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In reply please
refer to: P5-447-3/KR/MK/1
Your reference:

Ms S.V. Anuradha
Vimta Labs Ltd
Life Sciences Facility, M N Park (Formerly
Alexandria Knowledge Park), Plot No 5
Genome Valley, Shamirpet Mandal
Medchal-Malkajgiri District, Telangana
Hyderabad, 500 101
Inde

29 August 2023

Dear Ms Anuradha,

**WHO Prequalification Unit – Inspection Services
Inspection Report: Vimta Labs Ltd**

I refer to the inspection that was performed by the WHO Prequalification Inspection Team and specifically Ms Kim Richards and Dr Adriaan J. Van Zyl the details of which are outlined below:

Name: Vimta Labs Ltd
Address: Life Sciences Facility, M N Park (Formerly Alexandria Knowledge Park), Plot No 5 Genome Valley, Shamirpet Mandal Medchal-Malkajgiri District, Telangana Hyderabad, 500 1011, India
Date: 18-20 January 2023

Thank you for your email correspondence dated 24 August 2023 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 response has been considered acceptable. Therefore, considering your proposed CAPA plan, as well as the findings of the inspection, the WHO Prequalification Inspection Team recommended that the Laboratory can be considered to be compliant with the standards of the WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization (WHO), for the scope of activities listed below:

Areas 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, Zetasizer, GC MS.	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, Zetasizer, GC MS.
Identification	HPLC (UV Vis), GC (FID, ECD), TLC, UV-VIS Spectrophotometry, IR, AAS, XRD, DSC, FT Raman, PSA, Zetasizer, LCMS, IC, SDS-PAGE, Western blot, Isoelectric focusing, Intact mass, Charge	HPLC (UV Vis), GC (FID, ECD), TLC, UV-VIS Spectrophotometry, IR, FTIR, AAS, Chemical reaction, XRD, DSC, FT Raman, Zetasizer, LCMS, IC, SDS-PAGE, Western blot, Iso-electric focusing, Intact mass, Charge variant analysis, Glycan

Areas of expertise inspected and considered compliant with the standards of WHO GPPQCL		
<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
	variant analysis, Glycan profiling, Disulphide mapping, Bioassays, GC MS.	profiling, Disulphide mapping, Bioassays, GC MS.
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, GC MS.	HPLC (Fluorescence, PDA, RI, light scattering detector), GC (FID, ECD), TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC, GC MS.
Content	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, DSC, RP-HPLC (PDA, RI and FLD), SEC-HPLC (GPC), ELISA.	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICP-OES, GCMS, RPHPLC (PDA, RI and FLD), SEC-HPLC (GPC), ELISA.
Microbiology Analysis	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	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
Other	Growth Promotion Testing of Media, Disinfectant Efficacy Evaluation, Invitro Microbial Kill Rate Study	

Based on the said conclusion, the prequalification of the laboratory can be finalized. Kindly be advised that the next step is an agreement on the published information with the prequalification of the laboratory by WHO declared through a separate communication.

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,

pp.

Mr Deusdedit Mubangizi

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