WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA775 trade name]*

Sulfamethoxazole/trimethoprim 800 mg/160 mg tablets

[HA775 trade name], manufactured at Shouguang Fukang Pharmaceutical Company Limited, Shouguang, Shouguang-262700, China, was included in the WHO list of prequalified medicinal products for the treatment and prevention of infections in HIV/AIDS patients on 18 December 2023.

[HA775 trade name] is indicated for treatment and prevention of infections in infants, children and adults with HIV infection. 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 [HA775 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 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 in HIV/AIDS, the team of assessors advised that [HA775 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA775 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA775 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	18 December 2023	listed
Pharmaceutical quality	27 November 2023	MR
Bioequivalence	06 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	11 December 2023	MR*
GCP/GLP (re-)inspection	21 April 2023	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.