



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, ✉dm@esic.nic.in

U-25/12/NSQ_Drug_Declared_Supplied_By_PMBI/2025-Med.V (E-1228697) / Dated: 346

सेवा में,
**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/06/2025

विषय: Drugs declared "Not of Standard Quality" on Testing -Reg.

महोदय/महोदया

It is hereby informed that following Drug/item reported as "Not of Standard Quality", procured through Authorized Distributor Channel partner of PMBI, as detailed below:-

| NSQ Reported by | