

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

**[HA628 trade name]<sup>1</sup>**

**Darunavir (as ethanolate) 600 mg Tablets**

[HA628 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.

[HA628 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 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 (API) of [HA628 trade name] is darunavir.

The efficacy and safety profile of [HA628 trade name] is well-established, based on extensive 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 in HIV/AIDS, the team of assessors advised that [HA628 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA628 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [HA628 trade name]:**

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

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.