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

## [TB068 trade name]*

Rifampicin/Isoniazid 150 mg/75 mg Tablets

[TB068 trade name] manufactured at at Lupin Limited, Chikalthana, Aurangabad, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 19 December 2003.

[TB068 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 ingredients of [TB068 trade name] are the antimycobacterial agents rifampicin and isoniazid.

The efficacy and safety profile of [TB068 trade name] is well established based on extensive clinical experience in the treatment of malaria.

On the basis of data submitted and public information on the use of [TB068 trade name] in tuberculosis, the team of assessors advised that [TB068 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB068 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB068 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 13 December 2003 | listed |
| Quality | NA | NA |
| Bioequivalence | NA | NA |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | NA | NA |
| FPP | 31 October 2002 | MR |
| **GCP/GLP (re-)inspection** | NA | NA |
| API: active pharmaceutical ingredient<br>FPP: finished pharmaceutical product<br>GCP: good clinical practice [quality standard]<br>GLP: good laboratory practice [quality standard] | GMP: good manufacturing practice [quality standard]<br>MR: meets requirements<br>MR*: desk review (based on recent inspection reports)<br>NA: not applicable, not available<br>PQ: prequalification | |

The table represents the status of relevant completed activities only.

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|---|---|
| **Requalification** | 17 June 2019 |

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