batch control/testing only), Austria	PVC/Alu blister 1x10, 2x10, 3x10, 5x10, 6x10, 10x10	HA638 (a)	2014-Dec-12	
HIV	Morphine sulfate	Tablets 10mg	Paladin Labs Inc	Pharmascience, Montreal, Quebec (Manufacturing, packaging and release testing), Canada; Paladin Labs Inc, Quebec (Release), Canada	HDPE bottle 100; PVC/Alu blister 4x25	HA642 (a)	2014-Nov-27	
HIV	Nevirapine	Tablets 200mg	Cipla Ltd	Cipla Ltd, Goa, India; Meditab Specialties Pvt Ltd, Kundaim, Goa, India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda	Blister 10; HDPE bottle 60; HDPE bottle 1000(USFDA)	HA039*	2002-Mar-20	
HIV	Nevirapine	Tablets 200mg	Hetero Labs Limited	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	Blister 10; HDPE bottle 60; HDPE bottle 100, 500, 1000 (USFDA)	HA155*	2003-Jul-04	
HIV	Nevirapine	Tablets 200mg	Boehringer Ingelheim	Boehringer Ingelheim Pharma GmbH & Co, KG, Ingelheim, Germany; Boehringer Ingelheim Ellas A.E., Koropi, Greece	Blister 60	HA187 (a)	2003-Feb-28	
HIV	Nevirapine	Oral suspension 10mg/ml	Boehringer Ingelheim	Roxane, Columbus, USA	HDPE bottle 240ml + syringe 5ml	HA188 (a)	2003-Feb-28	
HIV	Nevirapine	Oral suspension 50mg/5ml	Cipla Ltd	Cipla Ltd, Goa, India; Meditab Specialties Pvt Ltd, Maharashtra, India; Indore, SEZ, Pithampur, Dist Dhar (M.P.), India	Amber coloured PET bottle 100ml, 240ml; Amber coloured glass bottle 25ml, 10ml	HA200	2009-May-25	
HIV	Nevirapine	Tablets 200mg	Strides Arcolab Ltd	Bangalore, India	HDPE bottle 60	HA268*	2005-Apr-01	
HIV	Nevirapine	Tablets 200mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 10; HDPE bottle 60	HA298*	2005-Sep-29	
HIV	Nevirapine	Tablets 200mg	Mylan Laboratories Ltd	Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra; Inda	HDPE bottle 60; Blister 10	HA396*	2008-Jul-25	
HIV	Nevirapine	Tablets 200mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 60; PVdC/PVC/Alu blister 6x10; 12x10 (USFDA)	HA465*	2011-Sep-29	
HIV	Nevirapine	Dispersible tablets 50mg	Cipla Ltd	Patalganga, India	HDPE bottle 60; 1000 (USFDA); Alu/PVC/PE/PVDC blister 6x10	HA510*	2014-Feb-19	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Nevirapine	Dispersible tablets 100mg	Cipla Ltd	Patalganga, India	HDPE bottle 60; 1000 (USFDA); Alu/PVC/PE/PVDC blister 6x10	HA511*	2014-Feb-19	
HIV	Nevirapine	Dispersible tablets 50mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA539	2014-Jul-14	
HIV	Nevirapine	Dispersible tablets 100mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA540	2014-Jul-14	
HIV	Nevirapine	Tablets 20mg	Micro Labs Limited	Verna, Goa, India	HDPE bottle 30, 60, 90; Alu/PVC/PVDC blister 3x10, 6x10	HA567	2014-Feb-19	
HIV	Nevirapine	Tablets 50mg	Micro Labs Limited	Verna, Goa, India	HDPE bottle 30, 60, 90; Alu/PVC/PVDC blister 3x10, 6x10	HA568	2014-Feb-19	
HIV	Nevirapine	Tablets 100mg	Micro Labs Limited	Verna, Goa, India	HDPE bottle 30, 60, 90; Alu/PVC/PVDC blister 3x10, 6x10	HA569	2014-Feb-19	
HIV	Nevirapine	Tablets 200mg	Micro Labs Limited	Verna, Goa, India	HDPE bottle 60; Alu/PVC/PVDC blister 6x10	HA570	2014-Feb-19	
HIV	Ondansetron (as hydrochloride dihydrate)	Tablets 4mg	Apotex Inc.	Etobicoke, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	PVC/PVDC/Al blister 1 x 10	HA584 (a)	2013-Jun-24	
HIV	Ondansetron (as hydrochloride dihydrate)	Tablets 8mg	Apotex Inc.	Etobicoke, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	PVC/PVDC/Al blister 1 x 10	HA585 (a)	2013-Jun-24	
HIV	Ondansetron (as hydrochloride dihydrate)	Solution for injection 4mg/2ml	DEMO SA	Krioneri, Attica, Greece	Glass ampoule 1 x 2ml; 5 x 2ml	HA597 (a)	2013-Oct-21	
HIV	Ondansetron (as hydrochloride dihydrate)	Solution for injection 8mg/4ml	DEMO SA	Krioneri, Attica, Greece	Glass ampoule 1 x 4ml; 5 x 4ml	HA607 (a)	2013-Oct-21	
HIV	Rifabutin	Capsules 150mg	Lupin Ltd	Chikalthana, Aurangabad, India	HDPE bottle 100	HA640 (a)	2014-Nov-17	
HIV	Ritonavir	Capsules 100mg	Abbott Laboratories	RP Scherer, Florida, USA; Beinheim, France	HDPE bottle 84	HA095 (a)	2002-Mar-20	
HIV	Ritonavir	Oral solution 80mg/ml	Abbott Laboratories	Queensborough, Kent, UK	PET bottle 90ml	HA096 (a)	2002-Mar-20	
HIV	Ritonavir	Tablets 100mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 30, 120	HA467	2010-Dec-14	
HIV	Ritonavir	Tablets 100mg	Abbott GmbH and Co. KG	Ludwigshafen, Germany	HDPE bottle 30, 60	HA491 (a)	2010-Jun-01	
HIV	Saquinavir	Capsules 200mg	F.Hoffman-La Roche	RP Scherer, Baden, Germany	Glass bottle 180	HA133 (a)	2002-Mar-20	
HIV	Saquinavir	Capsules 200mg	F.Hoffman-La Roche	Basel, Switzerland	Glass bottle 270	HA136 (a)	2002-Dec-16	
HIV	Saquinavir	Tablets 500mg	F.Hoffman-La Roche	Madrid, Spain	HDPE bottle 120	HA384 (a)	2006-Nov-03	
HIV	Stavudine	Capsules 15mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	Blister 14; HDPE bottle 60	HA061 (a)	2002-Mar-20	
HIV	Stavudine	Capsules 20mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	Blister 14; HDPE bottle 60	HA062 (a)	2002-Mar-20	
