WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA392 trade name][*]

Lamivudine/Zidovudine 150 mg/300 mg Tablets

[HA392 trade name], manufactured at Mylan Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 23 April 2008.

[HA392 trade name] is indicated for HIV-1. 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 [HA392trade 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA392 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA392 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA392 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.
[#] Formerly known as "Matrix Lab. Ltd".

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**23 April 08**	**listed**
Pharmaceutical quality	11 Mar 08	MR
Bioequivalence	22 Sep 07	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	17 Oct 06	MR
FPP	26 July 07	MR
GCP/GLP (re-)inspection	19 Jan 08	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	24 October 2023