

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA708 trade name]*

Dolutegravir (sodium) 50 mg tablets

[HA708 trade name], manufactured at Sun Pharmaceutical Industries Limited, Paonta Sahib, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 18 August 2020.

[HA708 trade name] is indicated, in combination with other antiretroviral medicines, for the treatment of HIV infection in patients weighing at least 20 kg and may also be used for HIV post-exposure prophylaxis (PEP). 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 [HA708 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 [HA708 trade name] is of acceptable quality, efficacy and safety to allow the inclusion of [HA708 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA708 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	18 August 2020	listed
Pharmaceutical quality	04 August 2020	MR
Bioequivalence	11 August 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 March 2019	MR*
FPP	12 October 2017	MR
GCP/GLP (re-)inspection		
GCP	12 January 2019	MR
GCP/GLP	14 September 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		