WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA549 trade name]*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 600 mg/300 mg/300 mg tablets

[HA549 trade name], manufactured at Hetero Labs Limited, Telangana, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 30 June 2017.

[HA549 trade name], is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents weighing at least 35 kg.

The active pharmaceutical ingredients (APIs) of [HA549 trade name] are the nonnucleoside reverse transcriptase inhibitor efavirenz, the nucleoside reverse transcriptase inhibitor lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil.

The APIs, as separate formulations, have been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of efavirenz, lamivudine and tenofovir disoproxil is 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 combination therapy in HIV/AIDS, the team of assessors advised that [HA549 trade name], is of acceptable quality, efficacy and safety to allow the inclusion of [HA549 trade name], in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA549 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**30 June 2017**	**listed**
Quality	15 June 2017	MR
Bioequivalence	19 April 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	18 September 2014	MR
API	25 February 2017	MR
FPP	12 June 2015	MR
GCP/GLP (re-)inspection		
GCP (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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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