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In reply please  
refer to: P5-447-3/ VS/TK/1  
Your reference:

Dr Kamal Vashi  
Director, Technical & Operations  
Mangalam Drugs & Organics Ltd  
Plot No 1203 (Unit II), 3<sup>rd</sup> Phase  
G.I.D.C, Vapi – 396195  
Valsad District, Gujarat  
Inde

23 May 2017

Dear Dr Vashi,

**WHO Prequalification Team – Inspection Services  
Closing of Inspection**

I refer to the inspection that was performed by Mr Vimal Sachdeva and Mrs Luisa Stoppa the details of which are outlined below:

Site name: Mangalam Drugs & Organics Ltd  
Unit: II  
Block: Production blocks (2A, 2B and 2C)  
Address: Plot No 1203 (Unit II), 3<sup>rd</sup> Phase, G.I.D.C, Vapi – 396195  
Valsad District, Gujarat, India

Date: 13 - 16 February 2017

Thank you for your email dated 22 April 2017 and the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by the Prequalification Inspection Group.

The Prequalification Inspection Group has recommended that the APIs:

- Lumefantrine (APIMF100)
- Tenofovir Disoproxil Fumarate (APIMF204)
- Artemether (APIMF138)
- Emtricitabine (WHOAPI134)
- Efavirenz (WHOAPI318)

can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (APIs) published by the World Health Organization (WHO), for the scope of activities listed below:

- Manufacture and packaging of Active Pharmaceutical Ingredients by chemical synthesis (Lumefantrine: APIMF100, Tenofovir Disoproxil Fumarate: APIMF204, Artemether: APIMF138, Emtricitabine: WHOAPI134 and Efavirenz: WHOAPI318).

.../...

Furthermore, the inspection findings and your response allow us to recommend to the Prequalification Assessment Group that the site inspected to be named as API manufacturing site in dossiers assessed within the WHO Prequalification Team.

Please note that 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](mailto:prequalinspection@who.int) should you require any further information regarding the closing of this inspection.

Yours sincerely,



Ms Josée Hansen  
Acting Group Lead, Inspection Services  
Prequalification Team  
Regulation of Medicines and other Health Technologies