WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA102 trade name]*

Artesunate/Amodiaquine (as hydrochloride) 25mg/67.5mg tablets

[MA102 trade name], manufactured at Cipla Limited, Patalganga, India was included in the WHO list of prequalified medicinal products for the treatment of malaria on 8 April 2014

[MA102 trade name] is currently indicated for treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to amodiaquine as well as 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 [MA102 trade name] are artesunate and amodiaquine (as hydrochloride).

The efficacy and safety of artesunate and amodiaquine 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 artesunate/amodiaquine (as hydrochloride), the team of assessors advised that [MA102 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA102 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA102 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	08 April 2014	listed
Pharmaceutical quality	25 March 2014	MR
Bioequivalence	28 March 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	20 Jan 2011	MR
API	14 Feb 2014	MR
FPP	21 Feb 2014	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	3 June 2020