WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA725 trade name]*

Darunavir 800 mg Tablets

[HA725 trade name], manufactured at MSN Laboratories Private Limited, Rangareddy District, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV on 01 March 2022.

[HA725 trade name] is indicated for HIV treatment. 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 [HA725 trade name] is darunavir.

The efficacy and safety of darunavir are well established based on extensive clinical experience in the treatment of HIV.

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 darunavir in HIV, the team of assessors advised that [HA725 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA725 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA725 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 March 2022	listed
Quality	08 February 2022	MR
Bioequivalence	21 February 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	05 May 2020	MR*
FPP	05 May 2020	MR*
GCP/GLP (re-)inspection	29 January 2020	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.

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