WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA551 trade name]*

Emtricitabine / tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA551 trade name], manufactured at Shasun Pharmaceuticals Limited, Puducherry, India, was included in the WHO list of prequalified medicinal products for HIV on 12 February 2015.

[HA551 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 [HA551 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 and prophylaxis of HIV as well as the treatment of chronic hepatitis B.

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, the team of assessors advised that [HA551 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA551 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA551 trade name]:

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

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

** Formerly known as Ranbaxy Laboratories Limited

Initial acceptance	**Date**	**Outcome**
Status on PQ list	12 Feb 2015	listed
Pharmaceutical quality	27 Jan 2015	MR
Bioequivalence	04 Feb 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 March 2014	MR
API	18 Sept 2014	
FPP	16 March 2012	MR
GCP/GLP (re-)inspection	NA	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	03 August 2021	MR