WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA756 trade name]*

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

[HA756 trade name], manufactured at Aizant Drug Research Solutions Pvt Ltd, Block No. B, Survey No. 172 &173, Apparel Park Road, Dulapally Village, Dundigal Gandimaisamma Mandal, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV and Aids on 28 December 2022.

[HA756 trade name] It is indicated for the treatment of human immunodeficiency virus type 1 (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 ingredient(s) of [HA756 trade name] are efavirenz, lamivudine and tenofovir disoproxil fumarate

The efficacy and safety of efavirenz, lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of human immunodeficiency virus type 1 (HIV-1) 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 efavirenz, lamivudine and tenofovir disoproxil fumarate in of HIV and Aids the team of assessors advised that [HA756 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA756 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 [HA756 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	28 December 2022	listed
Quality	21 December 2022	MR
Bioequivalence	22 December 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 January 2019	MR
APIs	19 June 2020	MR*
FPP	20 June 2022	MR*
GCP/GLP (re-)inspection		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

The table represents the status of relevant completed activities only.