

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP027 trade name]*

Daclatasvir (as dihydrochloride) 30 mg Tablets

[HP027 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. [HP027 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 [HP027 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 [HP027 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP027 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP027 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	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	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	

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