WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA742 trade name]*

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

[HA742 trade name], manufactured at Sun Pharmaceutical Industries Limited, Goregaon (East), Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 23 September 2024.

[HA742 trade name] is indicated for the treatment of HIV-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 [HA742 trade name] are atazanavir (as sulfate) and ritonavir.

The efficacy and safety of atazanavir (as sulfate) 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 (as sulfate) and ritonavir in HIV/AIDS, the team of assessors advised that [HA742 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA742 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA742 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 September 2024	listed
Pharmaceutical quality	09 September 2024	MR
Bioequivalence	13 September 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	25 May 2020	MR*
API	05 March 2024	MR*
API	26 January 2024	MR
FPP	21 April 2023	MR
GCP/GLP (re-)inspection	29 September 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

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