WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA459 trade name]*

Lamivudine/Zidovudine 150 mg/300 mg Tablets

[HA459 trade name], manufactured at Macleods Pharmaceuticals Ltd, Baddi, Himachal Pradesh, India and Macleods Pharmaceuticals Ltd, Kachigam Daman ,U.T, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 October 2011.

[HA459 trade name] is indicated for the treatment of HIV-1 infection in combination with at least one other antiretroviral agent. 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 [HA459 trade name] are the nucleoside reverse transcriptase inhibitors (NRTIs), 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 as combination therapy in HIV/AIDS the team of assessors advised that [HA459 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA459 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA459 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	18 October 2011	listed
Pharmaceutical quality	19 September 2011	MR
Bioequivalence	28 January 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	21 January 2011 18 March 2011 19 August 2011	MR MR MR
FPP	19 February 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
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

Requalification	24 October 2023	MR

MR: meets requirements