WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA157 trade name]*

Dihydroartemisinin /Piperaquine (as phosphate) 30mg/240mg Dispersible Tablets

[MA157 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Oral Solid Dosage Workshop, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of Malaria on 25 November 2020.

[MA157 trade name] is indicated for treatment of uncomplicated malaria in children. 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 [MA157 trade name] are Dihydroartemisinin and Piperaquine (as phosphate).

The efficacy and safety of Dihydroartemisinin and Piperaquine (as phosphate) 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 [MA157 trade name] in malaria, the team of assessors advised that [MA157 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA157 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA157 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 November 2020	listed
Quality	17 November 2020	MR
Bioequivalence	23 November 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	04 May 2018	MR
FPP	19 October 2018	MR
GCP/GLP (re-)inspection	NA	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.