

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA306 trade name]*

Efavirenz 600 mg film-coated tablets

[HA306 trade name], manufactured at Sun Pharmaceutical Industries Limited, Himachal Pradesh, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 23 May 2006.

[HA306 trade name] is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in 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 of [HA306 trade name] is the non-nucleoside reverse transcriptase inhibitor efavirenz.

The efficacy and safety of efavirenz is well established based on extensive clinical experience in the treatment of HIV-1 infection in combination with other antiretroviral agents.

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 efavirenz in the treatment of HIV-1 infection, the team of assessors advised that [HA306 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA306 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA306 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	23 May 2006	Listed
Quality	27 March 2006	MR
Bioequivalence	08 September 2005	MR
Safety, efficacy		
GMP (re-)inspection		
API	28 May 2005	MR
FPP	15 June / 20 October 2005	MR
GCP/GLP (re-)inspection	24 March 2006	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.

Requalification	11 December 2018
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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.