WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA572 trade name]*

Lamivudine/zidovudine dispersible Tablets 30mg/60mg

[HA572 trade name], manufactured at Mylan Laboratories Ltd., Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on Prequalification date 10 April 2014.

[HA572 trade name] is indicated for the treatment of HIV-1 infection in children 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 [HA572 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 in combination with other products.

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 [HA572 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA572 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA572 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	10 April 2014	listed
Pharmaceutical quality	26 March 2014	MR
Bioequivalence	02 April 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 Feb 2011	MR
API	19 Aug 2011	MR
API	14 Dec 2012	MR
API	05 Jan 2013	MR
FPP	11 May 2013	MR
GCP/GLP (re-)inspection	MR	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

Requalification	28 March 2022