HIV	Stavudine	Capsules 30mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	Blister 14; HDPE bottle 60	HA063 (a)	2002-Mar-20	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Stavudine	Capsules 40mg	Bristol-Myers Squibb	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	Blister 14; HDPE bottle 60	HA064 (a)	2002-Mar-20	
HIV	Stavudine	Capsules 30mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 60; HDPE bottle 60	HA296	2006-May-23	
HIV	Stavudine	Capsules 30mg	Strides Arcolab Ltd	Bangalore, India	HDPE bottle 60	HA312*	2006-Aug-14	
HIV	Stavudine	Powder for oral solution 1mg/ml	Bristol-Myers Squibb	Evansville, Indiana, USA	HDPE bottle 200ml	HA333 (a)	2006-May-23	
HIV	Stavudine	Powder for oral solution 1mg/ml	Cipla Ltd	Goa, India	HDPE bottle 200ml	HA367*	2010-Oct-25	
HIV	Stavudine	Capsules 30mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister 10 (USFDA)	HA394*	2008-Mar-07	
HIV	Stavudine	Capsules 40mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister 10 (USFDA)	HA395*	2008-Mar-07	
HIV	Stavudine	Capsules 30mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 60	HA460	2011-Feb-08	
HIV	Sulfadiazine	Tablets 500mg	Doms Recordati	Saint Victor, Parc Mecatronic, France	Blister 10	HA034 (a)	2002-Mar-20	
HIV	Sulfamethoxazole + Trimethoprim	Tablets 400mg + 80mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA586 (a)	2013-Jun-24	
HIV	Sulfamethoxazole + Trimethoprim	Tablets 800mg + 160mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	HA587 (a)	2013-Jun-24	
HIV	Sulfamethoxazole + Trimethoprim	Oral suspension (40mg + 8mg)/ml	F.Hoffman-La Roche	Basel, Switzerland	Bottle glass 100ml	HA130 (a)	2003-Feb-28	
HIV	Sulfamethoxazole + Trimethoprim	Tablets 800mg + 160mg	F.Hoffman-La Roche	Basel, Switzerland	Blister,10	HA131 (a)	2002-May-29	
HIV	Sulfamethoxazole + Trimethoprim	Tablets 400mg + 80mg	F.Hoffman-La Roche	Basel, Switzerland	Blister,20,100	HA132 (a)	2002-Dec-16	
HIV	Tenofovir	Tablets 300mg	Gilead Sciences, Inc.	Patheon Inc., Mississauga, Ontario, Canada; Altana Pharma, Oranienburg GmbH, Oranienburg, Germany; Aspen Pharmacare, OSD Facility, Korsten, Port Elizabeth, South Africa	HDPE bottle 30	HA329 (a)	2006-Mar-01	
HIV	Tenofovir disoproxil fumarate	Tablets 300mg	Cipla Ltd	Goa, India	HDPE bottle 30; HDPE bottle 1000 (USFDA)	HA401*	2009-Jun-30	
HIV	Tenofovir disoproxil fumarate	Tablets 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	HDPE bottle 30, 100; Blister 2 X 10 (USFDA)	HA410*	2009-Oct-27	
HIV	Tenofovir disoproxil fumarate	Tablets 300mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 30	HA423	2009-Dec-16	
HIV	Tenofovir disoproxil fumarate	Tablets 300mg	Hetero Labs Limited	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	HDPE bottle 30; 30, 60, 100, 500, 1000 (USFDA)	HA508*	2012-Oct-31	
HIV	Tenofovir disoproxil fumarate	Tablets 300mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	Al/Al blister 3 x 10; HDPE bottle 30; HDPE bottle 30 (USFDA)	HA535*	2013-Oct-21	
HIV	Tenofovir Disoproxil Fumarate	Tablets 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Solan, Himachal Pradesh, India	HDPE bottle 30	HA516	2013-May-23	
HIV	Tenofovir disoproxil fumarate + [Emtricitabine + Nevirapine]	Tablets (co-packaged) 300mg + [200mg + 200mg]	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	Alu/Alu blister (1+2) per blister, 3 blisters in a carton	HA594	2014-Dec-12	
HIV	Vinblastine	Injection solution 1mg/ml	Cipla Ltd	Goa, India	Vials 10ml	HA050	2002-Mar-20	
HIV	Zalcitabine	Tablets 0.375mg	F.Hoffman-La Roche	Basel, Switzerland; New Jersey, USA	Blister 6; Bottle Glass 100	HA141 (a)	2002-Mar-20	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Zalcitabine	Tablets 0.75mg	F.Hoffman-La Roche	Basel, Switzerland; New Jersey, USA	Blister 6; Bottle Glass 100	HA142 (a)	2002-Mar-20	
HIV	Zidovudine	Capsules 250mg	Combino Pharm S.L.	Medea, Barcelona, Spain	Blister 40, 300	HA028 (a)	2002-Dec-16	
HIV	Zidovudine	Capsules 300mg	Combino Pharm S.L.	Medea, Barcelona, Spain	Blister 60, 300	HA029 (a)	2002-Dec-16	
HIV	Zidovudine	Tablets 300mg	Cipla Ltd	Goa, India	Blister 5x10, 20x10, 40x10; Blister 10x10 (USFDA); HDPE bottle 60; HDPE bottle 1000 (USFDA)	HA051*	2002-Sep-11	
HIV	Zidovudine	Capsules 100mg	Cipla Ltd	Goa, India; Indore, SEZ, Pithampur, District Dhar (M.P.), India	HDPE bottle 100; HDPE bottle 1000 (USFDA)	HA052*	2002-Sep-11	
HIV	Zidovudine	Oral solution 50mg/5ml	Cipla Ltd	Cipla Ltd, Goa, India; Meditab Specialities Pvt Ltd, Maharashtra, India; Cipla Ltd Indore, Pithampur, Dist Dhar (M.P.), India	PET bottle 100ml, 240ml; HDPE bottle 100ml, 240ml (USFDA)	HA054*	2002-Mar-20	
HIV	Zidovudine	Capsules 100mg	ViiV HealthCare	S.C. Europharm, Brasov, Romania	Blister 100; Bottle glass 100	HA108 (a)	2002-May-29	
HIV	Zidovudine	Capsules 250mg	ViiV HealthCare	S. C. Europharm, Brasov, Romania	Blister 40	HA109 (a)	2002-May-29	
