WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA621 trade name]*

Ritonavir 25 mg tablets

[HA621 trade name], manufactured at Mylan Laboratories Limited, Nashik, Maharashtra, 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 currently indicated for the treatment of HIV-1. 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-1.

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, 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
Pharmaceutical 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

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

Requalification	09 February 2022