WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP033 trade name][*]

Daclatasvir (as dihydrochloride) 30 mg Tablets

[HP033 trade name], manufactured at Zydus Lifesciences Limited, Goa-403 115, India, was included in the WHO list of prequalified medicinal products for the treatment of hepatitis C infections on 22 December 2023.

[HP033 trade name] is indicated in combination with sofosbuvir for the treatment of chronic hepatitis C virus (HCV) infection in adults and children. 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 [HP033 trade name] is the antiviral agent daclatasvir.

The efficacy and safety of daclatasvir is well established based on extensive clinical experience in the treatment of chronic hepatitis C virus (HCV) infection in adults and children.

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 daclatasvir in the treatment of hepatitis C infections, the team of assessors advised that [HP033 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP033 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP033 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	22 December 2023	listed
Pharmaceutical quality	17 December 2023	MR
Bioequivalence	21 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 June 2020	MR*
FPP	21 April 2023	MR
GCP/GLP (re-)inspection	NA	NA

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