HIV	Zidovudine	Infusion solution 10mg/ml	ViiV HealthCare	Barnard Castle, County Durham, UK	Glass Vials 20ml	HA114 (a)	2002-Mar-20	
HIV	Zidovudine	Oral solution 50mg/5ml	ViiV HealthCare	Mississauga, Ontario, Canada	Glass bottle 200ml	HA115 (a)	2002-Mar-20	
HIV	Zidovudine	Tablets 300mg	ViiV HealthCare	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; Glaxo Wellcome SA, Aranda (packaging and release), Spain	Blister 28, 60; Bottle glass 28	HA116 (a)	2002-Sep-11	
HIV	Zidovudine	Oral solution 50mg/5ml	Combino Pharm S.L.	Medea, Barcelona, Spain	PET bottle 200ml + syringe 10ml	HA184 (a)	2004-Jan-01	
HIV	Zidovudine	Tablets 300mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	Blister 10; HDPE bottle 60; Blister 8 (USFDA)	HA294*	2005-Aug-11	
HIV	Zidovudine	Tablets 300mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister 2 x 10	HA404*	2008-Jul-25	
HIV	Zidovudine	Oral solution 50mg/5ml	Meditab Specialities Pvt Ltd	Maharashtra, India	PET bottle 100ml	HA431	2011-Nov-15	
HIV	Zidovudine	Tablets 300mg	Hetero Labs Limited	Hyderabad, Andhra Pradesh, India	HDPE bottle 60, 600	HA457*	2010-Sep-29	
HIV	Zidovudine	Tablets 100mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60	HA464*	2010-Mar-30	
HIV	Zidovudine	Tablets 300mg	Micro Labs Limited	Verna, Goa, India	PVDC/PVC/Alu blister 10; HDPE bottle 30, 60, 90	HA483	2010-Aug-20	
HIV	Zidovudine	Oral solution 50mg/5ml	Hetero Labs Limited	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	HDPE bottle 240ml	HA486	2011-Nov-03	
HIV	Zidovudine	Tablets 300mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	HDPE bottle 60; Alu/PVC/PVdC/Blister 10 x 10	HA517	2012-May-02	
HIV	Zidovudine	Oral solution 50mg/5ml	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	HDPE bottle 240ml	HA526	2013-Jun-14	
HIV	Zidovudine	Dispersible tablets 60mg	Ranbaxy Laboratories Ltd	Paonta Sahib, Himachal Pradesh, India	HDPE bottle 60	HA534	2013-Jan-24	
HIV	Zidovudine	Tablets 60mg	Micro Labs Limited	Verna, Goa, India	PVC/PVdC/Alu blister 10x10; HDPE bottle 60, 100, 500, 1000	HA537	2013-Jun-14	
HIV	Zidovudine	Capsules 100mg	Combino Pharm S.L.	Medea, Barcelona, Spain	Al strip 100	HA027 (a)	2002-Mar-20	
IN	Oseltamivir (as phosphate)	Capsules 75mg	Cipla Ltd	Goa, India	HDPE bottle 30; PVC/PE/PVdC Aluminum blister 10	IN001	2009-May-13	
IN	Oseltamivir (as phosphate)	Capsules 75mg	Strides Arcolab Limited	Anekal Taluk, Bangalore, India	PVDC/PVC/Alu blister	IN002	2010-Oct-25	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
IN	Oseltamivir (as phosphate)	Powder for oral suspension 12mg/ml	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Rottendorf Pharma GmbH, Ennigerloh, Germany (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging); GP Grenzach Produktions GmbH, Wyhlen, Germany (packaging)	Amber glass bottle 30g	IN003 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 30mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN004 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 45mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN005 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsules 75mg	Roche Ltd	Grenzacherstr, Basel, Switzerland (Galenic bulk production); Catalent Germany Schorndorf GmbH, Schorndorf, Germany (Galenic bulk production); CENEXI SAS, Fontenay-sous-Bois, France (Galenic bulk production); Hoffmann-La Roche Inc., New Jersey, USA (Galenic bulk production); Patheon Inc., Cincinnati, OH, USA (Galenic bulk production); DSM Pharmaceuticals Inc, Greenville, USA (Galenic bulk production); Catalent Germany Schorndorf GmbH, Schorndorf, Germany (packaging); GP Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany (packaging); Wurmisweg, Kaiseraugst, Switzerland (packaging)	Blister (PVC/PE/PVDC, sealed with aluminium foil) 10	IN006 (a)	2009-Sep-21	
IN	Oseltamivir (as phosphate)	Capsule 30mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN009	2014-Jun-13	
IN	Oseltamivir (as phosphate)	Capsule 45mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN010	2014-Jun-13	
IN	Oseltamivir (as phosphate)	Capsule 75mg	Mylan Laboratories Ltd	Waluj, Aurangabad, Maharashtra, India	Alu/PVC blister 10; Alu/PVC/PE/PVDC blister 10; HDPE bottle 30	IN011	2014-Jun-13	
IN	Zanamivir	Inhalation powder 5mg/dose	GlaxoSmithKline	GlaxoSmithKline Australia Pty Ltd, Boronia, Australia; Glaxo Wellcome Production, Evreux, France	Alu/Alu blister, 4 blisters per disk (a pack contains 1 or 5 Alu foil disks)	IN007 (a)	2009-Sep-22	
MA	Amodiaquine	Film-coated tablets 150mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	PVC/Alu blisters 6; Cardboard box 2 x 6	MA045	2007-Aug-30	
