WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA698 trade name][1]

Abacavir (as sulfate)/Lamivudine 600 mg/300 mg tablets

[HA698 trade name], manufactured at Sun Pharmaceutical Industries Limited., Village Ganguwala, Paonta Sahib, District Sirmour, Himachal Pradesh-173025, India, was included in the WHO list of prequalified medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infection on 11 June 2019.

[HA698 trade name], is indicated in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus (HIV). 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 ingredients of [HA698 trade name] are abacavir (as sulfate) and lamivudine [APIs].

The efficacy and safety of abacavir (as sulfate) and lamivudine are well established based on extensive clinical experience in the treatment of HIV.

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 [HA698 trade name] in HIV, the team of assessors advised that [HA698 trade name], is of acceptable quality, efficacy and safety to allow inclusion of [HA698 trade name], in the list of prequalified medicinal products.

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

Summary of Prequalification Status for [HA698 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 June 2019	listed
Quality	20 May 2019	MR
Bioequivalence	21 May 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 Feb 2017	MR
API	18 Jan 2019	MR
FPP	12 Oct 2017	MR
GCP/GLP (re-)inspection	14 Sept 2018	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