THE GLOBAL FUND

List Of Pharmaceutical Products (HIV)
classified according to the Global Fund Quality Assurance Policy

Edition: Version 189- 30-Sep-2026 for HIV

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 defined in the Global Fund Quality Assurance Policy (Nov 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. **https://www.theglobalfund.org/media/ojmj2qqn/psm_qa-pharmaceutical-products_policy_en.pdf**

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" (https://www.theglobalfund.org/media/7482/psm_medicinesnotification_form_en.docx) 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.
For more information on procurement of ERP Reviewed Products: add link for ERP please look at: **https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/**

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. https://www.theglobalfund.org/media/ojmj2qqn/psm_qa-pharmaceutical-products_policy_en.pdf

YELLOW **s**ignifies 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/.

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.**

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, 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.

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Abacavir	20 mg / ml	Oral Solution	ViiV HealthCare	HA107	NA	NA	Bora Pharmaceutical Services Inc. 7333 Mississauga North Mississauga, Ontario L5N 6L4 Canada	Canada	HDPE Bottle	240ml
Abacavir	20 mg / ml	Oral Solution	Aurobindo Pharma Ltd	NA	ANDA 077950	NA	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle	240ml
Abacavir	20 mg / ml	Oral Solution	Hetero Labs Ltd	NA	ANDA 201107	NA	Hetero Drugs Limited Unit III Plot No. 22-110, Part-II, IDA Jeedimetla, Hyderabad, Telangana India. -500 055	India	HDPE Bottle	240ml
Abacavir	300 mg	Tablet	Cipla Ltd.	NA	ANDA 78119	NA	A-23, MIDC Patalganga	India	HDPE Bottle	60
Abacavir	300 mg	Tablet	ViiV HealthCare	NA	H106 EU/1/99/112/001	NA	Glaxo Operations UK, Ltd, Ware, Herthfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	Blister	6x10's
Abacavir	300 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 078742	NA	Sinnar,Nashik, Maharashtra / Mylan	India	HDPE Bottle; Blister	60; 6x10's
Abacavir	300 mg	Tablet	Hetero Labs Ltd	NA	ANDA 91560	NA	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad -500 055 Andhra Pradesh,	India	HDPE Bottle	60
Abacavir	300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 77844	NA	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	NA	ANDA 206725	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	Blister HDPE Bottle	1x10's 60
Abacavir (as Sulfate)	60 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 200733	NA	Mylan Laboratories Limited (FDF-1) Plot No. F-4 and F-12 Malegaon M.I.D.C., Sinnar Nashik District, Maharashtra, India	India	HDPE	60
Abacavir (as Sulfate)	60 mg	Dispersible Tablet	Microlabs Ltd	NA	ANDA 208656	NA	Micro Labs Limited Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate Verna, Goa 403 722 India	India	HDPE	60

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Abacavir (as Sulfate)	300 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 091050	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle; Blister	60; 6x10's
Abacavir (as Sulfate) + Lamivudine	120 mg / 60 mg	Disp. Tablet	Cipla Ltd.	HA662	NDA 208775	NA	Cipla Ltd Unit 2, Plot A-42 MIDC, Patalganga, Raigad District Maharashtra 410 220 India; Unit IV, Plot No 9, 10 & 15 Indore Special Economic Zone, Phase II, Dhar District Pithampur, Madhya Pradesh 454 775 India Cipla Ltd, Plot No A - 33, A - 2 (Unit - I), MIDC, Patalganga District Raigad, Maharashtra, 410 220 India	India	HDPE Bottle	30, 60
Abacavir (as Sulfate) + Lamivudine	120 mg / 60 mg	Disp. Tablet	Microlabs Ltd	HA763	NA	NA	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
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	HA740	NA	NA	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	30 10x6's
Abacavir (as Sulfate)+ Lamivudine + Zidovudine	300 mg + 150 mg + 300 mg	Tablet	Mylan Laboratories Ltd	ANDA 090309	ANDA 090309	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60
Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible Tablet	Aurobindo Pharma Limited	NA	ANDA 217070	NA	APL Healthcare Limited,Unit-IV, Plot No.16, APIIC Multi Products SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District, Andhra Pradesh,	India	HDPE Bottle	90, 180
Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible Tablet	Cipla Limited	HA779	NA	NA	Cipla Limited, Indore Unit IV, Plot No. 9 & 10, Pharma Zone, Phase-II, Indore Special Economic Zone, Pithampur, District Dhar, Madya Pradesh, India. Pin code- 454775	India	HDPE Bottle	30, 90, 180
Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible Tablet	Lupin Ltd.	NA	ANDA 218723	NA	Lupin Limited Unit-1, Plot 6A1, 6A2, Sector -17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, India, 441108	India	HDPE Bottle	30, 60, 90, 120's, and 180 with desiccant along with one 40-mL dosing cup
Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible Tablet	Mylan Laboratories Ltd	NA	based on ANDA 218193 USFDA	NA	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	India	HDPE Bottle	60, 90, 120, 180

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Abacavir + Dolutegravir + Lamivudine		Dispersible Tablet	Macleods Pharmaceuticals Limited	NA	ANDA 217830	NA	Oxalis Labs, Baddi Village Theda, Post Office Lodhimajra, Tehsil Baddi, Solan, Himachal Pradesh-174101, India	India	HDPE Bottle	30, 90, 180 with desiccant along with one 40-mL dosing cup
Abacavir + Dolutegravir + Lamivudine	60 mg /5 mg / 30 mg	Dispersible Tablet	Microlabs Ltd	HA809	NA	NA	Micro Labs Limited (ML06) Plot No: S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa - 403722. India.	India	HDPE Bottle	30,90, 180
Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Laurus Laboratories Ltd	NA	ANDA 216223	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh, INDIA.	India	HDPE Bottle	30, 90
Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Aurobindo Pharma Limited	NA	ANDA 210642	NA	APL Healthcare Limited Unit-IV Plot No.16, APIIC, M.P. SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District Andhra Pradesh, 524421 -	India	HDPE Bottle	30
Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Emcure Pharmaceuticals Limited	NA	ANDA 212181	NA	New Survey N°485, (Old Survey N°. 160/P-1) Village-Kadu, Taluka-Lakhtar, Surendranagar 382775, Gujarat	India	HDPE Bottle	30, 90, 180
Abacavir + Dolutegravir Lamivudine	600+50+300 mg	Tablet	Hetero Labs Ltd	NA	ANDA 215348	NA	Hetero Labs Limited Unit V Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Mahabubnagar, Telangana 509301, India	Inida	HDPE Bottle	30, 90
Abacavir + Lamivudine	120 mg / 60 mg	Tablets for Oral Suspension	Mylan Laboratories Ltd	NA	ANDA 204915	NA	Mylan Laboratories Limited (FDF-2) Plot No. H-12 & H-13, MIDC Waluj, Aurangabad - 431136 Maharashtra, India	India	HDPE Bottle	30, 60
Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 090159	NA	Unit - III Survey No. 313 & 314, Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh	India	HDPE Bottle; Blister	30, 10x10's
Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA635	ANDA090519	NA	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, District Dhar Pithampur, Madhya Pradesh 454 775 India	India	HDPE Bottle	30 28, 30