MA	Amodiaquine (as hydrochloride) + [Pyrimethamine + Sulfadoxine]	Tablets (co-blisters) 150mg + [25mg + 500mg]	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	PVC/Alu blister 50x(3+1), 25x(3+1)	MA098	2014-Oct-20	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets (co-blistered) 153mg + 50mg	Strides Arcolab Limited	Bangalore, India	Alu/PVC/PE/PVDC blister 10 x (12+12), 10 x (6+6), 10 x (3+3)	MA074	2011-Dec-22	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 67.5mg+25mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 25x3	MA080	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 135mg+50mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 25x3	MA081	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 270mg+100mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 10x1x6, 25x3, 25x6	MA082	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 67.5mg + 25mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/Alu/PVC blister 1 x 3	MA083	2012-Nov-16	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 135mg + 50mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/Alu/PVC blister 1 x 3	MA084	2012-Nov-16	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 270mg + 100mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/ALu/PVC blister 1 x 3, 1 x 6	MA085	2012-Nov-16	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 67.5mg + 25mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	Alu/Alu blister 1 x 3	MA095	2013-Jul-10	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 135mg + 50mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	Alu/Alu blister 1 x 3	MA096	2013-Jul-10	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 270mg + 100mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	Alu/Alu blister 1 x 3; 1 x 6	MA097	2013-Jul-10	
MA	Amodiaquine + Artesunate	Tablets 153mg (200mg as hydrochloride) + Tablets 50mg	Ipca Laboratories Limited	Dadra and Nagar Haveli (U.T.), India	PVdC/PVC/Alu blister 12+12, 6+6, 3+3	MA001	2008-Apr-23	
MA	Amodiaquine + Artesunate	Tablets 150mg + 50mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	PVC/Alu blister 3x(4+4), 3+3, 6+6, 12+12	MA046	2007-Aug-30	
MA	Amodiaquine + Artesunate	Tablets 153mg (200mg as hydrochloride) + Tablets 50mg	Cipla Ltd	Patalganga, India; Goa, India	PVC/PVDC/Alu blister 3 + 3, 6 + 6, 12 + 12	MA047	2008-Nov-11	
MA	Amodiaquine + Artesunate	Tablets 67.5mg + 25mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25	MA056	2008-Oct-14	
MA	Amodiaquine + Artesunate	Tablets 135mg + 50mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25	MA057	2008-Oct-14	
MA	Amodiaquine + Artesunate	Tablets 270mg + 100mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco; Rottendorf Pharma, Ennigerloh, Germany; Batch released by: Sanofi-Aventis Maroc, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25, 6 x 1, 6 x 25	MA058	2008-Oct-14	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Novartis Pharma	Beijing, China; Suffern, USA	Blister 6, 12, 18, 24	MA026 (a)	2004-Apr-26	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	PVDC/PVC/Alu blister 30 x 6, 30 x 12, 30 x 18, 30 x 24	MA062	2009-Dec-15	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Cipla Ltd	Patalganga, Himachal Pradesh, Goa, Kurkumbh, Indore, India; Cipla Quality Chemical Industries Ltd, Kampala, Uganda	PVC-PCTFE/Alu Blister 6, 12, 18, 24; Alu/Alu Blister 6 (1x6), 12 (2x6), 18 (3x6), 24 (4x6)	MA064	2009-May-22	
MA	Artemether + Lumefantrine	Dispersible tablets 20mg + 120mg	Novartis Pharma AG	Novartis Pharmaceuticals Corporation, Suffern, USA	PVC/PCTFE/PVC/Alu blister or PVC/PCTFE/Alu blister 30 X 6; 30 X 12; 30 X 18	MA069 (a)	2009-Feb-27	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Strides Pharma Global Pte Ltd	Strides Arcolab Ltd, Bangalore, India	PVC/PE/PVDC/Alu blister 4x6, 1x6, 1x12, 1x18, 1x24	MA088	2013-Jun-24	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Al/PVC/PE/PVDC blister (1/2/3/4/30)x6, 3x8, (1/2/30)x12, (1/30)x18, (1/30)x24; Al/PVC/Aclar blister (1/2/3/4/30)x6, 3x8, (1/2/30)x12, (1/30)x18, (1/30)x24	MA091	2013-Oct-21	
MA	Artemether + Lumefantrine	Dispersible tablets 20mg + 120mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	PVC/PVdC/Alu blister 1 x 6, 30 x 6, 1 x 12, 30 x 12	MA092	2012-Dec-19	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Mylan Laboratories Ltd	Sinnar, Nashik, Maharashtra, India	Alu/Alu (desiccant embedded) blister 1x6, 2x6, 3x6, 4x6; Alu/Alu blister 1x6, 2x6, 3x6, 4x6; Alu/PVC/Aclar blister 1x6, 2x6, 3x6, 4x6	MA099	2014-May-16	
MA	Artemether + Lumefantrine	Tablets 40mg + 240mg	Mylan Laboratories Ltd	Sinnar, Nashik, Maharashtra, India	Alu/Alu (Desiccant embedded) blister 1x12; Alu/Alu blister 1x12; Alu/PVC/Aclar blister 1x12	MA100	2014-May-16	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	PVC/PVdC/Alu blister 1x6, 1x12, 1x18, 1x24	MA111	2014-Oct-06	
MA	Artemotil	Solution injection 50mg/ml	Artecef BV	Rotexmedica GmbH, Trittau, Germany	Glass ampoules 1ml	MA027 (a)	2006-Mar-01	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
MA	Artemotil	Solution injection 150mg/ml	Artecef BV	Rotexmedica GmbH, Trittau, Germany	Glass ampoules 1ml	MA028 (a)	2006-Mar-01	
