World Health Organization

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

Your reference:

Dr Roman Markin
Central Laboratory for Quality Control of Medicines and Medical Products (CLQCM)
10 G Kudryavska Street
Kyiv, 04053
Ukraine

14 September 2020

Dear Dr Markin,

WHO Prequalification Unit – Inspection Services
Closing of Inspection:
Central Laboratory for Quality Control of Medicines and Medical Products (CLQCM)

I refer to the inspection that was performed by the WHO Prequalification Unit and specifically Dr Elham Kossary and Dr Tibor Kosa the details of which are outlined below:

Laboratory name:	Central Laboratory for Quality Control of Medicines and Medical Products
Address:	10 G Kudryavska Street, Kyiv 04053, Ukraine
Date:	17 – 20 February 2020

Thank you for your email communication dated 8 April, 15 May, 3 July & 20 August 2020, together with the supporting documentation and 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 Services.

In general, they are acceptable. In addition, it is noted that the laboratory has been prequalified since 16 April 2010. Therefore, considering these responses, as well as the findings of the inspection, the Prequalification Inspection Team re-confirms compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization and that the Laboratory is retained in the WHO list of prequalified quality control laboratories, for the scope of activities listed below:

…/…

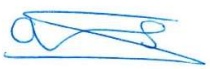
Area of expertise inspected and considered compliant with the standards of WHO GPPQCL		
Type of analysis	***Finished products***	***Active pharmaceutical ingredients***
Physical/Chemical analysis	Appearance, clarity and degree of opalescence of liquids, degree of coloration of liquids, potentiometric determination of pH, relative density, refractive index, optical rotation, viscosity (falling ball method), melting point, volumetric and potentiometric titration, AAS, FTIR, UV-vis, TLC, GC, HPLC, loss on drying, conductivity, determination of nitrogen by sulphuric acid, water content: semi-micro determination, Disintegration (tablets, capsules, suppositories, pessaries), Dissolution , Friability of uncoated tablets), test for extractable volume of parenteral solution, particulate contamination: visible and visible particles, Uniformity of Dosage Units	Appearance, potentiometric determination of pH, relative density, refractive index, optical rotation, viscosity (falling ball method), melting point, volumetric and potentiometric titration, AAS, FTIR, UV-vis, TLC, GC, HPLC, loss on drying, conductivity, determination of nitrogen by sulphuric acid, water content: semi-micro, residual solvents, sulphated ash, limit tests.
Identification	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests	HPLC (UV-Vis, RI detection), GC (FID), TLC, UV-VIS spectrophotometry, FTIR, basic tests
Assay, impurities and related substances	HPLC (UV-Vis, RI), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations, optical rotation	HPLC (UV-Vis, RI), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, volumetric titrations, optical rotation
Microbiological tests	Sterility test, microbiological examination of non-sterile products: microbial enumeration tests and tests for specified micro-organisms, microbiological assay of antibiotics	Sterility test, microbiological examination of non-sterile products: microbial enumeration tests and tests for specified micro-organisms, microbiological assay of antibiotics
Bacterial endotoxin testing (BET)	Bacterial endotoxins test, (LAL, gel- clot method)	Bacterial endotoxins test, (LAL, gel- clot method)

However due to the concerns related to the qualification of computerized systems and the respective data integrity and CAPA plan, please be advised that Prequalification Inspection Team will verify the effective implementation of the improvements by performing the next inspection of the operations of CLQCM at an earlier date than normal.

Kindly be advised that the areas of expertise inspected and considered prequalified are specified in the list, published on the WHO website - Laboratory at *www.who.int/prequal.*

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