WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HP030 trade name][*]

Tenofovir disoproxil fumarate 300 mg film-coated tablets

[HP030 trade name], manufactured at Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd., Shijiazhuang, Hebei, China, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B on 27 August 2024.

[HP030 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of HIV infection in adults and adolescents weighing at least 30 kg. It is also indicated for the treatment of chronic hepatitis B in adults and adolescents from 12 years of age. 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 of [HP030 trade name] is tenofovir disoproxil fumarate

The efficacy and safety of tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of HIV/AIDS and 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 tenofovir disoproxil fumarate in HIV/AIDS and hepatitis B, the team of assessors advised that [HP030 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HP030 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HP030 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	27 August 2024	listed
Quality	15 March 2023	MR
Bioequivalence	22 March 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	11 October 2023	MR
FPP	17 October 2023	MR
GCP/GLP (re-)inspection	11 March 2022	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
NA: not applicable, not available
PQ: prequalification