WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA678 trade name]*

Dolutegravir (as sodium) 50 mg tablets

[HA678 trade name], manufactured at, Mylan Laboratories Limited, Pithampur, Madhya Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 31 October 2018.

[HA678 trade name] is currently 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 [HA678 trade name] is dolutegravir sodium.

The efficacy and safety of dolutegravir are well established based on extensive clinical experience in the treatment of HIV.

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, the team of assessors advised that [HA678 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA678 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA678 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	31 October 2018	Listed
Pharmaceutical quality	20 September 2018	MR
Bioequivalence	03 October 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 April 2016	MR
FPP	25 May 2018	MR
GCP (re-)inspection	21 July 2017	MR
GLP (re-)inspection	15 July 2016	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

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

Requalification	10 May 2024