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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	(mass content), Friability, Tablet Hardness, Particulate matter test, melting point, XRD, DSC, FT Raman, TGA, PSA,	viscosity, Loss on drying, Melting Point, Water Content, Heavy metals, Sulphated ash, Acid insoluble ash, Acid value, Iodine value, Ester value, Acety	

.../...

Assay, impurities and related scattering detector), GC (FID, ECD), substances TLC, HPTLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC Content FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, RP-HPLC (PDA, RI and FLD), SECHPLC (GPC), ELISA Microbiological Sterility test, Microbial Limit Test, tests Bacterial Endotoxin Test (gel clot), Microbial Assay, Anti-Microbial Effectiveness Testing Stability studies Others MIPLC (PDA, Fluorescence, PDA, RI, light scattering detector),), GC (FID, ECD) TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC TLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, Potentiom	<u>- </u>		
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Transfer Terms of Trading Distriction Entitle July Evaluation, Mivilio		Protocol based on ICH Guidelines	protocol based on ICH Guidelines
Microbial Kill Rate Study	Others		
		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

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Regulation of Medicines and other Health Technologies