

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

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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 (November 2023). 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;

C classified product - Authorised for use by WLA if the scope of listing includes the marketing authorisation function as published and regularly updated in the WHO website

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, C 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/WLA - 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" with similar formulation and dosage has been identified in this list with a unique "Product reference number" (Column A). Please see examples below.

However, 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 significant differences among them regarding interchangeability. For example, within solid forms, some capsules will have same reference number as tablets while within liquids, oral solution and suspension are grouped together. Following the same principles, the entero coated tablet or dispersible tablet will not share the same reference number as a normal tablets.

Product Ref.No	International Non-proprietary name	Strength	Dosage form	Supplier/Manufacturer*	Global Fund QA Standard	WHO Pre-qualified/SRA/WLA	Manufacturing site*	Country	Material	Pack
A16	XYZ	50mg	Tablet	"Pharma Company A"	A - B	Yes	"Pharmaville"	Country A	HDPE bottle	60
A17		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 A16 and A17). 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/WLA	Manufacturing site*	Country	Packaging	
A25	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, Blister	60, 10

In this second example both products have same reference number (A25) 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 or C 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/WLA	Manufacturing site	Country	Material	Pack
A1	Abacavir	20 mg / ml	Oral solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	HDPE bottle	240ml
	Abacavir	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
	Abacavir	20 mg / ml	Oral Solution	Hetero Labs Limited	B	NDA201107	Hetero Drugs Limited Unit III Plot No. 22-110, Part-II, IDA Jeedimetla, Hyderabad, Telangana India. -500 055	India	HDPE Bottle	240ml
A2	Abacavir (as Sulfate)	60 mg	Dispersible Tablet	Cipla Ltd.	A -B	Yes	A-33, MIDC Patalganga	India	HDPE Bottle	60
	Abacavir (as Sulfate)	60 mg	Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar, Nashik, Maharashtra	India	HDPE	60
	Abacavir (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
A3	Abacavir	300 mg	Tablet	Cipla Ltd.	A - B	Yes	A-23, MIDC Patalganga	India	HDPE Bottle,	60
	Abacavir	300 mg	Tablet	ViiV HealthCare	A - B	Yes	Glaxo Operations UK, Ltd, Ware, Herthfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	Blister	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Abacavir	300 mg	Tablet	Mylan Laboratories Ltd	B	ANDA 078742	Sinnar,Nashik, Maharashtra / Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE Bottle; Blister	60; 6*10
	Abacavir (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	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	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
	Abacavir	300 mg	Tablet	Microlabs Ltd	B	ANDA 206725 22/12/17	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	Blister, HDPE Bottle	10, 60
A113	Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Laurus Laboratories Ltd	B	ANDA 210899	Laurus Labs Limited, Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District-531011, 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 on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Aurobindo Pharma Limited	B	ANDA 210642	APL Healthcare Limited Unit-IV Plot No.16, APIIC, M.P. SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District Andhra Pradesh, 524421 - India	India	HDPE Bottle	30
A136	Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible tablet	Aurobindo Pharma Limited	B	ANDA 217070	APL Healthcare Limited, Unit-IV, Plot No.16, APIIC Multi Products SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District, Andhra Pradesh, INDIA	India	HDPE Bottle	90, 180
	Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible tablet	Mylan Laboratories Ltd	B	ANDA 218193	Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE Bottle	60, 90, 120, 180
	Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible tablet	Cipla Limited	A	HA779	Cipla Limited, Indore Unit IV, Plot No. 9 & 10, Pharma Zone, Phase-II, Indore Special Economic Zone, Pithampur, District Dhar, Madhya Pradesh, India. Pin code- 454775.	India	HDPE bottle	30; 90

