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

## [NT011 trade name]*

Praziquantel 600 mg tablets

[NT011 trade name], manufactured at Hetero Labs Limited, Jadcherla Mandal, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of neglected tropical disease on 23 August 2022.

[NT011 trade name] is indicated for schistosoma infections. 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 [NT011 trade name] is praziquantel.

The efficacy and safety of praziquantel is well established based on extensive clinical experience in the treatment of schistosoma infections.

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 [NT011 trade] in neglected tropical diseases the team of assessors advised that [NT011 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [NT011 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [NT011 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 23 August 2022 | listed |
| Quality | 11 July 2022 | MR |
| Bioequivalence | 15 July 2022 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 29 January 2021 | MR* |
| FPP | 28 September 2020 | MR* |
| **GCP/GLP (re-)inspection** | 27 May 2022 | 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]
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.