WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA486 trade name]*

Zidovudine 50 mg/5 mL oral solution

[HA486 trade name], manufactured at Hetero Labs Limited, Hyderabad, India, was included in the WHO list of prequalified medicinal products for the treatment and prophylaxis of HIV/AIDS on 3 November 2011.

[HA486 trade name] is indicated for HIV treatment and prophylaxis. 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 [HA486 trade name] is zidovudine. The efficacy and safety of 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 zidovudine in HIV/AIDS, the team of assessors advised that [HA486 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA486 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA486 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	**3 Nov 2011**	listed
Pharmaceutical quality	**21 Oct 2011**	MR
Bioequivalence	**20 Oct 2011**	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	**27 Jan 2011**	MR
FPP	**28 Aug 2011**	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	04 September 2020	MR

MR: meets requirements

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