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
A6	Abacavir + Lamivudine	120 mg / 60 mg	Tablets for Oral Suspension	Mylan Laboratories Ltd	B	ANDA 204915	Mylan Laboratories Limited (FDF-2) Plot No. H-12 & H-13, MIDC Waluj, Aurangabad - 431136 Maharashtra, India; Mylan Laboratories Limited (FDF-3) Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madhya Pradesh, 454 775, India	India	HDPE bottle	30, 60
	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	30, 60
	Abacavir (as Sulfate) + Lamivudine	120 mg / 60 mg	Disp. Tablet	Microlabs Ltd	A	HA763	Micro Labs Ltd, Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722, India	India	HDPE Bottle	30
A7	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, Heriortourismre; 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 Cipla Goa Unit 7	India	HDPE Bottle; Blister	30; 3*10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	ANDA090519HA635	Mylan Laboratories Ltd, F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113, India Mylan Laboratories Ltd, Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775, India	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	United Kingdom of Great Britain and Northern Ireland	Child resistant blister, PVC/PVdC-Alu/Paper	1x1;10x3
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Sun Pharmaceutical Industries Ltd	A	HA698	Village Ganguwala, Paonta Sahib, District Sirmour, Himanchal Pradesh, 173 025	India	Bottle, HDPE	30x1, 90x1
	Abacavir (as Sulfate) + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India	A	HA740	Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India	India	Bottle HDPE, Blister	30x1, Blister of 6x10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Remedica	B	22346	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE bottle PVC/PE/PVDC /Aluminium blisters	30, 3X30 3X10 3X3X10
	Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Laurus Laboratories Ltd	B	NDA216332	Laurus Labs Limited, (VSP-2) Plot No. 19, 20 and 21, Western Sector, APSEZ, Atchutapuram Visakhapatnam, Andhra Pradesh India 531011	India	HDPE Bottle	30, 90, 180
A8	Abacavir (as Sulfate)+ Lamivudine + Zidovudine	60 mg + 30 mg + 60 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar,Nashik, Maharashtra	India	HDPE	60
A9	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
A11	Atazanavir	50 mg / 1.5g	Oral powder	Bristol-Myers Squibb	B	Yes	Hounslow	UK	Bottle (HDPE)	180g
A12	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
A13	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
	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
A14	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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
A15	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
	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
	Atazanavir (as Sulfate)	300 mg	Capsule	TEVA Pharmaceutical Israel Ltd	A	HA750	PLIVA Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb; TEVA PHARMA S.L.U., C/C, n. 4, Poligono Industrial Malpica, 50016 Zaragoza; Teva Operations Poland Sp. z.o.o, ul. Mogilska 80, 31-546, Krakow; TEVA Pharmaceutical Works, Private Limited Company, Pallagi út 13, 4042 Debrecen; Merckle GmbH, Ludwig- Merckle-Straße 3, 89143 Blaubeuren; Merckle GmbH, Graf-Arco-Str. 3, 89079 Ulm; TEVA UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG; MPF B.V., 13 Appelhof, Oudehaske, 8465; MPF B.V., Neptunus 12, 8448 CN HEERENVEEN TjoaPack Netherlands B.V., Nieuwe Donk 9, 4879 A.C Etten-Leur	Croatia, Spain, Poland, Germany, Hungary, United Kingdom of Great Britain and Northern Ireland, Netherlands	HDPE Bottle	30
A16	Atazanavir (sulfate)+ Ritonavir	300mg + 100mg	Tablet	Mylan Laboratories Ltd	B	NDA 022282	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	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
	Atazanavir (sulfate)/Ritonavir	300mg+100mg	Film Coated Tablet	Lupin Limited	A	HA720	Lupin Limited, Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, 441 108, India	India	Bottle HDPE	30
	Atazanavir (sulfate)/Ritonavir	300mg+100mg	Film Coated Tablet	Shanghai Desano Bio-Pharmaceutical Co Ltd	A	HA749	Shanghai Desano Bio-Pharmaceutical Co Ltd, 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China (People's Republic of)	China	Bottle HDPE	30
	Atazanavir (sulfate)/Ritonavir	300mg+100mg	Film Coated Tablet	Laurus Labs Limited	A	HA772	Laurus Labs Limited Unit-II, Plot No:19, 20 & 21, Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal Anakapalli, Andhra Pradesh 531011 India	India	HDPE Bottle	30, 90
A17	[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

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A137	Cabotegravir (as cabotegravir free acid)	600 mg/3 mL vial	Prolonged-release Suspension for Injection	ViiV Healthcare Pty Ltd	B	ARTG ID 377474	Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations) Harmire Road Barnard Castle County Durham DL12 8DT UK	UK	Type I glass vial, sealed with rubber stopper and an aluminum overseal with a removeable plastic cap	single 3 mL vial or 25 x 3 mL vials
A138	Cabotegravir (as cabotegravir sodium)	30mg	Film coated tablets	ViiV Healthcare Pty Ltd	B	ARTG ID 377442	Glaxo Wellcome, S.A. Avda. Extremadura, 3 Aranda De Duero Burgos 09400 Spain	Spain	HDPE bottle	30
A114	Dapivirine	25 mg, vaginal delivery system	Vaginal Ring	International Partnership for Microbicides	B	EMA Art58 H/W/0021 68/001 EMA Art 58 H/W/0021 68/002	Sever Pharma Solutions (formerly QPharma) P.O. Box 590, 201 25 Malmö, Sweden	Sweden	Opaque, heat-sealed laminate pouch	1/pk or 3/pk
A20	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
	Darunavir (as Ethanolate)	75 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	A-B	HA529 (a) EU/1/06/3 80/005	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	480
	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Darunavir	75 mg	Film coated Tablets	Remedica	B	22546	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle and Alu-Transparent-PVC/PE/PVDC blisters	480 30 (3x10) 60 (6x10) 90 (9x10)
	Darunavir	75 mg	Film coated Tablets	Cipla	B	ANDA 207189	Cipla Limited, Plot no a-33, a-42, a-2, Patalganga Industrial Area, Patalganga District - Raigad, Maharashtra IN 410220	India	HDPE Bottle	480
A21	Darunavir (as Ethanolate)	150 mg	Tablets	Cipla	B	ANDA 207189	Cipla Limited, Plot no a-33, a-42, a-2, Patalganga Industrial Area, Patalganga District - Raigad, Maharashtra IN 410220	India	HDPE Bottle	240
	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
	Darunavir (as Ethanolate)	150 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	A-B	HA530 (a) EU/1/06/380/004	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Darunavir (as Ethanolate)	150 mg	Tablets	Micro Labs Ltd,	B	ANDA 210187 14/12/20	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle	60 120 240
	Darunavir	150 mg	Film coated Tablets	Remedica	B	22547	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle and Alu-Transparent-PVC/PE/PVDC blisters	240 30 (3x10) 60 (6x10) 90 (9x10)
A115	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	HDPE Bottle	120; 360
	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
A22	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	400mg	Tablet, Film-coated	Laurus Labs Limited	A	HA709	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh, 531011	India	HDPE Bottle	60
	Darunavir	400 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	B	EU/1/06/3 80/003	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60
	Darunavir	400mg	Tablet	Hetero Labs limited	B	Yes	UNIT-III, Hyderabad	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Darunavir (as 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
	Darunavir (as Ethanolate)	400mg	Tablet	Micro Labs Ltd,	B	ANDA 210187 14/12/20	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle	60
	Darunavir	400 mg	Film coated Tablets	Remedica	B	22549	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle and Alu-Transparent-PVC/PE/PVDC blisters	60 30 (3x10) 60 (6x10) 90 (9x10)
A116	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	Tablet, Film-coated	Laurus Labs Limited	A	HA710	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal,Visakhapatnam-District, Andhra	India	HDPE Bottle	60
	Darunavir (as Ethanolate)	600 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	A -B	HA780 EU/1/06/380/002	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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 Estate, 3056 Limassol, Cyprus	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	600 mg	Film coated Tablet	Krka, d.d., Novo mesto	A	HA733	TAD Pharma GmbH, Heinz-Lohmann - Straße 5, 27472 Cuxhaven, Germany Prestige Promotion Verkaufsförderung & Werbeservice GmbH, Lindigstraße 6, 63801 Kleinostheim, Germany (Additional secondary packaging) RAFARM S A, Thesi Pousi-Xatzi Agiou Louka, Paiania Attiki TK 19002, TΘ 37, Greece	Slovenia, Germany, Greece	Bottle, HDPE	30 (1x30); 60 (2x30), 90 (3x30), 180 (6x30)
	Darunavir	600 mg	Film coated Tablet	Remedica	B	22550	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle and Alu- Transparent- PVC/PE/PVDC blisters	60 30 (3x10) 60 (6x10) 90 (9x10)
	Darunavir (as Ethanolate)	600mg	Tablet	Cipla	A-B	HA628 ANDA 207189	(Unit II), MIDC, Patalganga	India	HDPE Bottle	60
	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Darunavir (as Ethanolate)	600mg	Tablet	Mylan Laboratories Ltd	A	HA685	FDF-Unit-2, Aurangabad site, (Plot No. H-12 and H-13), MIDC, Waluj Industrial Area Aurangabad-431126	India	HDPE Container	60
	Darunavir (as Ethanolate)	600mg	Tablet	Micro Labs Ltd,	B	ANDA 210187 14/12/20	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle	60
A117	Darunavir	800 mg	Tablet, Film-coated	Laurus Labs Limited	A	HA711	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh 531011	India	HDPE Bottle	30
	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	Mylan Laboratories Ltd	A	HA683	FDF-Unit-2, Aurangabad site, (Plot No. H-12 and H-13), MIDC, Waluj Industrial Area Aurangabad-431126	India	HDPE Container	30
	Darunavir	800 mg	Film coated Tablet	Remedica	B	22551	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle and Alu-Transparent-PVC/PE/PVDC blisters	30 30 (3x10) 60 (6x10) 90 (9x10)

