

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA787 trade name]*

Ritonavir 100mg tablets

[HA787 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 human immunodeficiency virus (HIV) on 02 July 2024.

[HA787 trade name] is indicated for HIV. 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 [HA787 trade name] is ritonavir.

The efficacy and safety of ritonavir is well established based on extensive clinical experience in the treatment of HIV.

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 ritonavir in HIV, the team of assessors advised that [HA787 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA787 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA787 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	02 July 2024	listed
Pharmaceutical quality	03 June 2024	MR
Bioequivalence	14 June 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 July 2023	MR
FPP	20 March 2024	MR
GCP/GLP (re-)inspection	24 May 2024	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	