WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA650 trade name]*

Lopinavir / Ritonavir 100 mg/25 mg tablets

[HA650 trade name], manufactured at Hetero Labs Limited, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 June 2018.

[HA650 trade name] is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults and children weighing 10 kg or more. 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 ingredients of [HA650 trade name] are the protease inhibitors (PI) lopinavir and ritonavir.

The efficacy and safety profile of Lopinavir and 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA650 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA650 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA650 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	**19 June 2018**	**listed**
Pharmaceutical quality	08 May 2018	MR
Bioequivalence	11 May 2018	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 September 2014	MR
API	24 February 2017	MR
FPP	23 March 2018	MR
GCP/GLP (re-)inspection		

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