WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA467 trade name]*

Ritonavir 100 mg tablets

[HA467 trade name], manufactured at Mylan Laboratories Ltd, Malegaon, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 14 December 2010.

[HA467 trade name] is indicated for HIV treatment. 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 [HA467 trade name] is ritonavir.

The efficacy and safety of 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 ritonavir in HIV/AIDS, the team of assessors advised that [HA467 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA467 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA467 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	Dec 2010	listed
Quality	Nov 2010	MR
Bioequivalence	Dec 2010	MR
Safety, efficacy	Dec 2010	MR
GMP (re-)inspection		
API	June 2008	MR
FPP	Aug 2009	MR
GCP/GLP (re-)inspection	Apr 2009	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	31 October 2019

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.