WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA555 trade name]*

Lamivudine/zidovudine 30 mg/60 mg tablets

[HA555 trade name], manufactured at Micro Labs Limited, Verna, Goa, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 13 January 2015.

[HA555 trade name] is indicated for 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 ingredient(s) of [HA555 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 infection.

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 [HA555 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA555 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA555 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	13 January 2015	listed
Pharmaceutical quality	30 July 2014	MR
Bioequivalence	11 August 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2011	MR
API	14 December 2011	MR
API	05 January 2013	MR
APIs	07 March 2014	MR
API	11 April 2014	MR
API	15 April 2014	MR
APIs	16 April 2014	MR
API	12 September 2014	MR
API	18 September 2014	MR
FPP	17 October 2014	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

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

Requalification	17 February 2023