WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA354 trade name]*

Lamivudine 300mg film-coated tablets

[HA354 trade name], manufactured at Cipla Limited, Verna Salcete, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 29 September 2010.

[HA354 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 ingredient of [HA354 trade name] is the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine.

The efficacy and safety of lamivudine is 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 lamivudine in HIV, the team of assessors advised that [HA354 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA354 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA354 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	29 September 2010	listed
Quality	21 July 2010	MR
Bioequivalence	11 March 2008	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 July 2005 14 October 2006	MR MR
FPP	10 September 2010	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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	04 November 2021

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