

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[HA679 trade name]\***

Tenofovir disoproxil fumarate 300 mg tablets

[HA679 trade name], manufactured at Laurus Labs Limited, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 December 2017.

[HA679 trade name] is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults and adolescents over 10 years of age and weighing at least 30 kg or more and for pre-exposure prophylaxis (PrEP) as an additional prevention choice for adults and adolescents (weighing at least 35 kg). It is also indicated for the treatment of chronic hepatitis B in adults with compensated liver disease and evidence immune active disease, adults with evidence of lamivudine-resistant hepatitis B virus, and adults with decompensated liver disease. 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 [HA679 trade name] is the nucleotide reverse transcriptase inhibitor 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 infections.

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 [HA679 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA679 trade name] in the list of prequalified medicinal products.

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

**Summary of prequalification status for [HA679 trade name]:**

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	12 December 2017	listed
Quality	08 December 2017	MR
Bioequivalence	11 December 2017	MR
Safety, efficacy	NA	<b>NA</b>
<b>GMP (re-)inspection</b>		
API	07 September 2017	MR
FPP	17 March 2017	MR
<b>GCP/GLP (re-)inspection</b>	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	

The table represents the status of relevant completed activities only.