

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA494 trade name]*

Abacavir (as sulfate) 300 mg film-coated tablets

[HA494 trade name], manufactured at Strides Pharma Science Limited, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 22 December 2011.

[HA494 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults, adolescents and children. 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 [HA494 trade name] is the nucleoside analogue reverse transcriptase inhibitor (NRTI) abacavir.

The efficacy and safety of abacavir is 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 abacavir in HIV/AIDS, the team of assessors advised that [HA494 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA494 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA494 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	22 December 2011	Listed
Quality	15 July 2011	MR
Bioequivalence	27 June 2011	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	22 November 2011	MR
FPP	13 December 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	

The table represents the status of relevant completed activities only.

Requalification	11 December 2018
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.