WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA792 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA792 trade name], manufactured at Shanghai Desano Bio-Pharmaceutical Co., Ltd, Shanghai, China, was included in the WHO list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) on 17 July 2025.

[HA792 trade name] is currently indicated for treatment and prophylaxis of human immunodeficiency virus (HIV) and treatment of chronic hepatitis B. 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 [HA792 trade name] are emtricitabine and tenofovir.

The efficacy and safety of emtricitabine and tenofovir are well established based on extensive clinical experience in the treatment and prophylaxis of HIV and treatment of chronic hepatitis B.

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, the team of assessors advised that [HA792 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA792 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA792 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2025	listed
Pharmaceutical quality	03 July 2025	MR
Bioequivalence	04 July 2025	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 July 2023	MR
API	24 May 2019	MR
FPP	20 March 2024	MR
GCP/GLP (re-)inspection	24 May 2024 15 June 2023	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

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