WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA492 trade name]*

Lopinavir / Ritonavir 200 mg/50 mg Tablets

[HA492 trade name], manufactured at Hetero Labs Limited, Hyderabad, Telangana, India, was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 11 January 2013.

[HA492 trade name] is indicated for HIV/AIDS. 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 [HA492 trade name] are lopinavir and ritonavir.

The efficacy and safety of lopinavir and 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 lopinavir and ritonvair in HIV/AIDS the team of assessors advised that [HA492 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA492trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA492 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	11 January 2013	listed
Pharmaceutical quality	04 January 2013	MR
Bioequivalence	27 September 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API 1	27 January 2011	MR
API 2	23 June 2011	MR
FPP	16 February 2012	MR
GCP/GLP (re-)inspection	24 June 2011	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	30 July 2019