WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB335 trade name]*

Pyrazinamide 150 mg Dispersible Tablets

[TB335 trade name], manufactured at Micro Labs Ltd, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment tuberculosis on 26 September 2017.

[TB335 trade name] is indicated for the 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 [TB335 trade name] is antimycobacterial agent pyrazinamide.

The efficacy and safety of pyrazinamide is 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 therapy, the team of assessors advised that [TB335 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB335 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB335 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 Sept 2017	listed
Quality	30 Aug 2017	MR
Bioequivalence	13 Sept 2017	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 Aug 2017	MR
FPP	08 Dec 2015	MR
GCP/GLP (re-)inspection	NA	NA

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.

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