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
A118	Darunavir (as Ethanolate) / Ritonavir	400mg/50mg	Tablet	Hetero Labs Ltd, Hetero Corporate, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad, Ranga Reddy District, Telangana, 500 018, India	A	HA719	Hetero Labs Ltd, Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055, India	India	HDPE Bottle	30x1, 60x1,120x1
A119	Dolutegravir (as sodium salt)	5mg	Disp. Tablet	ViiV Healthcare BV, Van Asch van Wijckstraat 55H, Amersfoort, 3811 LP, Netherlands	A	HA768	Glaxo Operations UK Limited, Priory Street, Ware, Hertfordshire, SG12 0DJ, United Kingdom of Great Britain and Northern Ireland; Glaxo Wellcome SA, Avenue de Extremadura 3, Aranda de Duero, Burgos. Spain	India	HDPE Bottle	60x1
A120	Dolutegravir (as sodium salt)	10mg	Tablet for Oral Suspension	Mylan Laboratories Ltd	B	NDA 214521	Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE Bottle	30,60,90

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Dolutegravir (as sodium salt)	10mg	Dispersible Tablets for oral suspension	Macleods Pharmaceuticals Limited	A-B	ANDA 214566 HA765	1. Macleods Pharmaceuticals limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam Daman, PIN-396210 India 2. Macleods Pharmaceuticals Limited Plot No. M-50 to M-54-A, SEZ Phase - II Pithampur, Tehsil-Patera Dhar Indore, Madhya Pradesh - 454774 India 3. Macleods Pharmaceuticals Ltd Unit 1, Survey No 10 IDA, Gaddapothoram Village, Jinnaram (M), Sangareddy District Telangana 502319 India	India	HDPE bottle	90, 180 90
ARV121	Dolutegravir (as sodium salt)	10mg	Tablets	Macleods Pharmaceuticals Limited	B	ANDA 214397	Macleods Pharmaceuticals limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam Daman, PIN-396210 India	India	HDPE bottle	30's, 90's and 180's
A122	Dolutegravir (as sodium salt)	25mg	Tablets	Macleods Pharmaceuticals Limited	B	ANDA 214397	Macleods Pharmaceuticals limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam Daman, PIN-396210 India	India	HDPE bottle	30's, 90's and 180's
A34	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Hetero Labs Ltd	A	HA682	Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055; Unit V, Sy.No.439, 440, 441 & 458 TSIIC Formulation SEZ Polepally Village, Jadcherla Mandai Mahaboobnagar District	India	Blister,Alu/Alu; Bottle,HDPE	10x8; 30x1; 90x1
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	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
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	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, 90
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Laurus Lab Ltd	A-B	HA718-ANDA 210963	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal,Visakhapatnam-District, Andhra Pradesh, 531011	India	HDPE bottle	30, 90

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Emcure Pharmaceuticals Ltd	A	HA701	Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057	India	Bottle, HDPE	30x1, 90x1, 180x1
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Sun Pharmaceutical Industries Limited	A	HA708	Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh, 173 025	India	Bottle, HDPE	30x1, 90x1
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Shanghai Desano Bio-Pharmaceutical Co Ltd	A	HA694	479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203	China	Bottle, HDPE	30x1
	Dolutegravir (as sodium salt)	50mg	Tablets, Film-coated	Micro Labs Ltd,	A	HA751	Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722	India	Bottle, HDPE	30x1, 60x1, 90x1
	Dolutegravir (as sodium salt)	50mg	Tablets	Macleods Pharmaceuticals Limited	B	ANDA 214397	Macleods Pharmaceuticals limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam Daman, PIN-396210 India	India	HDPE bottle	30's, 90's and 180's

