Wh0WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA779 trade name][*]

Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine 60mg/5mg/30mg film-coated dispersible tablets

[HA779 trade name], manufactured at Cipla Limited, Mumbai, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 November 2023.

[HA779 trade name] is indicated for treatment of HIV-1 infection in infants and children aged from 4 weeks and weighing 6 to 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 [HA779 trade name] are abacavir (as sulfate), dolutegravir (as sodium) and lamivudine.

The efficacy and safety of abacavir (as sulfate), dolutegravir (as sodium) and lamivudine are well established based on extensive clinical experience in the treatment of HIV-1 infection in infants and children aged from 4 weeks and weighing 6 to 25 kg.

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 abacavir (as sulfate), dolutegravir (as sodium) and lamivudine in HIV/AIDS, the team of assessors advised that [HA779 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA779 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA779 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 November 2023	listed
Quality	01 November 2023	MR
Bioequivalence	10 November 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	19 June 2020	MR*
APIs	03.June 2020	MR*
API	16 June 2021	MR
FPP	16 June 2023	MR
GCP/GLP (re-)inspection	23 March 2023	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

The table represents the status of relevant completed activities only.

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