WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA718 trade name]*

Dolutegravir (as sodium) 50 mg tablets

[HA718 trade name], manufactured at Laurus Labs Limited (Unit-II), Anakapalli, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 14 October 2019.

[HA718 trade name] is indicated in combination with other antiretroviral medicines, for the treatment of human immunodeficiency virus (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 [HA718 trade name] is dolutegravir sodium.

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 [HA781 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA718 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA718 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	14 October 2019	listed
Pharmaceutical quality	03 October 2019	MR
Bioequivalence	07 October 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 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	

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