WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA657 trade name]*

Abacavir / Lamivudine 600 mg/300 mg Tablets

Abstract

[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 for the treatment of HIV infection. 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 sulfate and lamivudine.

The efficacy and safety profiles of abacavir and lamivudine are well established based on extensive clinical experience in the treatment of HIV/AIDS.

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 abacavir/lamivudine, 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]:

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	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

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

Requalification	07 March 2024