

**List Of ARV Pharmaceutical Products
classified according to the Global Fund Quality Assurance Policy**

Edition: Version 153 - 18th December 2018

The list is an overview of pharmaceutical products subject to the Global Fund Quality Assurance Policy that are listed in National and/or WHO standard treatment guidelines and classified according to the various options (A, B, and ERP reviewed) defined in the Global Fund Quality Assurance Policy (July 2009, amended in December 2010). The list is developed as a tool to assist Principal Recipients (PR) of Global Fund grants to identify the status of finished pharmaceutical products according to the Global Fund Quality Assurance Policy.

The pharmaceutical products are classified based on the following information

- A classified product - Listed on WHO prequalification list;
- B classified product - Stringent NDRA Registration letter/Marketing Authorization;
- ERP reviewed product- **Permitted for time-limited procurement** based on advice by the Expert Review Panel (ERP);

Please note that the list is not an exhaustive list. A PR can procure product(s) not listed in the current list as long as PR demonstrates that the product is compliant with the Global Fund Quality Assurance Policy.

The Global Fund list includes the following information:

- **"Important Notes" for helpful information;**
 - **A, B, and ERP reviewed products;**
 - **Period validity of the ERP reviewed products;**
 - **"+" 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 fixed-dose formulation and C is co-packaged**
- YELLOW signifies a new entry; PINK signifies modification of an existing entry.**

For more information, please look at:

<https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>.

Expert Review Panel (ERP): Expert Review Panel is an independent technical body composed of external technical experts, hosted by WHO Department of Essential Medicines and Pharmaceutical Policies, to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized and to advise the Global Fund in its decision on whether to allow grant funds to be used to procure FPP. ERP reviewed products can be procured for a limited time (maximum 12 months). However, under certain circumstances, it is possible to extend the recommendation period. Contracts to supplier/manufacturer for an ERP reviewed products should not be longer than the validity period of the recommendation of that product. For detail information on ERP process and Quality Assurance information, please look at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>.

Procurement of ERP Reviewed Products: Principal Recipients (PRs) must inform the concerned Fund Portfolio Manager (FPM) at the Global Fund in writing by filling the “Notification Form” (available on website) if they intend to procure ERP-reviewed product(s). The Global Fund Secretariat will review the notification request and upon issuing a “ no objection” letter to the PR for the requested selection, procurement can only proceed.

Important Notes

This List may be used by Principal Recipients of Global Fund grants when considering options with respect to procurement of pharmaceutical products pharmaceutical products subject to the Global Fund Quality Assurance Policy. The list aims at providing countries with information that will assist them in their procurement options. Please note that the list is not designed to be a basis for countries to select medicines to be included in their National Treatment Guidelines or to replace any applicable and legally required procurement processes. The Global Fund requires its grant recipients to comply with applicable procurement laws and provides the list only for the **identification of products/manufacturers that comply with the Global Fund's quality assurance policy**. It is important to note that there is no strict requirement to procure according to the list, as long as the Principal Recipients can ensure that the product selected is compliant with the Quality Assurance policy criteria. Furthermore, the Principal Recipient should not rely solely on the information provided in the list but should obtain evidence of products compliance with the Quality Assurance policy. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

The Lists will be updated regularly based on evidence received by the Global Fund. Interested parties are invited to supply information and evidence of products meeting the policy criteria on an ongoing basis. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

According to the Global Fund QA policy, if there are two or more A or B classified manufacturers available for any given product AND the product is available from these manufacturers (available-means that the manufacturer can supply the selected product within 90 days after receiving the Purchase Order), then such product must be procured from A or B classified product manufacturers. The PR must notify by writing to the Global Fund Secretariat (Fund Portfolio Manager) and receive the "No Objection" letter from GF secretariat before procuring any products complying with option " ERP Reviewed".

For ease of reference, each "product" has been identified in this list with a unique "Product reference number" (Column A). Please see examples below.

Several different dosage forms may be grouped under the same Product Reference Number and therefore will be considered the same type of products when identifying the number of available manufacturers for the application of this policy. These products share the same dosing protocol, target the same population, and there are no fundamental differences among them. For example, within solid forms, some capsules will have same reference number as tablets while within liquids, oral solution and suspension are grouped together. Similarly, the entero coated tablet or dispersible tablet will not share the same reference number as non entero coated or dispersible tablets.

Product Ref.No	International Non-proprietary name	Strength	Dosage form	Supplier/Manufacturer *	Global Fund QA Standard	WHO Pre-qualified/SRA	Manufacturing site*	Country	Material	Pack
16	XYZ	50mg	Tablet	"Pharma Company A"	A - B	Yes	"Pharmaville"	Country A	HDPE bottle	60
17		100mg	Tablet	"Pharma Company B"	A - B	Yes	"Pharmaville"	Country B	HDPE bottle	60

The example above shows 2 different variants of the same medicine. Because the strength is different, it is considered 2 different products (there are two different reference numbers 16 and 17). If the strength had been the same but the dosage form had been different (i.e. tablet and liquid) it would also have been considered two different "products".

Product Ref.No	International Non-proprietary name	Strength	Dosage form	Supplier/Manufacturer*	Global Fund QA Standard	WHO Pre-qualified/SRA	Manufacturing site*	Country	Packaging	
25	ABC	150mg	Tablet	"Pharma Company A"	A - B	Yes	"Pharmaville"	Country A	Blister, HDPE bottle	10, 60
			Capsules	"Pharma Company B"	A - B	Yes	"Pharmaville"	Country B	HDPE Bottle,	60, 10

In this second example both products have same reference number (25) because both manufacturers are supplying the same strength and the dosage forms are considered similar as per explanation above.

* See below

Disclaimer:

The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS, HCV, tuberculosis or malaria. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use of treatment of any disease in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

*** As from version 137, please note that we consider under**

**Supplier / Manufacturer :
Marketing authorization/ product authorization or license holder**

**Manufacturing Site:
The Site responsible for the release of the FPP**

List of A or B products:

If there are two or more ‘A’ or ‘B’ products available, then the product **must be procured from one of the A or B products.**

Note: if the product intended for selection is not listed in this list , please refer to the List of ERP (Expert Review Panel) Reviewed Products which are permitted for time limited procurement:

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
1	Abacavir (ABC)	20 mg / ml	Oral solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	HDPE bottle	240ml
	Abacavir (ABC) as sulfate	20 mg / ml	Oral Solution	Meditabs Specialities Pvt Ltd	A	Yes	Satara, Maharastra	India	PET Bottle	100ml
	Abacavir (ABC) as sulfate	20 mg / ml	Oral Solution	Hetero labs limited	A	Yes	Unit III 22-110 Industrial development Area Jeedimetla, Hyderabad Andhra Pradesh, India	India	HDPE Bottle	240ml
	Abacavir (ABC)	20 mg / ml	Oral Solution	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle	240ml
2	Abacavir (ABC) as sulfate	60 mg	Dispersible Tablet	Cipla Ltd.	A -B	Yes	A-33, MIDC Patalganga	India	HDPE Bottle	60
	Abacavir (ABC) as sulfate	60 mg	Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar, Nashik, Maharashtra	India	HDPE	60
	Abacavir (ABC) as sulfate	60 mg	Dispersible Tablet	Microlabs Ltd	A	HA674	Micro Labs Ltd, Phase III & Phase IV, Plot No. S-155 to S-159 & N1 Verna Industrial Estate, Verna, Goa	India	HDPE	60
3	Abacavir (ABC)	300 mg	Tablet	Cipla Ltd.	A - B	Yes	A-23, MIDC Patalganga	India	HDPE Bottle,	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Abacavir (ABC)	300 mg	Tablet	ViiV HealthCare	A - B	Yes	Glaxo Operations UK, Ltd, Ware, Herthfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	Blister	60
	Abacavir (ABC)	300 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	60; 6*10
	Abacavir (ABC)	300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE Bottle; Blister	60; 6*10
	Abacavir (ABC) as sulfate	300 mg	Film coated Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle; Blister	60; 6*10
	Abacavir (ABC)	300 mg	Tablet	Hetero labs limited	A-B	Yes	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad -500 055 Andhra Pradesh,	India	HDPE Bottle; Blister Film Package	60, 100, 500; 10
	Abacavir (ABC)	300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No 313 Bachyupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle;	60 ;
4	Abacavir + Lamivudine	60 mg + 30 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 and 314, Bachupally Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle; Blister	30, 60; 10*10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Abacavir (as Sulfate)+ Lamivudine	60 mg + 30 mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Ltd, F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113; Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775	India	HDPE bottle	30, 60
	Abacavir+Lamivudine	60 mg + 30 mg	Tablet	Hetero labs limited	B	NDA 207369	Hetero Labs Limited Unit V SEZ Unit I in APIIC SEZ Polepally Village, Jadcherla Mandal Mahaboob Nagar	India	HDPE bottle Alu-Alu blisters	30 10X10
5	Abacavir Sulfate + Lamivudine	60 mg + 30 mg	Tablets for oral suspension	Cipla Ltd.	A-B	Yes	A-33, MIDC Patalganga	India	HDPE container; Blister	60, 120; 10
	Abacavir Sulfate + Lamivudine	60 mg + 30 mg	Tablets for oral suspension	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle	60
6	Abacavir and Lamivudine Tablets for Oral Suspension	120 mg / 60 mg	Tablets for Oral Suspension	Mylan Laboratories Ltd	B	Yes	Waluj, Aurangabad, Maharashtra,	India	HDPE bottle	30, 2000
	Abacavir (as Sulfate) + Lamivudine	120 mg / 60 mg	Disp. Tablet	Cipla Ltd.	A-B	HA662 NDA 208775	Plot No A – 33, A – 2 (Unit – I), MIDC, Patalganga District Raigad, Maharashtra, 410 220	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
7	Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle; Blister	30; 10
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet Film coated	Glaxo SmithKline Ltd.	B	Yes	Ware, Hertfordshire; Aranda de Duero, Burgos; Research Triangle Park, NC	UK, Spain, USA	HDPE Bottle Blister	30 30
	Abacavir Sulfate+ Lamivudine	600 mg + 300 mg	Tablet	Cipla Ltd.	B	Yes	A-33, MIDC Patalganga,	India	HDPE Bottle; Blister	30; 3*10
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Sinnar, Nashik, Maharashtra	India	HDPE Bottle	28; 30
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Hetero labs limited	A-B	HA657	Hetero Labs Limited, Unit-V SEZ Unit I Survey No. 439, 440, 441 & 458 Mahaboob Nagar.	India	HDPE Bottle Blister	30 10's x 10
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet	ViiV Healthcare UK Limited	A	HA706	Glaxo Operations UK Limited, Priory Street, Ware, Hertfordshire, SG12 0DJ, United Kingdom of Great Britain and Northern Ireland GlaxoSmithKline Pharmaceuticals S. A. ul., Grunwaldzka 189, 60-332 Poznan, Poland Glaxo Wellcome SA, Avenue de Extremadura 3, Aranda de Duero, Burgos, Spain	United Kingdom of Great Britain and Northern Ireland	Child resistant blister, PVC/PVdC-Alu/Paper	1x1; 10x3
8	Abacavir (as Sulfate)+ Lamivudine + Zidovudine	60 mg + 30 mg + 60 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar, Nashik, Maharashtra	India	HDPE	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
9	Abacavir + Lamivudine + Zidovudine	300 mg + 150 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle	60
	Abacavir + Lamivudine + Zidovudine	300 mg + 150 mg + 300 mg	Tablet	ViiV HealthCare	A - B	Yes	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	HDPE Botte Blister,	60; 40; 60
	Abacavir (as Sulfate)+ Lamivudine + Zidovudine	300 mg + 150 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60
	Abacavir + [Lamivudine + Zidovudine]	300 mg + 150 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey 313 & 314, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh,	India	PVC / PVdC / Aluminum Foil	Blister Card Contains: 10 + 10 Each Carton Contains: 60 + 60
10	Aciclovir	200 mg	Tablet	Mylan Laboratories Ltd	A	HA625	Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136, India	India	PVC/Alu blister PVC/PVdC/ Alu blister	10x1
	Aciclovir	400 mg	Tablet	Hetero labs limited	A	HA554	Unit 5, Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301	India	HDPE Container	500x1, 100x1

