

भारत सरकार/ Government of India
केंद्रीय औषध मानक नियंत्रण संगठन/ Central Drugs Standard Control Organization
आंचलिककार्यालय, सी. डी.एस. सी. ओ. भवन, हैदराबाद / Zonal Office, CDSCO BHAVAN,
Hyderabad,

स्वास्थ्य एवं परिवार कल्याण मंत्रालय/ Ministry of Health & Family Welfare,
स्वास्थ्य सेवा महानिदेशालय/ Directorate General of Health Services,
एस.आर. नगर, हैदराबाद- ५०००३८/ S.R. Nagar, Hyderabad -500038.
Certified for IMS (ISO-9001:2015, ISO-14001:2015, ISO 45001:2018)

File No.: 6-2(1)/SKK/NSQ-01/HZ/2025-26/ 2033

Date: 02.02.2026

To

Dr. Vemula Savya, Store in-charge
ESI Medical College and Hospital Medical Store
Sanath Nagar,
Hyderabad, Telangana-500038.

Ph: 9949863488

Email id: ms-nacharam.ts@esic.nic.in

Sub: Drugs and Cosmetics Act, 1940 and Rules made there under- Sample drawn for test/ analysis: - Form-13 forwarding for **Sample No. LS/SKK/HZ/2025-11/008** named as **Tranexamic Acid injection I.P. (TRAXAGE) Batch no: TG-156 , Mfg. Date: Aug-2025, Exp Date: July 2027,** Manufactured by: Marc Laboratories Ltd. Unit-III, Plot No. 107 & 112, H.P.S.I.D.C., Baddi, Distt. Solan (H.P.) declared as **Not of Standard Quality by Govt. Analyst, CDTL, Hyderabad - Regarding.**

Ref:

1. Form 17 dated 24.11.2025 for Sample No **LS/SKK/HZ/2025-11/008**.
2. Form-13 test report No: **HYD/LS/2025-26/1201** dated 23.01.2026 issued by Government Analyst, CDTL, Hyderabad .

Sir,

It is to inform that, the Drug Sample "" as **Tranexamic Acid injection I.P. (TRAXAGE) Batch no: TG-156 , Mfg. Date: Aug-2025, Exp Date: July 2027.**" was drawn under Section 23 of the Drugs & Cosmetics Act, 1940 on 24.11.2025 from your premises at M/s ESI Medical College and Hospital Medical Store Sanath nagar, Hyderabad Telangana -500038 and sent to the Government Analyst, Central Drugs Testing Laboratory, Mumbai for test/analysis under Form-13 vide Serial No. of Memorandum: **6-2(1)HZ/2025-2026/1393** dated **28.11.2025..**

The said sample was declared as **Not of Standard Quality** by the Government Analyst, Central Drugs Testing Laboratory, Hyderabad vide test report No. **HYD/LS/2025-26/1201** dated 23.01.2026 for the reasons that the sample does not conform to I.P.-2022 specification **with respect to the test for Bacterial Endotoxins Only.** As required under Section 25(2) of Drugs & Cosmetics Act 1940, please find enclosed one set of above-mentioned Test Report. **(Original copy enclosed.)**

In this regard, **you are asked to stop the sale / distribution** of subject drug as per Section 18(a)(i) of Drugs and Cosmetics Act 1940 and **also to disclose the following required information** under Section 18A (read with Section 24) and relevant documents under section 18(B) of Drugs and Cosmetics Act 1940 and Rules:

1. Name, address and other particulars like contact number/official e-mail id of the firm/person from whom the said sample/drug was obtained/ procured along with the relevant documents (Copy of Indent or/and Purchase invoice(s) duly attested, Copy of certificate of Analysis and etc.).
2. The total quantity of the subject sample/drug procured, distributed, used and stocks available with you.
3. Details regarding date of receipt of the subject sample/drug at your premises, storage condition maintained during storage of subject drug at your premises along with the relevant documents, if any.

Further, you are required not to use subject cited Not of Standard Quality drug and intimate the same to this office.

You are requested to acknowledge receipt of this letter and forward the **required details in a covering letter duly signed and stamped by the authorized person, indicating the name and designation of the signatory.**

This is to be treated as most urgent and you are requested to reply to this office within 07 days of receipt of this letter by Fax/ E-mail/ Post.

Yours Sincerely

S. Kalpana Kumari 02/02/2026

S.Kalpana Kumari
Drugs Inspector
CDSCO, Hyderabad.