WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP021 trade name]*

Daclatasvir dihydrochloride 30 mg tablets

[HP021 trade name], manufactured at Cipla limited, Mumbai, Maharashtra, 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.

[HP021 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 [HP021 trade name] is daclatasvir (as dihydrochloride).

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

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 C virus (HCV) infections, the team of assessors advised that [HP021 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP021 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP021 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 Dec 2019	listed
Pharmaceutical quality	09 Dec 2019	MR
Bioequivalence	10 Dec 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 Sept 2017	MR
API	25 Jan 2018	MR
FPP	25 Jan 2018	MR
GCP/GLP (re-)inspection	15 Dec 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	

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