WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA565 trade name]*

Ritonavir 100 mg tablets

[HA565 trade name], manufactured at Hetero Labs Limited, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV-1 on 20 July 2017.

[HA565 trade name] is 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 [HA565 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 in HIV-1, the team of assessors advised that [HA565 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA565 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA565 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	20 July 2017	listed
Pharmaceutical quality	11 July 2017	MR
Bioequivalence	13 July 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 September 2014	MR
FPP	18 September 2014, 12 June 2015	MR
GCP/GLP (re-)inspection	27 April 2013	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.