WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA514 trade name]*

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

[HA514 trade name], manufactured at Macleods Pharmaceutical Limited, Daman, India, was included in the WHO list of prequalified medicinal products for HIV on 10 April 2014.

[HA514 trade name] is currently indicated for treatment and prophylaxis 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 [HA514 trade name] are lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment and prophylaxis of human immunodeficiency virus (HIV) as well as the 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 lamivudine and tenofovir disoproxil fumarate, the team of assessors advised that [HA514 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA514 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA514 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	10 April 2014	Listed
Pharmaceutical quality	21 March 2014	MR
Bioequivalence	21 March 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	14 June 2012	MR
API	24 May 2013	MR
FPP	24 Feb 2012	MR
GCP/GLP (re-)inspection	12 Feb 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

Requalification	24 October 2023	MR