WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA655 trade name]*

Lamivudine/Zidovudine 150 mg/300 mg Tablets

[HA655 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co., Ltd., Shanghai, China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 July 2017.

[HA655 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection 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 [HA655 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 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA655 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA655 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA655 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	21 July 2017	listed
Pharmaceutical quality	07 May 2016	MR
Bioequivalence	12 July 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	09 Jan 2015	MR
GCP/GLP (re-)inspection	16 March 2016	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	MR

MR: meets requirements