WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB199 trade name]*

Ethambutol hydrochloride/ isoniazid/ rifampicin 275 mg/ 75mg/ 150mg tablets

[TB199 trade name], manufactured at Lupin Ltd, Aurangabad, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis (TB) on 11 January 2013.

[TB199 trade name] is indicated for TB treatment. 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 [TB199 trade name] are ethambutol hydrochloride, isoniazid and rifampicin.

The efficacy and safety of ethambutol hydrochloride, isoniazid and rifampicin are well established based on extensive clinical experience in the treatment of TB.
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 ethambutol hydrochloride, isoniazid and rifampicin ethambutol hydrochloride, isoniazid and rifampicin in TB, the team of assessors advised that [TB199 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB199 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [TB199 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 January 2013	listed
Quality	21 December 2012	MR
Bioequivalence	10 August 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API 1	18 February 2011	MR
API 2	16 June 2011	MR
API 3	18 February 2012	MR
API 4	18 February 2011	MR
FPP	NA	MR
GCP/GLP (re-)inspection	15 July 2011	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.