WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA552 trade name][*]

Emtricitabine/tenofovir disoproxil fumarate 200mg/300mg tablets

[HA552 trade name], manufactured at Strides Pharma Science Ltd 36/7, Suragajakknahalli, Indlavadi Cross, Anekal Taluk, Bangalore-562 106, India, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) on 18 February 2015.

[HA552 trade name] is indicated in combination with other antiretrovirals products for the treatment human immunodeficiency virus (HIV) infection in adults and adolescents weighing more than 30 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 [HA552 trade name] are emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of 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 emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA552 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA552 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA552 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	18 February 2015	listed
Pharmaceutical quality	04 February 2015	MR
Bioequivalence	12 February 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	05 January 2013	MR
API	19 June 2014	MR
APIs	28 August 2014	MR
API	12 September 2014	MR
API	24 January 2015	MR
FPP	22 October 2013	MR
GCP/GLP (re-)inspection	18 February 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	01 December 2021