World Health Organization

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

Your reference:

Mr K Sreedhar
Director – Analytical
Sipra Labs Limited
7-2-1813/5/A, Adjacent to post office
Industrial Estate, Sanathnagar
Hyderabad, 500018, Telangana
Inde

15 October 2019

Dear Mr K Sreedhar,

WHO Prequalification Team – Inspection Services
Closing of Inspection: Sipra Labs Limited

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:	Sipra Labs Limited
Address:	7-2-1813/5/A, Adjacent to post office, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana; India
Date:	8-10 March 2019

Thank you for your email dated 30 May 2019, together with the supplementary information sent on 23 July & 30 September 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. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group confirmed compliance of the site, **Sipra Labs Limited** with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL), as published by the World Health Organization. Kindly be advised that the Laboratory, **Sipra Labs Limited** is placed in the WHO list of prequalified quality control laboratories, with the areas of expertise inspected and considered prequalified as per the scope of activities listed below:

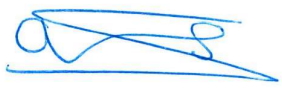
The area of expertise inspected and considered compliant with the standards of WHO GPPQCL		
Type of analysis	*Finished products*	*Active pharmaceutical ingredients*
Physical/Chemical analysis	pH, Solubility, Density, Viscosity, Conductivity, Water content (Karl Fischer), (Micro, Semi-Micro determination), Loss on drying, Refractive Index, Specific optical rotation, Limit tests, Saponification value, Iodine value, Acid value, Ester value, Peroxide value, Melting Point, Specific gravity, Residual solvents, Dimensions, Uniformity of dosage units (Mass, Content), Dissolution, Disintegration (Tablets, Capsules), Hardness, Friability, Nitrogen determination, Heavy metals, Osmolality,	pH, Solubility, Water content, Melting point, Refractometry, Loss on drying, Limit tests, X-ray diffractometry, Thermal analysis (DSC, TGA), Optical rotation, Conductivity, Density, Specific gravity, Viscosity, Osmolarity, Heavy metals, Limit tests, Sulphated ash, Acid insoluble ash, Residual solvents, Nitrogen value, Osmolality, Particulate contamination, Appearance, Clarity and Degree of opalescence of liquids, Degree of coloration of liquids, Test for extractable volume of parenteral solution, Distilling range, Acid value, Ester value, Hydroxyl value, Iodine

	Particulate matter (Visible & Sub visible), Clarity and Degree of opalescence of liquids, Degree of coloration of liquids. Total organic carbon, Appearance, Test for extractable volume of parenteral solution, Particle size, Re-dispersibility/ Reconstitution time, AA.	value, Peroxide value, Saponification value, Total organic carbon, Residue on ignition, Particle size, Freezing point, Drop point, Boiling point, Unsaponifiable matter, Organic volatile impurities, ICP-MS, AA.
Identification	IR, HPLC (UV-Visible, PDA, RI detection, Electro chemical), TLC, AA Spectrophotometry and basic tests, GC (FID, TCD), UV-Vis Spectrophotometry, Chemical reaction, LC/MS, Capillary Electrophoresis, CHNS Analysis, Residual solvents, Determination of degradation products, LC/MS/MS, Optical rotation.	IR, HPLC (UV-Visible, PDA, RI detection, Electro chemical), TLC, AA Spectrophotometry and basic tests, GC (FID, TCD), UV-Vis Spectrophotometry, Chemical reaction, FT-IR, GC/MS, LC/MS, CHNS Analysis, Residual Solvents, Determination of degradation products, LC/MS/MS, Optical rotation.
Assay, impurities and related substances	HPLC (UV-VIS, PDA, RI detection), GC, UV, AA and FTIR spectrophotometry and volumetric titrations, Determination of related substances and impurities by comparison with a reference standard, Polarimetry, Determination of degradation products, Gravimetric analysis, Residual Solvents, Potentiometry, Total organic carbon, LC/MS, Coulometry, ICP-MS, GC/MS, TLC (Semi-Quantitative), Optical rotation, Potentiometric titration, Electrophoresis, Capillary electrophoresis, Nitrogen determination, Ethylene oxide residual analysis, Water determination, Amperometry.	HPLC (UV-VIS, RI detection), GC, UV, AA and FTIR spectrophotometry and Volumetric titrations, Determination of related substances and impurities by comparison with a reference standard, Polarimetry, Determination of degradation products, Residual solvents, Gravimetric analysis, Potentiometry, Total organic carbon, LC/MS, Coulometry, ICP-MS, GC/MS, TLC (Semi-Quantitative), Optical rotation, Potentiometric titration, Electrophoresis, Capillary electrophoresis, Nitrogen determination, Ethylene oxide residual analysis, Oxygen flask combustion, Composition of fatty acids, Water determination, ICP-MS, Thermal analysis (DSC).
Microbiological tests	Sterility test, Microbial purity, Bacterial endotoxins test (LAL), Microbial assay of antibiotics, Microbial limit tests, Disinfectant efficacy of preservatives, Test for pyrogens, Anti-microbial effectiveness, Microbiological examination of non-sterile products, Identification of microorganisms.	Microbial purity, Microbial assay, Sterility test, Microbial limit tests, Test for pyrogens, Bacterial endotoxins test (LAL), Microbial assay of antibiotics, Preservative efficacy test, Anti-microbial effectiveness, Microbiological examination of non-sterile products, Identification of microorganisms.
Stability studies	ICH Conditions	ICH Conditions
Bacterial Endotoxin Testing (BET)	Detection and quantification of endotoxins from gram negative bacteria, Determination of maximum valid dilution.	Detection and quantification of endotoxins from gram negative bacteria, Determination of maximum valid dilution.

Kindly note that the information will be published on the WHO web site 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,



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