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Aciclovir	400 mg	Tablet	Mylan Laboratories Ltd	A	HA626	Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136, India	India	PVC/Alu blister PVC/PVdC/ Alu blister	10x1
11	Atazanavir	50 mg / 1.5g	Oral powder	Bristol-Myers Squibb	B	Yes	Hounslow	UK	Bottle (HDPE)	180g
12	Atazanavir	100 mg	Hard Capsule	Bristol-Myers Squibb	B	Yes	Hounslow	UK	Bottle (HDPE) Blister (alu)	60, 60
	Atazanavir	100 mg	Capsule	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle;	60;
	Atazanavir	100 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle Blister	60,500 10
13	Atazanavir	150 mg	Capsule	Bristol-Myers Squibb	A	Yes	Evansville, Indiana, Mount Vernon, Indiana (primary packaging)	USA	HDPE bottle	60
	Atazanavir	150 mg	Capsule Hard	Bristol-Myers Squibb	B	Yes	Hounslow	UK	Bottle (HDPE) Blister (alu)	60 60
	Atazanavir	150 mg	Capsule	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle	60
	Atazanavir	150 mg	Capsule	Aspen Pharmacare Limited	B	ANDA 091641	Elizabeth (Pty) Ltd, Corner Fairclough and Gibaud Roads, Korsten, Port Elizabeth, 6020	South Africa	HDPE bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Atazanavir (as Sulfate)	150 mg	Capsule	Mylan Laboratories Ltd	A -B	Yes	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	India	HDPE Bottle	30, 100
	Atazanavir (as Sulfate)	150 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle Blister	60,180, 500 10
14	Atazanavir	200 mg	Capsule Hard	Bristol-Myers Squibb	B	Yes	Hounslow	UK	Bottle (HDPE) Blister (alu)	60, 60
	Atazanavir	200 mg	Capsule	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle;	60;
	Atazanavir	200 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle Blister	60,180, 500 10
	Atazanavir	200 mg	Capsule	Aspen Pharmacare Limited	B	ANDA 091641	Elizabeth (Pty) Ltd, Corner Fairclough and Gibaud Roads, Korsten, Port Elizabeth, 6020	South Africa	HDPE bottle	60
15	Atazanavir (as Sulfate)	300 mg	Capsule	Bristol-Myers Squibb	B	Yes	Evansville, Indiana,	USA	HDPE Bottle	30
	Atazanavir (as Sulfate)	300 mg	Capsule	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE Bottle	30
	Atazanavir (as Sulfate)	300 mg	Capsule	Mylan Laboratories Ltd	A- B	Yes	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	India	HDPE Bottle	30, 100

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Atazanavir (as Sulfate)	300 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle Blister	30, 90,500 10
16	Atazanavir (sulfate)+ Ritonavir	300mg + 100mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90, 120
	Atazanavir (sulfate)+Ritonavir	300mg+100mg	Tablet (FDC)	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE Bottle	30
	Atazanavir (sulfate)/Ritonavir	300mg+100mg	Tablet	Cipla Ltd.	A	HA632	Cipla, Unit 2, Plot A-42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra	India	Bottle HDPE Alu/Alu Blister	30x1; 10x3
17	[Atazanavir Sulfate+ Ritonavir] +[Lamivudine and Zidovudine]	[300 mg / 100 mg] +[150 mg / 300 mg]	co-packaged Tablets	Mylan Laboratories Ltd	B	Yes	Sinnar, Nashik District 422 113, Maharashtra	India	PVC blister	Cartons containing 5 blister packs (consisting of PVC/Aclar film and coated aluminum foil), each containing two 1-day cards, for a 10 day supply. Three cartons are further packaged together for a 30 day supply
	Darunavir	75mg	Tablets	Mylan Laboratories Ltd	B	Yes	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	100; 500; 480
20	Darunavir (as Ethanolate)	75 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	A-B	Yes	Janssen Ortho LLC, Gurabo, Puerto Rico, United States (Manufacturing and release testing); Janssen-Cilag SpA, Latina, Italy (Testing and final QC release and packaging)	Puerto Rico	HDPE Bottle	480

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Darunavir (as Ethanolate)	75 mg	Tablets	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	480
	Darunavir (as Ethanolate)	150 mg	Tablets	Cipla	B	ANDA 207189	(Unit II), MIDC, Patalganga	India	HDPE Bottle	480
	Darunavir	150mg	Tablets	Mylan Laboratories Ltd	B	Yes	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	240; 300
21	Darunavir (as Ethanolate)	150 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	A-B	Yes	Janssen Ortho LLC, Gurabo, Puerto Rico, United States (Manufacturing and release testing); Janssen-Cilag SpA, Latina, Italy (Testing and final QC release and packaging)	Puerto Rico	HDPE Bottle	240
	Darunavir (as Ethanolate)	150 mg	Tablets	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	240
	Darunavir	300mg	Tablets	Mylan Laboratories Ltd	B	Yes	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	120; 360

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Darunavir (as Ethanolate)	300 mg	Tablets	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	120
22	Darunavir	400mg	Tablets	Mylan Laboratories Ltd	B	Yes	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	60; 180; 360
	Darunavir	400 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmcare South Africa	B	Yes	Jansen Ortho LLC, Gurabo	Puerto Rico	HDPE Bottle	60
	Darunavir	400mg	Tablet	Hetero Labs limited	B	Yes	UNIT-III, Hyderabad	India	HDPE Bottle	60
	Darunavir Ethanolate	400mg	Tablet	Cipla	A-B	HA627 ANDA 207189	(Unit II), MIDC, Patalganga	India	HDPE Bottle	60
	Darunavir (as Ethanolate)	400mg	Tablet	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	60
23	Darunavir	600mg	Tablets	Mylan Laboratories Ltd	B	Yes	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	60; 180; 360

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Darunavir	600 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	B	Yes	Jansen Ortho LLC, Gurabo	Puerto Rico	HDPE Bottle	60
	Darunavir	600 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	A	Yes	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)	USA	HDPE Bottle	60
	Darunavir	600mg	Tablet	Hetero Labs limited	B	Yes	UNIT-III, Hyderabad	India	HDPE Bottle	60
	Darunavir	600 mg	Film coated Tablet	Sandoz Ltd, UK	B	Yes	Manufacturer LEK farmacevtska družba d.d. Verovškova 57, 1526 Ljubljana, Slovenia or Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany or Remedica Ltd, Aharnon Street, Limassol Industrial (Unit II), MIDC, Patalganga	Slovenia Germany Cyprus	Aluminium-PVC/PE/PVDC perforated blisters HDPE bottles	60x1 unit dose blister 10, 30, 60, 90, 120 60, 120 (2x60), 180 (3x60), 240 (4x60)
	Darunavir Ethanolate	600mg	Tablet	Cipla	A-B	HA628 ANDA 207189	(Unit II), MIDC, Patalganga	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Darunavir (as Ethanolate)	600mg	Tablet	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	60
	Darunavir (as Ethanolate)	800mg	Tablet	Lupin Limited	B	Yes	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	30 & 90
	Darunavir (as Ethanolate)	800mg	Tablet	Cipla	A	HA664	Unit 2, Plot A-42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra, 410 220	India	HDPE Bottle	30
24	Didanosine (ddI)	2 g	Powder for Oral Solution	Bristol-Myers Squibb	B	Yes	Mount Vernon, Indiana, USA; Anagni (Secondary packaging and batch release), Italy	USA	Glass Bottle	2g
25	Didanosine (ddI)	10 mg / ml	Powder for Oral Solution	Bristol-Myers Squibb	B	Yes	Meymac Evansville, Indiana,	France USA	HDPE bottle	2g
26	Didanosine (ddI)	25 mg	Tablet	Bristol-Myers Squibb	B	Yes	Emcure, New jersey	USA	HDPE bottle	60
27	Didanosine (ddI)	50 mg	Tablet	Bristol-Myers Squibb	B	Yes	Emcure, New jersey	USA	HDPE bottle	60
28	Didanosine (ddI)	100 mg	Tablet	Bristol-Myers Squibb	B	Yes	Emcure, New jersey	USA	HDPE bottle	60
29	Didanosine (ddI)	125 mg	Capsule Delayed release	Mylan Laboratories Ltd	B	Yes	Sinnar, Nashik, Maharashtra	India	HDPPE Bottle	30, 500
	Didanosine (ddI)	125 mg	Capsule Delayed release	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle Blister	30, 500; 14