MA	Artesunate	Tablets 50mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	Blister 12	MA044	2005-Dec-21	
MA	Artesunate	Powder for Injection 60mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, P.R. China	Vial [1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (1ml:50mg) and 1 ampoule of sodium chloride injection (5ml:45mg)]	MA051	2010-Nov-05	
MA	Artesunate	Powder for injection 30mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (0.5mL:25mg) and 1 ampoule of sodium chloride injection (2.5mL:22.5mg)	MA089	2013-May-23	
MA	Artesunate	Powder for injection 120mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (2mL:100mg) and 1 ampoule of sodium chloride injection (10mL:90mg)	MA090	2013-May-23	
MA	Artesunate + [Sulfadoxine + Pyrimethamine]	Tablets + Tablets 50mg + [500mg + 25mg]	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	PVC/Alu blister 3 + 1; 6 + 2	MA066	2012-May-24	
MA	Artesunate + Amodiaquine (as hydrochloride)	Tablets 25mg + 67.5mg	Cipla Ltd	Patalganga, India	Alu/Alu blister 1 x 3	MA102	2014-Apr-08	
MA	Artesunate + Amodiaquine (as hydrochloride)	Tablets 50mg + 135mg	Cipla Ltd	Patalganga, India	Alu/Alu blister 1 x 3	MA103	2014-Apr-08	
MA	Artesunate + Amodiaquine (as hydrochloride)	Tablets 100mg + 270mg	Cipla Ltd	Patalganga, India	Alu/Alu blister 1 x 3, 1 x 6	MA104	2014-Apr-08	
MA	Artesunate + Mefloquine (as hydrochloride)	Tablets 25mg + 50mg	DNDi, Switzerland (Cipla Ltd is the supplier and is responsible for the product)	Cipla Ltd, Patalganga, India	Alu/Alu strip 1 x 3, 2 x 3	MA078	2012-Sep-12	
MA	Artesunate + Mefloquine (as hydrochloride)	Tablets 100mg + 200mg	DNDi, Switzerland (Cipla Ltd is the supplier and is responsible for the product)	Cipla Ltd, Patalganga, India	Alu/Alu strip 1 x 3, 2 x 3	MA079	2012-Sep-12	
NTD	Diethylcarbamazine citrate	Tablets 100mg	Eisai Co, Ltd - Japan	Eisai Pharmatechnology & Manufacturing Pvt Ltd, Parawada, Andhra Pradesh, India	HDPE bottle 1000	NT002	2013-Aug-20	
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Famy Care Ltd	Ahmedabad, Gujarat, India	PVC/PVdC/Alu blister in a sealed laminated film pouch 21	RH037 (a)	2013-Aug-14	
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Lupin Ltd	Pitampur, Madhya Pradesh, India	Alu/PVC blister (available in a wallet) 28 (21 active and 7 placebo tablets per wallet further packed in a pouch). 3 pouches are packed in a carton	RH044 (a)	2013-Oct-21	
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Famy Care Ltd	Ahmedabad, Gujarat, India	AL/PVC/PVDC blister 28 (21 active and 7 placebo tablets per blister in a sealed laminated film in pouch). 1 or 3 pouches in a carton	RH049 (a)	2014-Apr-08	
RH	Ethinylestradiol + Desogestrel	Tablets 0.030mg + 0.150mg	NV Organon	Kloosterstraat, Oss, The Netherlands	PVC/Alu blister further packed in an Aluminium bag 21 + 7 (placebo)	RH025 (a)	2010-Sep-29	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany (bulk manufacturing); Bayer Pharma AG, Berlin, Germany (packaging and release)	Al/PVC/PVDC blister 28 (21 active and 7 ferrous fumarate 75mg tablets per blister). 1, 3 or 6 such blisters are packed in a carton	RH003 (a)	2009-May-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	PVC/PVdC/Alu blister 1x21, 3x21, 6x21, 13x21, 100x21	RH013	2011-Sep-29	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Cipla Ltd	Goa, India	Al/PVC/PVDC/PE strip 21 + 7 (placebo) per strip, (1 or 3 strips in a carton)	RH030	2011-Dec-22	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	Al/PVC/PVDC blister 28 (21 active and 7 ferrous fumarate 75mg tablets per blister). 1, 3 or 6 such blisters are packed in a carton	RH038	2014-Mar-11	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 28 (21 active and 7 placebo tablets per strip)	RH041 (a)	2013-Aug-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets (91-day cycle pack) 30?g + 150?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 91 (84 active and 7 placebo tablets per strip)	RH042 (a)	2013-Aug-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	Al/PVC/PVDC blister 28 (21 active and 7 placebo tablets per blister). 1, 3, 6 or 100 such blisters are packed in a carton	RH035	2013-Oct-21	
RH	Etonogestrel	Implants 68mg	NV Organon	Kloosterstraat, Oss, The Netherlands	Blister pack (polyethyleneterephthalate glycol sealed with coated paper) 1 implant (in the cannula of a disposable sterile applicator)	RH020 (a)	2010-Jun-02	
RH	Etonogestrel	Implant (X-ray detectable) 68mg	NV Organon	Kloosterstraat, Oss, The Netherlands	Blister pack (PETG sealed with HDPE lidding): 1 implant (preloaded in the stainless steel needle of a ready-to-use, disposable, sterile applicator)	RH036 (a)	2013-May-23	
RH	Levonorgestrel	Coated tablets 30?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany	PVC/Alu blister 3 x 35	RH002 (a)	2009-May-26	
