WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA743 trade name]*

Abacavir sulfate/lamivudine 600 mg/300 mg tablets

[HA743 trade name], manufactured at Cipla Limited, Patalganga, Maharashtra, India, and Cipla Limited, Verna Industrial Estate, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 10 March 2023.

[HA743 trade name] is currently indicated as part of antiretroviral combination therapy for the treatment of 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 [HA743 trade name] are abacavir (as sulfate) and lamivudine.

The efficacy and safety 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 and lamivudine, the team of assessors advised that [HA743 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA743 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA743 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	10 March 2023	listed
Pharmaceutical quality	22 February 2023	MR
Bioequivalence	03 March 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 April 2019	MR
API	22 November 2019	MR
FPP	23 October 2020	MR
GCP/GLP (re-)inspection	21 September 2020	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

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

PQ: prequalification