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

Your reference:

Dr Mohammad Harun-Or-Rashid
Head of QA, Assistant Chief and Govt. Analyst
IPH Campus
Directorate General of Drug Administration
National Control Laboratory (NCL)
Mohakhali
Dhaka, 1212
Bangladesh

9 March 2020

Dear Dr Harun-Or-Rashid,

WHO Prequalification Unit – Inspection Services
Closing of Inspection: National Control Laboratory

I refer to the inspection that was performed by the WHO Prequalification Inspection Team, Dr Elham Kossary and Mr Pascal Baillet the details of which are outlined below:

Laboratory name:	National Control Laboratory (NCL)
Address:	IPH Campus, Directorate General Drug Administration (DGDA), Mohakhali, Dhaka-1212, Bangladesh
Date:	23-26 September 2019

Thank you for your emails dated 28 January and 20 February 2020 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 Team.

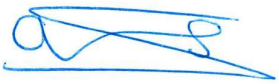
In general, the CAPA plan that you have proposed in your response appears to be satisfactory and the Prequalification Inspection Team has recommended that the Laboratory can be considered to be compliant with the standards of WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization (WHO), for the scope of activities listed below:

The area of expertise inspected and considered compliant with the standards of WHO GPPQCL		
Type of analysis	***Finished products***	***Active pharmaceutical ingredients***
Physical/Chemical analysis	pH, Loss on Drying, Water Content, Disintegration Tests, Dissolution, Uniformity of Dosage Units	pH, Loss on Drying, Water Content, Disintegration Tests, Dissolution, Uniformity of Dosage Units
Identification	HPLC, TLC, Spectrophotometry (UV-Vis and FTIR)	HPLC, TLC, Spectrophotometry (UV-Vis and FTIR)
Assay, impurities and related substances	DHPLC, TLC, Spectrophotometry (UV-Vis and FTIR) and Titration	HPLC, TLC, Spectrophotometry (UV-Vis and FTIR) and Titration
Microbiological tests	Sterility Test, Microbiological Assay, Microbial Limit Test, Identification of E. Coli, P. Auroginosa, S. Typhi	Sterility Test, Microbiological Assay, Microbial Limit Test, Identification of E. Coli, P. Auroginosa, S. Typhi
Bacterial Endotoxin testing (BET)	Endotoxin Test	Endotoxin Test

However, since a significant number of major deficiencies were made during this inspection, the Prequalification Inspection Team would like to remind the laboratory that the improvements outlined in the corrective measures must robustly be implemented and the laboratory's improved level of WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) compliance sustained. Kindly be advised that the Prequalification Inspection Team will therefore verify the effective implementation of the improvements by performing the next inspection of your operations at an earlier date than normal.

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
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