WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[DI014 trade name]*

Zinc 20 mg dispersible tablets

[DI014 trade name], manufactured at Swiss Pharma Nigeria Limited, Agege-Lagos, Nigeria, was included in the WHO list of prequalified medicinal products for the treatment of acute and persistent paediatric diarrhoea on 02 May 2023.

[DI014 trade name] is indicated for the treatment of acute and persistent diarrhoea in infants and children aged up to 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 [DI014 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 acute and persistent 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 in acute and persistent diarrhoea, the team of assessors advised that [DI014 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [DI014 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [DI014 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	02 May 2023	listed
Quality	16 April 2023	MR
Bioequivalence	16 April 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	MR
FPP	19 September 2022	MR
GCP/GLP (re-)inspection	NA	MR

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

The table represents the status of relevant completed activities only.

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