WHO Prequalification Programme
WHO PU//BLIC ASSESSMENT REPORT (WHOPAR)

[MA080 trade name]*

Artesunate/Amodiaquine 25/67.5 mg Tablets

[MA080 trade name], manufactured at Ipca Laboratories Ltd, Silvassa, Dadra and Nagar Haveli, India was included in the WHO list of prequalified medicinal products for the treatment of malaria on 1 June 2012.

[MA080 trade name] is a so called artemisinin-based combination therapy (ACT) indicated for the 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 [MA080 trade name] are the artemisinin derivative artesunate and the 4-aminoquinoline amodiaquine.

The efficacy and safety profile of [MA080 trade name] is well established based on extensive clinical experience in the treatment of malaria.

On the basis of data submitted and public information on the use of [MA080 trade name] in malaria, the team of assessors advised that [MA080 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA080 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA080 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 June 2012	listed
Quality	29 May 2012	MR
Bioequivalence	23 April 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API 1	03 Dec 2010	MR
API 2	29 March 2012	MR
FPP	19 April 2012	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	

The table represents the status of relevant completed activities only.

Requalification	13 May 2019

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