WHO Prequalification Programme
WHO PUBLIC 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 currently 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 the artemisinin derivative artesunate and the 4-aminoquinoline 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 artemisinin-based combination therapy 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]:

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	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	

Requalification	13 May 2019
2nd Requalification	24 February 2025