WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI009 trade name]*

Zinc (as sulfate monohydrate) 20 mg dispersible tablets

[DI009 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.

[DI009 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 [DI009 trade name] is zinc sulfate monohydrate

The efficacy and safety of zinc sulfate 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 sulfate monohydrate, the team of assessors advised that [DI009 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI009 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [DI009 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	28 June 2023	MR
Bioequivalence	01 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.