World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 36 15
Fax direct: +41 22 791 47 30
E-mail : prequalinspection@who.int

In reply please refer to: P5-447-3/ VS/TK/1/2
Your reference:

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

25 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), 3rd 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 (WHOAPI314)
- 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: WHOAPI314 and Efavirenz: WHOAPI318).

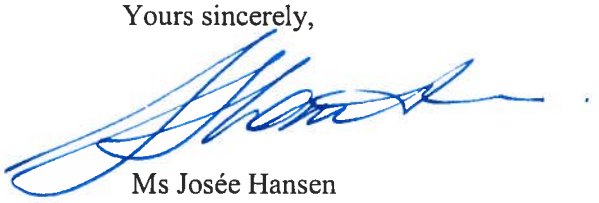
.../...

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** 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