World Health Organization

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In reply please refer to: P5-447-3/DC/SC/1

Your reference:

Dr Kamal Vashi
Mangalam Drugs and Organics Ltd
Unit-2
G.I.D.C, 3rd Phase, Plot no. 1203
Vapi, Valsad, Gujarat, 396 195
Inde

14 April 2023

Dear Dr Vashi,

WHO Prequalification Unit – Inspection Services
Closing of Inspection: Mangalam Drugs and Organics Ltd Unit-2

I refer to the inspection that was performed by Dr Catsoulacos and Dr Dimas the details of which are outlined below:

Name:	Mangalam Drugs and Organics Ltd, Unit 2
Address:	G.I.D.C, 3rd Phase, Plot no. 1203, Vapi, Valsad, Gujarat, 396 195, India
Date:	25-28 June 2022

Thank you for your correspondence dated 5 August and 16 December 2022 and the corrective actions to the observations listed in the inspection report. The actions taken, or proposed to be taken, to correct 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 responses the inspectors have recommended that the APIs:

- APIMF 100 Lumefantrine
- APIMF 138 Artemether
- APIMF 134 Amodiaquine Hydrochloride
- APIMF 135 Artesunate
- APIMF 149 Piperaquine Phosphate
- APIMF 204 Tenofovir Disoproxil Fumarate
- APIMF 314 Emtricitabine
- APIMF 318 Efavirenz
- APIMF 356 Sulfadoxine
- APIMF 360 Pyrimethamine
- APIMF 386 Dolutegravir
- APIMF 405 Pyronaridine Tetraphosphate []
- Primaquine Phosphate (to be submitted to WHO PQ)

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

- Manufacture and packaging of APIs.
- Analytical and microbiological testing of raw materials and associated intermediates and API.

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

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,

Mr Deus Mubangizi
Unit Head
Prequalification Unit

Acting Team Lead, Inspection Services
Regulation and Prequalification Department
Access to Medicines and Health Products Division