WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA763 trade name]*

Abacavir (as sulfate) / Lamivudine 120mg/60mg Dispersible Tablets

[HA763 trade name], manufactured at Micro Labs Ltd, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV on 26 April 2022.

[HA763 trade name] is indicated for treatment of 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 [HA763 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.

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 in HIV treatment, the team of assessors advised that [HA763 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA763 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA763 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 April 2022	listed
Quality	23 February 2022	MR
Bioequivalence	13 March 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	May 2019	MR*
API	12 April 2019	MR*
FPP	12 April 2019	MR
GCP/GLP (re-)inspection	08 April 2022	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.