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Abacavir + Lamivudine	600 mg + 300 mg	Tablet	Hetero Labs Ltd	HA657	NA	NA	Hetero Labs Limited, Unit-V SEZ Unit I Survey No. 439, 440, 441 & 458 Mahaboob Nagar.	India	HDPE Bottle; Blister	30, 10x10's
Abacavir + Lamivudine	600 mg + 300 mg	Tablet	ViiV Healthcare UK Limited	HA706	NA	NA	Glaxo Operations UK Limited, Priory Street, Ware, Hertfordshire, SG12 0DJ, United Kingdom of Great Britain and Northern Ireland GlaxoSmithKline Pharmaceuticals S. A. ul., Grunwaldzka 189, 60-332 Poznan, Poland Glaxo Wellcome SA, Avenue de Extremadura 3, Aranda de Duero, Burgos, Spain	UK	Child resistant blister, PVC/PVdC-Alu/Paper	3x10's
Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Sun Pharmaceutical Industries Ltd	HA698	NA	NA	Village Ganguwala, Paonta Sahib, District Sirmour, Himanchal Pradesh, 173 025	India	Bottle HDPE	30, 90
Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Remedica	NA	Cyprus 22346	NA	Remedica Ltd, Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	HDPE bottle PVC/PE/PVDC/Aluminium blisters	30, 3X30's 3X10's 3X3X10's
Abacavir + Lamivudine	600 mg + 300 mg	Tablet, Film-coated	Laurus Laboratories Ltd	NA	NDA216332	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh, INDIA.	India	HDPE Bottle	30, 90, 180
Abacavir Sulfate+ Lamivudine	600 mg + 300 mg	Tablet	Cipla Ltd.	NA	ANDA 091144	NA	A-33, MIDC Patalganga Cipla Goa Unit 7	India	HDPE Bottle; Blister	30, 3x10's
Atazanavir	50 mg / 1.5g	Oral powder	Bristol-Myers Squibb	NA	ANDA 206352	NA	Hounslow	UK	Packets	Pack of 30's
Atazanavir	100 mg	Capsule	Emcure Pharmaceuticals Limited	NA	ANDA 078785	NA	Hinjwadi, Pune	India	HDPE bottle; Al/Al Strip	60, 10x6's
Atazanavir	100 mg	Capsule	Aurobindo Pharma Ltd	NA	ANDA 204806	NA	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	60, 500 3x10's

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Atazanavir	150 mg	Capsule	Emcure Pharmaceuticals Limited	NA	ANDA 078785	NA	Hinjwadi, Pune	India	HDPE bottle AluAlu strips	60 10 x6's
Atazanavir	200 mg	Capsule Hard	Bristol-Myers Squibb	NA	ANDA 021567	NA	Hounslow	UK	Bottle (HDPE)	60
Atazanavir	200 mg	Capsule	Emcure Pharmaceuticals Limited	NA	ANDA 078785	NA	Hinjwadi, Pune	India	HDPE bottle AluAlu strips	60 10 x6's
Atazanavir	200 mg	Capsule	Aurobindo Pharma Ltd	NA	ANDA 204806	NA	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	60, 180, 500 3x10's
Atazanavir (as Sulfate)	150 mg	Capsule	Mylan Laboratories Ltd	NA	ANDA 091611	NA	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra, India	India	HDPE Bottle	30
Atazanavir (as Sulfate)	150 mg	Capsule	Aurobindo Pharma Ltd	NA	ANDA 204806	NA	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	60, 180, 500 3x10's
Atazanavir (as Sulfate)	300 mg	Capsule	Bristol-Myers Squibb	NA	ANDA 021567	NA	Evansville, Indiana,	USA	HDPE Bottle	30
Atazanavir (as Sulfate)	300 mg	Capsule	Emcure Pharmaceuticals Limited	NA	ANDA 078785	NA	Hinjwadi, Pune	India	HDPE bottle AluAlu strips	60 10 x6's
Atazanavir (as Sulfate)	300 mg	Capsule	Mylan Laboratories Ltd	NA	ANDA 091611	NA	Sinnar, Nashik District, Maharashtra, India; Waluj, Aurangabad, Maharashtra	India	HDPE Bottle	30

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Atazanavir (as Sulfate)	300 mg	Capsule	Aurobindo Pharma Ltd	NA	ANDA 204806	NA	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	30, 90,500 3x10's
Atazanavir (sulfate)/Ritonavir	300mg+100mg	Tablet	Cipla Ltd.	NA	ANDA206451	NA	Cipla, Unit 2, Plot A-42 MIDC Industrial Area, Patalganga, Raigad District, Maharashtra	India	Bottle HDPE Alu/Alu Blister	30, 10x10's
Atazanavir (sulfate)/Ritonavir	300mg+100mg	Film Coated Tablet	Lupin Ltd.	HA720	NA	NA	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	HA749	NA	NA	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	HA772	NA	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30, 90
Atazanavir (sulfate)/Ritonavir	300mg+100mg	Film Coated Tablet	Sun Pharmaceutical Industries Ltd	HA742	NA	NA	Village Ganguwala, Paonta Sahib, District Sirmour, Himanchal Pradesh, 173 025	India	HDPE Bottle	30, 90
Atazanavir (sulfate)+ Ritonavir	300mg+100mg	Tablet	Mylan Laboratories Ltd	NA	NDA 022282	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90, 120
Cabotegravir (as cabotegravir free acid)	600 mg/3 mL vial	Prolonged-release Suspension for Injection	ViiV Healthcare Pty Ltd	HA789	ARTG ID 377474	NA	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	single 3 mL vial or 25 x 3 mL vials
Cabotegravir (as cabotegravir sodium)	30mg	Film Coated Tablets	ViiV Healthcare Pty Ltd	HA788	ARTG ID 377442	NA	Glaxo Wellcome, S.A. Avda. Extremadura, 3 Aranda De Duero Burgos 09400 Spain	Spain	HDPE Bottle	30

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Dapivirine	25 mg, vaginal delivery system	Vaginal Ring	International Partnership for Microbicides	NA	EMEA Art58 H/W/002168/001 EMEA Art 58 H/W/002168/002	NA	Sever Pharma Solutions (formerly QPharma) P.O. Box 590, 201 25 Malmö, Sweden	Sweden	Opaque, heat-sealed laminate pouch	1/pk or 3/pk
Darunavir	400mg	Tablet	Hetero Labs Ltd	NA	ANDA 216168	NA	Annora Pharma Private Limited, Sy.No.261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State - 502313, India	India	HDPE Bottle	60
Darunavir	600mg	Tablet	Hetero Labs Ltd	NA	ANDA 216168	NA	Annora Pharma Private Limited, Sy.No.261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State - 502313, India	India	HDPE Bottle	60
Darunavir	800mg	Tablet	Hetero Labs Ltd	NA	ANDA 216168	NA	Annora Pharma Private Limited, Sy.No.261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telangana State - 502313, India	India	HDPE Bottle	60
Darunavir	75mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 202136	NA	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	150 mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 202136	NA	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	240; 300
Darunavir	300 mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 202136	NA	Mylan Laboratories Ltd F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India.	India	HDPE Bottle	120; 360
Darunavir	400mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 202136	NA	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	HA709	NA	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	60

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Darunavir	400mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	NA	EU/1/06/380/003	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60
Darunavir	400mg	Tablet	Hetero Labs Ltd	NA	ANDA 202083	NA	UNIT-III, Hyderabad	India	HDPE Bottle	60
Darunavir	600 mg	Tablets	Janssen Infectious Diseases - Diagnostics BVBA/ Pharmacare South Africa	NA	ANDA 021976	NA	Jansen Ortho LLc, Gurabo	Puerto Rico	HDPE Bottle	60
Darunavir	600 mg	Tablet, Film-coated	Laurus Labs Limited	HA710	NA	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	60
Darunavir	600 mg	Tablet	Hetero Labs Ltd	NA	ANDA 202083	NA	UNIT-III, Hyderabad	India	HDPE Bottle	60
Darunavir	800 mg	Tablet, Film-coated	Laurus Labs Limited	HA711	NA	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30
Darunavir (as Ethanolate)	75mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	HA529	(a) EU/1/06/380/005	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	480
Darunavir (as Ethanolate)	150 mg	Tablets	Cipla	NA	ANDA 207189	NA	Cipla Limited, Plot no a-33, a-42, a-2, Patalganga Industrial Area, Patalganga District - Raigad, Maharashtra IN 410220	India	HDPE Bottle	240
Darunavir (as Ethanolate)	150 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	HA530 (a) EU/1/06/380/004	HA530 (a) EU/1/06/380/004	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	240