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Dolutegravir (as sodium salt)	50mg	Tablets	Strides Pharma Science Limited	A	HA731	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	28x1, 30x1, 56x1, 60x1, 84x1, 90x1
A123	Dolutegravir + Emtricitabine+ Tenofovir Alafenamide*	50 mg+200 mg+25 mg	Tablets, Film-coated	Laurus Labs Limited	B	NDA 213681	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh, 531011	India	Bottle, HDPE	30, 90, 180
	Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets, Film-coated	Mylan Laboratories Ltd	B	NDA 210237	Plot No. 11, 12 & 13 Indore Special Economic Zone Pharma Zone, Phase II, Sector III, Pithampur Dhar, Madhya Pradesh, India, 454775	India	Bottle, HDPE	30, 90
	Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Lupin Limited	B	ANDA 214544	Lupin Limited Unit-1, Plot No. 6A1, 6A2, Sector-17 Special Economic Zone, MIHAN Nagpur, Maharashtra, India - 441108	India	Bottle, HDPE	30, 60, 90 and 1000
	Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Aurobindo Pharma Ltd	B	ANDA 215448	APL Healthcare Limited, Unit IV Plot No. 16, APIIC M.P. SEZ, Menakuru Village Naidupeta mandal, Tirupati, Andhra Pradesh -524421, India	India	Bottle, HDPE	30, 90

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A124	Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Tablet	Mylan Laboratories Ltd	B	NDA 210865	Plot No. 11, 12 & 13 Indore Special Economic Zone Pharma Zone, Phase II, Sector III, Pithampur Dhar, Madhya Pradesh, India, 454775	India	Bottle, HDPE	30, 90,180
	Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Film coated Tablet	Laurus Labs Limited	B	NDA 213696	Laurus Labs Limited, (VSP-2), Plot No. 19, 20 and 21, Western Sector APSEZ, Atchutapuram, Visakhapatnam Andhra Pradesh – 531011, India	India	Bottle, HDPE	30, 90,180
	Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Tablets	Cipla Limited	B	NDA 212527	Cipla Limited – Patalganga Plot No. A – 42 (Unit - II) MIDC Patalganga, District Raigad, Patalganga 410220 Maharashtra, India	India	HDPE Bottle	30, 90
	Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Tablets	Lupin Limited	B	NDA 215187	Lupin Limited Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, 441 108, India.	India	HDPE Bottle	30, 90

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A125	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg + 300 mg + 300 mg	Tablet	Celltrion Pharm, Inc.	B	NDA 211912	Celltrion Pharm, Inc. 82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do 28117; Aizant Drug Research Solutions Pvt. Ltd. Survey No 172/173, Apparel Park Road, Dulapally Village, Dundigal-Gandimaisamma Mandal, Medchal-Malkhajgiri District, Hyderabad, 500 100, Telangana	republic of Korea India	HDPE Bottle	30, 90, 180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg + 300 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	NDA 209618	1) Aurobindo Pharma Limited Unit VII, SEZ, APIIC Plot No SI, Survey No 411, 425, 434, 435 and 458, Green Industrial Park, Village Polepally, Mandal Jedcherla, District Mahaboobnagar, Andhra Pradesh; 2) APL Health Care limited, (UNIT-IV), Plot No.16, APIIC Multi Product SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District, telangan, Andhra Pradesh	India	HDPE Bottle	30, 90, 180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg + 300 mg + 300 mg	Tablet	Mylan laboratories Ltd	A-B	HA688 NDA 209670	Mylan Laboratories Limited (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
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Cipla Ltd	A	HA702	1) Cipla Goa (Unit-VII) Verna Industrial Estate, Verna, Salcette, Goa – 403 722 2) Cipla Unit-VII PD II Verna Industrial Estate, Verna Salcette, Goa - 403722 3) Cipla Quality Chemical Industries Ltd, PO Box 34871, Plot No 1-7 Ring Road, Luzira Industrial Park, Kampala, Uganda	India and Uganda	HDPE Bottle	28, 30, 84, 90, 180, 500

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	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Laurus Lab Ltd	A-B	HA707-NDA 210787 USFDA 2	(Unit-II), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District- 531011, Andhra Pradesh	India	HDPE Container	30, 90,180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Sun Pharmaceutical Industries Limited	A	HA699	Village Ganguwala, Paonta Sahib, District Sirmour, Himanchal Pradesh, 173 025	India	HDPE Bottle	30x1, 90x1, 180x1
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Hetero Labs Ltd	A-B	HA696/ NDA 210880	Unit 5, Survey No 439, 440, 441 & 458 TSIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301; - Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055; - I156 Annora Pharma Private Limited Annaram Village, Gummadidala Mandal Sangareddy District, Telangana State	India	HDPE Bottle	30, 60, 90, 100,180, 750
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Strides Pharma Science Limited	A	HA729	1) Strides Pharma Science Limited Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk Bangalore, Karnataka 562 106 India 2) Strides Pharma Science Limited Unit II, RS No 32-34, PIMS Road, Periyakalpet Puducherry 605 014 India 3) Universal Corporation Ltd PO Box 1748, Club Road, Plot No 13777 Kikuyu, 902 Kenya	India	Bottle, HDPE	28x1, 30x1, 56x1, 60x1, 84x1, 90x1, 168x1, 180x1
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	tablet FDC	Macleods Pharmaceuticals Ltd	A-B	HA713 NDA 210796	1. Block N 2, Village Theda (GB1, GB2 and GB3) P.O. Lodhi Majra, Tehsil Baddi , Dist.: Solan, Himachal Pradesh, 174101 India 2. Phase III, Unit II Plot No. 25 - 27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman -	India	Bottle, HDPE	30x1, 90x1, 100x1, 180x1
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Tablet	Emcure Pharmaceuticals Ltd	A	HA722	Plot No P-1 & P-2, I.T.B.T., Park Phase II MIDC, Hinjewadi, Pune, Maharashtra, 411057	India	Bottle, HDPE	30x1, 90x1, 180x1

