



कर्मचारी राज्य बीमा निगम
(श्रम एवं रोजगार मंत्रालय, भारत सरकार)
EMPLOYEES' STATE INSURANCE CORPORATION
(Ministry of Labour & Employment, Govt. of India)



मुख्यालय/HEADQUARTERS
पंचदीप भवन, सी.आई.जी. मार्ग, नई दिल्ली -110 002
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in ☎011-23604773, ☒dmc-rc@esic.nic.in

File No.: U-25/12/NSQ/2021-MedV (E-1119) / *sa* Dated:-23-02-2026

To,

Director (Medical) Delhi / Director (Medical) Noida,
Dean, All ESIC PGIMSR's, Medical & Dental Colleges
Medical Superintendents – All ESIC Hospitals,
Directors, ESI Scheme, All States

NSQ-03/2026

Subject: **Declaration of Drug “Not of Standard Quality” on Testing – reg**

Sir/Madam

It is hereby informed that the Drug/item has been reported as “Not of Standard Quality”. The details of the drug reported NSQ is given below:

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
ESIC Medical College & Hospital Sanath Nagar, Hyderabad	Marc Laboratories Limited	Inj. Tranexamic Acid 500mg TRAXAGE	160 522	Batch No.- TG-156 DOM:08/25 DOE:07/27	The Government Analyst, Central Drug Testing Laboratory, Hyderabad HYD/LS/2025-26/1201 Dated - 23/01/2026	The sample received does not conform to IP 2022 Specification with respect to the test for Bacterial Endotoxins only (copy enclosed).

In context to above, it is directed to:

1. Medical Store to immediately withdrawn stock from respective sub-stores/Dispensaries/patient care area.
2. Medical Store to immediately write a letter to vendor for replacement of stock with another batch, within 15 days or to pick up stock and return the payment made other process of risk purchase to be initiated and recover cost of testing (if any) from the vendor.

3. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality".
4. Initiate action as per relevant clause of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.
5. Stop accepting said NSQ drug of this batch in future orders.
6. Maintain record of action taken at in respective user units.

This issues with the approval of Medical Commissioner (Procurement).

Enclosures: As above

Yours Sincerely,

Digitally signed by
Sanjiv Kochhar
Date: 24-02-2026
11:42:59

Dy. Medical Commissioner
(Rate Contract)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (Email: dci@nic.in).
2. Office of Deputy Drug Controller (I), Central Drug Standard Control Organization , North Zone, C.G.O. Building-I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad- 201 002 (U.P.) (Email: nzghaziabad@cdsco.nic.in)-
3. Office of Deputy Drug Controller (I), Central Drugs Standard Control Organisation Baddi, (Container Corporation of India Ltd. Complex) Village-Sheetalpur, Tehsil-Baddi, District- Solan, Himachal Pradesh-173205 (Email: chandigarh@cdsco.nic.in)
4. Marc Laboratories Limited, Avanbai Mansion, 3, Vidhan Sabha Marg, Lucknow 226001(UP) (Email: institution.marclabs@gmail.com, Amit.kishore@marclabs.in)
5. Marc Laboratories Limited, Plot No. 107 & 112, HPSIDC, Baddi, Distt. Solan Himachal Pradesh 173205.
6. Website Content Manager with request for uploading on ESIC website.
7. Guard file



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

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 Tranexamic 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

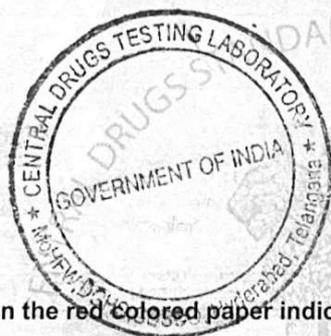
In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

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



Kirti
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 निदेशक जनरल / Directorate General of Health Services

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**

----- END OF REPORT -----



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: 9949663488

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

Sub: Drugs and Cosmetics Act, 1940 and Rules made there under- Sample drawn for test/ analysis: - Fom-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.



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

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 Tranexamic 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

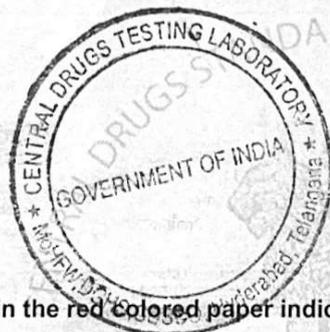
In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

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



Kirti
GOVERNMENT ANALYST

के. नितिन कुमार / K. NITIN KUMAR
सरकारी विश्लेषक / Government Analyst

केंद्रिय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory
केंद्रिय औषधि मानक नियंत्रण संगठन

Central Drugs Standard Control Organization
स्वास्थ्य सेवा विभाग, दिशानिर्देशक / Directorate General of Health Services

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**

----- END OF REPORT -----

