

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP009 trade name]*

Sofosbuvir 400 mg tablets

[HP009 trade name], manufactured at Strides Pharma Science Limited, Bangalore, Karnataka, India, was included in the WHO list of prequalified medicinal products for the treatment of chronic hepatitis C (CHC) on 03 March 2020.

[HP009 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 < 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 [HP009 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.

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 the treatment of chronic hepatitis C, the team of assessors advised that [HP009 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP009 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP009 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	3 March 2020	Listed
Pharmaceutical quality	20 February 2020	MR
Bioequivalence	25 February 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	15 February 2018	MR
FPP	17 June 2016	MR
GCP/GLP (re-)inspection	27 February	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	

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