

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP002 trade name]*

Sofosbuvir 400 mg film-coated tablets

[HP002 trade name], manufactured at Hetero Labs Limited, Mahaboob Nagar, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of Hepatitis C on 07 February 2018.

[HP002 trade name] is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults and in adolescents aged 12 to less than 18 years. 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 [HP002 trade name] is sofosbuvir.

The efficacy and safety of sofosbuvir is well established based on extensive clinical experience in the treatment of chronic hepatitis C (CHC) in adults and in adolescents aged 12 to less than 18 years.

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 [HP002 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP002 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP002 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	07 February 2018	listed
Quality	12 January 2018	MR
Bioequivalence	18 January 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	11 October 2018	MR
FPP	03 November 2017	MR
GCP/GLP (re-)inspection	19 July 2016	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.