



World Health Organization

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

Your reference:

Dr Natalia Ostanina
 Head of the Laboratory
 The State Scientific Research Laboratory for Quality Control of Medicines
 The Testing Laboratory
 50 Popudrenka str.
 Kyiv, 02094
 Ukraine

20 January 2020

Dear Dr Ostanina,

WHO Prequalification Team – Inspection Services
Closing of Inspection- The State Scientific Research Laboratory for Quality Control of Medicines, The Testing Laboratory, Kyiv, Ukraine

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: The State Scientific Research Laboratory for Quality Control of Medicines, The Testing Laboratory
 Address: 50 Popudrenka str., Kyiv, 02094, Ukraine
 Date: 12-14 June 2019

Thank you for your emails dated 23 August, 3 September & 15 November 2019 respectively 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 WHO Prequalification Inspection Team.

In general, they are acceptable. The Testing laboratory, which included the Microbiology laboratory has been WHO prequalified since 22 January 2016. However, during the aforementioned inspection, it was agreed that the Microbiology laboratory be excluded from the scope of the inspection and the prequalification of microbiological testing is therefore not eligible for inclusion in the list of prequalified tests until a comprehensive re-design of the Microbiology Laboratory together with an inspection is performed.

Therefore, considering the inspection and the Laboratory response to the inspection report, the Prequalification Inspection Team re-confirms compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization. Please be advised that the Physico-Chemistry Laboratory is retained in the WHO list of prequalified quality control laboratories, 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	Clarity and degree of opalescence of liquids, degree of coloration of liquids, pH, density, osmolality, refractometry, optical rotation, viscosity, conductivity, water content, acid value, iodine value, peroxide	pH, density, refractometry, optical rotation, viscosity, osmolality, conductivity, melting point, water content, acid value, iodine value, peroxide value, ester value, hydroxyl

	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, particulate contamination (sub-visible/visible particles)	value, saponification value, unsaponifiable matter, nitrogen determination, heavy metals, loss on drying, limit tests
Identification	HPLC (DAD, RID, UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis Spectrophotometry, FTIR spectroscopy, basic tests	HPLC (DAD, RID, UV-Vis, FLD), GC (FID, ECD), TLC, UV-Vis Spectrophotometry, FTIR spectroscopy, basic tests
Assay, impurities and related substances	HPLC (DAD, RID, UV-Vis, FLD), GC (Au/HS (FID, ECD)), UV-Vis Spectrophotometry, FTIR spectroscopy, Water determination, basic tests	HPLC (DAD, RID, UV-Vis, FLD), GC (Au/HS (FID, ECD)), UV-Vis Spectrophotometry, FTIR spectroscopy, Water determination, basic tests
Microbiological tests	Not prequalified	Not prequalified

However, since a significant number of major deficiencies were made during this inspection, the Prequalification Inspection Team would remind the Laboratory that the improvements outlined in the corrective measures must robustly be implemented and the improved level of WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) compliance sustained. Kindly note that the Prequalification Inspection Team will therefore verify the effective implementation of the improvements by performing the next inspection of the Laboratory 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
Team Lead, Inspection Services
Regulation and Prequalification
Regulation of Medicines and other Health Technologies