

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA621 trade name]*

Ritonavir 25 mg tablets

[HA621 trade name], manufactured at Mylan Laboratories Ltd, Nashik, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 16 December 2015.

[HA621 trade name] is indicated for HIV treatment. 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 [HA621 trade name] is ritonavir.

The efficacy and safety of 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 ritonavir in HIV/AIDS, the team of assessors advised that [HA621 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA621 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA621 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	16 Dec 2015	listed
Quality	08 Dec 2015	MR
Bioequivalence	08 Dec 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 Sept 2014	MR
FPP	12 June 2015	MR
GCP/GLP (re-)inspection	05 Dec 2015	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	

Requalification	09 February 2022
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.