WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA627 trade name]*

Darunavir (as ethanolate) 400 mg Tablets

[HA627 trade name], manufactured at Cipla Limited, District- Raigad, Maharashtra, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 December 2016.

[HA627 trade name], co-administered with low dose ritonavir, is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV) infection. Detailed information on theuse of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of [HA627 trade name] is darunavir.

The efficacy and safety of darunavir (as ethanolate) is well-established, based onextensive clinical experience in the treatment of HIV 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 darunavir combination therapy in HIV/AIDS, the team of assessors advised that [HA627 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA627 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA627 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 Dec 2016	listed
Quality	19 Dec 2016	MR
Bioequivalence	16 Dec 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 March 2016	MR
FPP	21 Feb 2014	MR
GCP/GLP (re-)inspection	18 May 2012	MR

API: active pharmaceutical ingredient	GMP: good manufacturing practice [quality standard]
FPP: finished pharmaceutical product	MR: meets requirements
GCP: good clinical practice [quality standard]	MR*: desk review (based on recent inspection reports)
GLP: good laboratory practice [quality standard]	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.