

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI005 trade name]*

Zinc (as sulfate) 20 mg dispersible tablets

[DI005 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of diarrhoea on 7 December 2016.

[DI005 trade name] is currently indicated for the treatment of acute watery or persistent diarrhoea in children up to 10 years of age. 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 [DI005 trade name] is Zinc (as sulfate).

The efficacy and safety of Zinc (as 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 (as sulfate), the team of assessors advised that [DI005 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI005 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [DI005 trade name]:

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

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

Initial acceptance	Date	Outcome
Status on PQ list	07 December 2016	Listed
Pharmaceutical quality	02 December 2016	MR
Bioequivalence	05 August 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 July 2016	MR
FPP	17 July 2014	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		

Requalification	05 March 2025
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