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	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Tablet	Lupin Pharmaceuticals, Inc. 111 South Calvert Street Harborplace Tower, 24th Floor Baltimore, MD 21202	A-B	HA737 NDA 212303	Lupin Limited, Unit 1, Plot No. 6A1, 6A2 , Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra – 441 108, India	India	Bottle, HDPE	30x1, 60x1, 90x1 30x1, 60x1, 90x1 or 180x1
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co., Ltd., China	B	NDA 213556	1.Aizant Drug Research Solutions Pvt. Ltd. Hyderabad- 500100, India. 2. Shanghai Desano Bio-Pharmaceutical Co. Ltd. 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China	India	Bottle, HDPE	30, 90
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Film Coated Tablet	Microlabs Ltd	A	HA755	Micro Labs Ltd, Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722, India	India	Bottle, HDPE	30, 90, 180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Tablet	Celltrion Pharm, Inc.	B	NDA 211912	Celltrion Pharm, Inc. 82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu , Cheongju-si, Chungcheongbuk-do, Korea, 28117	India Korea	Bottle, HDPE	30, 90, 180
	Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50mg+300mg + 300mg	Tablet	Desano Pharmaceuticals Private Ltd	A	HA746	Shanghai Desano Bio-Pharmaceutical Co Ltd, 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China (People's Republic of)	China	HDPE Bottle	30, 90
A35	Efavirenz (EFV)	30 mg / ml	Oral Solution	Merck Sharp & Dohme Limited	A - B	Yes	Patheon Inc. Mississauga, Ontario Harlem	Canada Netherlands	HDPE Bottle	180ml

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
A36	Efavirenz (EFV)	50 mg	Capsule	Merck Sharp & Dohme Limited	A	Yes	Manati, Harlem	Puerto Rico Netherlands	HDPE bottle	30
	Efavirenz (EFV)	50 mg	Tablet	Microlabs Ltd	NDA 205389	Yes	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate , Verna Salcette , Goa - 403 722	India	HDPE Bottle	30, 60, 90
	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
A38	Efavirenz (EFV)	100mg	Tablet	Mylan Laboratories Ltd	B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
	Efavirenz (EFV)	100 mg	Tablet	Microlabs Ltd	NDA 205389	Yes	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate , Verna Salcette , Goa - 403 722	India	HDPE Bottle	30,60,90
A40	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	Aurobindo Pharma Ltd	B	Yes	Unit III, Survey No. 313 & 314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahabub Nagar (DT)	India	HDPE bottle; Blister	30, 90; 10

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Efavirenz (EFV)	200 mg	Tablet	Microlabs Ltd	NDA 205389	Yes	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate , Verna Salcette , Goa - 403 722	India	HDPE Bottle	30,60,90
	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
A42	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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	HA403 NDA 078883	Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136, India Mylan Laboratories Ltd, Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madhya Pradesh, 454 775, India Mylan Laboratories Ltd, F4 & F12 Malad West MIDC, Sion, Mumbai, Maharashtra, 400 022, India	India, Kenya	HDPE bottle; Blister	28, 30; 10
	Efavirenz (EFV)	600 mg	Tablet	Shanghai Desano Biopharmaceutical 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
	Efavirenz (EFV)	600 mg	Film coated Tablet	Strides Arcolab Limited	A-B	HA390	Strides Shasun Ltd, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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	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
A42	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 on/SRA/WLA	Manufacturing site	Country	Material	Pack
A44	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	HA444 ANDA 090437	Sinnar,Nashik, Maharashtra, Waluj, Aurangabad, Maharashtra; Mylan Pithampur, Dhar Dist., Madhya Pradesh	India	HDPE bottle	30, 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	Macleods Pharmaceuticals Limited	A-B	HA562 ANDA 204287	Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India	India	HDPE Bottle	30, 90, 180
	Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Strides Arcolab Limited	A	Yes	Anekal Taluk, Bangalore, India	India	HDPE Bottle	30

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	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 on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Efavirenz + Emtricitabine + Tenofovir (Disoproxil Fumarate)	600 mg+200 mg+300 mg	Tablet	Gilead Sciences, Inc.	B	Yes	Patheon Inc. Mississauga, Ontario	Canada	HDPE Bottle	30
	Efavirenz + Emtricitabine + Tenofovir (Disoproxil Fumarate)	600 mg+200 mg+300 mg	Film coated Tablet	Laurus Labs Ltd	B	ANDA 213541	Laurus Labs Limited, (VSP-2) Plot No. 19, 20 and 21, Western Sector, APSEZ Atchutapuram, Visakhapatnam, Andhra Pradesh – 531011, India	India	HDPE Bottle	30, 90
	Efavirenz + Emtricitabine + Tenofovir (Disoproxil Succinate)	600 mg+200 mg+245 mg	Film coated Tablet	Remedica	B	22699	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE Bottle	30, 90 (3X30)
A45	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A- B	HA466 NDA022142	Sinnar, Nasrik, Maharashtra; H-12 & H-13, M.I.D.C, Waluj, Aurangabad Maharashtra; Mylan Pithampur, 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, 90& 500