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Darunavir (as Ethanolate)	150 mg	Tablets	Microlabs Ltd	NA	ANDA 210187 14/12/20	NA	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 (as Ethanolate)	400mg	Tablet	Cipla	NA	ANDA 207189	NA	(Unit II), MIDC, Patalganga	India	HDPE Bottle	60
Darunavir (as Ethanolate)	400mg	Tablet	Lupin Ltd.	NA	ANDA 202073	NA	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	60
Darunavir (as Ethanolate)	400mg	Tablet	Microlabs Ltd	NA	ANDA 210187 14/12/20	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle	60
Darunavir (as Ethanolate)	600 mg	Tablets	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium	HA780 EU/1/06/380/002	HA780 EU/1/06/380/002	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60
Darunavir (as Ethanolate)	600 mg	Tablet	Cipla	NA	ANDA 207189	NA	(Unit II), MIDC, Patalganga	India	HDPE Bottle	60
Darunavir (as Ethanolate)	600 mg	Tablet	Lupin Ltd.	NA	ANDA 202073	NA	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	60
Darunavir (as Ethanolate)	600 mg	Tablet	Mylan Laboratories Ltd	HA685	NA	NA	FDF-Unit-2, Aurangabad site, (Plot No. H-12 and H-13), MIDC, Waluj Industrial Area Aurangabad-431136 Maharashtra	India	HDPE Container	60
Darunavir (as Ethanolate)	600 mg	Tablet	Microlabs Ltd	NA	ANDA 210187 14/12/20	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle	60

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Darunavir (as Ethanolate)	800 mg	Tablet	Lupin Ltd.	NA	ANDA 202073	NA	Plot No. 15B, Phase 1 A, Verna Industrial Area, Verna, Salcette Goa - 403722	India	HDPE Bottle	30 & 90
Darunavir (as Ethanolate)	800 mg	Tablet	Mylan Laboratories Ltd	HA683	NA	NA	FDF-Unit-2, Aurangabad site, (Plot No. H-12 and H-13), MIDC, Waluj Industrial Area Aurangabad-431136 Maharashtra	India	HDPE Container	30
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	HA719	NA	NA	Hetero Labs Ltd, Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055, India	India	HDPE Bottle	30x1, 60x1,120x1
Darunavir/Ritonavir	400mg/50mg	Tablet, Film-coated	Hetero Labs Ltd	HA757	NA	NA	Hetero Labs Limited UNIT- III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, India	India	HDPE Bottle	56x1, 60x1, 180x1
Darunavir/Ritonavir	800mg/100mg	Tablet, Film-coated	Hetero Labs Ltd	HA758	NA	NA	Hetero Labs Limited UNIT- III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, India	India	HDPE Bottle	56x1, 60x1, 180x1
Dolutegravir (as sodium salt)	5mg	Disp. Tablet	ViiV Healthcare BV, Van Asch van Wijckstraat 55H, Amersfoort, 3811 LP, Netherlands	HA768	NA	NA	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
Dolutegravir (as sodium salt)	10mg	Dispersible Tablets	Macleods Pharmaceuticals Limited	HA765	ANDA 214566	NA	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	India	HDPE Bottle	90, 180 90
Dolutegravir (as sodium salt)	10mg	Dispersible Tablets	Mylan Laboratories Ltd	NA	NDA 214521	NA	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	India	HDPE Bottle	30; 60; 90
Dolutegravir (as sodium salt)	10mg	Dispersible Tablets	Microlabs Ltd	HA793	NA	NA	Micro Labs Limited (ML06) Plot No: S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa - 403722. India.	India	HDPE Bottle	30, 60, 90

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Dolutegravir (as sodium salt)	10mg	Dispersible Tablets	Hetero Labs Ltd	NA	ANDA 209565	NA	Hetero Labs Limited Unit III Plot No. 22 – 110, Part-II, Industrial Development Area, Jeedimetla, Hyderabad, Telangana, India 500055	India	HDPE bottle Alu Alu Blister	30,84,90,180 1x10's, 15x10's
Dolutegravir (as sodium salt)	10mg	Tablets	Macleods Pharmaceuticals Limited	NA	ANDA 214397	NA	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
Dolutegravir (as sodium salt)	25 mg	Tablets	Macleods Pharmaceuticals Limited	NA	ANDA 214397	NA	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
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	ViiV Healthcare	HA634	NA	NA	Glaxo Operations UK Ltd, Hertfordshire (manufacturing and quality control), UK; Glaxo Wellcome S.A., Burgos (primary and secondary packaging, batch release), Spain	UK	Bottle	30
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Hetero Labs Ltd	HA682	NA	NA	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	HDPE bottle Blister Pack	30, 60, 90 8x10's
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Cipla Ltd.	HA680	NA	NA	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	30, 90
Dolutegravir (as sodium salt)	50 mg	Tablets	Aurobindo Pharma Ltd	NA	ANDA 208355	NA	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)	50 mg	Tablets, Film-coated	Laurus Lab Ltd	HA718	ANDA 210963	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30, 90
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Emcure Pharmaceuticals Ltd	HA701	USFDA 210036	NA	Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057 New Survey N°485, (Old Survey N°. 160/P-1) Village-Kadu, Taluka-Lakhtar, Surendranagar 382775, Gujarat	India	Bottle HDPE	30, 90 30, 90, 180

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Sun Pharmaceutical Industries Limited	HA708	NA	NA	Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh, 173 025	India	Bottle HDPE	30, 90
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Shanghai Desano Bio-Pharmaceutical Co Ltd	HA694	NA	NA	479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203	China	Bottle HDPE	30
Dolutegravir (as sodium salt)	50 mg	Tablets, Film-coated	Microlabs Ltd	HA751	NA	NA	Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa, 403 722	India	Bottle HDPE	30, 60, 90
Dolutegravir (as sodium salt)	50 mg	Tablets	Macleods Pharmaceuticals Limited	NA	ANDA 214397	NA	Macleods Pharmaceuticals limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam Daman, PIN-396210 India	India	HDPE Bottle	30, 90, 180
Dolutegravir (as sodium salt)	50 mg	Tablets	Strides Pharma Science Limited	HA731	NA	NA	Strides Pharma Science Limited, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106	India	HDPE Bottle	28, 30, 56, 60, 84, 90
Dolutegravir (as sodium salt)	50 mg	Tablets	Mylan Laboratories Ltd	HA678	ANDA 209602	NA	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	India	HDPE bottle Blister, PVC/ACLAR HDPE bottle	30; 90; 180 1x10's 30
Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Lupin Ltd.	NA	ANDA 214544	NA	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	NA	ANDA 215448	NA	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
Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Hetero Labs Ltd	NA	ANDA 212427	NA	Hetero Labs Limited, Unit-III, Plot No. 22-110, Part-II, IDA Jeedimetla, Hyderabad Telangana – 500055, India	India	Bottle HDPE	30, 100

