WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA573 trade name][*]

Lopinavir/ritonavir 100 mg /25 mg tablets

[HA573 trade name], manufactured at Macleods Pharmaceuticals Limited, Solan, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 9 September 2015.

[HA573 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 [HA573 trade name] are the protease inhibitors (PI) lopinavir and ritonavir.

The efficacy and safety of lopinavir and ritonavir are well established based on extensive clinical experience in the treatment of HIV infection.

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/ritonavir in HIV/AIDS, the team of assessors advised that [HA573 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA573 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA573 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	09 Sept 2015	listed
Pharmaceutical quality	20 Aug 2015	MR
Bioequivalence	27 Aug 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API 1	07 March 2014	MR
API 2	18 Sept 2014	MR
FPP	17 July 2014	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

Requalification	15 May 2023