WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA444 trade name][*]

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

[HA444 trade name], manufactured at Mylan Laboratories Limited, Maharashtra state, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 25 October 2010.

[HA444 trade name] is indicated for the treatment of HIV-1 infection in patients 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 [HA444 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 in HIV/AIDS, the team of assessors advised that [HA444 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA444 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA444 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.
[#] Formerly known as 'Matrix Laboratories Limited'.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 October 2010	listed
Quality	7 October 2010	MR
Bioequivalence	10 October 2010	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 May 2009	MR
FPP	11 August 2009	MR
GCP/GLP (re-)inspection	21 July 2009	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	18 July 2025