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Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 210237	NA	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	India	Bottle HDPE	30, 90
Dolutegravir + Emtricitabine+ Tenofovir Alafenamide	50 mg+200 mg+25 mg	Tablets	Cipla Limited	NA	ANDA 212205	NA	Cipla Limited Goa Unit VII Plot No. S-103 to S-105, S-107 to S-112 and L-147, L-147/1 to L-147/3, L-147A and L-138 Verna Industrial Estate, Verna Salcette, Verna, Goa, India, 403 722	India	Bottle HDPE	30, 90
Dolutegravir + Emtricitabine+ Tenofovir Alafenamide*	50 mg+200 mg+25 mg	Tablets, Film-coated	Laurus Labs Limited	NA	NDA 213681	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	Bottle HDPE	30, 90,180
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	NA	NDA 209618	NA	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	28, 30, 90, 180
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Mylan	HA688 (2,3)	NDA 209670 (1)	NA	1) Mylan Laboratories Limited (FDF-1), a Viatris Company F/4 and F/12 Malegaon MIDC, Sinnar Nashik Dist., Maharashtra, 422113, India 2) Fabrica Nacional De Medicamentos SA Parcela 726, Avenida das industrias Machava Maputo, Mozambique 3) Mylan Laboratories Limited (FDF-3) Plot No. 11, 12 and 13, Indore Special Economic Zone Pharma Zone, Phase II,	India	HDPE Bottle	30, 90, 180
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Cipla Ltd.	HA702	NA	NA	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
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Laurus Lab Ltd	HA707	NDA 210787 USFDA 2	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Container	30, 90,180
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Sun Pharmaceutical Industries Limited	HA699	NA	NA	Village Ganguwala, Paonta Sahib, District Sirmour, Himanchal Pradesh, 173 025	India	HDPE Bottle	30x1, 90x1, 180x1
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Hetero Labs Ltd	HA696	NDA 210880	NA	Unit 5, Survey No 439, 440, 441 & 458 TSIIC 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 LimitedAnnaram Village, Gummadidala Mandal	India	HDPE Bottle	30, 60, 90, 100,180, 750

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Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Strides Pharma Science Limited	HA729	NA	NA	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, Periyakalapet Puducherry 605 014 India 3) Universal Corporation Ltd	India	Bottle HDPE	28, 30, 56, 60, 84, 90, 168, 180	
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	tablet FDC	Macleods Pharmaceuticals Ltd	HA713 NDA 210796	HA713 NDA 210796	NA	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 - 396210, India 3. Plot No.- M-50 to 54-A, SEZ, Phase II, Pithampur, Dist.-Dhar, Madhya Pradesh-454774, India	India	Bottle HDPE	30, 90, 180	
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Emcure Pharmaceuticals Ltd	HA722 (a)	ANDA USFDA-211868 (b,c)	NA	a) Emcure Pharmaceuticals Ltd. Plot No P-1 & P-2, I.T.B.T., Park Phase II MIDC, Hinjewadi, Pune, Maharashtra, 411057 b) Milan Laboratories (India) Private Limited Plot No. Z-96/A, Dahej, SEZ Phase– 2, Bharuch, Gujarat, India, 392130 - India c)Emcure Pharmaceuticals Ltd.New Survey N°485, (Old Survey N°. 160/P-1)	India	Bottle HDPE	30, 90, 180	
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Lupin Pharmaceuticals, Inc. 111 South Calvert Street Harborplace Tower, 24th Floor Baltimore, MD 21202	HA737	NDA 212303	NA	Lupin Limited, Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, 441 108, India	India	Bottle HDPE	30, 60, 90 30, 60, 90, 180	
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co., Ltd., China	NA	NDA 213556	NA	1. Shanghai Desano Bio-Pharmaceutical Co. Ltd. 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China 2. Desano Pharmaceuticals Private Limited Plot No.600 - 612, Harohalli KIADB Industrial Area, 3rd	China India	Bottle HDPE	30, 90	ok
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Film Coated Tablet	Microlabs Ltd	HA755	NA	NA	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	ok
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet	Celltrion Pharm, Inc.	NA	NDA 211912	NA	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	50 mg+300 mg + 300 mg	Tablet	Desano Pharmaceuticals Private Ltd	HA746	NA	NA	1. Shanghai Desano Bio-Pharmaceutical Co. Ltd. 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China 2. Desano Pharmaceuticals Private Limited Plot No.600 - 612, Harohalli KIADB Industrial Area, 3rd	China India	HDPE Bottle	30, 90	
Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Tablet (single layer)	Emcure Pharmaceuticals Limited	HA786	NA	NA	Emcure Pharmaceuticals Ltd. Plot No. P-1 & P-2, I.T.B.T. Park, Phase II, MIDC, Hinjawadi Pune, Maharashtra 411057 India	India	HDPE Bottle	30, 90, 180	

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Dolutegravir + Lamivudine + Tenofovir disoproxil fumarate	50 mg+300 mg + 300 mg	Film Coated Tablets	Aspen SA Operations (Pty) Ltd	NA	NDA219804	NA	Aspen SA (OSD) Operations (Pty) Ltd, CNR Fairclough rd and Gibaud rd, Port Elizabeth (Gqeberha), Eastern Cape 6020, South Africa (ZAF)	South Africa	HDPE Bottle	30 ,90
Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Film coated Tablet	Laurus Labs Limited	NA	NDA 213696	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	Bottle HDPE	30, 90,180
Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Tablets	Cipla Limited	NA	NDA 212527	NA	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 Ltd.	NA	NDA 215187	NA	Lupin Limited, Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, 441 108, India	India	HDPE Bottle	30, 90
Dolutegravir + Lamivudine+ Tenofovir Alafenamide	50 mg+300 mg+25 mg	Tablets	Mylan Laboratories Ltd	NA	based on NDA 210865 USFDA	NA	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	India	HDPE Bottle	30's, 90's, 180's
Dolutegravir+ Lamivudine	50 mg+300 mg.	Tablets	Hetero Labs Ltd	NA	ANDA 216543	NA	HETERO LABS LIMITED,UNIT-III, 22-110,I.D.A, Jeedimetla , Quthbullapur ,Medchal-Malkajgiri(Dist), PINCODE 500055 Telangana,India	India	HDPE Bottle	30, 90
Dolutegravir+ Lamivudine	50 mg+300 mg.	Tablets	Emcure Pharmaceuticals Ltd	NA	ANDA 219623	NA	Emcure Pharmaceuticals Ltd., New Survey No. 485, (Old Survey No. 160/P-1), Village-Kadu, Taluka-Lakhtar, Surendranagar, Gujarat, 382775, India	India	HDPE Bottle	30, 90
Dolutegravir+ Lamivudine	50 mg+300 mg.	Tablets	Cipla Limited	NA	ANDA 213495	NA	Cipla Limited, L-139 to L-146, S-103 to S-105, S-107 to S-112, L-147/1/2/3, L-147/A, L-138, L-150, S-116, Verna Industrial Area, Salcette, Goa 403722, India	India	HDPE Bottle	30, 90
Efavirenz (EFV)	50 mg	Tablet	Microlabs Ltd	NA	ANDA 205389	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle PVC/Alu blister	30, 90 10x10's

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Efavirenz (EFV)	50 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 022461	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
Efavirenz (EFV)	100 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 022461	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
Efavirenz (EFV)	100 mg	Tablet	Microlabs Ltd	NA	NDA 205389	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle PVC/Alu blister	30, 90 10x10's
Efavirenz (EFV)	200 mg	Capsule	Cipla Ltd.	NA	ANDA 090155	NA	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	90, 1000
Efavirenz (EFV)	200 mg	Capsule	Aurobindo Pharma Ltd	NA	ANDA 078064	NA	Unit III, Survey No. 313 &314 Bachupally, Quthubullapur Mandal Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle; Blister	30, 90, 1x10's, 3x10's, 9x10's
Efavirenz (EFV)	200 mg	Tablet	Microlabs Ltd	NA	NDA 205389	NA	Plot No. S-155 to S- 159 & N1, Phase III & IV , Verna Industrial Estate, Verna Salcette, Goa -403 722	India	HDPE Bottle PVC/Alu blister	30, 90 10x10's
Efavirenz (EFV)	200 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 022420	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	90
Efavirenz (EFV)	200 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 022461	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 90
Efavirenz (EFV)	600 mg	Tablet	Sun Pharmaceutical Industries Ltd	HA306	NA	NA	Paonta Sahib, Himachal Pradesh	India	HDPE bottle Alu/alu blister and PVdC/PE/PVC blister	30, 3x10's