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	Tablet	Cipla Ltd.	A-B	HA593	Plot No 1-7 Ring Road, Luzira Industrial Park, Kampala, Uganda Unit 7, Plot No L-139 to L-147-1, S-103 to S-105, S-107 to S-112 & M-61 to M-63, Verna Industrial Estate, Salcette, Goa, 403 722, Unit 2, Plot A-42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra, 410 220	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	India	HDPE Container	30, 90, 100
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	tablet FDC	Laurus Labs Limited	A-B	HA727- ANDA 212786	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh, 531011	India	HDPE Bottle	30x1, 90x1
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	tablet FDC	Microlabs Ltd	A	HA767	Micro Labs Ltd, Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722	India	HDPE Bottle	30x1

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	tablet	Desano Pharmaceuticals Private Ltd	A	HA764	Aizant Drug Research Solutions Pvt. Ltd, Block No. B, Sy. No. 172 & 173, Apparel Park Rd., Dulapally Village, Hyderabad, Dundigal-Gandimaisamma Mandal, Medchal-Malkhajiri District, Telangana, 500 100, India	India	HDPE Bottle	30, 90
ARV126	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, 90
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	tablet FDC	Laurus Labs Limited	A-B	HA732-ANDA 213038	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh, 531011	India	HDPE Container	30, 90, 180

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	tablet FDC	Macleods	A-B	HA714- NDA 210649	Block N-2, Village Theda; Post Office Lodhimajra Tehshil Baddi, Distt.Solan, Himachal Pradesh-174101 Survey No 366, Premier Industrial Estate, Kachigam Plot No. 25 - 27 Daman, Daman, India.396210.	India	HDPE Bottle	30, 90, 180
	Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	tablet FDC	Hetero	A	HA759	Hetero Labs Limited_UNIT_V Survey No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla (Mandal) Mahabubnagar (District), Telangana 509301, India (IND)	India	HDPE Bottle	30, 90, 180
A46	Emtricitabine	10 mg/ml	oral solution	Gilead Sciences, Inc.	B	Yes	Country Cork	Ireland	Bottle	170ml
A47	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	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
	Emtricitabine	200 mg	Capsule	Micro Labs Ltd,	B	NDA 204396	Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE Bottle	30,60,90
A49	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 on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Emtricitabine +Tenofovir Disoproxil succinate	200 mg + 245 mg	Tablet Film coated	Remedica	B	22347	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Bottle (HDPE)	30, 90(3x30) tablets
	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	HA417 ANDA 090049	1) Mylan Laboratories Ltd Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, District Dhar Pithampur, Madhya Pradesh 454 775 India 2) Mylan Laboratories Ltd F4 & F12 Malegaon MIDC, Nashik District Sinnar, Maharashtra 422 113 India 3) Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Aurangabad, Maharashtra 431 136 India	India	HDPE bottle; Al/Al blister HDPE bottle; blister	28, 30,100; 3x10's 30, 100 2x10's
	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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	HA561	Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India Macleods Pharmaceuticals Ltd, Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210, India	India	HDPE bottle Alu/Alu blister	30; 10 x 10
	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Laurus Lab Ltd	A	HA717	(Unit-2), Plot No:19, 20 & 21, Western Sector, APSEZ, Atchutapuram Mandal, Visakhapatnam-District, Andhra Pradesh, 531011	India	Bottle, HDPE	30x1, 90x1
	Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Emcure Pharmaceuticals Ltd	A	HA726	Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057	India	Bottle, HDPE	30x1
A139	Emtricitabine + Tenofovir Alafenamide	200mg/25mg	Tablet	Aurobindo Pharma Ltd	B	NDA 216875	APL Healthcare Limited Unit-IV Plot No.16, APIIC, M.P. SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District Andhra Pradesh, 524421 - India	India	HDPE Bottle	30, 90
	Emtricitabine + Tenofovir Alafenamide	200mg/25mg	Tablet	Laurus Labs Limited	B	ANDA 213989	Laurus Labs Limited, (VSP-2) Plot No. 19, 20 and 21, Western Sector, APSEZ, Atchutapuram Visakhapatnam, Andhra Pradesh India, 531011	India	HDPE Bottle	30, 90
A50	[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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	[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
A51	Enfuvirtide	90mg/ml	Injection	Hoffmann-La Roche Inc.	B	Yes	Basle	Switzerland	Vials	60+60 vials of water for inj+syringe
A52	Etravirine	25mg	Tablet	Janssen-Cilag International NV, Belgium	A-B	HA600 (a) EU/1/08/468/003	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	120
A53	Etravirine	100mg	Tablet	Janssen-Cilag International NV, Belgium	A-B	HA532 (a) EU/1/08/468/001	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	120
A54	Etravirine	200mg	Tablet	Janssen-Cilag International NV, Belgium	B	EU/1/08/468/002	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60
A55	Fosamprenavir (FPV)	700 mg	Tablet	Glaxo SmithKline Ltd.	B	Yes	Glaxo Wellcome Operations	UK	HDPE bottle	60
A56	Indinavir (IDV)	200 mg	Capsule Hard	Merck Sharp & Dohme Limited	B	Yes	Hertford Road, Hertfordshire	UK	HDPE Bottle	180,270, 360
A57	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
A58	Lamivudine (3TC)	10 mg / ml	Oral Solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	HDPE bottle	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
	Lamivudine (3TC)	10 mg / ml	Oral Solution	Macleods Pharmaceuticals Limited	A	Yes	Solan, Himachal Pradesh, India	India	HDPE Bottle	100ml, 240ml
A59	Lamivudine (3TC)	30mg	Tablet	Cipla Ltd.	A	Yes	Goa	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Lamivudine (3TC)	30mg	Tablet	Microlabs Ltd	A	Yes	Verna, Goa	India	PVC/PVdC/Alu blister ; HDPE bottle	10 60,100,500,1000
A61	Lamivudine (3TC)	100 mg	Tablet Film coated	Glaxo SmithKline Ltd.	B	Yes	Ware, Hertfordshire	UK	Blister; Bottle	28, 84
A62	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 Film coated	ViiV HealthCare	A - B	Yes	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland Pharmacare (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-B	HA644	Verna, Goa	India	Alu/PVC/PvdC blister HDPE Bottle	6x10 60
	Lamivudine (3TC)	150 mg	Tablet	Alkem Laboratories Ltd	B	Yes	Amaliya, Daman	India	HDPE Bottle	60

