

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA553 trade name]*

Efavirenz/emtricitabine/tenofovir disoproxil fumarate 600 mg/200 mg/300 mg tablets

[HA553 trade name], manufactured at Strides Pharma Science Limited, Bilekahalli, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 December 2014.

[HA553 trade name] is currently indicated for human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents (from 10 years of age and 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 [HA553 trade name] are efavirenz, emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of efavirenz, emtricitabine and tenofovir disoproxil fumarate 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 fumarate, the team of assessors advised that [HA553 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA553 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA553 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	12 December 2014	listed
Pharmaceutical quality	28 November 2014	MR
Bioequivalence	08 December 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2011	MR
API	19 January 2014	MR
API	19 June 2014	MR
APIs	28 August 2014	MR
API	12 September 2014	MR
FPP	22 October 2013	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		

Requalification	03 August 2021
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