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

## [TB227 trade name]*

Levofloxacin (as hemihydrate) 500 mg Tablets

[TB227 trade name], manufactured at Cipla Limited, Verna Industrial Estate, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 22 December 2011.

[TB227 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 ingredients of [TB227 trade name] is levofloxacin.

The efficacy and safety profile of [TB227 trade name] is well established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use of [TB227 trade name] in malaria, the team of assessors advised that [TB227 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB227 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [TB227 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 22 Dec 2011 | listed |
| Quality | 13 Dec 2011 | MR |
| Bioequivalence | 14 Dec 2011 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 30 June 2011 | MR |
| FPP | 9 Sept 2010 | 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** | 11 February 2020 |

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