

# WHO List of Prequalified Medicinal Products

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For information about the listing of prequalified products and the alternative approval procedure, please see "General information" at [http://www.who.int/prequal/info\\_general/notes\\_registry.htm](http://www.who.int/prequal/info_general/notes_registry.htm).

## Legend:

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

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

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

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

| Therapeutic area | INN  | Formulation and strength | Applicant | Manufacturing site                     | Packaging  | Reference | Date of PQ  | Status |
|------------------|--|--------------------------|-----------|--|--|-----------|-------------|--------|
| HIV              | Lamivudine + tenofovir disoproxil fumarate | Tablets 300mg + 300mg    | Cipla Ltd | Patalganga, Raigad, Maharashtra, India | HDPE bottle 30;<br>Alu/Aclar/PVC blister 3x10;<br>Alu/Alu blister 3x10 | HA666     | 2016-Dec-21 |        |