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
30	Didanosine (ddI)	150 mg	Tablet	Bristol-Myers Squibb	B	Yes	Emcure, New jersey	USA	HDPE bottle	60
31	Didanosine (ddI)	200 mg	Capsule Delayed release	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle	30, 500
	Didanosine (ddI)	200 mg	Capsule Delayed release	Barr Laboratories, Inc.	B	Yes	Pomona, NY	USA	Bottle	30
	Didanosine (ddI)	200 mg	Capsule Delayed release	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle Blister	30, 500; 10
32	Didanosine (ddI)	250 mg	Capsule Delayed release	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 500
	Didanosine (ddI)	250 mg	Capsule	Bristol-Myers Squibb	B	Yes	Mount Vernon, Indiana, USA; Anagni (Primary and secondary packaging and batch release), Italy	USA	Blister	30
	Didanosine (ddI)	250 mg	Capsule Delayed release	Barr Laboratories, Inc.	B	Yes	Pomona, NY	USA	Bottle	30
	Didanosine (ddI)	250 mg	Capsule Delayed release	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle; Blister	30, 500 10
33	Didanosine (ddI)	400 mg	Capsule Delayed release	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 500

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Didanosine (ddI)	400 mg	Capsule	Bristol-Myers Squibb	B	Yes	Mount Vernon, Indiana, USA; Anagni (Primary and secondary packaging and batch release), Italy	USA	Blister	30
	Didanosine (ddI)	400 mg	Capsule Delayed release	Barr Laboratories, Inc.	B	Yes	Pomona, NY	USA	Bottle	30
	Didanosine (ddI)	400 mg	Capsule Delayed release	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle; Blister	30, 500; 5
34	Dolutegravir (as sodium salt)	50mg	Tablets	ViiV Healthcare	A	Yes	Glaxo Operations UK Ltd, Hertfordshire (manufacturing and quality control), UK; Glaxo Wellcome S.A., Burgos (primary and secondary packaging, batch release), Spain	UK	Bottle	30
	Dolutegravir (as sodium salt)	50mg	Tablets	Hetero Labs Ltd	A	HA682	Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055	India	Blister,Alu/Alu; Bottle,HDPE	10x8; 30x1
	Dolutegravir (as sodium salt)	50mg	Tablets	Mylan Laboratories Ltd	A	HA678	Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775	India	Blister,PVC/ACLAR; Bottle,HDPE	10X1; 30X1,90X1,180X1

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Dolutegravir (as sodium salt)	50mg	Tablets	Cipla Ltd	A	HA680	Cipla Ltd, Unit IV, Plot No 9, 10 & 15 Indore Special Economic Zone, Phase II, Pithampur, Dhar District, Madhya Pradesh, 454 775, India	India	Bottle, HDPE	30x1;90x1
	Dolutegravir (as sodium salt)	50mg	Tablets	Aurobindo Pharma Ltd	B	ANDA 208355	Aurobindo Pharma Ltd, Unit –VII, SEZ, TSIIC, Plot No. S1, Survey No.'s 411, 425, 434, 435 & 458, Green Industrial Park, Polepally village, Jedcherla Mandal, Mahaboob Nagar District, Telangana State	India	HDPE bottle	30
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate +	50mg + 300 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	NDA 209618	Unit VII,SEZ, TSIIC, Plot No. SI, Survey No. 411/P, 425/P,434/P, 435/P,458/P Green industrial Park, Polepally Village, Jedcherla Mandal, Mahaboob Nagar Telangana	India	HDPE Container	30
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate +	50mg + 300 mg + 300 mg	Tablet	Mylan laboratories Ltd	A-B	HA688 NDA 209670	(FDF-3) Plot No. 11, 12 & 13, Indore Special Economic Zone Pharma Zone, Phase II, Sector III, Pithampur District Dhar – 454775 Madhya Pradesh	India	HDPE Bottle	30, 90, 180

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate +	50mg + 300 mg + 300 mg	Tablet	Hetero labs limited	B	NDA210880	Hetero Labs Limited Unit – III (Formulations), # 22 – 110, IDA Jeedimetla, Hyderabad, Telangana	India	HDPE Container	30, 60, 90, 100, 750
35	Efavirenz (EFV)	30 mg / ml	Oral Solution	Merck Sharp & Dohme Limited	A - B	Yes	Patheon Inc. Mississauga, Ontario Harlem	Canada Netherlands	HDPE Bottle	180ml
36	Efavirenz (EFV)	50 mg	Capsule	Merck Sharp & Dohme Limited	A	Yes	Manati, Harlem	Puerto Rico Netherlands	HDPE bottle	30
	Efavirenz (EFV)	50 mg	Capsule	Microlabs Ltd	B	Yes	Verna, Goa	India	Bottle	30, 60, 90
	Efavirenz (EFV)	50 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle; Blister	30 10
37	Efavirenz (EFV)	50 mg	Tablet	Merck Sharp & Dohme Limited	A	Yes	South Granville, BN Haarlem (packager, responsible for batch release in the EU)	Australia	HDPE bottle	30
	Efavirenz (EFV)	50 mg	Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
38	Efavirenz (EFV)	100mg	Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
	Efavirenz (EFV)	100mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle; Blister	30, 500; 10
39	Efavirenz (EFV)	100mg	Dispersible Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Mohali, Punjab	India	HDPE Bottle	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
40	Efavirenz (EFV)	200 mg	Capsule	Cipla Ltd.	A - B	Yes	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	90, 1000
	Efavirenz (EFV)	200 mg	Capsule	Merck Sharp & Dohme Limited	A	Yes	Manati, Harlem	Puerto Rico Netherlands	HDPE bottle	90
	Efavirenz (EFV)	200 mg	Capsule	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle; Blister	90; 90
	Efavirenz (EFV)	200 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 & 314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle; Blister	30, 90; 10
	Efavirenz (EFV)	200 mg	Capsule	Microlabs Ltd	B	Yes	Verna, Goa	India	Bottle	30,60,90
41	Efavirenz (EFV)	200 mg	Film coated Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle	90
	Efavirenz (EFV)	200 mg	Tablet	Merck Sharp & Dohme Limited	A	Yes	South Granville, BN Haarlem (packager, responsible for batch release in the EU)	Australia	HDPE bottle	90
	Efavirenz (EFV)	200 mg	Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar, Nashik, Maharashtra	India	HDPE Bottle	30, 90

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
42	Efavirenz (EFV)	600 mg	Tablet	Merck Sharp & Dohme Limited	A	Yes	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	Puerto Rico Australia Netherlands China	HDPE bottle	30
	Efavirenz (EFV)	600 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle Blister;	30; 30
	Efavirenz (EFV)	600 mg	Tablet Film coated	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	30, 10
	Efavirenz (EFV)	600 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle; Blister	28, 30; 10
	Efavirenz (EFV)	600 mg	Tablet	Shanghai Desano Bio-pharmaceutical Co.	A	HA658	1479 Zhangheng Road, Zhangjiang Hi-Tech Park, Shanghai 201203	China	HDPE bottle	30x1
	Efavirenz (EFV)	600 mg	Tablet	Cipla Ltd.	A - B	Yes	L-139 to L-146, Verna Goa Quality Chemical Industries Ltd, Kampala	India Uganda	HDPE bottle Blister	30, 500 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Efavirenz (EFV)	600 mg	Film coated Tablet	Strides Arcolab Limited	A-B	HA390	Universal Corporation Ltd, PO Box 1748, Club Road, Plot No 13777, Kikuyu, 902; Strides Shasun Ltd, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106	Kenya; India	HDPE bottle	30
	Efavirenz (EFV)	600 mg	Tablet Film coated	Hetero labs limited	A-B	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; Unit-V, Mahaboob Nagar, Andhra Pradesh, India	India	HDPE Container	28, 30, 250
	Efavirenz (EFV)	600 mg	Tablet	Macleods Pharmaceuticals Limited	A-B	Yes	Himachal Pradesh	India	HDPE container	30
	Efavirenz (EFV)	600 mg	Tablet	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle; Blister	30, 60; 3*10
	Efavirenz (EFV)	600 mg	Tablet	Microlabs Ltd	A-B	HA633	Verna, Goa	India	HDPE bottle; Blister	30x1 10x3
	Efavirenz (EFV)	600 mg	Tablet	Pharmacare Ltd.(trading as Aspen Pharmacare)	A	HA649	Aspen Port Elizabeth , (Pty) Ltd, Korsten Port Elizabeth, South Africa	South Africa	Layflat laminat Bag(PET/Alu/LLDPE) HDPE Bottle	30 30
	Efavirenz (EFV)	600 mg	Tablet	Edict Pharmaceuticals Private Limited	B	Yes	Chennai	India	HDPE container	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Efavirenz (EFV)	600 mg	Film coated Tablet	Sandoz Ltd, UK	B	Yes	Lek Pharmaceuticals d.d., Ljubljana or Salutas Pharma GmbH, 39179 Barleben, or LEK S.A., 672 Warszawa or Salutas Pharma GmbH, Dieselstr. 5, 70839 Gerlingen, Germany or S.C. Sandoz, Targu-Mures	Slovenia Germany Poland Romania	White opaque PVC/Aclar/ Al blisters HDPE bottles	10, 28, 30, 50, 60, 84, 90, 100 or 120 30, 90 (3x30) or 120 (4x30)
	Efavirenz (EFV)	600 mg	Film coated Tablet	Government Pharmaceutical Organization (GPO), 75/1 Rama VI Road, Ratchathewi, Bangkok, 10400, Thailand	A	HA681	The Government Pharmaceutical Organization (GPO), Rangsit Pharmaceutical Production Plant 1, 138 Moo 4, Rangsit-Nakhonnayok Road, Bueng Sanan, Thanyaburi, Pathumthani, 12110	Thailand	HDPE bottle	30
43	Efavirenz + [Lamivudine + Zidovudine]	600 mg + [150 mg + 300 mg]	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	PVC/PE/Aclar-Al foil ; Carton	6 blisters per box Each blister has 5 x (2+1)
	Efavirenz + [Lamivudine + Zidovudine]	600 mg + [150 mg + 300 mg]	Tablet	Strides Arcolab Limited	B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle	30 + (60)
	Efavirenz + [Lamivudine + Zidovudine]	600 mg + [150 mg + 300 mg]	Co packed Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar, Nashik District 422 113, Maharashtra	India	Blister cards.	10-day supply (5 two-day blister cards consisting of PVC/PvDC film and coated aluminum foil)

