WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA500 trade name]*

Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate 600mg/200mg/300mg Tablets

[HA500 trade name], manufactured at Cipla Ltd., Unit VII, III, IV, L-147 to L147-1 and L-139 to L-146, Verna Industrial Estate, Goa – 403722, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 8 December 2011.

[HA500 trade name] is indicated for human immunodeficiency virus infection in adults and adolescents who weigh at least 35 kg. 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 ingredients of [HA500 trade name] are efavirenz, emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of efavirenz, emtricitabine and tenofovir disoproxil fumarate 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 [HA500 trade name] in HIV/AIDS, the team of assessors advised that [HA500 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA500 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA500 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**08 Dec 2011**	**Listed**
Quality	29 Nov 2011	MR
Bioequivalence	29 Nov 2011	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 Feb 2011	MR
API	19 Aug 2011	MR
FPP	09 Sep 2010	MR*
GCP/GLP (re-)inspection	20 May 2011	MR

MR: meets requirements

MR*: desk review (based on recent inspection reports)
NA: not applicable, not available

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