RH	Levonorgestrel	Implants (without inserter) 2 rods each with 75mg	Bayer Oy	Turku, Finland	PE bag (manufactured from spunbonded PE film and a PET/PE film), 2 rods in one package	RH017 (a)	2009-Sep-23	
RH	Levonorgestrel	Tablets 0.75mg	Gedeon Richter Plc	Budapest, Hungary	Al/PVC blister 1 x 2	RH024 (a)	2010-Aug-20	
RH	Levonorgestrel	Tablets 1.5mg	Famy Care Ltd	Ahmedabad, Gujarat, India	Al/PVC/PVDC blister 1 x 1	RH031	2013-Oct-21	
RH	Levonorgestrel	Tablets 750?g	Famy Care Ltd	Ahmedabad, Gujarat, India	PVC/PVdC/Alu blister 1x2	RH032	2013-Jun-14	
RH	Levonorgestrel	Tablets 0.75mg	Cipla Ltd	Verna, Goa, India	Al/PVC/PE/PVDC blister 1 x 2	RH040	2014-Apr-08	
RH	Lynestrenol	Tablets 500?g	NV Organon	Kloosterstraat, Oss, The Netherlands	PVC/Alu strip 1 x 28, 3 x 28	RH021 (a)	2010-Jun-02	
RH	Medroxyprogesterone acetate	Suspension for injection 150mg/ml	Pfizer	Rijksweg, Puurs, Belgium	Glass vial 1ml	RH018 (a)	2010-Aug-20	
RH	Mifepristone	Tablets 200mg	Linepharma International Ltd, United Kingdom	Laboratorios Leon Farma SA, Villaquilambre, Léon, Spain; Delpharm Lille S.A.S, Lys-Lez-Lannoy, France	PVC/PVDC/Alu blister 1x1, 30x1	RH051 (a)	2014-Oct-06	
RH	Misoprostol	Tablets 200?g	Cipla Ltd	Verna, Goa, India	Alu/Alu blister 1 x 4, 7 x 4, 15 x 4	RH039	2014-Apr-08	
RH	Norethisterone	Tablets 350?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 28	RH043 (a)	2013-Aug-26	
RH	Norethisterone	Tablets 350?g	Lupin Ltd	Pithampur, Mdhya Pradesh, India	Alu/PVC/Aclar blister (available in wallet) 3 x 28	RH045 (a)	2013-Oct-21	
RH	Norethisterone enantate	Injection 200mg/ml	Bayer Schering Pharma AG	Berlin, Germany	Glass ampoule 1ml (100 per carton)	RH022 (a)	2011-Oct-05	
TB	Amikacin (as sulfate)	Injection 500mg/2ml	Cipla Ltd	Goa, India	Glass vial 2ml	TB217	2011-Jan-14	
TB	Capreomycin (as sulfate)	Powder for injection 1g	Hisun Pharmaceutical (Hangzhou) Co Ltd	Fuyang, Hangzhou City, Zhejiang Province, China	Glass vial 1g	TB261	2014-Oct-06	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
TB	Cycloserine	Capsules 250mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Himachal Pradesh, India	Al strip 10	TB154	2007-Mar-23	
TB	Cycloserine	Capsules 250mg	Aspen Pharmacare Limited	Port Elizabeth, South Africa	HDPE bottle 100	TB166	2009-Jun-19	
TB	Cycloserine	Capsules 250mg	Biocom JSC	Stavropol, Russia	HDPE bottle 100	TB222	2013-Aug-20	
TB	Cycloserine	Capsules 250mg	Dong-A ST Co, Ltd	Cheonan-si, Chungcheongnam-do, Republic of Korea	Alu/Alu strip 10 x 10	TB236	2012-Nov-16	
TB	Ethambutol	Tablets 400mg	Cadila Pharmaceuticals Ltd	Dholka, Ahmedabad, India	HDPE bottle 1000; PVC/Alu blister 10x10; PVC/PVdC/Alu blister 24x28	TB008	2003-Nov-13	
TB	Ethambutol	Tablets 400mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Blister 10, 28; HDPE bottle 1000	TB134	2007-Mar-23	
TB	Ethambutol + Isoniazid	Tablets 400mg + 150mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Blister 10, 28; HDPE bottle 1000	TB157	2007-Mar-23	
TB	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	Tablets 275mg + 75mg + 400mg + 150mg	Wyeth Pakistan Ltd	Karachi, Pakistan	Blister 80	TB024	2003-Nov-13	Suspended
TB	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	Tablets 275mg + 75mg + 400mg + 150mg	Lupin Ltd	Aurangabad, India; Bari Brahmana, Jammu (J & K), India	PVC/PVdC/Alu Blister 15x6, 24x28; HDPE bottle 1000	TB070	2003-Nov-13	
TB	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	Tablets 275mg + 75mg + 400mg + 150mg	Sandoz Pty Ltd	Strides Arcolab, Bangalore, India; Sandoz Pty Ltd, Kalwe, Navi Mumbai, Thane, India	PVC/PE/PVdC/Alu blister 30, 60, 120, 240, 672, 1000; Polypropylene containers 500, 1000; HDPE bottle 500	TB090 (a)	2004-Sep-14	
TB	Ethambutol + Isoniazid + Rifampicin	Tablets 275mg + 75mg + 150mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Triple laminated LDPE/PET/AL bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 10, 28	TB183	2008-Oct-22	
TB	Ethambutol hydrochloride	Tablets 400mg	Lupin Ltd	Chikalthana, Aurangabad, India; Bari Brahmana, Jammu (J & K), India	PVC/PVDC/Alu blister 10x10; 24x28 LDPE bag in HDPE bottles 100, 500, 1000;	TB177	2010-Apr-08	
TB	Ethambutol hydrochloride	Tablets 100mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Al/PVC/PVDC blister 10 x 10, 24 x 28; HDPE bottle 1000	TB226	2013-Nov-04	
TB	Ethambutol hydrochloride	Tablets 400mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 2x10, 150x10	TB264 (a)	2013-Feb-28	
TB	Ethambutol hydrochloride + Isoniazid	Tablets 400mg + 150mg	Cadila Pharmaceuticals Ltd	Dholka, Ahmedabad, India	PVC/PVDC/Alu blister 10x10, 24x28, 14x28	TB009	2010-Apr-28	
TB	Ethambutol hydrochloride + Isoniazid	Tablets 400mg + 150mg	Lupin Ltd	Chikalthana, Aurangabad, India	Alu/PVC/PVDC blister 24 x 28; HDPE bottle 1000	TB198	2012-Dec-19	