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
44	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Merck Sharp & Dohme Limited	B	Yes	Patheon Inc. Mississauga, Ontario MSD BV Haarlem (packaging and batch release site)	Canada	HDPE bottle	30
	Efavirenz + Emtricitabine + Tenofovir Disoproxil Fumarate	600 mg + 200 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Sinnar,Nashik, Maharashtra, Waluj, Aurangabad, Maharashtra; Mylan Pithampur, Dhar Dist., Madhya Pradesh	India	HDPE bottle	28, 30, 100
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Cipla Ltd.	A	Yes	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle	30, 100
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Hetero labs limited	A-B	Yes	Hetero Labs Limited, Unit-V SEZ Unit I Survey No. 439, 440, 441 & 458 Mahaboob Nagar.	India	HDPE Bottle	28's, 30's and 500's,
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Shasun Pharmaceuticals Ltd, Periyakalpet, Pondicherry, India	India	HDPE Bottle	30
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A-B	Yes	Kachigam, Damam	India	HDPE Bottle	30
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Strides Arcolab Limited	A	Yes	Anekal Taluk, Bangalore, India	India	HDPE Bottle	30
	Efavirenz + Emtricitabine + Tenofovir Disoproxil	600 mg+200 mg+300 mg	Tablet	Bristol-Myers Squibb and Gilead Sciences Ltd	B	Yes	Carrigtohill, County Cork	Ireland	HDPE Bottle	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Efavirenz + Emtricitabine + Tenofovir Disoproxil	600 mg+200 mg+300 mg	Tablet	Gilead Sciences, Inc.	B	Yes	Patheon Inc. Mississauga, Ontario	Canada	HDPE Bottle	30
45	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	600 mg + 300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A- B	Yes	Sinnar,Nashik, Maharashtra; H-12 & H-13, M.I.D.C, Waluj, Aurangabad Maharastra; Mylan Pithambur, Dhar Dist., Madhya Pradesh	India	HDPE Bottle	30, 100
	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	600 mg + 300 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Aurobindo Pharma Limited Unit-VII (SEZ) Mahaboob Nagar (Dt) AP;	India	HDPE Bottle	30, 100 & 500
	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	600 mg + 300 mg + 300 mg	Tablet	Cipla Ltd.	A-B	Yes	UNIT-II-Patalganga	India	HDPE Bottle	30
	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	600 mg + 300 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A-B	Yes	Macleods Pharmaceuticals Limited Baddi, District Solan, Himachal Pradesh	India	HDPE Bottle	30
	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	600 mg + 300 mg + 300 mg	Tablet	Hetero labs limited	A-B	HA549 NDA 204119	Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana (Unit-V) S.No. 439,440, 441, & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla (Mandal), Mahaboobnagar-(District). Pin-509301 Telangana	India	HDPE Container	30, 90, 100

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Efavirenz+ Lamivudine + Tenofovir Disoproxil Fumarate	400 mg + 300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	HA721	(FDF-3) Plot No. 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector -III, Pithampur, District Dhar - 454775, Madhya Pradesh	India	HDPE Bottle (white, blue)	30
46	Emtricitabine	10 mg/ml	oral solution	Gilead Sciences, Inc.	B	Yes	Country Cork	Ireland	Bottle	170ml
47	Emtricitabine	200 mg	Capsule	Cipla Ltd.	A - B	Yes	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30, 1000
	Emtricitabine	200 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle, Blister	30, 500 10
	Emtricitabine	200 mg	Capsule	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	30, 100; 2*10, 3*10
	Emtricitabine	200 mg	Capsule	Gilead Sciences, Inc.	B	Yes	Foster City	USA	HDPE Bottle,	30
48	(Emtricitabine + Nevirapine) +Tenofovir	(200+200)+ 300	Tablets co-packed	Mylan Laboratories Ltd	A	Yes	Sinnar,Nashik, Maharashtra	India	Alu/Alu blister	(1+2) per blister, 3 blisters in a carton
49	Emtricitabine +Tenofovir Disoproxil Fumarate	200 mg + 245 mg	Tablet Film coated	Gilead Sciences, Inc.	B	Yes	Granta Park Abington, Cambridge	UK	Bottle (HDPE)	30, 90(3x30) tablets

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Emtricitabine + Tenofovir	200 mg + 300 mg	Tablet	Gilead Sciences, Inc.	A	Yes	Altana Pharma, Oranienburg GmbH, Patheon Inc. Mississauga, Ontario Aspen Pharmacare, Port Elizabeth,	Germany Canada South Africa	HDPE bottle	30
	Emtricitabine + Tenofovir disoproxil fumarate	200 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle	30
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle; blister	28, 30,100; 10
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Cipla Ltd.	A-B	Yes	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Hetero labs limited	A-B	Yes	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad-500055	India	HDPE bottle	28, 30, 56 & 60
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle	30
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A	Yes	Kachigam, Daman,	India	HDPE bottle/Alu/Alu blister	30; 10 x 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Pharmacare Ltd	A	HA601	Aspen Port Elizabeth , (Pty) Ltd, Korsten Port Elizabeth, South Africa	South Africa	HDPE bottle	30
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Shasun Pharmaceuticals Limited, Periyakalpet, Puducherry, India	India	HDPE bottle	30
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Microlabs Ltd	A	HA631	Micro Labs Ltd, Phase III and Phase IV, Plot No S-155 to S-159 Verna Industrial Estate, Verna, Goa, 403 722, India	India	Blister Alu/Alu Bottle HDPE	10X1 30X1, 100X1
50	[Emtricitabine + Tenofovir Disoproxil Fumarate]+Nevirapine	200 mg /300 mg co-packaged with 200 mg	Co packed Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar, Nashik District 422 113, Maharashtra	India	Blister cards.	Cartons containing 5 blister packs (consisting of aluminum-aluminum blisters), each containing two 1-day cards, for a 10 day supply. Three cartons are further packaged together for a 30 day supply
	[Emtricitabine + Tenofovir Disoproxil Fumarate]+Nevirapine	200 mg /300 mg co-packaged with 200 mg	Co packed Tablet	Macleods Pharmaceuticals Limited	A	Yes	Kachigam, Daman,	India	Alu/Alu blister	(1 + 2) combipack
51	Enfuvirtide	90mg/ml	Injection	Hoffmann-La Roche Inc.	B	Yes	Basle	Switzerland	Vials	60+60 vials of water for inj+syringe
52	Etravirine	25mg	Tablet	Janssen-Cilag International NV, Belgium	A-B	Yes	Janssen-Cilag SpA, Latina, Italy	Italy	HDPE Bottle	120

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
53	Etravirine	100mg	Tablet	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	A-B	Yes	Borgo San Michele, Latina Janssen-Cilag SpA, Latina, Italy (Manufacturing, packaging, release testing and final QC release)	Italy	HDPE Bottle	120
54	Etravirine	200mg	Tablet	Janssen-Cilag International NV, Belgium	A-B	Yes	Janssen-Cilag SpA, Latina, Italy	Italy	HDPE Bottle	60
55	Fosamprenavir (FPV)	700 mg	Tablet	Glaxo SmithKline Ltd.	B	Yes	Glaxo Wellcome Operations	UK	HDPE bottle	60
56	Indinavir (IDV)	200 mg	Capsule Hard	Merck Sharp & Dohme Limited	B	Yes	Hertford Road, Hertfordshire	UK	HDPE Bottle	180,270, 360
57	Indinavir (IDV)	400 mg	Capsule	Hetero Labs Limited	A	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	India	Al/Al strip; HDPE bottle	10; 180
	Indinavir (IDV)	400 mg	Capsule	Merck Sharp & Dohme Limited	A	Yes	Elkton, Virginia	USA	HDPE bottle	180
	Indinavir (IDV)	400 mg	Capsule Hard	Merck Sharp & Dohme Limited	B	Yes	Hertford Road, Hertfordshire	UK	Bottle (HDPE)	18, 90, 180
58	Lamivudine (3TC)	10 mg / ml	Oral Solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	HDPE bottle	240ml
	Lamivudine (3TC)	10 mg / ml	Oral Solution	Cipla Ltd.	A - B	Yes	Cipla Limited L-139 to L-146, Verna Goa, Indore, SEZ, Pithampur, Dist Dhar (M.P.)	India	PET bottle; HDPE bottle	100ml; 240ml
	Lamivudine (3TC)	10 mg / ml	Oral Solution	Hetero labs limited	B	Yes	Unit-III 22-110, Industrial Development Area Jeedimetla, Hyderabad	India	HDPE Bottle	240ml
	Lamivudine (3TC)	10 mg / ml	Oral Solution	Aurobindo Pharma Ltd	B	Yes	Hyderabad, Telangana	India	HDPE Bottle	240ml

