WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA439 trade name][*]

Emtricitabine and tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA439 trade name], manufactured at Cipla Ltd, Verna Industrial Estate, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 5 October 2011.

[HA439 trade name] is currently indicated for treatment and prophylaxis of human immunodeficiency virus (HIV) and treatment of chronic hepatitis B. 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 [HA439 trade name] are emtricitabine and tenofovir disoproxil fumarate.The efficacy and safety of emtricitabine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV/AIDS.

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 in HIV/AIDS, the team of assessors advised that [HA439 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA439 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA439 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	5 Oct 2011	listed
Pharmaceutical quality	30 Aug 2011	MR
Bioequivalence	6 July 2011	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	10-12 Feb 2011	MR
FPP	6-9 Sept 2010	MR
GCP/GLP (re-)inspection	25-26 Sept 2011	MR

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

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

Requalification	19 December 2019	MR