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Efavirenz (EFV)	600 mg	Tablet Film coated	Aurobindo Pharma Ltd	NA	NDA77673	NA	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle Alu/Alu and PVdC/PE/PVC blister pack	30, 3x10's
Efavirenz (EFV)	600 mg	Tablet	Mylan Laboratories Ltd	HA403	ANDA 078883	NA	Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136, India 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, District Dhar Pithampur, Madhya Pradesh 454 775 India	India, Kenya	HDPE bottle; Blister HDPE bottle;	28, 30, 2x5's 30, 90
Efavirenz (EFV)	600 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 078509	NA	Strides Shasun Ltd, Oral Solid Dosage Forms Division, KRS Gardens, 36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore, Karnataka, 562 106	India	HDPE Bottle	30
Efavirenz (EFV)	600 mg	Tablet Film coated	Hetero Labs Ltd	NA	ANDA 078886	NA	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	NA	ANDA 091579	NA	Himachal Pradesh	India	HDPE Container	30
Efavirenz (EFV)	600 mg	Tablet	Emcure Pharmaceuticals Limited	NA	ANDA 078958	NA	Hinjwadi, Pune	India	HDPE bottle; Al/PVC blister	30, 60, 3x10's
Efavirenz (EFV)	600 mg	Tablet	Microlabs Ltd	NA	ANDA 202301	NA	Verna, Goa	India	HDPE bottle PVC/PVDC-al blister HDPE bottle blister	30 3x10's 30,60,90 5x10's
Efavirenz + [Lamivudine + Zidovudine]	600 mg + [150 mg + 300 mg]	Tablet	Strides Arcolab Limited	NA	ANDA 022096	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	30 Efavirenz + 60 Lamivudine/Zidovudine)
Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Cipla Ltd.	NA	ANDA 091593	NA	Cipla limited, Plot no. L-147 to L-147-1 (Unit VII) Verna Industrial Estate Verna, Salcette, Goa, India. 403722	India	HDPE Bottle	30

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 203041	NA	Unit-VII (SEZ), Mahaboob Nagar (DT), Andhra Pradesh	India	HDPE Bottle	30
Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Hetero Labs Ltd	HA538	ANDA203053	NA	Hetero Labs Limited, Unit-V SEZ Unit I Survey No. 439, 440, 441 & 458 Mahaboob Nagar.	India	HDPE Bottle	28, 30, 500 30
Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	HA562	ANDA 204287	NA	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, IndiaKachigam, Damam	India	HDPE Bottle	30, 90, 180 30
Efavirenz + Emtricitabine + Tenofovir	600 mg + 200 mg + 300 mg	Tablet	Strides Arcolab Limited	HA553	NA	NA	Anekal Taluk, Bangalore, India	India	HDPE Bottle	28, 30, 84, 90
Efavirenz + Emtricitabine + Tenofovir Disoproxil Fumarate	600 mg + 200 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA444	ANDA 090437	NA	Mylan Laboratories Ltd F4 & F12 Malegaon MIDC, Nashik District Sinnar, Maharashtra 422 113 India Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Chhatrapati Sambhajinagar, Maharashtra 431 136 India Mylan Laboratories Ltd Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma	India	HDPE Bottle	30, 28 30, 100
Efavirenz + Emtricitabine + Tenofovir Disoproxil Fumarate	600 mg + 200 mg + 300 mg	Film coated Tablet	Laurus Labs Ltd	NA	ANDA 213541	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30, 90
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA466 ANDA022142	HA466 ANDA022142	NA	Mylan Laboratories Ltd F4 & F12 Malegaon MIDC, Nashik District Sinnar, Maharashtra 422 113 India Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Chhatrapati Sambhajinagar, Maharashtra 431 136 India Mylan Laboratories Ltd Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma	India	HDPE Bottle	30, 90 30
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	Tablet	Hetero Labs Ltd	HA549	ANDA 204119	NA	Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana (Unit-V) S.No. 439,440, 441, & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla (Mandal), Mahaboobnagar-(District). Pin-509301 Telangana	India	HDPE Bottle	30, 90, 100
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	tablet FDC	Laurus Labs Limited	HA727	ANDA 212786	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30, 90

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	600 mg + 300 mg + 300 mg	tablet	Desano Pharmaceuticals Private Ltd	HA764	NA	NA	Aizant Drug Research Solutions Pvt. Ltd, Block No. B, Sy. No. 172 & 173, Apparel Park Rd., Dulapally Village, Hyderabad, Dundigal- Gandimaisamma Mandal, Medchal-Malkhajgiri District, Telangana, 500 100, India	India	HDPE Bottle	30, 90
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA721	ANDA 208255	NA	Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Chhatrapati Sambhajinagar, Maharashtra 431 136 India 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	India	HDPE Bottle (white, blue)	30, 90 30
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	tablet FDC	Laurus Labs Limited	HA732	ANDA 213038	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Container	30, 90, 180
Efavirenz+ Lamivudine + Tenofovir (Disoproxil Fumarate)	400 mg + 300 mg + 300 mg	tablet FDC	Macleods	HA714	NDA 210649	NA	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	HA759	NA	NA	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
Emtricitabine	200 mg	Capsule	Cipla Ltd.	NA	ANDA 091168	NA	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30, 1000
Emtricitabine	200 mg	Capsule	Mylan Laboratories Ltd	NA	ANDA 090488	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	30, 100; 2*10's, 3*10's
Emtricitabine	200 mg	Capsule	Microlabs Ltd	NA	NDA 204396	NA	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
Emtricitabine + Tenofovir	200 mg + 300 mg	Tablet	Gilead Sciences, Inc.	NA	ANDA 021752	NA	Altana Pharma, Oranienburg GmbH, Patheon Inc. Mississauga, Ontario Aspen Pharmacare, Port Elizabeth,	Germany Canada South Africa	HDPE Bottle	30

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Emtricitabine + Tenofovir Alafenamide	200mg/25mg	Tablet	Aurobindo Pharma Ltd	NA	NDA 216875	NA	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	NA	ANDA 213989	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30, 90
Emtricitabine + Tenofovir Alafenamide	200mg/25mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 211148	NA	Mylan Laboratories Limited (FDF-3), a Viatris Company Plot No. 11, 12 & 13, Indore Special Economic Zone Pharma Zone, Phase - II, Sector - III, Pithampur, District Dhar, Madhya Pradesh, India, 454775	India	HDPE Bottle	30, 90
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 245 mg	Tablet Film coated	Gilead Sciences, Inc.	NA	ANDA 021500	NA	Granta Park Abington, Cambridge	UK	HDPE Bottle	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 090513	NA	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	HA417	ANDA 090049	NA	Mylan Laboratories Ltd F4 & F12 Malegaon MIDC, Nashik District Sinnar, Maharashtra 422 113 India 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	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.	HA439	ANDA 090958	NA	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Hetero Labs Ltd	HA498	ANDA 201806	NA	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad-500055	India	HDPE Bottle	28, 30, 56 & 60

