World Health Organization

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

Your reference:

Dr Kamal Vashi
Vice President – Technical & Operations
Mangalam Drugs & Organics Ltd
Plot No 187, II[nd] Phase
G.I.D.C., Vapi 396195
Tal. Pardi, Valsad
Gujarat
Inde

29 July 2015

Dear Dr Vashi,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the inspection that was performed by Ms Xingyu Chen and Mr Andrew Lattimore, the details of which are outlined below:

Name:	Mangalam Drugs & Organics Ltd
Address:	Plot No 187, II[nd] Phase, G.I.D.C., Vapi 396195 Tal. Pardi, Valsad, Gujarat, Inde
Date:	17 to 20 November 2014

Thank you for your letter dated 22 June 2015 and the corrective actions to the deficiencies listed in the inspection report. The actions taken or proposed to be taken in relation to the deficiencies have been reviewed by the inspectors.

In general, they are considered acceptable and their satisfactory implementation will be verified during future inspections.

On the basis of the findings of the inspection and these subsequent response the inspectors have recommended that the Active Pharmaceutical Ingredients (API):

1. APIMF 100 Lumefantrine
2. APIMF 101 APIMF 138 Artemether
3. APIMF 134 Amodiaquine Hydrochloride
4. APIMF 135 Artesunate
5. APIMF 149 Piperaquine Phosphate
6. APIMF 151 Dihydroartemisinin
7. APIMF 204 Tenofovir Disoproxil Fumarate

.../...

are considered to be manufactured in compliance with World Health Organization (WHO) Good Manufacturing Practices (GMPs) for APIs published by WHO for manufacture and packaging of APIs by chemical synthesis.

Furthermore, the inspection findings and your response allows us to recommend to the Prequalification Assessment Group that the site inspected may be named/continue to be named as an API manufacturing site in dossiers assessed within the WHO Prequalification Team (PQT).

Please note that the acceptance of compliance with WHO-GMP does not necessarily mean that the API product has been prequalified by WHO. You will be notified of the outcome of the assessment of your prequalification application in due course.

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,

Mr Deus Mubangizi
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies