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

## [DI010 trade name]*

Zinc (as sulfate) 10 mg/5 mL oral solution

[DI010 trade name], manufactured at PharmEvo Private Limited, Port Qasim, Karachi-75020, Pakistan, was included in the WHO list of prequalified medicinal products for the treatment of diarrhoea on 12 July 2023.

[DI010 trade name] is indicated for the treatment of acute and persistent diarrhoea in infants and children aged up to 5 years. 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 [DI010 trade name] is zinc sulfate monohydrate.

The efficacy and safety of zinc (as sulfate) is well established based on extensive clinical experience in the treatment of diarrhoea.

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 zinc (as sulfate) in diarrhoea, the team of assessors advised that [DI010 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI010 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [DI010 trade name]:**

| **Initial acceptance** | **Date** | **Outcome** |
|---|---|---|
| **Status on PQ list** | 12 July 2023 | listed |
| Quality | 03 July 2023 | MR |
| Bioequivalence | 05.July 2023 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | NA | NA |
| FPP | 16 September 2022 | 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>NA: not applicable, not available<br>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.