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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
A63	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	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Lamivudine (3TC)	300 mg	Film-coated Tablet	Beximco Pharmaceuticals Limited	A	HA668	Track-II, 126, Kathaldia, Auchpara, Tongi-1711, Gazipur, Bangladesh	Bangladesh	HDPE Bottle	30x1
A67	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
	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
A127	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
A70	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-B	HA712-NDA 211284	Celltrion Pharm, Inc. 82, 2Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do	Republic of Korea	HDPE Bottle	30, 60, 100

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	A-B	HA414 NDA022141	Mylan Laboratories Ltd, Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madhya Pradesh, 454 775, India 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;	India	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
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Cipla Ltd.	A- B	HA666	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	HA525	Sun Pharmaceutical Industries Limited, Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh, 173 025, India	India	HDPE Bottle	30, 90
	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	HA620	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	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/WLA	Manufacturing site	Country	Material	Pack
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Lupin Ltd	A	HA703	Lupin Limited, Unit 1, Plot No. 6A1, 6A2 , Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra – 441 108, India	India	HDPE Bottle	30
	Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Film coated Tablet	Celltrion Pharm, Inc.	A	HA712	CELLTRION PHARM, Inc., 82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea	Republic of Korea	HDPE Bottle	30, 60, 100
A71	[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
A73	Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Mylan Laboratories Ltd	A -B	HA572 ANDA 200748	1) Mylan Laboratories Ltd Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, District Dhar Pithampur, Madhya Pradesh 454 775 India 2) Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Aurangabad, Maharashtra 431 136 India 3) Mylan Laboratories Limited (FDF-1) Plot No. F-4 and F-12 Malegaon M.I.D.C., Sinnar Nashik District, Maharashtra, India. 422113	India	HDPE	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Mylan Laboratories Ltd	A -B	HA572; NDA	Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, Madya Pradesh, 454 775: Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136	India	HDPE	60
A74	Lamivudine + Zidovudine	30 mg + 60 mg	Tablet	Mylan Laboratories Ltd	A -B	Yes	Sinnar-Nashik, Maharashtra Waluj, Aurangabad	India	HDPE bottle	60
	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
A128	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co Ltd	A	HA655	Shanghai Desano Bio-Pharmac+H309eetical 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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	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; Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE bottle ; Blister	60; 10
	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 Biopharmaceutical Co., Ltd.,	A	HA656	Anhui Biochem Biopharmaceutical 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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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
	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
	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	B	NDA 077558	Aurobindo Pharma Limited, Unit-III, Survey No. 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana State, INDIA. Zip Code: 500090	India	HDPE bottle	60

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	Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Universal Corporation Ltd	A	HA490	Universal Corporation Ltd PO Box 1748, Club Road, Plot No 13777 Kikuyu, 902 Kenya	Kenya	HDPE bottle	60
A78	Lopinavir (LPV) + Ritonavir (RTV)	(80 mg + 20 mg) / ml	Oral Solution	AbbVie Ltd	A -B	HA098ND A 021251	AbbVie Inc., 1 N Waukegan Road, IL 60064, North Chicago, Aesica Queenborough Limited, North Road, Queenborough, Kent, ME11 5EL, UPS SCS B.V., Marco Poloweg 22-24, 5928 LE Venlo, Netherlands	USA, UK, Netherlands	PET bottle	160ml
A79	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
	Lopinavir+Ritonavir	40mg/10mg	Oral Granules	Mylan Laboratories Limited	A-B	HA697- NDA 210540	Mylan Laboratories Limited (FDF-1) Plot # F/4 & F/12, Malegaon MIDC Sinnar, Nashik District- 422113 Maharashtra; Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	aluminum foil sachets	120
A129	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	AbbVie Ltd	B	EMA Art 58 H-W-764-2	Ludwigshafen	Germany	HDPE bottle	60
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	AbbVie Ltd	B	NDA21906	North Chicago	USA	Bottle (HDPE) Bottle (PVC)	60

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	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Mylan Laboratories Ltd	A-B	HA429 ANDA#79074	Mylan Laboratories Limited, F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India ;Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar Madhya	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
	Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Laurus Labs Limited	B	ANDA 213857	Laurus Labs Limited (VSP-2), Plot No. 19, 20 and 21, Western Sector, APSEZ, Atchutapuram, Visakhapatnam, Andhra Pradesh, India 531011	India	HDPE bottle	60; 120
A82	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra; Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase - II, Sector - III, Pithampur – 454775 Dist. Dhar, Madhya Pradesh.	India	HDPE Bottle; Blister	120; 6. 12

