WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA131 trade name][1]

Dihydroartemisinin /piperaquine phosphate 40mg/320mg Tablets

[MA131 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 19 November 2019.

[MA131 trade name]. is currently indicated for the treatment of uncomplicated malaria. 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 [MA131 trade name] are dihydroartemisinin and piperaquine phosphate.

The efficacy and safety of dihydroartemisinin and piperaquine phosphate are well established based on extensive clinical experience in the treatment of treatment of uncomplicated 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 dihydroartemisinin and piperaquine phosphate, the team of assessors advised that [MA131 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA131 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA131 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

.

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	19 Nov 2019	listed
Pharmaceutical quality	25 Oct 2019	MR
Bioequivalence	05 Nov 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 May 2018	MR
FPP	19 Oct 2018	MR
GCP/GLP (re-)inspection	23 Feb 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
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

Requalification	**1 September 2025**