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine (3TC)	10 mg / ml	Oral Solution	Macleods Pharmaceuticals Limited	A	Yes	Solan, Himachal Pradesh, India	India	HDPE Bottle	240ml
59	Lamivudine (3TC)	30mg	Tablet	Cipla Ltd.	A	Yes	Goa	India	HDPE Bottle	60
	Lamivudine (3TC)	30mg	Tablet	Microlabs Ltd	A	Yes	Verna, Goa	India	PVC/PVdC/ Alu blister ; HDPE bottle	10 60,100,500, 1000
60	Lamivudine (3TC)	30mg	Disp Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE Bottle	60
61	Lamivudine (3TC)	100 mg	Tablet Film coated	Glaxo SmithKline Ltd.	B	Yes	Ware, Hartfordshire	UK	Blister; Bottle	28, 84
62	Lamivudine (3TC)	150 mg	Tablet Film Coated	Macleods Pharmaceuticals Limited	A - B	Yes	Kachigam, Daman Baddi, H.P.	India	HDPE Bottle; Blister	60; 6*10
	Lamivudine (3TC)	150 mg	Film coated Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle; Blister	30, 60; 10
	Lamivudine (3TC)	150 mg	Tablet	Aspen Pharmacare Ltd.	A	Yes	Port Elizabeth, Korsten	South Africa	Metallised lay flat pack, PP bottle	60
	Lamivudine (3TC)	150 mg	Tablet	Cipla Ltd.	A	Yes	Goa; Meditab Specialities Ltd, Goa	India	HDPE Bottle	30, 60
	Lamivudine (3TC)	150 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh, Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	60; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine (3TC)	150 mg	Tablet Film coated	ViiV HealthCare	A - B	Yes	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland Pharmicare (ASPEN), Port Elizabeth,	UK South Africa	HDPE bottle	60
	Lamivudine (3TC)	150 mg	Tablet	Hetero labs limited	A-B	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; STADA-VN Joint Venture Co, Ltd, Duong Province, Vietnam	India Vietnam	HDPE Bottle Blister,	60, 600 10;
	Lamivudine (3TC)	150 mg	Tablet	Microlabs Ltd	A	HA644	Verna, Goa	India	Alu/PVC/Pv dC blister HDPE Bottle	6x10 60
	Lamivudine (3TC)	150 mg	Tablet	Sun Pharmaceutical Industries Ltd	A - B	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE Bottle, Blister	60, 10
	Lamivudine (3TC)	150 mg	Tablet	Alkem Laboratories Ltd	B	Yes	Amaliya, Daman	India	HDPE Bottle	60
	Lamivudine (3TC)	150 mg	Tablet	Microlabs Ltd	B	Yes	Verna, Goa	India	HDPE bottle Blister	30, 60, 90 10
	Lamivudine (3TC)	150 mg	Tablet	Centaur Pharmaceutical Private Limited	B	Yes	Biotech Park Hinjewadi Phase II Pune, Maharashtra	India	HDPE bottle	60
	Lamivudine (3TC)	150 mg	Tablet	MYLAN	B	NDA# 078545	Mylan Laboratories Limited, F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	Blister PVC/PVDC/ Aluminium) HDPE bottle	10x1 ; 60x1

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
63	Lamivudine (3TC)	300 mg	Tablet	MYLAN	A-B	ANDA 078545 USFDA 2	Mylan Laboratories Limited, F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	Blister PVC/PVDC/ Aluminium) ; HDPE bottle	10x1 ; 60x1
	Lamivudine (3TC)	300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh,	India	HDPE Bottle; Blister	30; 10
	Lamivudine (3TC)	300 mg	Tablet	Cipla Ltd.	A	Yes	Goa	India	HDPE Bottle	30,60
	Lamivudine (3TC)	300 mg	Film coated Tablet	Strides Arcolab Limited	B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle,	30; 60
	Lamivudine (3TC)	300 mg	Tablet	Macleods Pharmaceuticals Limited	A - B	Yes	Kachigam, Daman	India	HDPE Bottle; Blister	30; 3* 10; 6*10
	Lamivudine (3TC)	300 mg	Tablet	Glaxo SmithKline Ltd.	B	Yes	Greenford, Middlesex	UK	High density polyethylene (HDPE) bottle	30
	Lamivudine (3TC)	300 mg	Tablet	Hetero labs limited	B	Yes	Unit III 22-110, I.D.A., Jeedimetla Jeedimeta, Hyderabad	India	HDPE bottle	30, 600
	Lamivudine (3TC)	300 mg	Tablet	Microlabs Ltd	B	Yes	Verna, Goa	India	HDPE bottle Blister	30, 60, 90 10
64	Lamivudine + Nevirapine + Stavudine	30 mg + 50 mg + 6 mg	Dispersible Tablet	Cipla Ltd.	A - B	Yes	Plot No. L-139, L146- Verna, Goa	India	HDPE bottle	60, 1000
65	Lamivudine + Nevirapine + Stavudine	60 mg + 100 mg + 12 mg	Dispersible Tablet	Cipla Ltd.	A - B	Yes	Plot No. L-139, L146- Verna, Goa	India	HDPE Bottle	60, 1000

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
66	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Cipla Ltd.	A - B	Yes	Kurkumbh India , Patalganga, India; Plot 136,146(UNITIII&IV), L147,L147-1 UNIT-VII-Goa,; Himachal Pradesh, India; Cipla Ltd Indore, SEZ, Pithampur, Dist Dhar (M.P.), India	India	HDPE bottle	30; 60; 1000
	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle	60
	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60
	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Macleods Pharmaceuticals Limited	B	Yes	Kachigam, Daman	India	HDPE Bottle	60
	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Strides Arcolab Limited	B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	60
	Lamivudine + Nevirapine + Stavudine	150 mg +200 mg+ 30 mg	Tablet	Pharmacare Ltd.	B	Yes	Strides Ltd, Bangalore	India	HDPE Bottle	60
67	Lamivudine + Nevirapine + Zidovudine	30mg+ 50mg +60mg	Dispersible Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Nevirapine + Zidovudine	30mg+ 50mg +60mg	Tablet for Oral Suspension	Strides Pharma Science Limited	A-B	HA557	Strides Pharma Science Limited, Strides house, Opp. IIMB, Bilekahali, Bannerghatta Road, Bangalore, Karnataka, 560 076, India	India	HDPE Bottle	60
	Lamivudine + Nevirapine + Zidovudine	30mg+ 50mg +60mg	Tablet for Oral Suspension	Cipla Ltd.	B	Yes	Plot No. L-147, L147-1 (Unit VII), Verna Industrial Estate, Verna Salcette Goa, 403 722	India	HDPE Bottle	60, 1000
68	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar Nashik, Maharashtra; Waluj, Aurangabad, Maharashtra, India; Mission Vivacare Limited, Pithampur, Dhar, M.P., India; Shasun Pharmaceutical Ltd, Periyakalpet, Puducherry	India	HDPE bottle ; PVC/PVdC/ Alu blister;	60; 6 X 10;
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Cipla Ltd.	A - B	Yes	Cipla Ltd, Goa, UNIT-III & UNIT-IV India; Cipla Ltd, Indore, SEZ; Mylan Pithampur, Dhar Dist., Madhya Pradesh; Quality Chemical Industries Ltd, Kampala, Uganda; Cipla Ltd Baddi, Himachal Pradesh, India	India Uganda	HDPE bottle	30, 60, 500

