WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA755 trade name]*

Dolutegravir (as Sodium) /Lamivudine/Tenofovir disoproxil fumarate
50 mg/300 mg/300 mg Tablets

[HA755 trade name], manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 26 April 2022.

[HA755 trade name] is indicated for treatment of HIV/AIDS. 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 [HA755 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/tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA755 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA755 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA755 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	26 April 2022	listed
Quality	19 April 2022	MR
Bioequivalence	22 April 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	11 October 2017	MR
APIs	26 August 2019	MR*
API	01 October 2019	MR*
FPP	22 November 2018	MR
GCP (re-)inspection	23 September 2020	MR
GLP (re-)inspection	08 April 2022	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