

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI011 trade name]*

Zinc (as sulfate monohydrate) Dispersible 20mg Tablets

[DI011 trade name], manufactured at Ipca Laboratories Limited, Silvassa, Dadra and Nagar Haveli (U.T.), India was included in the WHO list of prequalified medicinal products for the treatment of diarrhea on 25 May 2020.

[DI011 trade name] is indicated for the treatment of acute and persistent diarrhoea in children and infants aged less than 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 [DI011 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 acute diarrhea.

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 diarrhea, the team of assessors advised that [DI011 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI011 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [DI011 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	25 May 2020	listed
Pharmaceutical quality	16 May 2020	MR
Bioequivalence	20 May 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	27 August 2019	MR*
GCP/GLP (re-)inspection	06 December 2019	MR
<div> <div> API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard] </div> <div> GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification </div> </div>		