MEDOCHEMIE GROUP	**QUALITY AUDIT COMPLETION REPORT** **CORPORATE QUALITY ASSURANCE**	Report No.: REP00297

Date	06th October 2023
Audit report date	8th August 2023
Audit date	17th July 2023
Supplier/contractor name	**Shilpa Pharma LifeSciences Ltd (formerly Shilpa Medicare Ltd, Unit - 2).**
Supplier/contractor site address	Plot. No. 33, 33A and 40 to 47, Raichur Industrial growth centre, Chicksugur cross, Wadloor Road, Raichur District, 584 134 Karnataka, India.
Lead auditor	Jaiganesh Venkatesan, PhD – Group Quality Compliance Manager
Auditor(s)	Bhumika Thaker – Asst. Manager Group Quality Compliance.
Audit purpose	A programmed Onsite audit by Medochemie Ltd using Eudralex volume 4, Part II & ICH Q7: Manufacturing, packaging and testing site for the below material – • Tranexamic acid.
References	- EudraLex, Volume 4, Part II: Basic Requirements for Active Substances used as Starting Materials requirements. - ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

Evaluation of corrective action report:

The Initial corrective action report with supporting data is received dated on 07/09/2023 and reviewed for the adequacy of proposed correctives measures. All the proposed corrective actions are adequate and found to be satisfactory. Final CAPA report is received dated on 06/10/2023 and all the actions were implemented and closed.

Effective implementation of the proposed actions will be evaluated during the next audit / visit.

Attachment	Audit response and supporting data as annexures, attached to the report.

Audit conclusion:

It was concluded that the manufacturing and quality control systems in place are satisfactory for the manufacture, packaging and testing of the listed material and that the facility operates in accordance with the requirements of ICH Q7 and "EudraLex, Volume IV, Part II: Basic Requirements for Active Substances used as Starting Materials."

Facility is approved as a manufacturer of the above listed material.

A re-audit of the manufacturing facility in three years is recommended.

Prepared by Name/signature/date	 06/10/2023 Jaiganesh Venkatesan - PhD, Group Quality Compliance Manager.