



Tel. direct: +41 22 791 14 74
Fax direct: +41 22 791 47 30
E-mail : prequalinspection@who.int

In reply please
refer to: P5-447-3/XC/CB/1

Your reference:

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

13 June 2012

Dear Dr Vashi,

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

Thank you for your letter dated 9 May 2012 and 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, IInd Phase, G.I.D.C.
Vapi 396 195, Gujarat
India
Date: 28 to 30 November 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 Active Pharmaceutical Ingredients (APIs) are considered to be manufactured in compliance with World Health Organization (WHO) Good Manufacturing Practices (GMP):

- Piperaquine phosphate (APIMF 149)
- Dihydroartemisinin (APIMF 151)

Please do not hesitate to send an e-mail to prequalinspection@who.int should you require any further information regarding the closure of this inspection.

Yours sincerely,

Ian R. Thrussell
Head of Inspections
Prequalification of Medicines Programme
Quality Assurance & Safety: Medicines