WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP035 trade name]*

Entecavir 0.5 mg tablets

[HP035 trade name], manufactured at RV Lifesciences Limited , Plot No. H-19, MIDC Waluj, Aurangabad 431133, Maharashtra State, India was included in the WHO list of prequalified medicinal products for the treatment of chronic hepatitis on 19 February 2025.
[HP035 trade name] is indicated for the treatment of chronic hepatitis B virus (HBV) 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(s) of [HP035 trade name] is entecavir monohydrate.

The efficacy and safety of entecavir are well established based on extensive clinical experience in the treatment of chronic hepatitis B (HBV) 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 entecavir in treatment of chronic hepatitis, the team of assessors advised that [HP035 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP035 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP035 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 February 2025	listed
Pharmaceutical quality	04 February 2025	MR
Bioequivalence	13 February 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	MR
FPP	24 January 2025	MR*
GCP/GLP (re-)inspection	30 May 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.