WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA782 trade name]*

Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets

[HA782 trade name], manufactured at Reyoung Pharmaceutical Co. Limited, Yiyuan County, Shandong Province, China, was included in the WHO list of prequalified medicinal products for the treatment of conditions associated with HIV/AIDS on 02 July 2024.

[HA782 trade name] is currently indicated for the prevention of infections in HIV/AIDS patients. 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 ingredients of [HA782 trade name] are sulfamethoxazole and trimethoprim.

The efficacy and safety of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in the treatment and prevention of infections in HIV/AIDS patients.

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 sulfamethoxazole and trimethoprim, the team of assessors advised that [HA782 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA782 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA782 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 July 2024	Listed
Pharmaceutical quality	07 June 2024	MR
Bioequivalence	19 June 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 January 2018	MR
FPP	24 October 2023	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.