WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA731 trade name]*

Dolutegravir (sodium) 50mg film-coated tablets

[HA731 trade name], manufactured at Strides Pharma Science Limited, Bangalore, Karnataka, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS infection on 23 August 2022.

[HA731 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 [HA731 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 [HA731 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA731 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA731 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	23 August 2022	listed
Pharmaceutical quality	05 August 2022	MR
Bioequivalence	09 August 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 January 2019	MR
FPP	31 October 2019	MR*
GCP/GLP (re-)inspection	27 May 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

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