



**World Health
Organization**

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

Your reference:

Mr Rajesh Kshirsagar
Chief Technical Officer
Micro Labs (Hosur)
92 Sipcot Industrial Complex
Hosur, 635 126
Tamil Nadu
Inde

2nd October 2019

Dear Mr Kshirsagar,

**WHO Prequalification Team – Inspection Services
Closing of Inspection:
Micro Labs (Hosur) Unit 3, India**

I refer to the inspection that was performed by Ms. Xingyu Chen and Mr. Ian Thrussell in conjunction with the inspectors from the National Medicines Regulatory Authority of the UK, the MHRA the details of which are outlined below:

Site name: Micro Labs (Hosur)
Unit: 3
Address: 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India
Date: 8 to 10 April 2019

The said inspection focused on the review of the submitted CAPA by Micro Labs (Hosur) unit 3 to the previous MHRA inspection which identified critical deficiencies related to controls over cross contamination and the use of health-based exposure limits in cleaning validation in shared facilities as well as assessing the possible impact of these deficiencies and proposed CAPA on the WHO prequalified products manufactured at Micro labs (Hosur) Unit 3.

I wish to thank you for your email correspondence dated 31 August 2019 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.

In general, they are considered to be acceptable. Therefore, considering these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the site can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) published by the World Health Organization (WHO).

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,

Dr Joey Gouws
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies

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