

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[HA635 trade name]*

Abacavir / Lamivudine 600 mg/300 mg Tablets

Abstract

[HA635 trade name] manufactured at Mylan Laboratories Limited, Sinnar, Maharashtra State, India was included in the WHO list of prequalified medicinal products for HIV/AIDS on 16 December 2015.

[HA635 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 (APIs) of [HA635 trade name] are abacavir sulfate and lamivudine.

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

On the basis of data submitted and public information on the abacavir/lamivudine, the team of assessors advised that [HA635 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA635 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA635 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	Date	Outcome
Status on PQ list	16 Dec 2015	listed
Pharmaceutical quality	11 Dec 2015	MR
Bioequivalence	08 Dec 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	03 Jan 2013	MR
API	16 April 2014	MR
API	09 Sept 2014	MR
API	12 Sept 2014	MR
API	24 Jan 2015	MR
FPP	12 June 2015	MR
GCP/GLP (re-)inspection	NA	NA
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		

Requalification	10 May 2022
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