WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP001trade name]*

Sofosbuvir 400 mg tablets

[HP001trade name], manufactured at Mylan Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of hepatitis C on 20 July 2017.

[HP001trade name] is indicated for hepatitis C treatment. 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 [HP001trade name] is sofosbuvir.

The efficacy and safety of 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 sofosbuvir in hepatitis C, the team of assessors advised that [HP001trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP001trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP001trade 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	20 July 2017	listed
Pharmaceutical quality	14 June 2017	MR
Bioequivalence	11 July 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 September 2014	MR
FPP	12 June 2015	MR
GCP/GLP (re-)inspection	22 March 2013 (GCP) 16 July 2016 (GLP)	MR 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

Requalification	24 April 2023