# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

## [TB347 trade name]*

Isoniazid 50 mg dispersible tablets

[TB347 trade name] manufactured at Micro Labs Limited, Hosur, India was included in the WHO list of prequalified medicinal products for treatment of tuberculosis on 16 March 2020.

[TB347 trade name] is indicated in with other tuberculosis medicines for the treatment of tuberculosis due to Mycobacterium tuberculosis, including in regimens for drug-resistant tuberculosis. It is also indicated as monotherapy or with other medicines for the prevention of tuberculosis in persons at risks. 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 [TB347 trade name] is the antimycobacterial agent isoniazid. The efficacy and safety of isoniazid are well established based on extensive clinical experience in treatment and prevention 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 isoniazid for treatment and prevention of tuberculosis, the team of assessors advised that [TB347 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB347 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB347 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| Status on PQ list | 16 March 2020 | listed |
| Quality | 5 March 2020 | MR |
| Bioequivalence | 10 March 2020 | MR |
| Safety, Efficacy | NA | NA |
| GMP (re-)inspection | | |
| API | 23 Nov 2018 | MR |
| FPP | 10 April 2019 | MR |
| GCP/GLP (re-)inspection | 15 Dec 2017 | MR |

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|---|---|
| API: active pharmaceutical ingredient | GMP: good manufacturing practice [quality standard] |
| FPP: finished pharmaceutical product | MR: meets requirements |
| GCP: good clinical practice [quality standard] | MR*: desk review (based on recent inspection reports) |
| GLP: good laboratory practice [quality standard] | 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.