WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB168 trade name]*

Rifampicin/Isoniazid/Pyrazinamide/Ethambutol 150mg/75mg/400mg/275mg film-coated tablets

[TB168 trade name], manufactured at Macleods Pharmaceutical Ltd, Kachigam, Daman, Uttarakhand, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 7 March 2008.

[TB168 trade name] is indicated for the initial treatment of tuberculosis due to *Mycobacterium tuberculosis*. 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 [TB168 trade name] are the rifampicin, isoniazid, pyrazinamide and ethambutol.

The efficacy and safety of rifampicin, isoniazid, pyrazinamide and ethambutol are well established based on extensive clinical experience in the treatment of tuberculosis due to *Mycobacterium tuberculosis*.

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 the rifampicin, isoniazid, pyrazinamide and ethambutol in tuberculosis, the team of assessors advised that [TB168 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB168 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [TB168 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	07 Mar 2008	listed
Quality	23 Jan 2008	MR
Bioequivalence	30 Mar 2006	MR
Safety and efficacy	Not applicable	Not applicable
GMP (re-)inspection		
API	17 Mar 2007	MR
API	30 Nov 2006	MR
API	14 Oct 2006	Waived (only source)
API	06 Dec 2005	MR
FPP	20 Jun 2007	MR
GCP/GLP (re-)inspection	26 May 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
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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