WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA598 trade name]*

Sulfamethoxazole/trimethoprim 400mg/80mg tablets

[HA598 trade name], manufactured at Micro Labs Limited, Bengaluru, Karnataka, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 23 May 2016.

[HA598 trade name] is indicated for treatment/prevention of certain opportunistic infections in patients with HIV/AIDS. 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 [HA598 trade name] are sulfamethoxazole and trimethoprim.

The efficacy and safety of sulfamethoxazole and trimethoprim are well established based on extensive clinical experience in HIV/AIDS management.

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 sulfamethozaxole/trimethoprim in HIV/AIDS, the team of assessors advised that [HA598 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA598 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA598 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	23 May 2016	Listed
Pharmaceutical quality	07 July 2016	MR
Bioequivalence	09 July 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	05 February 2015	MR
FPP	10 December 2015	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	8 March 2023