# 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. 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.

| **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

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