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-blister)
[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
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	Mylan Laboratories Ltd, Sinnar, Nashik District, Maharashtra, India; Mission Vivacare Ltd, Pithampur, Dhar, M.P., 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, Herthfordshire, 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	
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	

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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, Indianna, USA; Mount Vernon, Indianna (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	
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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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	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); Pharmacare 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	Blister 30	HA330 (a)	2006-May-23	
HIV	Didanosine	Capsules 400mg	Bristol-Myers Squibb	Mount Vernon, Indiana, USA; Anagni (Primary and secondary packaging and batch release), Italy	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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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	
HIV	Efavirenz	Tablets 600mg	Cipla Ltd	Goa, India; Himachal Pradesh, India; 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, Periyakalapet, Pondicherry, India	HDPE bottle 30	HA527	2014-Oct-24	

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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	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 10	HA209	2004-Jul-13	
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	

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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	
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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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; 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; Mission Vivacare Limited, Pithampur, Dhar, M.P., India; Shasun Pharmaceutical Ltd, Periyakalapet, 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	Tablets 150mg + 30mg	Mylan Laboratories Ltd	Sinnar, Nashik District, Maharashtra, India	HDPE bottle 60; Blister 10 (USFDA)	HA405*	2008-Jul-25	
HIV	Lamivudine + Stavudine	Tablets 150mg + 40mg	Mylan Laboratories Ltd	Sinnar, Nashik Dsitrict, Maharashtra, India	HDPE bottle 60; Blister 10 (USFDA)	HA406*	2008-Jul-25	
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	
HIV	Lamivudine + Tenofovir disoproxil fumarate	Tablets 300mg + 300mg	Mylan Laboratories Ltd	Mylan Laboratories Ltd, Sinnar, Nashik District, Maharashtra, India; Mission Vivacare Ltd, Pithampur, Dhar, M.P., India; Waluj, Aurangabad, Maharashtra; Inda	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; 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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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, Periyakalapet, 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	Mylan Laboratories Ltd, Sinnar, Nashik District, Maharashtra, India; Mission Vivacare Ltd, Pithampur, Dhar M.P., India; Mylan Laboratories Ltd, 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	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; 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	Oral solution (80mg + 20mg)/ml	Abbott Laboratories	Queensborough, Kent, UK	PET bottle 60ml	HA098 (a)	2002-Mar-20	
HIV	Lopinavir + Ritonavir	Tablets 200mg + 50mg	Abbott Laboratories	Ludwigshafen, Germany	HDPE bottle 120	HA381 (a)	2006-Oct-30	
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 100mg + 25mg	Abbott Laboratories	Ludwigshafen, Germany	HDPE bottle 60	HA434 (a)	2008-Jul-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	
HIV	Lopinavir + Ritonavir (ALUVIA)	Tablets 200mg + 50mg (red)	Abbott Laboratories	Ludwigshafen, Germany	HDPE bottle 120	HA412 (a)	2007-Jun-06	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
HIV	Nevirapine	Tablets 200mg	Cipla Ltd	Cipla Ltd, Goa, India; Meditab Specialties Pvt Ltd, Kundaim, Goa, India; 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	Mylan Laboratories Ltd, Nashik District, Maharashtra, India; Mission Vivacare Ltd, Pithampur, Dhar, M.P., 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	
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.	Etobioke, 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.	Etobioke, 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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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	
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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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	HDPE bottle 30	HA516	2013-May-23	
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	
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 Specialties 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	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
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	