



**World Health
Organization**

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In reply please
refer to: P5 447 3/SC/Sc

Your reference:

Dr Kamal Vashi
General Manager - Operations
Mangalam Drugs and Organics Ltd
Plot No 187, G.I.D.C.
Vapi 396 195
Gujarat
Inde

13 April 2011

Dear Dr Vashi,

**WHO Prequalification of Medicines Programme
Closing of Inspection**

Thank you for your letter dated 22 February 2011 and for the corrective actions to the observations listed in the inspection report following the inspection as detailed below:

Name: Mangalam Drugs and Organics Ltd
Address: Plot No 187, II Phase, G.I.D.C.
Vapi 396 195, Gujarat
India
Date: 17 to 21 January 2011

The actions taken or proposed to be taken in relation to the observations listed in the WHO inspection report have been reviewed by the inspectors. In general, they are considered acceptable and will be verified during future inspections.:

The following APIs:

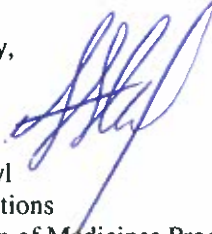
- Lumefantrine (APIMF100)
- Artemether (APIMF101, APIMF138)
- Artesunate (APIMF135)
- Amodiaquine HCl (APIMF134)

are considered to be manufactured in compliance with WHO GMPs for Active Pharmaceutical Ingredients.

Please do not hesitate to send an email to prequalinspection@who.int should you require any further information regarding the close out of this inspection.

Yours sincerely,

P.P.


Dr A. J. van Zyl
Head of Inspections
Prequalification of Medicines Programme
Quality Assurance & Safety: Medicines

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