

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI013 trade name]*

Zinc (as sulfate monohydrate) 20 mg Dispersible Tablets

[DI013 trade name], manufactured at The ACME Laboratories Limited, Dhaka, Bangladesh, was included in the WHO list of prequalified medicinal products for the treatment of diarrhoea in children on 02 November 2021.

[DI013 trade name] is indicated for diarrhoea in children. 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 [DI013 trade name] is zinc (as sulfate monohydrate).

The efficacy and safety of zinc are well established based on extensive clinical experience in the treatment of diarrhoea in children.

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 in diarrhoea, the team of assessors advised that [DI013 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI013 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [DI013 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	02 November 2021	listed
Quality	27 October 2021	MR
Bioequivalence	28 October 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	NA	NA
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 NA: not applicable, not available PQ: prequalification		

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