WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP016 trade name]*

Daclatasvir (as dihydrochloride) 60 mg Tablets

[HP016 trade name], manufactured at Mylan Laboratories Ltd, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of chronic hepatitis C infections (CHC) on 15 May 2019.

[HP016 trade name] is indicated in combination with other medicinal products for the treatment of

CHC 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 [HP016 trade name] is the antiviral agent daclatasvir.

The efficacy and safety of daclatasvir are well established based on extensive clinical experience in the treatment of hepatitis.

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 CHC therapy, the team of assessors advised that [HP016 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP016 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP016 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	15 May 2019	listed
Pharmaceutical quality	30 April 2019	MR
Bioequivalence	10 May 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 October 2017	MR
FPP	10 November 2017	MR
GCP/GLP (re-)inspection	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
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification