World Health Organization

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

Your reference:

Dr Oleksandr Burmaka
Laboratory of Pharmaceutical Analysis
State Expert Centre
Ministry of Health of Ukraine (LPA)
14, Antona Tsedika Street
Kiev, 03680
Ukraine

24 July 2020

Dear Dr Burmaka,

WHO Prequalification Unit – Inspection Services
Closing of Inspection: Laboratory of Pharmaceutical Analysis
State Expert Centre, Ministry of Health of Ukraine (LPA)

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

Laboratory name:	Laboratory of Pharmaceutical Analysis, State Expert Centre, Ministry of Health of Ukraine (LPA)
Address:	14, Antona Tsedika Street, Kiev, 03680, Ukraine
Date:	11-14 February 2020

Thank you for your email communication dated 9 April & 16 July 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, 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 confirms the compliance of the laboratory with the current Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) as published by the World Health Organization and the retainment of the Laboratory 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	pH, density, refractometry, viscosity, conductivity, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, nitrogen determination, heavy metals, loss on drying, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability, tablet hardness, dimensions	pH, density, refractometry, viscosity, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl value, saponification value, acid neutralizing capacity, nitrogen determination, heavy metals, loss on drying, limit tests

…/…

Area of expertise inspected and considered compliant with the standards of WHO GPPQCL		
Type of analysis	***Finished products***	***Active pharmaceutical ingredients***
Identification	HPLC (UV-Vis, DAD, fluorescence, RI conductive detection), GC, TLC, UV-Vis and basic tests	HPLC (UV-Vis, DAD, fluorescence, RI conductive detection), GC, TLC, UV-Vis and basic tests
Assay, impurities and related substances	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, UV-Vis spectrophotometry, AAS, volumetric titrations	HPLC (UV-Vis, DAD, fluorescence, RI detection), GC, UV-Vis spectrophotometry, AAS, volumetric titrations
Microbiological tests	Sterility test, microbial limit tests, microbial assay of antibiotics	Sterility test, microbial limit tests, microbial assay of antibiotics
Bacterial Endotoxin Testing (BET)	Bacterial endotoxins test (LAL)	Bacterial endotoxins test (LAL)

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