WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA662 trade name]*

Abacavir (as sulfate)/Lamivudine 120 mg/60 mg Dispersible Tablets

[HA662 trade name], manufactured at Cipla Limited, Patalganga, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 December, 2016.

[HA662 trade name] is indicated for HIV/AIDS infection in infants and children over 4 weeks of age who weigh between 3 kg and 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 [HA662 trade name] are abacavir (as sulfate) and lamivudine.

The efficacy and safety of abacavir (as sulfate) and lamivudine 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 [HA662 trade name] in HIV/AIDS, the team of assessors advised that [HA662 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA662 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA662 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 Dec 2016	listed
Quality	16 Dec 2016	MR
Bioequivalence	16 Dec 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	14 Feb 2014	MR
API	22 Aug 2016	MR
API	22 Aug 2016	MR
FPP	14 Feb 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

Requalification	20/09/2023