WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA078 trade name]*

Artesunate + Mefloquine (as hydrochloride) 25 mg/50 mg Tablets

[MA078 trade name] manufactured at Cipla Ltd, Patalganga, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of Malaria on 12 September 2012.

[MA078 trade name] is indicated for 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 [MA078 trade name] are artesunate and mefloquine (as hydrochloride). The efficacy and safety of artesunate/mefloquine (as hydrochloride) 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/mefloquine (as hydrochloride) in malaria, the team of assessors advised that [MA078 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA078 trade name] in the list of prequalified medicinal products.

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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
# Formerly known as Cipla Limited

Summary of prequalification status for [MA078 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	**12 Sept 2012**	listed
Pharmaceutical quality	**24 Aug 2012**	MR
Bioequivalence	**04 Sept 2012**	MR
Safety, efficacy	**16 Aug 2012**	MR
GMP (re-)inspection		
API	**17 Feb 2011**	MR
FPP	**24 Feb 2011**	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	21 March 2020