Central Drugs Testing Laboratory
CDSCO Bhavan, S.R. Nagar, Hyderabad-500038
Phone No.040-23811327
Email: cdtlhyd@cdsco.nic.in

FORM 13
(See rule 46)
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. **Name of Inspector from whom received** : Mr. Salem Kalpana Kumari ,Drugs Inspector
Mr. Salem Kalpana Kumari
Hyderabad Zone CDSCO, Zonal office, Hyderabad ,
CDSCO BHAVAN, Beside T.B. & Demonstration
Centre, S.R. Nagar, Hyderabad - 500038, AP (India) -

2. **Serial No. and date of Inspector's memorandum** : 6-2(1)HZ/2025/1393 , 28-NOV-2025

3. **Number of Sample** : LS/SKK/HZ/2025-11/008

4. **Date of receipt** : 28-NOV-2025

5. **Names of drugs purporting to be contained in the sample** : Tranexamic Acid Injection I.P, (TRAXAGE)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/HYD/2025-26/1036	HYD/LS/2025-26/1201	TG-156	Aug-2025 Jul-2027	NA	Marc Laboratories Ltd. Unit-III, Plot No. 107 & 112, H.P.S.I.D.C., Baddi, Distt. Solan (H. P.)

6. **Condition of seals on** [the packet or on portion of sample or container] : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. **Result of test or analysis with protocols or test or analysis applied** : **Please see below**

Date of Testing : From 19-Dec-2025 To 05-Jan-2026

COMPOSITION : Each ml contains: Tranexamic Acid I.P 100mg Water for Injection I.P q.s.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear, colourless, sterile solution, packed in sealed transparent glass ampoules arranged in plastic tray, enclosed in paper carton box.	
2	Identification	Positive for Tranaxemic Acid	
3	pH	7.37	6.5 to 8
4	Bacterial Endotoxins	Does not complies	NMT 0.5 EU/mg of Tranexamic Acid
5	Sterility	Complies	

6	Particulate Matter (Visual Inspection)	Complies	
7	Extractable Volume	5.01 ml	NLT Nominal Volume (5.0)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Tranexamic Acid	94.602 mg	100 mg	94.602	90 to 110 %	I.P.2022

In the opinion of the undersigned the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

THE SAMPLE RECEIVED DOES NOT CONFORM TO I.P. 2022 SPECIFICATION WITH RESPECT TO THE TEST FOR BACTERIAL ENDOTOXINS ONLY.

Note: Related Substances performed without placebo. Requested placebo is not received from the Manufacturer. While performing related substances test observed extra unknown peaks in test solution, Hence we are unable to conclude that test results for related substances Standard Quality or Not of Standard Quality.

CDTLH REPORT NO.: CDTLH/1534/F-1115/2025-26

Date: 23-JAN-2026

CENTRAL DRUGS TESTING LABORATORY * GOVERNMENT OF INDIA * Hyderabad, Telangana *

GOVERNMENT ANALYST

के. नितिन कुमार / K. NITIN KUMAR
सरकारी विश्लेषक / Government Analyst
केंद्रीय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory
केंद्रीय औषधि मानक नियंत्रण संगठन
Central Drugs Standard Control Organization
स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
भारत सरकार / Government of India
एस.आर.नगर, हैदराबाद-५०००३८/S.R. Nagar, Hyderabad 500 038.

Report in the red colored paper indicates the sample is not of standard quality.

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