World Health Organization

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

Your reference:

Mrs V Anuradha
QA-Head
Vimta Labs Ltd, Life Sciences Facility
MN Park (Formerly Alexandria Knowledge Park), Plot No 5, Genome Valley, Shamirpet Mandal, Hyderabad
Medchal-Malkajgiri District
Telangana, 500 101
Inde

31 July 2019

Dear Mrs Anuradha,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the inspection that was performed by Dr Elham Kossary and Mrs Joy van Oudtshoorn the details of which are outlined below:

Laboratory name:	Vimta Labs Ltd, Life Sciences Facility
Address:	MN Park (Formerly Alexandria Knowledge Park), Plot No 5, Genome Valley, Shamirpet Mandal, Hyderabad, Medchal- Malkajgiri District Telangana; 500 101, India
Date:	13 – 15 March 2019

Thank you for your emails dated 31 May 2019, together with the supplementary information sent on 19 July 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. The laboratory has been prequalified since 17 July 2008. Therefore, considering these responses, as well as the findings of the inspection, the Prequalification Inspection Group re-confirmed compliance WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization and the 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	pH, Color test, Polarimeter, Density, Loss on Drying, Water Content, Disintegration, Dissolution, Uniformity of dosage units (mass content), Friability, Tablet Hardness, Particulate matter test, melting point, XRD, DSC, FT Raman, TGA, PSA, AAS, Particulate count, Water activity, Osmolality, Viscosity	pH, Density, specific optical rotation, viscosity, Loss on drying, Melting Point, Water Content, Heavy metals, Sulphated ash, Acid insoluble ash, Acid value, Iodine value, Ester value, Acetyl value, Peroxide value, XRD, DSC, FT Raman, Particle Size Analyzer, AAS, TGA

.../...

Identification	HPLC (UV Vis), GC, (FID, ECD) GC/MS, TLC, UV-VIS Spectrophotometry, IR, AAS, XRD, DSC, FT Raman, LCMS, IC, SDSPAGE, Western blot, Iso-electric focusing, Intact mass, Charge variant analysis, Glycan profiling, Disulphide mapping, Bioassays	HPLC (UV Vis), GC (FID, ECD), TLC, UV-VIS Spectrophotometry, IR, FTIR, AAS, Chemical reaction, XRD, DSC, FT Raman, LCMS, IC, SDS-PAGE, Western blot, Isoelectric focusing, Intact mass, Charge variant analysis, Glycan profiling, Disulphide mapping, Bioassays
Assay, impurities and related substances	HPLC (PDA, Fluorescence, RI, light scattering detector), GC (FID, ECD), TLC, HPTLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC	HPLC (Fluorescence, PDA, RI, light scattering detector),), GC (FID, ECD), TLC,UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC
Content	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, DSC, RP-HPLC (PDA, RI and FLD), SECHPLC (GPC), ELISA	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, RP-HPLC (PDA, RI and FLD), SEC-HPLC (GPC), ELISA
Microbiological tests	Sterility test, Microbial Limit Test, Bacterial Endotoxin Test (gel clot), Microbial Assay, Anti-Microbial Effectiveness Testing	Microbial Assay, Microbial Limit Test, Bacterial Endotoxin Testing and Sterility
Stability studies	Storage and testing as per client's Protocol based on ICH Guidelines	Storage and testing as per client's protocol based on ICH Guidelines
Others	Growth Promotion Testing of Media, Disinfectant Efficacy Evaluation, Invitro Microbial Kill Rate Study	

The areas of expertise inspected and considered prequalified are specified in the list, which is published on the WHO web 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,

For:

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