TB	Ethambutol hydrochloride + Isoniazid + Pyrazinamide + Rifampicin	Tablets 275mg + 75mg + 400mg + 150mg	Svizera Europe B.V. - The Netherlands	Svizera Labs Private Ltd, Navi Mumbai, India	Alu/PVDC blister 24 x 28; HDPE bottle 1000	TB193	2012-Dec-19	
TB	Ethambutol hydrochloride + Isoniazid + Pyrazinamide + Rifampicin	Tablets 275mg + 75mg + 400mg + 150mg	Strides Arcolab Limited	Bangalore, India	Al/PVC/PE/PVDC blister 24 x 28, 18 x 10; HDPE bottle 1000	TB216	2012-May-24	
TB	Ethambutol Hydrochloride + Isoniazid + Pyrazinamide + Rifampicin	Film-coated tablets 275mg + 75mg + 400mg + 150mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	LDPE bag in sealed Alu sachet further packed in HDPE container 500, 1000; PVC/PVdC/Alu blister 10, 28	TB168	2008-Mar-07	
TB	Ethambutol hydrochloride + Isoniazid + Rifampicin	Tablets 275mg + 75mg + 150mg	Svizera Europe B.V. - The Netherlands	Svizera Labs Private Ltd, Navi Mumbai, India	PVC/Alu blister 24 x 28; HDPE bottle 1000	TB192	2012-Dec-19	
TB	Ethambutol hydrochloride + Isoniazid + Rifampicin	Tablets 275mg + 75mg + 150mg	Lupin Ltd	Chikalthana, Aurangabad, India	Alu/PVC/PVDC blister 24 x 28; HDPE bottle 1000	TB199	2013-Jan-11	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
TB	Ethionamide	Tablets 250mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Al/PET/LDPE triple lam pouch further in HDPE jar 100; Alu/Alu strip 10	TB133	2007-Dec-21	
TB	Ethionamide	Tablets 250mg	Cipla Ltd	Patalganga, India	Alu/PVC/PE/PVdC blister 10; HDPE bottle 100	TB215	2011-Dec-22	
TB	Ethionamide	Tablets 250mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVDC/PVC/Alu blister 10; HDPE bottle 100	TB242	2012-Dec-19	
TB	Ethionamide	Tablets 250mg	Lupin Ltd	Chikalthana, Aurangabad, India	Alu/Alu strip 5 x 10; HDPE bottle 100	TB207	2012-Dec-19	
TB	Isoniazid	Tablets 100mg	Micro Labs Limited	Hosur, Tamilnadu, India	PE bag further packed in HDPE container 1000	TB173	2010-Nov-01	
TB	Isoniazid	Tablets 300mg	Micro Labs Limited	Hosur, Tamilnadu, India	PE bag further packed in HDPE container 1000	TB174	2010-Nov-01	
TB	Isoniazid	Tablets 100mg	Macleods Pharmaceuticals Limited	Kachigam, Daman, India	LDPE bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 3x10, 3x28	TB178	2008-Apr-23	
TB	Isoniazid	Tablets 300mg	Macleods Pharmaceuticals Limited	Kachigam, Daman, India	LDPE bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 3x10, 3x28	TB179	2008-Apr-23	
TB	Isoniazid	Tablets 100mg	Lupin Ltd	Chikalthana, Aurangabad, India	Al/PVC/PVDC blister 100; HDPE bottle 100, 1000	TB196	2012-Oct-31	
TB	Isoniazid	Tablets 100mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 2x10, 150x10	TB265 (a)	2013-Feb-28	
TB	Isoniazid	Tablets 300mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 3x10, 150x10	TB266 (a)	2013-Feb-28	
TB	Isoniazid + Pyrazinamide + Rifampicin	Dispersible tablets 30mg + 150mg + 60mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Triple laminated LDPE/PET/AL bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 10, 28; Alu/Alu strip 3 x 10, 10 x 10, 28 x 3, 14 x 6, 3 x 28, 6 x 14	TB180	2009-Mar-03	
TB	Isoniazid + Pyrazinamide + Rifampicin	Dispersible tablets 30mg + 150mg + 60mg	Lupin Ltd	Chikalthana, Aurangabad, India; Bari Brahmana, Jammu (J&K), India	Al/Al strip 15 x 6, 14 x 6	TB185	2012-Jul-02	
TB	Isoniazid + Rifampicin	Tablets 75mg + 150mg	Lupin Ltd	Aurangabad, India; Bari Brahmana, Jammu (J & K), India	Blister 15; HDPE bottle 100, 500, 1000	TB068	2003-Dec-19	
TB	Isoniazid + Rifampicin	Tablets 75mg + 150mg	Sandoz Pty Ltd	Strides Arcolab, Bangalore, India; Sandoz Pty Ltd, Kalwe, Navi Mumbai, Thane, India	Alu/Alu blister 30, 60, 120, 240, 1000; PVC/PE/PVdC/Alu blister 10, 30, 60, 120, 240, 672, 1000; PP bottle 500, 1000; HDPE bottle 500	TB085 (a)	2004-Sep-14	
TB	Isoniazid + Rifampicin	Film-coated tablets 75mg + 150mg	Macleods Pharmaceutical Ltd	Kachigam, Daman, India	PET/Alu/LLDPE triple laminated sachet further in HDPE container 500, 1000; PVC/PVdC/Alu blister 10, 28	TB158	2008-Mar-07	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
TB	Isoniazid + Rifampicin	Dispersible tablets 30mg + 60mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Triple laminated LDPE/PET/AL bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 10, 28; Alu/Alu strip 3 x 10, 10 x 10, 28 x 3, 14 x 6, 3 x 28, 6 x 14	TB181	2009-Mar-03	
TB	Isoniazid + Rifampicin	Dispersible tablets 60mg + 60mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Triple laminated LDPE/PET/AL bag further packed in HDPE container 1000; PVC/PVdC/Alu blister 3 x 28, 24 x 28, 10 x 10; Alu/Alu strip 3 x 10, 10 x 10, 28 x 3, 14 x 6, 3 x 28, 6 x 14	TB182	2009-Nov-09	
TB	Isoniazid + Rifampicin	Dispersible tablets 30mg + 60mg	Lupin Ltd	Chikalthana, Aurangabad, India; Bari Brahmana, Jammu (J&K), India	Al/Al strip 15 x 6, 14 x 6	TB184	2012-Jul-02	
TB	Isoniazid + Rifampicin	Tablets 75mg + 150mg	Svizera Europe B.V. - The Netherlands	Svizera Labs Private Ltd, Navi Mumbai, India	PVC/Alu blister 24 x 28; HDPE jar 1000	TB189	2012-Dec-19	