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Strides Arcolab Limited	HA552	ANDA 091055	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	HA561	NA	NA	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	Sun Pharmaceutical Industries Ltd	HA551	NA	NA	Shasun Pharmaceuticals Limited, Periyakalapet, Puducherry, India	India	HDPE Bottle	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet	Microlabs Ltd	HA631	NA	NA	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	3x10's, 10x10's 100, 30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Laurus Lab Ltd	HA717	ANDA 212114	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	Bottle HDPE	30, 90
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Emcure Pharmaceuticals Ltd	HA726	NA	NA	Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057	India	Bottle HDPE	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Lupin	HA715	NA	NA	Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN Nagpur, Maharashtra 441 108	India	Bottle HDPE	30
Emtricitabine + Tenofovir Disoproxil Fumarate	200 mg + 300 mg	Tablet Film coated	Desano Pharmaceuticals Private Ltd	HA792	NA	NA	Shanghai Desano Bio-Pharmaceutical Co., Ltd. 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China	China	Bottle HDPE	30
Etravirine	25 mg	Tablet	Janssen-Cilag International NV, Belgium	HA600 (a)	EU/1/08/468/003	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	120

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Etravirine	100 mg	Tablet	Janssen-Cilag International NV, Belgium	HA532 (a)	EU/1/08/468/001	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	120
Etravirine	200 mg	Tablet	Janssen-Cilag International NV, Belgium	NA	EU/1/08/468/002	NA	Janssen-Cilag SpA Via C. Janssen Borgo San Michele 04100 Latina, Italy	Italy	HDPE Bottle	60
Lamivudine (3TC)	10 mg / ml	Oral Solution	ViiV HealthCare	HA128	NA	NA	Mississauga, Ontario	Canada	HDPE Bottle	240ml
Lamivudine (3TC)	10 mg / ml	Oral Solution	Hetero Labs Ltd	NA	ANDA91475	NA	Unit-III 22-110, Industrial Development Area Jeedimetla, Hyderabad	India	HDPE Bottle	240ml
Lamivudine (3TC)	10 mg / ml	Oral Solution	Aurobindo Pharma Ltd	NA	ANDA077695	NA	Aurobindo Pharma Limited Unit-III, Survey No.313 & 314, Bachupally Bachupally Mandal, Medchal-Malkajgiri District Medchal, Telangana, India. 500090.	India	HDPE Bottle	240ml
Lamivudine (3TC)	10 mg / ml	Oral Solution	Macleods Pharmaceuticals Limited	HA523	NA	NA	Solan, Himachal Pradesh, India	India	HDPE Bottle	100ml, 240ml
Lamivudine (3TC)	150 mg	Tablet Film Coated	Macleods Pharmaceuticals Limited	NA	ANDA 090198	NA	Kachigam, Daman Baddi, H.P.	India	HDPE Bottle	60
Lamivudine (3TC)	150 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 090457	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	60
Lamivudine (3TC)	150 mg	Tablet	Cipla Ltd.	NA	ANDA 077221	NA	Goa; Meditab Specialities Ltd, Goa	India	HDPE Bottle	30, 60

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lamivudine (3TC)	150 mg	Tablet Film coated	ViiV HealthCare	HA 117	ANDA 020564	NA	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 Ltd	NA	ANDA 078850	NA	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India; STADA-VN Joint Venture Co, Ltd, Duong Province, Vietnam	India Vietnam	HDPE Bottle	60, 600
Lamivudine (3TC)	150 mg	Tablet	Microlabs Ltd	NA	ANDA 200406	NA	Verna, Goa	India	Alu/PVC/PvdC blister HDPE Bottle	1x10's 60
Lamivudine (3TC)	150 mg	Tablet	Alkem Laboratories Ltd	NA	ANDA 090433	NA	Amaliya, Daman	India	HDPE Bottle	60
Lamivudine (3TC)	150 mg	Tablet	Centaur Pharmaceutical Private Limited	NA	ANDA 203586	NA	Biotech Park Hinjewadi Phase II Pune, Maharashtra	India	HDPE Bottle	60
Lamivudine (3TC)	150 mg	Tablet	MYLAN	NA	ANDA 078545	NA	Mylan Laboratories Limited, F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	Blister PVC/PVDC /Al HDPE bottle	6x10's 60
Lamivudine (3TC)	300 mg	Tablet	MYLAN	NA	ANDA 078545	NA	Mylan Laboratories Limited, F- 4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113 Maharashtra	India	Blister PVC/PVDC /Al HDPE bottle	1x10's 60
Lamivudine (3TC)	300 mg	Tablet	Cipla Ltd.	NA	ANDA 077221	NA	Goa	India	HDPE Bottle	30,60
Lamivudine (3TC)	300 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 090457	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	30

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lamivudine (3TC)	300 mg	Tablet	Macleods Pharmaceuticals Limited	NA	ANDA 090198	NA	Kachigam, Daman	India	HDPE Bottle	30
Lamivudine (3TC)	300 mg	Tablet	Glaxo SmithKline Ltd.	NA	ANDA 020564	NA	Greenford, Middlesex	UK	HDPE Bottle	30
Lamivudine (3TC)	300 mg	Tablet	Microlabs Ltd	NA	ANDA 200406	NA	Verna, Goa	India	HDPE Bottle; Blister	30, 60, 90 5x10's
Lamivudine (3TC)	300 mg	Film-coated Tablet	Beximco Pharmaceuticals Limited	HA668	NA	NA	Track-II, 126, Kathaldia, Auchpara, Tongi-1711, Gazipur, Bangladesh	Bangladesh	HDPE Bottle	30x1
Lamivudine + Nevirapine + Zidovudine	30mg+ 50mg +60mg	Dispersible Tablet	Mylan Laboratories Ltd	HA433	ANDA 200793	NA	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	HA557	ANDA 202685	NA	Strides Pharma Science Limited, Strides house, Opp. IIMB, Bilekahali, Bannerghatta Road, Bangalore, Karnataka, 560 076	India	HDPE Bottle	60
Lamivudine + Nevirapine + Zidovudine	30mg+ 50mg +60mg	Tablet for Oral Suspension	Cipla Ltd.	NA	ANDA 203076	NA	Plot No. L-147, L147-1 (Unit VII), Verna Industrial Estate, Verna Salcette Goa, 403 722	India	HDPE Bottle	60, 1000
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Hetero Labs Ltd	HA 448	ANDA 022459	NA	Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad; and Unit V Mahaboob Nagar Dist, Andhra Pradesh.	India	HDPE Bottle	30, 60 30, 60, 100, 500
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA414 (1, 2, 3)	ANDA 022141 (2)	NA	1) Mylan Laboratories Ltd, F4 & F12 Malegaon MIDC, Sinnar, Nashik District, Maharashtra, 422 113; 2) Mylan Laboratories Ltd, Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136; 3) 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	India	HDPE Bottle	30, 100 30, 90

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Cipla Ltd.	HA666	ANDA 200623	NA	D-7 MIDC Kurkumbh; Quality Chemical Industries Ltd, Kampala, Uganda	India	HDPE Bottle Blister Al/Al HDPE Bottle	30 1x10's 30, 500
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	HA525	NA	NA	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	HA514	NA	NA	Kachigam- Daman Baddi- Himachal Pradesh	India	HDPE Bottle Blister Alu/OPA/Alu/PVC	30 10x10's
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Microlabs Ltd	HA620	NA	NA	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE Bottle	30, 100
Lamivudine + Tenofovir disoproxil fumarate	300 mg + 300 mg	Tablet	Lupin Ltd.	HA703	NA	NA	Lupin Limited, Unit 1, Plot No. 6A1, 6A2, Sector-17, Special Economic Zone, MIHAN, Nagpur, Maharashtra, 441 108, India	India	HDPE Bottle	30
Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Mylan Laboratories Ltd	HA572	ANDA 204914	NA	1) Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Aurangabad, Maharashtra 431 136 India 2) 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	India	HDPE	60
Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Cipla Ltd.	NA	NDA 202814	NA	L-147 to L-147.1 (Unit VII), Verna Industrial Estate, Verna Salcette, Goa 403 722 India	India	HDPE bottle; PVC/PE/PVDC/AluBlister	60; 1000 6x10,s
Lamivudine + Zidovudine	30 mg + 60 mg	Dispersible Tablet	Mylan Laboratories Ltd	HA572	ANDA 204914	NA	Plot No H-12 & H13 MIDC Waluj Industrial Area, Aurangabad, Maharashtra, 431 136	India	HDPE	60
Lamivudine + Zidovudine	30 mg + 60 mg	Tablet	Mylan Laboratories Ltd	ANDA 200748	ANDA 200748	NA	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 Bottle	60