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Hetero labs limited	A-B	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; Unit-V, Mahaboob Nagar, Andhra Pradesh	India	Blister; HDPE bottle	10; 60, 100, 500
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh; Shasun Pharmaceutical Ltd, Puducherry,	India	HDPE Bottle /PVdc/PVC blister	60, 10
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A-B	Yes	Kachigam, Daman Baddi, H.P.	India	HDPE Bottle	60
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 & 314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	60; 10
	Lamivudine + Nevirapine + Zidovudine	150 mg + 200 mg + 300 mg	Film coated Tablet	Strides Pharma Science Limited	A-B	HA524	Universal Corporation Ltd, PO Box 1748, Club Road, Plot No 13777, Kikuyu, 902, Kenya Strides Pharma Science Limited, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106, India	India	HDPE bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
69	Lamivudine + Stavudine	30 mg + 6mg	Tablet for Oral Suspension	Cipla Ltd.	A - B	Yes	L-139 to L-146, UNIT-III & VI, Verna Goa	India	HDPE bottle; Blister	30, 60, 1000; 14
70	Lamivudine + Stavudine	60 mg + 12mg	Tablet for Oral Suspension	Cipla Ltd.	A - B	Yes	L-139 to L-146, UNIT-III & VI, Verna Goa	India	HDPE bottle; Blister	30, 60, 1000; 14
71	Lamivudine + Stavudine	150 mg + 30 mg	Tablet	Cipla Ltd.	A - B	Yes	Patalganga, L-139 to L-146, UNIT-III & VI, Verna Goa	India	HDPE bottle	60, 30, 1000
	Lamivudine + Stavudine	150 mg + 30 mg	Tablet	Strides Arcolab Limited	A	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	60
	Lamivudine + Stavudine	150 mg + 30 mg	Tablet	Macleods Pharmaceuticals Limited	B	Yes	Kachigam, Daman	India	HDPE Bottle	60
	Lamivudine + Stavudine	150 mg + 30 mg	Tablet	Hetero labs limited	B	Yes	Unit III 22-110, I.D.A., Jeedimetla Jeedimeta, Hyderabad	India	HDPE Bottle	30, 60, 100, 500
	Lamivudine + Stavudine	150 mg + 30 mg	Tablet	Pharmacare Ltd.	B	Yes	Strides Ltd, Bangalore	India	HDPE Bottle	60
	Lamivudine + Tenofovir disoproxil fumarate	75 mg + 75 mg	Tablet	Hetero labs limited	B	NDA 207315	Unit III Plot No. 22-110, I.D.A., Jeedimetla, Hyderabad – 500 055, Telangana	India	HDPE Bottle	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
70	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Hetero labs limited	A-B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad; and Unit V Mahaboob Nagar Dist, Andhra Pradesh.	India	HDPE Bottle	30, 60, 100, 500
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Celltrion Pharm, Inc.	A	NDA 211284	Celltrion Pharm, Inc. 82, 2Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do	Republic of Korea	HDPE Bottle	30, 60, 100
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	Yes	Mylan Laboratories Ltd, F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113; Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136; Questa Care Limited, Plot No. 209/7184.	India, Kenya	HDPE bottle	30, 100
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Cipla Ltd.	A	HA666	Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra, 400 013, India	India	Tablet, Film coated	Bottle,HDP E 30x1; Blister,Alu/ Alu 10x1; Blister,Alu/ PVC-ACLAR 10x1
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Cipla Ltd.	A- B	Yes	D-7 MIDC Kurkumbh; Quality Chemical Industries Ltd, Kampala, Uganda	India	HDPE Bottle Blister	30, 500 10
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A-B	Yes	Shasun Pharmaceuticals Ltd	India	HDPE Bottle	30
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A-B	Yes	Kachigam- Daman Baddi- Himachal Pradesh	India	HDPE Bottle Blister	30 10
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Microlabs Ltd	A	Yes	Verna, Goa	India	HDPE Bottle	30, 100
71	[Lamivudine+Tenofovir] +Atazanavir+ Ritonavir	[300mg+300mg] +300mg+100mg	Capsules+ Tablets+ Tablets	Mylan Laboratories Ltd	A	Yes	Sinnar,Nashik, Maharashtra	India	Alu/Alu Blister per co packed blister	(1+1+1) per coblister; 3 blisters in a carton
72	[Lamivudine+Tenofovir] +Nevirapine	[300mg + 300mg] +200mg	Tablets (co-packaged)	Mylan Laboratories Ltd	A- B	Yes	Sinnar,Nashik, Maharashtra Village Theda, Post Office Lodhimajra	India	Alu/Alu Blister; Blister in Carton	(1+2) per blister; 3 blisters in a carton
	[Lamivudine+Tenofovir disoproxil fumarate] + Nevirapine	(300+300mg) + 200mg	Co-Blistered tablets	Aurobindo Pharma Ltd	B	Yes	Aurobindo Pharma Limited, Unit VII (SEZ) Andhra Pradesh	India	Blister	1 Blister contains(4+ 2) 15 blisters in a box.

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	[Lamivudine+Tenofovir disoproxil fumarate] + Nevirapine	(300+300mg) + 200mg	Co-Blistered tablets	Hetero labs limited	B	Yes	Hetero Labs Limited Unit III 22-110, I D A, Jeedimetla, Hyderabad	India	Co Blister	1 Blister contains(1+ 2) 10 blisters in a box.
	[Lamivudine+Tenofovir disoproxil fumarate] + Nevirapine	(300+300mg) + 200mg	Co-Blistered tablets	Macleods Pharmaceuticals Limited	A	Yes	Kachigam, Damam	India	Alu/Alu blister	one carton contains one blister of one lamivudine/ TDF tablet and one blister of two nevirapine tablets
73	Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar-Nashik, Maharashtra Waluj, Aurangabad	India	HDPE	60
	Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE Bottle	60
	Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Cipla Ltd.	B	NDA 202814	L-147 to L-147.1 (Unit VII), Verna Industrial Estate, Verna Salcette, Goa 403 722 India	India	HDPE bottle; Blister	60; 1000 10
74	Lamivudine + Zidovudine	30 mg + 60 mg	Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar-Nashik, Maharashtra Waluj, Aurangabad	India	HDPE	60
	Lamivudine + Zidovudine	30 mg + 60 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	UNIT III, Survey No. 313 and 314, Bachupally Quthubullapur Mandal, Hyderabad, Andhra Pradesh	India	HDPE Bottle; Blister	60, 1000; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Zidovudine	30 mg + 60 mg	Tablet	Microlabs Ltd	A	Yes	Verna, Goa	India	PVC/PVdC/ Alu blister HDPE	6 x 10; 60, 100, 1000
75	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey, Hyderabad, Andhra Pradesh Unit-VII (SEZ), Andhra Pradesh	India	HDPE bottle; Blister	60; 10
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co Ltd	A	HA655	Shanghai Desano Bio-Pharmac+H309eutral Co Ltd, 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203	China	HDPE bottle	60'
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Cipla Ltd.	A - B	Yes	Plot No. L-147, L147-1, Verna Goa, 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 Uganda	HDPE bottle ; Blister	60, 1000 ; 10, 14
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Hetero Labs Limited	A-B	Yes	Unit-III, 22-110, Jeedimetla, Hyderabad Unit-V, Hyderabad	India	HDPE bottle Blister;	60, 500 10;
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar, Nashik, Maharashtra	India	HDPE bottle ; Blister	60; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	ViiV HealthCare	A	Yes	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	Bottle Blister,	60, 60
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle; Alu/PA/PVC Blister; PVdC/PVC blister	60; 10
	Lamivudine + Zidovudine	150 mg + 300 mg	Film coated Tablet	Anhui Biochem Bio-pharmaceutical Co., Ltd.,	A	HA656	Anhui Biochem Bio-pharmaceutical Co., Ltd., No. 30 Hongfeng Road, Hi-Tech Development Zone, Hefei City, Anhui Province	China (People's Republic of)	HDPE bottle	60
	Lamivudine + Zidovudine	150 mg + 300 mg	Film coated Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle	60
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Universal Corporation	A	Yes	Kikuyu	Kenya	HDPE	60
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Microlabs Ltd	A	Yes	Verna, Goa	India	HDPE bottle; PVDC/PVC/ Alu blister;	30, 60, 90; 10*10;
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Pharmacare Ltd.	B	Yes	Port Elizabeth, Korsten	South Africa	Blister	60
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	A -B	Yes	Kachigam, Daman Baddi, H.P.	India	HDPE Bottle; Blister	60; 6*10, 12*10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE bottle Blister	60 10
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Lupin	A	Yes	Dhar, Pithampur, Madhya Pradesh; Verna, Salcette Goa,	India	HDPE bottle	60
76	[Lamivudine + Zidovudine] + Nevirapine	[150mg+300mg] +200mg	Co packaged Tablet	Hetero labs limited	B	Yes	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad	India	PVC/Alu Blister; Blister	10 doses on one blister sheet and 6 sheets included in the carton
77	[Lamivudine + Zidovudine] + Nevirapine	[150mg+300mg] +200mg	Co packaged Tablet	Pharmacare Ltd.	B	Yes	Fairclough Road, Korsten, Port Elizabeth, 6020,	South Africa	Blister cards.	Each card contains 6 lamivudine / zidovudine tablets and 6 nevirapine tablets.
	[Lamivudine + Zidovudine] + Nevirapine	[150mg+300mg] +200mg	Co packaged Tablet	Strides Arcolab Limited	B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	(60)+60
78	Lopinavir (LPV) + Ritonavir (RTV)	(80 mg + 20 mg) / ml	Oral Solution	Abbott Laboratories Ltd.	A -B	Yes	Queensborough, Kent	UK	PET bottle	60ml, 160ml
	Lopinavir (LPV) + Ritonavir (RTV)	(80 mg + 20 mg) / ml	Oral Solution	Abbott Laboratories Ltd.	B	Yes	North Chicago	Illinois,USA	PET bottle	160ml
	Lopinavir (LPV) + Ritonavir (RTV)	(80 mg + 20 mg) / ml	Oral Solution	Cipla Ltd.	B	Yes	Plot No. L-139, S-103 & M-62, Verna Industrial Estate, Verna Salcette, Goa	India	Amber coloured PET Bottle	160ml
79	Lopinavir+Ritonavir	40mg/10mg	Pellets in Capsule	Cipla Ltd.	B	NDA 205425	Plot L147 to L-147-1, Verna Industrial Estate, Verna, Goa	India	HDPE Bottle	120

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
80	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Abbott Laboratories Ltd.	A	Yes	Ludwigshafen	Germany	HDPE bottle	60
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Abbott Laboratories Ltd.	B	Yes	North Chicago	Illinois,USA	HDPE bottle	60
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Mylan Laboratories Ltd	A-B	HA429 ANDA#7907 4	Mylan Laboratories Limited, F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India	India	HDPE Bottle	60, 120
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE Bottle; Blister	60; 6*10
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Macleods Pharmaceuticals Limited	A	Yes	Solan, Himachal Pradesh	India	HDPE bottle	60
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Hetero labs limited	A-B	ANDA 091677 HA650	Unit III, Plot No 22- 110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055	India	HDPE bottle	60; 120
81	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	Capsule	Abbott Laboratories Ltd.	A	Yes	RP Scherer, Florida	USA	HDPE bottle	90
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	Capsule Soft	Abbott Laboratories Ltd.	B	Yes	Queenborough, Kent	UK	Bottle (HDPE) Bottle (PVC)	90, 180
82	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	120; 6. 12
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Abbott Laboratories Ltd.	A	Yes	Ludwigshafen	Germany	HDPE bottle	120

