WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA085 trade name]*

Amodiaquine (as hydrochloride)/artesunate 270 mg/100 mg tablets

[MA085 trade name], manufactured at Guilin Pharmaceutical Co. Ltd, Guilin, China, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 16 November.2012

[MA085 trade name] is currently indicated for the treatment of uncomplicated malaria due to *Plasmodium falciparum* susceptible to amodiaquine and to artesunate. 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 [MA085 trade name] are amodiaquine (as hydrochloride) and artesunate

The efficacy and safety of amodiaquine and artesunate 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 amodiaquine and artesunate, the team of assessors advised that [MA085 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA085 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA085 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	16 November 2012	Listed
Pharmaceutical quality	17 September 2012	MR
Bioequivalence	17 September 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	August 2012	MR
FPP	26 February 2010	MR
GCP/GLP (re-)inspection	25 October 2012	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

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

Requalification	17 May 2021