WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP012 trade name]*

Daclatasvir (as dihydrochloride) 60mg Tablets

Abstract

[HP012 trade name], manufactured at Hetero Labs Ltd, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of chronic hepatitis C virus (HCV) infections on 17 December 2019.

[HP012 trade name] is indicated in combination with other medicinal products for the treatment of chronic HCV in adults. 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 (API) of [HP012 trade name] is the antiviral agent daclatasvir.

The efficacy and safety profile of daclatasvir in combination with other medicinal products, is well established based on extensive clinical experience in the treatment of chronic hepatitis C virus infection in adults.
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 chronic HCV therapy, the team of assessors advised that [HP012 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP012 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.

Summary of Prequalification Status for [HP012 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	17 December 2019	listed
Pharmaceutical quality	27 November 2019	MR
Bioequivalence	03 December 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 February 2019	MR*
FPP	30 October 2017	MR
GCP/GLP (re-)inspection	15 December 2017	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