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	AbbVie Ltd	A-B	HA381, NDA21906	AbbVie LTD., Deutschland GmbH and Com KG, Knollstrasse 67061, Ludwigshafen, AbbVie LTD., KM 58 Carretera, 2 Cruce Davilla, Barceloneta 00617, Puerto Rico Fournier Laboratories Ireland Limited, Carrigtwohill business park, Anngrove, Carrigtwohill, Co. Cork	Germany, Ireland	Bottle HDPE,	120x1
	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/PVd C 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
	Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Laurus Labs Limited	B	ANDA 213857	Laurus Labs Limited (VSP-2), Plot No. 19, 20 and 21, Western Sector, APSEZ, Atchutapuram, Visakhapatnam, Andhra Pradesh, India 531011	India	HDPE bottle	60; 120
A83	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
A130	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
A131	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	Aurobindo Pharma Ltd	B	NDA 22299	Unit III Survey No. 313 and 314 Bachupally Mandal, Telangana	India	HDPE bottle	30
A86	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
A132	Nevirapine	200mg	Tablet	Microlabs Ltd	A-B	HA570, ANDA 203080	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE bottle Blister	60, 10's
A91	Raltegravir	400mg	Film-coated tablet	Merck & Co, USA	B	NDA 022145 EU/1/07/43 6/001	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Netherlands	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
A92	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/WLA	Manufacturing site	Country	Material	Pack
	Raltegravir (Potassium)	100mg	Granules for Oral Suspension	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Pays-Bas	B	NDA 205784	PATHEON PHARM INC., 2110 East Galbraith Road, OH45237-1625 – Cincinnati -USA	USA	child resistant single-use foil packet	60 packets+kit
A93	Raltegravir	25mg	Chewable tablet	Merck & Co, USA	B	Yes	Merck Sharp & Dohme B. V. Waarderweg 39 2031 BN Haarlem Pays-Bas	Netherland	Bottle	60
A94	Ritonavir (RTV)	80 mg / ml	Oral Solution	AbbVie Ltd	HA096	Yes	Queenborough, Kent	UK	PET bottle	90ml
A95	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
A96	Ritonavir (RTV)	50 mg	Tablet	Cipla Ltd.	B	NDA 205040	A-42, MIDC, Patalganga	India	HDPE Bottle	60
A133	Ritonavir (RTV)	100 mg	Tablet	Mylan Laboratories Ltd	A	Yes	Sinnar, Nashik, Maharashtra	India	HDPE Bottle	30, 120
	Ritonavir (RTV)	100 mg	Tablet	Mylan Laboratories Ltd	B	EU/1/17/12 42/003	Mylan Laboratories Limited, F-4 & F-12, Malegaon MIDC, Sinnar, Nashik -422113, Maharashtra, India.	India	HDPE Bottle	30
	Ritonavir (RTV)	100 mg	Tablet	AbbVie Ltd	HA491	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	ANDA2045 87	Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055	India	HDPE Bottle	30x1; 120x1
A99	Saquinavir	500mg	Tablet	F.Hoffman-La Roche	A	Yes	Madrid	Spain	HDPE Bottle	120
A104	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/ SRA/WLA	Manufacturing site	Country	Material	Pack
A105	Tenofovir Disoproxil Fumarate	300mg	Tablet Film coated	Gilead Sciences, Inc.	B	Yes	Patheon Inc. Mississauga, Ontario Nycomed Oranienburg GmbH Granta Park Abington, Cambridge	Canada Germany UK	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	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

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification on/SRA/WLA	Manufacturing site	Country	Material	Pack
	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	HA516	Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India Macleods Pharmaceutical limited, Plot No. M-50 to 54-A, SEZ, Phase II, Pithampur, Dist.-Dhar, Madhya Pradesh, 454774, India Macleods Pharmaceuticals Ltd, Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210, India	India	HDPE bottle	30
A135	Tenofovir Alafenamide	25 mg	Tablet	Laurus Labs Limited	B	ANDA 214030	Laurus Labs Limited (Unit-2) Plot No: 19, 20 & 21, Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli-District-531011, Andhra Pradesh, India.	India	HDPE bottle	30
A106	Zidovudine	60mg	Tablet	Microlabs Ltd	A	Yes	South Africa	India	PVC/PVdC/Alu blister HDPE bottle	10x10 60, 100, 500, 1000
A108	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	HA526	Solan, Himachal Pradesh	India	HDPE Bottle	100ml, 240ml
A109	Zidovudine	50mg/5ml	Oral solution	ViiV HealthCare	A	Yes	Mississauga, Ontario	Canada	PET bottle	200ml
	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;

Ref.No	International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	Global Fund QA Standard	WHO Prequalification/ SRA/WLA	Manufacturing site	Country	Material	Pack
	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
A110	Zidovudine	100mg	Tablet	Mylan Laboratories Ltd	A - B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60
	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	ViiV HealthCare	A	Yes	S.C. Europharm, Brasov	Romania	Bottle Blister	100; 100
A112	Zidovudine	250mg	Capsules	ViiV HealthCare	A	Yes	S. C. Europharm, Brasov	Romania	Blister	40
A134	Zidovudine	300mg	Tablets	Hetero labs limited	A-B	Yes	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad	India	HDPE bottle	60, 500, 600
	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	Mylan Laboratories Ltd	A -B	Yes	Sinnar,Nashik, Maharashtra	India	HDPE bottle; Blister	56, 60; 2 x 10
	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	Microlabs Ltd	A	yes	Verna, Goa	India	PVDC/PVC/Alu blister; HDPE bottle	10; 30, 60, 90

RAL-based regimens may be recommended as first line regimens for neonates (conditional recommendation) and for children >3kg, as an alternative to DTG-based regimens when
End of A or B or C 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 or C 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

End of ERP Reviewed products list