TB	Isoniazid + Rifampicin	Tablets 150mg + 150mg	Lupin Ltd	Chikalthana, Aurangabad, India	PVC/PVDC/Alu blister 24 x 28; HDPE bottle 1000	TB195	2013-Jan-29	
TB	Isoniazid + Rifampicin	Tablets 75mg + 150mg	Strides Arcolab Limited	Bangalore, India	Al/PVC/PE/PVDC blister 24 x 28, 48 x 10; HDPE bottle 1000	TB202	2012-May-24	
TB	Isoniazid + Rifampicin	Capsules 150mg + 300mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 1x10, 100x10	TB270 (a)	2013-Feb-28	
TB	Levofloxacin	Tablets 250mg	Cipla Ltd	Goa, India	Alu/PVC blister 10; HDPE bottle 50	TB205	2011-Dec-22	
TB	Levofloxacin	Tablets 500mg	Cipla Ltd	Goa, India	Alu/PVC blister 10; HDPE bottle 50	TB227	2011-Dec-22	
TB	Levofloxacin	Tablets 250mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVC/Alu blister 10 x 10	TB237	2012-Oct-03	
TB	Levofloxacin	Tablets 500mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVC/Alu blister 10 x 10	TB238	2012-Oct-03	
TB	Levofloxacin	Tablets 250mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	TB271 (a)	2013-Jun-24	
TB	Levofloxacin	Tablets 500mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	TB272 (a)	2013-Jun-24	
TB	Levofloxacin	Tablets 750mg	Apotex Inc.	Toronto, Ontario, Canada (Manufacturing); Weston, Ontario, Canada (Packaging)	HDPE bottle 100	TB273 (a)	2013-Jun-24	
TB	Levofloxacin	Tablets 250mg	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	Alu/PVC blister 5 x 20 Tablets	TB277	2014-Oct-24	
TB	Levofloxacin	Tablets 500mg	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	Alu/PVC blister 5 x 20 Tablets	TB278	2014-Oct-24	
TB	Levofloxacin	Tablets 750mg	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	Alu/PVC blister 10 x 10 Tablets	TB279	2014-Oct-24	
TB	Moxifloxacin (as hydrochloride)	Tablets 400mg	Cipla Ltd	Patalganga, India	HDPE bottle 30, 100, 1000; Blister 5	TB210	2010-Nov-01	
TB	Moxifloxacin (as hydrochloride)	Tablets 400mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Alu/Alu cold form blister 1x5, 20x5, 10x7, 10x10; Alu/Alu strip 1x5, 20x5, 10x7, 10x10	TB230	2012-Nov-16	
TB	Moxifloxacin (as hydrochloride)	Tablets 400mg	Ranbaxy Laboratories Ltd	MSN Laboratories Ltd, Medak District, Andhra Pradesh, India	Al/PVC/PVDC blister 1 x 5, 1 x 10	TB253	2013-Nov-04	
TB	Ofloxacin	Tablets 200mg	Macleods Pharmaceuticals Ltd	Solan, Himachal Pradesh, India	Al/PVC blister 10; HDPE bottle 100	TB218	2012-Oct-31	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
TB	Ofloxacin	Tablets 200mg	Cipla Ltd	Patalganga, India	Alu/PVC blister 10 x 10; HDPE bottle 100, 500, 1000	TB224	2011-Dec-22	
TB	Ofloxacin	Tablets 400mg	Cipla Ltd	Patalganga, India	Alu/PVC blister 10 x 10; HDPE bottle 100, 500, 1000	TB225	2011-Dec-22	
TB	Ofloxacin	Tablets 200mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVC/Alu blister 10 x 10; HDPE bottle 100	TB240	2012-Sep-11	
TB	Ofloxacin	Tablets 400mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVC/Alu blister 10 x 10; HDPE bottle 100	TB241	2012-Sep-11	
TB	p-Aminosalicylic acid (as sodium salt) (common name)	Powder for oral solution 4 g	OlainFarm JSC	Olaine, Latvia	25 or 300 per box	TB229 (a)	2011-Mar-22	
TB	Para-aminosalicylate sodium	Delayed release granules 60% w/w	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India; Himachal Pradesh, India	Solan, LDPE bag placed in triple laminated Alu/PET/Alu/LLDPE sachet further packed in HDPE container 100g; PET/Alu/LLDPE Sachet 9.2g	TB156	2009-Dec-14	
TB	Prothionamide	Tablets 250mg	Lupin Ltd	Chikalthana, Aurangabad, India	HDPE bottle 50	TB206	2014-Jun-13	
TB	Protonamide	Tablets 250mg	Micro Labs Limited	Hosur, Tamilnadu, India	PVC/PVdC-Alu blisters 10 x 14; HDPE bottle 100	TB239	2013-Feb-25	
TB	Pyrazinamide	Tablets 400mg	Cadila Pharmaceuticals Ltd	Dholka, Ahmedabad, India	HDPE bottle 1000; PVC/Alu blister 10x10; PVC/PVdC/Alu blister 24x28	TB015	2003-Nov-13	
TB	Pyrazinamide	Tablets 400mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	LDPE bag in HDPE container sealed with aluminium tagger 500, 1000; PVC/Alu blister 10; 28	TB159	2007-Mar-23	
TB	Pyrazinamide	Tablets 400mg	Micro Labs Limited	Hosur, Tamilnadu, India	PE bag further packed in HDPE container 1000	TB171	2009-Jun-29	
TB	Pyrazinamide	Tablets 500mg	Micro Labs Limited	Hosur, Tamilnadu, India	PE bag further packed in HDPE container 1000	TB172	2009-Jun-29	
TB	Pyrazinamide	Tablets 500mg	Macleods Pharmaceuticals Ltd	Kachigam, Daman, India	Alu/PVC blister 3 x 10, 10 x 10, 3 x 28, 24 x 28, 10 x 7; HDPE bottle 1000	TB243	2012-Dec-04	
TB	Pyrazinamide	Tablets 500mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 2x10, 150x10	TB267 (a)	2013-Feb-28	
TB	Rifampicin	Capsules 150mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 2x10, 100x10	TB268 (a)	2013-Feb-28	
TB	Rifampicin	Capsules 300mg	S.C. Antibiotice S.A.	Iasi, Romania	PVC/Alu blisters 1x10, 100x10	TB269 (a)	2013-Feb-28	