WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA286 trade name]*

Lamivudine/Zidovudine 150 mg/300 mg Tablets

[HA286 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 11 August 2005.

[HA286 trade name] is indicated for the treatment of HIV infection in combination with at least one other antiretroviral drug. 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 (APIs) of [HA286 trade name] are the nucleoside reverse transcriptase inhibitors (NRTI) lamivudine and zidovudine. Both APIs are marketed either alone or as components of fixed-dose combinations. Each is well established and documented for the treatment of HIV/AIDS in combination with other products.

The combination of lamivudine and zidovudine has been investigated in several clinical trials in both treatment-naïve and treatment-experienced patients. These studies have demonstrated significant decrease in HIV-1 viral load and increase in CD4-cell count. Clinical end-point data indicate that therapy with lamivudine and zidovudine (in combination with one or more other antiretroviral agents) results in significant reduction in disease progression and mortality rate.

With extensive clinical experience in the treatment of HIV infection, the efficacy and adverse-effect profile of lamivudine and zidovudine are well established.

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 combination therapy in HIV infection, the team of assessors advised that [HA286 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA286 trade name] in the list of prequalified medicinal products.

† Formerly Ranbaxy Laboratories Ltd.

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

Summary of prequalification status for [HA286 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 August 2005	listed
Pharmaceutical quality	11 August 2005	listed
Bioequivalence	11 August 2005	listed
Safety, efficacy	11 August 2005	listed
GMP (re-)inspection		
API	26 May 2005	MR
FPP	15 June 2005	MR
GCP/GLP (re-)inspection	6 July 2005	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

Requalification	30 July 2019