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE Bottle; Blister	120; 6*10
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Cipla Ltd.	B	Yes	A-42, MIDC Patalganga	India	HDPE Bottle Blister	120, 10
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Hetero labs limited	A-B	Yes	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad	India	HDPE Alu/Alu Blister Alu/PVC/PVdC blister	60, 120 10
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Macleods Pharmaceuticals Limited	A	Yes	Solan, Himachal Pradesh	India	HDPE bottle	120
83	Nevirapine (NVP)	10 mg / ml	Oral Suspension	Boehringer Ingelheim	A	Yes	Roxane, Columbus,	USA	HDPE bottle+ syringe	240ml + 5ml
	Nevirapine (NVP)	10 mg / ml	Oral Suspension	Cipla Ltd.	A	Yes	Cipla Ltd, Goa, India; Meditab Specialties Pvt Ltd, Maharashtra, India; Indore, SEZ, Pithampur, Dist Dhar (M.P.)	India	Amber coloured PET Bottle Amber coloured glass bottle	100ml, 240 25ml, 10ml
	Nevirapine (NVP)	50 mg /5 ml	Oral Suspension	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE bottle	240ml 100ml

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
84	Nevirapine	20mg	Tablet	Microlabs Ltd	A	Yes	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE bottle Blister	30,60,90 10
	Nevirapine (NVP)	50mg	Tablet for Oral Suspension	Cipla Ltd.	A-B	Yes	A-42, MIDC, Patalganga	India	HDPE bottle Blister	60, 1000 10
	Nevirapine (NVP)	50mg	Dispersible tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle	60
86	Nevirapine	50mg	Tablet	Microlabs Ltd	A	Yes	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE bottle Blister	30,60,90 10
87	Nevirapine (NVP)	100mg	Tablet for Oral Suspension	Cipla Ltd.	A-B	Yes	A-42, MIDC, Patalganga	India	HDPE bottle Blister	60, 1000 10
	Nevirapine (NVP)	100mg	Dispersible tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle	60
88	Nevirapine	100mg	Tablet	Microlabs Ltd	A	Yes	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE bottle Blister	30,60,90 10
89	Nevirapine (NVP)	200 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle; Blister	60; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Nevirapine (NVP)	200 mg	Tablet	Cipla Ltd.	A - B	Yes	Plot 136,146(UNITIII&IV), L147,L147-1 UNIT-VII-Goa; Meditab Specialties Pvt Ltd, Kundaim, Goa, Quality Chemical Industries Ltd, Kampala	India Uganda	HDPE Bottle; Blister	60, 1000 ; 10
	Nevirapine (NVP)	200 mg	Tablet	Hetero labs limited	A-B	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh	India	HDPE bottle Blister;	60, 100,500, 1000 10;
	Nevirapine (NVP)	200 mg	Tablet	Mylan Laboratories Ltd	A - B	HA396	Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775 F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113 Plot No H-12 & H13 MIDC Waluj Industrial Area	India	HDPE bottle; Blister	56, 60; 10
	Nevirapine (NVP)	200 mg	Tablet	Sun Pharmaceutical Industries Ltd	A - B	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle ; Blister	60, 1000; 10
	Nevirapine (NVP)	200 mg	Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Container	60
	Nevirapine (NVP)	200 mg	Tablet	Aspen Pharmacare Ltd.	A	Yes	Port Elizabeth, Korsten	South Africa	Blister	10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Nevirapine (NVP)	200 mg	Tablet	Boehringer Ingelheim	A	Yes	Boehringer Ingelheim Pharma GmbH & Co, KG, Ingelheim; Boehringer Ingelheim Ellas A.E., Koropi	Germany Greece	Blister	60
	Nevirapine (NVP)	200 mg	Tablet	Macleods Pharmaceuticals Limited	A- B	Yes	Kachigam, Daman	India	HDPE bottle; PVdC/PVC/ Alu Blister	60; 6*10, 12*10
	Nevirapine (NVP)	200 mg	Tablet	Emcure Pharmaceuticals Limited	B	Yes	Hinjwadi, Pune	India	HDPE Bottle; Blister	60; 10
	Nevirapine (NVP)	200 mg	Tablet	Huahai Pharmaceutical	B	Yes	Xunqiao, Linhai, Zhejiang	China	HDPE Bottle	60
	Nevirapine (NVP)	200 mg	Tablet	Microlabs Ltd	A-B	Yes	Verna, Goa	India	HDPE Blister	60 10
	Nevirapine (NVP)	200 mg	Tablet	ScieGen Pharmaceuticals	B	Yes	Hauppauge, NY	USA	HDPE Bottle	30, 500
90	Nevirapine (NVP)	400 mg	Tablet	Cipla Ltd.	B	ANDA 207064	L138-147 L150 S103-105 S107-112 M61-63 Verna, Salcette, GOA	India	HDPE Bottle; Blister	30; 10
91	Raltegravir	400mg	Tablet	Merck & Co, USA	B	Yes	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Pays-Bas	USA China Singapore Netherlands	Bottle	60
	Raltegravir	400mg	Tablet	Hetero labs limited	B	Yes	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad	India	Bottle Blister	60, 120 10'sx10 10'sx14
92	Raltegravir	100mg	Chewable tablet	Merck & Co, USA	B	Yes	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Pays-Bas	USA China	Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
93	Raltegravir	25mg	Chewable tablet	Merck & Co, USA	B	Yes	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Pays-Bas	Netherland	Bottle	60
94	Ritonavir (RTV)	80 mg / ml	Oral Solution	Abbott Laboratories Ltd.	A	Yes	Queenborough, Kent	UK	PET bottle	90ml
95	Ritonavir (RTV)	25 mg	Tablet	Cipla Ltd.	B	NDA 205040	A-42, MIDC, Patalganga	India	HDPE Bottle	60
	Ritonavir (RTV)	25 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar, Nashik, Maharashtra	India	HDPE Bottle	30
96	Ritonavir (RTV)	50 mg	Tablet	Cipla Ltd.	B	NDA 205040	A-42, MIDC, Patalganga	India	HDPE Bottle	60
97	Ritonavir (RTV)	100 mg	Capsule	Abbott Laboratories Ltd.	A	Yes	RP Scherer, Florida, Beinheim	USA France	HDPE bottle;	84,
	Ritonavir (RTV)	100 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 120
	Ritonavir (RTV)	100 mg	Tablet	Abbott Laboratories Ltd.	A	Yes	Luwigshafen,	Germany	HDPE Bottle	30, 60
	Ritonavir (RTV)	100 mg	Tablet	Cipla Ltd.	A-B	Yes	A-42, MIDC, Patalganga,	India	HDPE Bottle	30
	Ritonavir (RTV)	100 mg	Tablet	Hetero labs limited	B	ANDA20 4587	Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055	India	HDPE Bottle	30x1; 120x1
98	Saquinavir	200mg	Capsule	F.Hoffman-La Roche	A	Yes	RP Scherer, Baden; Basel	Germany; Switzerland	HDPE bottle	180; 270
99	Saquinavir	500mg	Tablet	F.Hoffman-La Roche	A	Yes	Madrid	Spain	HDPE Bottle	120
100	Stavudine (d4T)	1 mg / ml	Powder for Oral Solution	Bristol-Myers Squibb	A	Yes	Evansville, Indiana	USA	HDPE bottle	200ml
	Stavudine (d4T)	1 mg / ml	Powder for Oral Solution	Bristol-Myers Squibb	B	Yes	Meymac	France	HDPE Container	200ml

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Stavudine (d4T)	1 mg / ml	Powder for Oral Solution	Cipla Ltd.	A -B	Yes	M-61, M-62, M-63, Verna Goa	India	HDPE bottle	200ml
101	Stavudine (d4T)	15 mg	Capsule	Bristol-Myers Squibb	A	Yes	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	USA	HDPE bottle Blister	60 14
	Stavudine (d4T)	15 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle	60
	Stavudine (d4T)	15 mg	Capsule	Hetero labs limited	B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad	India	HDPE Bottle	60, 100, 1000
102	Stavudine (d4T)	20 mg	Capsule	Aspen Pharmacare Ltd.	A	Yes	Port Elizabeth, Korsten	South Africa	Glass bottle	60
	Stavudine (d4T)	20 mg	Capsule	Bristol-Myers Squibb	A	Yes	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	USA	HDPE bottle Blister	60 14

