# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [HA794 trade name]*

Dolutegravir (as sodium) 50 mg tablets

[HA794 trade name], manufactured at RV Lifesciences Limited, Waluj, Chhatrapati Sambhajinagar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 June 2026.

[HA794 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 [HA794 trade name] is dolutegravir (as sodium).

The efficacy and safety of dolutegravir (as sodium) are well established based on extensive clinical experience in the treatment of HIV infection.

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 (as sodium) in HIV/AIDS, the team of assessors advised that [HA794 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA794 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA794 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** | 19 June 2026 | listed |
| Pharmaceutical quality | 15 June 2026 | MR |
| Bioequivalence | 03 June 2026 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 04 July 2025 | MR* |
| FPP | 10 April 2026 | MR* |
| **GCP/GLP (re-)inspection** | 15 March 2024 | 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.