WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP025 trade name]*

Daclatasvir (as dihydrochloride)/Sofosbuvir 60mg/400mg Tablets

[HP025 trade name], manufactured at Mylan Laboratories Limited, Sinnar, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment hepatitis on 27 October 2020.

[HP025 trade name] is indicated for the treatment of chronic hepatitis C virus (HCV) infection 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 ingredients of [HP025 trade name] are daclatasvir (as dihydrochloride) and sofosbuvir.

The efficacy and safety of daclatasvir (as dihydrochloride) and sofosbuvir are well established based on extensive clinical experience in the treatment of hepatitis C.

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 combination therapy in chronic hepatitis C virus infections, the team of assessors advised that [HP025 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP025 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP025 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 October 2020	listed
Quality	04 February 2020	MR
Bioequivalence	18 February 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	22 November 2020	MR
FPP	10 November 2017	MR
GCP/GLP (re-)inspection		
GCP/GLP	08 September 2018	MR
GCP	21 July 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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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