

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA749 trade name]*

Atazanavir (as sulfate)/ritonavir 300 mg/100 mg tablets

[HA749 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 08 August 2022.

[HA749 trade name] is indicated for the treatment of HIV-1 infected adults and children weighing at least 25 kg, in combination with other antiretroviral medicinal products. 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 [HA749 trade name] are atazanavir and ritonavir.

The efficacy and safety of atazanavir and ritonavir 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 atazanavir and ritonavir in HIV/AIDS, the team of assessors advised that [HA749 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA749 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA749 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	08 August 2022	listed
Quality	27 July 2022	MR
Bioequivalence	28 July 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 January 2019	MR
FPP	24 September 2020	MR
GCP/GLP (re-)inspection	11 March 2022	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	

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.