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co Ltd	HA655	NA	NA	Shanghai Desano Bio-Pharmac+H309eutical 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.	1) HA 060	2) ANDA 077411	NA	1) 2) Cipla Ltd Unit 3, 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 India 1) 2) Cipla Ltd Unit 4, 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 India	1) 2) India 1) Uganda	HDPE bottle Blister, Alu/PVC/PVdC	1) 60 2) 30; 60, 1000 1) 1x10's, 1x14's 2) 10x10's
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Hetero Labs Ltd	HA521	ANDA 079124	NA	Unit-III, 22-110, Jeedimetla, Hyderabad Unit-V, Hyderabad	India	HDPE Bottle	60 60, 500
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Mylan Laboratories Ltd	HA392	ANDA 079079	NA	Mylan Laboratories Ltd F4 & F12 Malegaon MIDC, Nashik District Sinnar, Maharashtra 422 113 India Mylan Laboratories Ltd Plot No H-12 & H13 MIDC Waluj Industrial Area Chhatrapati Sambhajinagar, Maharashtra 431 136 India Mylan Laboratories Ltd Plot No 11, 12 & 13, Indore Special Economic Zone, Pharma	India	HDPE bottle HDPE bottle Blister	60 60 6x10's
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	ViiV HealthCare	HA110	NA	NA	Glaxo Operations UK, Ltd, Ware, Hertfordshire, UK; GSK, Poznan (packaging and release), Poland	UK	HDPE Bottle Blister, Alu/PVC	60, 6x10's
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Sun Pharmaceutical Industries Ltd	HA286	NA	NA	Paonta Sahib, Himachal Pradesh	India	HDPE bottle; Alu/PA/PVC Blister; PVdC/PVC blister	60 10x6's
Lamivudine + Zidovudine	150 mg + 300 mg	Film coated Tablet	Anhui Biochem Bio-pharmaceutical Co., Ltd.,	HA656	NA	NA	Anhui Biochem Bio-pharmaceutical Co., Ltd., No. 30 Hongfeng Road, Hi-Tech Development Zone, Hefei City, Anhui Province	China (People's Republic of)	HDPE Bottle	60
Lamivudine + Zidovudine	150 mg + 300 mg	Film coated Tablet	Strides Arcolab Limited	NA	ANDA 079128	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle	60
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Microlabs Ltd	HA485	NA	NA	Verna, Goa	India	HDPE bottle PVDC/PVC /Alblister	30, 60, 90 10*10's

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Macleods Pharmaceuticals Limited	HA459	ANDA 090679	NA	Kachigam, Daman Baddi, H.P.	India	HDPE Bottle Blister, PVC/PVdC/ Al	60 6x10's, 12x10's
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Emcure Pharmaceuticals Limited	NA	ANDA 078929	NA	Hinjwadi, Pune	India	HDPE Bottle; Blister	60 1x10's
Lamivudine + Zidovudine	150 mg + 300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 077558	NA	Aurobindo Pharma Limited, Unit-III, Survey No. 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana State, INDIA. Zip Code: 500090	India	HDPE bottle Blisters	60 6x10's
Lenacapavir	463.5mg/1.5mL	Solution for injection, subcutaneous injection	Hetero Labs Ltd	NA	NA	17-Jul-27	M/s. Aspiro Pharma Limited Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Siddipet District-502281, Telangana, INDIA.	India	Vial	2 vials pack (2 disposable syringes; 2 withdrawal needles; 2 injection needles) 10 vials pack+10 injection needles
Lenacapavir	463.5mg/1.5mL	Solution for injection, subcutaneous injection	Dr. Reddys	NA	NA	18-Sep-27	DE Reddys Formulations Unit-XI, Survey No. 1, 28, 30 to 39, APIIC Industrial Park, APIIC Industrial Park, Ranasthalam (M), Srikakulam District Andhra Pradesh-532 409.	India	Vial	2 vials pack (2 disposable syringes; 2 withdrawal needles; 2 injection needles) 10 vials pack+10 injection needles
Lenacapavir	463.5mg/1.5mL	Solution for injection, subcutaneous injection	Gilead Sciences, Inc.	HA811	ANDA 220018	NA	Patheon Italia, S.p.A. Viale Gian Battista Stucchi 110 Monza, 20900 Italy Hikma Farmaceutica (Portugal) S.A. Estrada do Rio Da Mo, 8/8A/8B Terrugem SNT, 2705-906	Italy Portugal	Vial	2 vials pack (2 disposable syringes; 2 withdrawal needles; 2 injection needles) 10 vials pack+10 injection needles
Lenacapavir	300 mg	Tablet	Gilead Sciences, Inc.	HA810	ANDA 220020	NA	Rottendorf Pharma GmbH Ostenfelder Strasse 51 – 61 Ennigerloh 59320 Germany	Germany	Bottle	4's
Lopinavir (LPV) + Ritonavir (RTV)	(80 mg + 20 mg) / ml	Oral Solution	AbbVie Ltd	HA098	ANDA 021251	NA	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	60ml
Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	AbbVie Ltd	NA	EMA Art 58 H-W-764-2	NA	Ludwigshafen	Germany	HDPE Bottle	60

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Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	AbbVie Ltd	NA	NDA21906	NA	North Chicago	USA	Bottle (HDPE) Bottle (PVC)	60
Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 079074	NA	Mylan Laboratories Limited, F-4, F-12, Malegaon M.I.D.C, Sinnar, Nashik – 422113, Maharashtra state, India	India	HDPE Bottle Blister packs	60; 120 2x10's
Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 090471	NA	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE Bottle; Blister	60; 6x10's
Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Macleods Pharmaceuticals Limited	HA573	ANDA 204739	NA	Solan, Himachal Pradesh	India	HDPE Bottle	60
Lopinavir (LPV) + Ritonavir (RTV)	100 mg + 25 mg	Tablet	Hetero Labs Ltd	HA650	ANDA 091677	NA	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	NA	ANDA 213857	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	60
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Mylan Laboratories Ltd	NA	NDA079074	NA	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 Bottle; Blister	120; 2x6's
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	AbbVie Ltd	HA381	NDA21906	NA	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,	120
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 090471b USFDA	NA	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE Bottle; Blister	120; 6x10's

