WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA165 trade name]*

Artemether/Lumefantrine 80mg/480mg Tablets

[MA165 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 26 January 2022.

[MA165 trade name] is indicated for treatment of malaria due to *Plasmodium falciparum*. 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 [MA165 trade name] are artemether and lumefantrine.

The efficacy and safety of artemether and lumefantrine are well established based on extensive clinical experience in the treatment of malaria.

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 artemether and lumefantrine in malaria, the team of assessors advised that [MA165 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA165 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA165 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 January 2022	listed
Quality	07 January 2022	MR
Bioequivalence	13 January 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	16 February 2017	MR
API	16 February 2017	MR
FPP	10 January 2020	MR
GCP/GLP (re-)inspection	23 February 2018	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.