World Health Organization

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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, SDSPAGE, Western blot, Iso-electric focusing, Intact mass, Charge variant analysis, Glycan |

| **Areas of expertise inspected and considered compliant with the standards of WHO GPPQCL** | | |
|---|---|---|
| ***Type of analysis*** | ***Finished products*** | ***Active pharmaceutical ingredients*** |
| | 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