WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA701 trade name][*]

Dolutegravir (sodium) 50mg film-coated tablets

[HA701 trade name], manufactured at Emcure Pharmaceuticals Ltd, Pune, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS infection on 3 March 2020.

[HA701 trade name] is indicated in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (HIV) infection in patients weighing at least 20 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 ingredient of [HA701 trade name] is the antiviral agent dolutegravir.

The efficacy and safety of dolutegravir 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 in HIV/AIDS, the team of assessors advised that [HA701 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA701 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA701 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	03 March 2020	Listed
Pharmaceutical quality	20 February 2020	MR
Bioequivalence	21 February 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 September 2017	MR
FPP	15 February 2019	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