WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA498 trade name]*

Emtrictabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA498 trade name], manufactured at Hetero Labs Limited, Telangana, India, was included in the WHO prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 24 June 2013.

[HA498 trade name] is indicated in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in patients weighing at least 30 kg. [HA498 trade name] may also be used in these patients as part of regimens for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for HIV. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [HA498 trade name] are emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of emtricitabine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of human immunodeficiency virus (HIV) infection.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of emtricitabine and tenofovir disoproxil fumarate therapy in human immunodeficiency virus (HIV), the team of assessors advised that [HA498 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA498 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA498 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	24 June 2013	Listed
Pharmaceutical quality	17 June 2013	MR
Bioequivalence	12 June 2013	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	27 January 2011	NA
FPP	16 February 2012	MR
GCP/GLP (re-)inspection	18 February 2013	NA

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

Requalification	17 May 2021	MR

MR: meets requirements

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.