WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA707 trade name][*]

Dolutegravir sodium, Lamivudine and tenofovir Disoproxil Fumarate
50 mg/300 mg/300 mg 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 HIV-1 infection. 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 sodium and the nucleoside reverse transcriptase inhibitors lamivudine and tenofovir disoproxil fumarate.
The efficacy and safety of dolutegravir/lamivudine/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 [HA707 trade name] 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]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Nov 2019	listed
Quality	24 Oct 2019	MR
Bioequivalence	28 Oct 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	08 Sept 2017	MR
APIs	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	

The table represents the status of relevant completed activities only

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