WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA751 trade name]*

Dolutegravir (as sodium) 50 mg Tablets

[HA751 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 infection on 06 January 2021.
[HA751 trade name] is indicated for HIV 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 ingredient of [HA751 trade name] is the antiviral agent dolutegravir. The efficacy and safety of dolutegravir is well established based on extensive clinical experience in the treatment of HIV infection.

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 in human immunodeficiency virus (HIV), the team of assessors advised that [HA751 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA751 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA751 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	06 January 2021	listed
Quality	04 January 2021	MR
Bioequivalence	05 January 2021	MR
Safety, efficacy		NA
GMP (re-)inspection		
API	16 April 2018	MR*
FPP	12 April 2019	MR
GCP/GLP (re-)inspection		
GCP	23 September 2020	MR
GLP	15 June 2018	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.