WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA485 trade name]*

Lamivudine/zidovudine 150 mg/300 mg tablets

[HA485 trade name], manufactured at Micro Labs Limited, Verna, Goa- 403722, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 25 October 2010.

[HA485 trade name] is indicated for the treatment of HIV infection in combination with at least one other antiretroviral drug. 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 [HA485 trade name] are lamivudine and zidovudine.

The efficacy and safety of lamivudine and zidovudine 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 lamivudine and zidovudine in HIV/AIDS, the team of assessors advised that [HA485 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA485 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA485 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	25 October 2010	listed
Pharmaceutical quality	11 October 2010	MR
Bioequivalence	NA	NA
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	26 May 2005	MR
API	28 May 2009	MR
API	31 May 2005	MR
FPP	18 Mar 2010	MR
GCP/GLP (re-)inspection	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	1 April 2019

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