WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB015 trade name]*

Pyrazinamide 400 mg Tablets

[TB015 trade name], manufactured at Cadila Pharmaceuticals Limited, Ahmedabad, Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis (TB) on 13 November 2003.

[TB015 trade name] is indicated for treatment of 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 ingredient of [TB015 trade name] is pyrazinamide.

The efficacy and safety of pyrazinamide are well established based on extensive clinical experience in the treatment of 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 pyrazinamide in tuberculosis, the team of assessors advised that [TB015 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB015 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB015 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	13 November 2003	listed
Quality	July 2003	MR
Bioequivalence	November 2002	MR
Safety, efficacy	May 2003	MR
GMP (re-)inspection		
API	June 2015	MR
FPP	June 2014	MR
GCP/GLP (re-)inspection	December 2013	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] NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

Requalification	04 March 2016

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