WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA561 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200mg/300mg tablets

[HA561 trade name], manufactured at Macleods Pharmaceuticals Limited, Kachigam, Daman, India, and Tehsil Baddi, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for HIV on 8 April 2014.

[HA561 trade name] is currently indicated for treatment and prevention of HIV and treatment of chronic hepatitis B. 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 [HA561 trade name] are emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of emtricitabine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment and prevention of HIV/AIDS and treatment of hepatitis B.

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 are emtricitabine and tenofovir disoproxil fumarate, the team of assessors advised that [HA561 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA561 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA561 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	08 April 2014	
Pharmaceutical quality	05 March 2014	MR
Bioequivalence	12 March 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	14 June 2012	MR
API	12 April 2013	MR
FPP	07 June 2012	MR
GCP/GLP (re-)inspection	12 February 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

The table represents the status of relevant completed activities only.

Requalification	09 February 2022