WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA707 trade name]*

Dolutegravir (as sodium), Lamivudine and Tenofovir Disoproxil Fumarate 50mg/300mg/300mg Tablets

[HA707 trade name], manufactured at Laurus Labs Ltd, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 November 2019.

[HA707 trade name] is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) 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 [HA707 trade name] are the integrase inhibitor dolutegravir (as sodium) and the nucleoside reverse transcriptase inhibitors lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety profile of dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate combination 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 [HA707 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA707 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA707 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	19 Nov 2019	listed
Pharmaceutical quality	24 Oct 2019	MR
Bioequivalence	28 Oct 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	08 Sept 2017	MR
API	19 Sept 2017	MR
FPP	17 March 2017	MR
GCP/GLP (re-)inspection	06 October 2017	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