WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA057 trade name]*

Artesunate/Amodiaquine Winthrop 50/135 mg Tablets

[MA057 trade name], manufactured at Maphar Laboratories, 20250 Casablanca, Morocco, were accepted for the WHO list of prequalified products for the treatment of malaria on 14 October 2008.

[MA057 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 [MA057 trade name] are the artemisinin derivative artesunate and the 4-aminoquinoline amodiaquine.

The efficacy and safety profile of [MA057 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 [MA057 trade name] in malaria, the team of assessors advised that [MA057 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA057 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA057 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	14 October 2008	listed
Quality	13 October 2008	MR
Bioequivalence	17 September 2008	MR
Safety, efficacy	17 September 2008	MR
GMP (re-)inspection		
API	13 September 2006	MR
FPP	16 January 2008	MR
GCP/GLP (re-)inspection	N/A	N/A
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.

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