WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA699 trade name]*

Dolutegravir (as sodium) /lamivudine/tenofovir disoproxil fumarate
50 mg/300 mg/300 mg tablets

[HA699 trade name], manufactured at Sun Pharmaceutical Industries Limited, Village Ganguwala, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 17 December 2019.

[HA699 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. 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 [HA699 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir (as sodium), lamivudine 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 dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA699 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA699 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA699 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.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 December 2019	Listed
Pharmaceutical quality	09 December 2019	MR
Bioequivalence	10 December 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 January 2019	MR
API	05 March 2019	MR*
APIs	26 August 2019	MR*
APIs	01 October 2019	MR*
FPP	12 October 2017	MR
GCP/GLP (re-)inspection	14 September 2018	MR
GCP (re-)inspection	15 January 2019	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