

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA657 trade name]*

Abacavir (as sulphate)/lamivudine 600 mg/300 mg tablets

[HA657 trade name] manufactured at Hetero Labs Limited, Mahaboobnagar District, Telangana, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 28 November 2017.

[HA657 trade name] is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in adults, adolescents and children weighing at least 25 kg. 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 [HA657 trade name] are abacavir (as sulphate) and lamivudine.

The efficacy and safety of abacavir (as sulphate) is well established based on extensive clinical experience in the treatment of human immunodeficiency virus infection.

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 [HA657 trade name] in HIV/AIDS, the team of assessors advised that [HA657 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA657 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA657 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	30 Jun 2017	listed
Quality	14 Mar 2017	MR
Bioequivalence	27 Mar 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	24 Feb 2017	MR
FPP	18 Jun 2017	MR
GCP/GLP (re-)inspection	NA	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	

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.