WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA656 trade name]*

Lamivudine/zidovudine 150 mg/300 mg tablets

[HA656 trade name], manufactured at Anhui Biochem Bio-Pharmaceutical Co. Ltd, Hefei city, Anhui Province, China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 18 December 2018.

[HA656 trade name] is indicated as part of antiretroviral combination therapy for the treatment of HIV-1 infection in adults, adolescents and children weighing at least 25 kg. 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 [HA656 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/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 HIV/AIDS, the team of assessors advised that [HA656 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA656 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA656 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 Dec 2018	listed
Pharmaceutical quality	06 Nov 2018	MR
Bioequivalence	07 Nov 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 Jan 2016	MR
FPP	18 Aug 2018	MR
GCP/GLP (re-)inspection	03 Aug 2018	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
NA: not applicable, not available
PQ: prequalification

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