WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA538 trade name]*

Efavirenz, emtricitabine and tenofovir disoproxil fumarate 600mg/200mg/300mg film-coated tablets

[HA538 trade name], manufactured at Hetero Labs Limited, Mahaboob Nagar District, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 19 February 2014.

[HA538 trade name] is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents weighing at least 35 kg. 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 [HA538 trade name] are efavirenz, emtricitabine and tenofovir disoproxil.

The efficacy and safety of efavirenz, emtricitabine and tenofovir disoproxil 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 efavirenz, emtricitabine and tenofovir disoproxil in HIV/AIDS, the team of assessors advised that [HA538 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA538 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA538 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 February 2014	Listed
Quality	07 February 2014	MR
Bioequivalence	10 February 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 September 2014	MR
FPP	18 June 2015	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

The table represents the status of relevant completed activities only.

Requalification	03 August 2021