WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA741 trade name]*

Ritonavir 25 mg tablets

[HA741 trade name], manufactured at Cipla Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection on 30 November 2021.

[HA741 trade name] is currently indicated as a pharmacokinetic enhancer for protease inhibitors when these are used in combination therapy with other antiretroviral agents for the treatment of HIV-1 infected patients. 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 [HA741 trade name] is ritonavir.

The efficacy and safety of ritonavir are 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, the team of assessors advised that [HA741 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA741 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA741 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	30 November 2021	listed
Pharmaceutical quality	19 November 2021	MR
Bioequivalence	26 November 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 January 2019	MR
FPP	23 October 2020	MR*
GCP/GLP (re-)inspection	NA	NA

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.