WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP028 trade name]*

Daclatasvir (as dihydrochloride) 60 mg Tablets

[HP028 trade name], manufactured at Laurus Labs Limited, Anakapalli - 531011, Andhra Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of chronic hepatitis C virus (HCV) infections on 18 December 2020.

[HP028 trade name] is indicated for chronic hepatitis C virus (HCV) 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 [HP028 trade name] is daclatasvir (as dihydrochloride).

The efficacy and safety of daclatasvir are well established based on extensive clinical experience in the treatment of chronic hepatitis C virus 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 daclatasvir in hepatitis, the team of assessors advised that [HP028 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP028 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP028 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	18 December 2020	listed
Quality	04 December 2020	MR
Bioequivalence	07 December 2020	MR
Safety, efficacy	04 December 2020	NA
GMP (re-)inspection		
API	03 June 2020	MR*
FPP	17 March 2017	MR
GCP/GLP (re-)inspection	22 October 2020	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