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Stavudine (d4T)	20 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle	60
	Stavudine (d4T)	20 mg	Capsule	Hetero labs limited	B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad	India	HDPE Bottle	60, 100, 1000
103	Stavudine (d4T)	30 mg	Capsule	Aspen Pharmacare Ltd.	A	Yes	Port Elizabeth, Korsten	South Africa	Glass bottle	60
	Stavudine (d4T)	30 mg	Capsule	Macleods Pharmaceuticals Limited	A	Yes	Kachigam, Daman	India	HDPE Bottle	60
	Stavudine (d4T)	30 mg	Capsule	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE bottle	60
	Stavudine (d4T)	30 mg	Capsule	Bristol-Myers Squibb	A - B	Yes	Emcure Pharmaceuticals USA, New Jersey (manufacturing and primary packaging), USA. Bristol-Myers Squibb, Anagni (Frosinone) (secondary packaging, testing and batch release), Italy.	USA	HDPE bottle Blister	60 14
	Stavudine (d4T)	30 mg	Capsule	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	60; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Stavudine (d4T)	30 mg	Capsule	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE bottle	60
	Stavudine (d4T)	30 mg	Capsule	Hetero labs limited	B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad	India	HDPE Bottle	60, 100, 500
104	Tenofovir Disoproxil Fumarate	40mg/gm(Eq to 33mg/gm of Tenofovir Disoproxil	granule	Gilead Sciences, Inc.	B	Yes	Takeda GmbH Country Cork	Germany Ireland	HDPE bottle	60g
105	Tenofovir Disoproxil Fumarate	300mg	Tablet Film coated	Gilead Sciences, Inc.	B	Yes	Patheon Inc. Mississauga, Ontario Nycomed Oranienburg GmbH	Canada Germany	HDPE container	30
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Cipla Ltd.	A - B	Yes	Plot No. L-147, L147-1, Verna Goa	India	HDPE bottle	30, 1000
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Gilead Sciences, Inc.	A	Yes	Patheon Inc., Mississauga, Ontario, Canada; Altana Pharma, Oranienburg GmbH, Oranienburg, Germany; Aspen Pharmacare, OSD Facility, Korsten, Port Elizabeth, South Africa	Germany Canada South Africa	HDPE bottle	30
	Tenofovir Disoproxil Fumarate	300mg	Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Shahib, Himachal Pradesh	India	HDPE Bottle	30
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Gilead Sciences, Inc.	B	Yes	Granta Park Abington, Cambridge	UK	HDPE bottle Blister	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	30,100; 2*10
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Strides Arcolab Limited	A-B	Yes	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle Blister	30 10
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Aurobindo Pharma Ltd	B	Yes	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle	30,
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Hetero labs limited	A-B	Yes	Unit III 22-110 Industrial development Area Jeedimetla, Hyderabad	India	HDPE Bottle	30, 60, 100, 500, 1000
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Pharmacare Ltd.	A-B	HA588 ANDA 203470	Aspen Port Elizabeth , (Pty) Ltd, Korsten Port Elizabeth, South Africa	South Africa	HDPE Bottle	30
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Laurus Labs Limited	A	HA679	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal,Visakhapatnam-District, Andhra Pradesh, 531011	India	HDPE Bottle	30x1, 500x1
	Tenofovir Disoproxil Fumarate	300 mg	Tablet	Macleods Pharmaceuticals Limited	A	Yes	Kachigam, Daman Baddi, H.P.	India	HDPE bottle	30,

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
106	Zidovudine	60mg	Tablet	Microlabs Ltd	A	Yes	South Africa	India	PVC/PVdC/ Alu blister HDPE bottle	10x10 60, 100, 500, 1000
107	Zidovudine	60mg	Dispersible Tablet	Sun Pharmaceutical Industries Ltd	A	Yes	Paonta Shahib, Himachal Pradesh	India	HDPE Bottle	60
108	Zidovudine	10mg/ml	Infusion solution	ViiV HealthCare	A	Yes	Barnard Castle, County Durham	UK	Glass vial	20ml
	Zidovudine	10mg/ml	Oral solution	Macleods Pharmaceuticals Limited	A	Yes	Solan, Himachal Pradesh	India	HDPE Bottle	100ml, 240ml
109	Zidovudine	50mg/5ml	Oral solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	PET bottle	200ml
	Zidovudine	50mg/5ml	Oral solution	Combino Pharm S.L.	A	Yes	Medea, Barcelona	Spain	PET bottle+10ml syringe	200ml + 10ml sy
	Zidovudine	50mg/5ml	Oral solution	Hetero labs limited	A	Yes	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	India	HDPE Bottle	240ml
	Zidovudine	50mg/5ml	Oral solution	Cipla Ltd.	A - B	Yes	Cipla Limited L-139 to L-146, Verna Goa, Meditab Specialities Ltd	India	HDPE bottle; PET Bottle	100ml, 240ml 100ml;
	Zidovudine	50mg/5ml	Oral solution	Meditabs Specialities Pvt Ltd	A	Yes	Maharastra	India	PET Bottle	100ml
	Zidovudine	50mg/5ml	Oral solution	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh	India	HDPE bottle, with dose delivery device	240ml
110	Zidovudine	100mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
111	Zidovudine	100mg	Capsules	Cipla Ltd.	A - B	Yes	L138-147 L150 s103-105 VernaGoa; Indore, SEZ, Pithampur, District Dhar (M.P.)	India	HDPE Bottle	100; 1000
	Zidovudine	100mg	Capsules	Combino Pharm S.L.	A	Yes	Medea, Barcelona	Spain	Al Strip	100
	Zidovudine	100mg	Capsules	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No 313 and 314, Bachupally Quthubullapur Mandal Hyderabad, Anda Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle; Blister	100 10
	Zidovudine	100mg	Capsules	ViiV HealthCare	A	Yes	S.C. Europharm, Brasov	Romania	Bottle Blister	100; 100
112	Zidovudine	250mg	Capsules	ViiV HealthCare	A	Yes	S. C. Europharm, Brasov	Romania	Blister	40
	Zidovudine	250mg	Capsules	Combino Pharm S.L.	A	Yes	Medea, Barcelona	Spain	HDPE bottle; Blister	40, 300
113	Zidovudine	300mg	Tablets	Aurobindo Pharma Ltd	B	Yes	Unit III Survey No. 313, Bachupally, Quthubullapur, Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE bottle; Blister	60; 10
	Zidovudine	300mg	Tablets	Hetero labs limited	A-B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad	India	HDPE bottle	60, 500, 600

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA	Manufacturing site	Country	Material	Pack
	Zidovudine	300mg	Tablets	ViiV HealthCare	A	Yes	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; Glaxo Wellcome SA, Aranda (packaging and release), Spain	UK	Bottle Blister	28 28, 60;
	Zidovudine	300mg	Tablets	Sun Pharmaceutical Industries Ltd	A -B	Yes	Paonta Sahib, Himachal Pradesh	India	HDPE bottle; Blister	60; 10, 8
	Zidovudine	300mg	Tablets	Mylan Laboratories Ltd	A -B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle; Blister	56, 60; 2 x 10
	Zidovudine	300mg	Capsules	Combino Pharm S.L.	A	Yes	Medea, Barcelona	Spain	Blister ; HDPE bottle	60, 300
	Zidovudine	300mg	Tablets	Cipla Ltd.	A - B	Yes	Plot No. L-147, L147-1, Verna Goa	India	HDPE Bottle; Blister	30, 60, 1000 ; 10
	Zidovudine	300mg	Tablets	HEC Pharma	B	Yes	Sunshine Lake Pharma Co. Ltd, GuangDong+H424	China	HDPE Bottle	60
	Zidovudine	300mg	Tablets	Microlabs Ltd	A	yes	Verna, Goa	India	PVDC/PVC/ Alu blister; HDPE bottle	10; 30, 60, 90
				titulaire AMM			release center			

End of A or B products List

**List Of ARV Pharmaceutical Products
classified according to the Global Fund Quality Assurance Policy**

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List of ERP (Expert Review Panel) Reviewed Products which are permitted for time limited procurement:

If there is no or only one A or B product available (supply of the product cannot be done within 90 days after the receipt of the Purchase Order by the manufacturer) , grant funds may be used to procure a ERP reviewed product eligible for procurement for limited time (12 months) period. The PR must send the "notification form" (available at https://www.theglobalfund.org/media/5863/psm_notification_form_en.doc) to the Global Fund and upon receiving the " No Objection" letter form the Global Fund, the procurement can proceed. Please note that the QC test of the selected ERP product will be performed by the Global Fund.

Ref. No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
	Dolutegravir (as Sodium) tablets	50 mg	tablets	Sun Pharmaceutical Industries Limited	ERP Reviewed	04-09-2019	Village Ganguwala, Paonta Sahib, District Sirmour – 173025 Himachal Pradesh	India	HDPE Bottle	30, 90
	Lamivudine+Tenofovir disoproxil fumarate + Efavirenz	300mg +300mg+ 400mg	tablet FDC	Macleods	ERP Reviewed	29-07-19	Block N-2, Village Theda; Post Office Lothimajra Tehshil Baddi, Distt.Solan, Himachal Pradesh-174101	India	HDPE Container	30, 60, 90
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Cipla Ltd	ERP Reviewed	07-05-2019	Cipla Limited, Goa (Unit-VII) Verna Industrial Estate, Verna, Salcette, Goa – 403 722C Unit-VII PD II Verna Industrial Estate, Verna Salcette, Goa - 403722	India	HDPE Container	30, 90, 500
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Macleods	ERP Reviewed	12-06-2019	Bock N2, Village Theda, P.O. Lothimajra Tehsil Baddi, Dist.: Solan, Himachal Pradesh, 174101	India	HDPE Container	30, 90, 100, 180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Sun Pharmaceutical Industries Ltd	ERP Reviewed	12-06-2019	Sun Pharmaceutical Industries Limited Village Ganguwala, Paonta Sahib, District Sirmour – 173025, Himachal Pradesh	India	HDPE Container	30, 90
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Laurus Lab Ltd	ERP Reviewed	30-07-2019	Laurus Labs Limited, (Unit-II), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam- District-534011, Andhra Pradesh, India.	India	HDPE Container	30, 90
	Darunavir ethanolate	800mg	Tablet	Mylan Laboratories Ltd	ERP Reviewed	31-05-2019	FDf-Unit-2, Aurangabad site, (Plot No. H-12 and H-13), MIDC, Waluj Industrial Area Aurangabad-431136 Maharashtra	India	HDPE Container	30
	Lopinavir and Ritonavir	40 mg/10 mg	Oral granules	Mylan Laboratories Limited	ERP Reviewed	28-10-2019	F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	Al/Al sachets	120 sachets/box

End of ERP Reviewed products list