WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA758 trade name]*

Darunavir (as ethanolate)/ ritonavir 800mg/100mg film-coated tablets

[HA758 trade name], manufactured at Hetero Labs Limited Unit - III (Formulations Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products the treatment of HIV/AIDS on 15 June 2026.

[HA758 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in paediatric patients, adults and adolescents. 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 [HA758 trade name] are darunavir and ritonavir.

The efficacy and safety of are darunavir and ritonavir are well established based on extensive clinical experience in the treatment of human immunodeficiency virus 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 [HA758 trade name] in the treatment of human immunodeficiency virus (HIV) infection, the team of assessors advised that [HA758 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA758 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA758 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	15 June 2026	listed
Pharmaceutical quality	01 June 2026	MR
Bioequivalence	17 May 2026	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	21 November 2025	MR
API	30 November 2025	MR
FPP	30 April 2026	MR
GCP/GLP (re-)inspection	30 May 2024	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