

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI010 trade name]*

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

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

[DI010 trade name] is currently indicated for the treatment of diarrhoea. 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 sulfate monohydrate are 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 monohydrate), 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]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	Date	Outcome
Status on PQ list	12 July 2023	listed
Pharmaceutical 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 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		

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