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Cipla Ltd.	NA	ANDA 090371	NA	A-42, MIDC, Patalganga	India	HDPE Bottle; Blister	120
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Hetero Labs Ltd	NA	ANDA 091677	NA	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad	India	HDPE Alu/Alu Blister Alu/PVC/PVdC blister	60, 120 8x10's
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Macleods Pharmaceuticals Limited	HA574	ANDA 204739	NA	Solan, Himachal Pradesh	India	HDPE Bottle	120
Lopinavir (LPV) + Ritonavir (RTV)	200 mg + 50 mg	Tablet	Laurus Labs Limited	NA	ANDA 213857	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	120
Lopinavir+Ritonavir	40mg/10mg	Pellets in Capsule	Cipla Ltd.	NA	NDA 205425	NA	Plot L147 to L-147-1, Verna Industrial Estate, Verna, Goa	India	HDPE Bottle	120
Lopinavir+Ritonavir	40mg/10mg	Oral Granules	Mylan Laboratories Limited	NA	NDA 210540	NA	Mylan Laboratories Limited (FDF-1) Plot # F/4 & F/12, Malegaon MIDC Sinnar, Nashik District-422113 Maharashtra	India	aluminum foil sachets	120
Nevirapine	200 mg	Tablet	Microlabs Ltd	NA	ANDA 203080	NA	Plot No: S-155 to S-159, Phase III, Verna Industrial Estate, Verna, Goa-403722	India	HDPE bottle PVC/PVDC-Al blisters	60, 6x10's
Nevirapine (NVP)	10 mg / ml	Oral Suspension	Cipla Ltd.	HA200	NA	NA	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, 240ml 25ml, 10ml
Nevirapine (NVP)	50 mg/5 ml	Oral Suspension	Aurobindo Pharma Ltd	NA	ANDA77702	NA	Unit III Survey No. 313 and 314 Bachupally Quthubullapur Mandal, Hyderabad Andhra Pradesh	India	HDPE Bottle	240ml 100ml

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Nevirapine (NVP)	50 mg	Tablet for Oral Suspension	Cipla Ltd.	NA	ANDA202212	NA	A-42, MIDC, Patalganga	India	HDPE Bottle; Blister	60, 1000 10x6's
Ritonavir (RTV)	25 mg	Tablet	Cipla Ltd.	NA	NDA 205040	NA	A-42, MIDC, Patalganga	India	HDPE Bottle	60
Ritonavir (RTV)	25 mg	Tablet	Mylan Laboratories Ltd	HA621	NA	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30
Ritonavir (RTV)	50 mg	Tablet	Cipla Ltd.	NA	NDA 205040	NA	A-42, MIDC, Patalganga	India	HDPE Bottle	60
Ritonavir (RTV)	100 mg	Tablet	Mylan Laboratories Ltd	HA467	ANDA 202738	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	30, 120 1x10's
Ritonavir (RTV)	100 mg	Tablet	Mylan Laboratories Ltd	NA	EU/1/17/1242/001	NA	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	HA 491	ANDA 022417	NA	Luwigshafen,	Germany	HDPE Bottle	30, 60 30
Ritonavir (RTV)	100 mg	Tablet	Cipla Ltd.	NA	ANDA 203759	NA	A-42, MIDC, Patalganga	India	HDPE Bottle	30
Ritonavir (RTV)	100 mg	Tablet	Hetero Labs Ltd	NA	ANDA204587	NA	Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055	India	HDPE Bottle	30, 120

International Non-proprietary name	Strength/ Dose	Dosage form	Supplier/ Manufacturer(s)	WHO Prequalification	SRA /WLA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
Ritonavir (RTV)	100 mg	Tablet	Shanghai Desano Bio-Pharmaceutical Co Ltd	HA787	NA	NA	Shanghai Desano Bio-Pharmaceutical Co., Ltd. 1479 Zhangheng Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203	China	HDPE Bottle	30
Tenofovir Alafenamide	25 mg	Tablet	Laurus Labs Limited	NA	ANDA 214030	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30
Tenofovir Disoproxil Fumarate	40mg/gm(Eq to 33mg/gm of Tenofovir Disoproxil	granule	Gilead Sciences, Inc.	NA	ANDA 022577	NA	Takeda GmbH Country Cork	Germany Ireland	HDPE Bottle	60g
Tenofovir Disoproxil Fumarate	300 mg	Tablet Film coated	Gilead Sciences, Inc.	NA	ANDA 021356	NA	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.	NA	ANDA 078800	NA	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle	30, 1000
Tenofovir Disoproxil Fumarate	300 mg	Tablet	Mylan Laboratories Ltd	HA410	ANDA 079071	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	30,100; 2*10
Tenofovir Disoproxil Fumarate	300 mg	Tablet	Strides Arcolab Limited	HA535	ANDA 090742	NA	36/7, Suragajakkanahalli Indlavadi cross Anekal Taluk Bangalore	India	HDPE Bottle; Blister	30 10
Tenofovir Disoproxil Fumarate	300 mg	Tablet	Aurobindo Pharma Ltd	NA	ANDA 090647	NA	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 Ltd	NA	ANDA 090636	NA	Unit III 22 - 110, Industrial development Area, Jeedimetla, Hyderabad	India	HDPE Bottle	30, 60, 100, 500, 1000

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Tenofovir Disoproxil Fumarate	300 mg	Tablet	Laurus Labs Limited	HA679	NA	NA	Laurus Labs Limited - Unit 2 Factory Plot No: 19, 20 & 21, Western Sector, APSEZ Gurajapalem Village, Rambilli Mandal Anakapalli - 531 011, Andhra Pradesh	India	HDPE Bottle	30x1, 500x1
Tenofovir Disoproxil Fumarate	300 mg	Tablet	Macleods Pharmaceuticals Limited	HA516	ANDA 203232	NA	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	India	HDPE Bottle	30
Zidovudine	10 mg / ml	Infusion solution	ViiV HealthCare	HA114	MHRA : PL 35728/0005	NA	Barnard Castle, County Durham	UK	Glass vial	5 vialsx20ml
Zidovudine	10 mg / ml	Oral Solution	Macleods Pharmaceuticals Limited	HA526	NA	NA	Solan, Himachal Pradesh	India	HDPE Bottle	100ml, 240ml
Zidovudine	50 mg/5 ml	Oral Solution	ViiV HealthCare	HA115	NA	NA	Mississauga, Ontario	Canada	PET bottle	200ml
Zidovudine	50 mg/5 ml	Oral Solution	Hetero Labs Ltd	HA486	NA	NA	Unit-III, Jeedimetla, Hyderabad, Andhra Pradesh, India	India	HDPE Bottle	240ml
Zidovudine	50 mg/5 ml	Oral Solution	Cipla Ltd.	NA	ANDA 077981	NA	Cipla Limited L-139 to L-146, Verna Goa, Meditab Specialities Ltd	India	HDPE bottle; PET Bottle	100ml, 240ml 100ml;
Zidovudine	50 mg/5 ml	Oral Solution	Aurobindo Pharma Ltd	NA	ANDA 077268	NA	Unit III Survey No. 313, Bachupally, Quthubullapur Mandal, Hyderabad, Andhra Pradesh	India	HDPE bottle, with dose delivery device	240ml
Zidovudine	100 mg	Tablet	Mylan Laboratories Ltd	NA	ANDA 200732	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle	60

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Zidovudine	100 mg	Capsule	Cipla Ltd.	NA	ANDA 078349	NA	L138-147 L150 s103-105 VernaGoa; Indore, SEZ, Pithampur, District Dhar (M.P.)	India	HDPE Bottle	100; 1000
Zidovudine	100 mg	Capsule	ViiV HealthCare	HA108	MHRA PL 35728/0001	NA	S.C. Europharm, Brasov	Romania	Bottle Blister, Alu/PVC	100 10x10's
Zidovudine	250mg	Capsule	ViiV HealthCare	HA109	NA	NA	S.C. Europharm, Brasov	Romania	Blister, Alu/PVC	4x10's
Zidovudine	300 mg	Tablets	Hetero Labs Ltd	NA	ANDA 090092	NA	Unit-III 22-110, Industrial Development Area Jeedimetla, Hyderabad	India	HDPE Bottle	60, 600
Zidovudine	300 mg	Tablets	Mylan Laboratories Ltd	NA	ANDA 078922	NA	Sinnar,Nashik, Maharashtra	India	HDPE Bottle; Blister	60; 1 x 10's
Zidovudine	300 mg	Tablets	Cipla Ltd.	NA	ANDA 090561	NA	Plot No. L-147, L147-1, Verna Goa,	India	HDPE Bottle; Blister	60, 1000 ; 10x10's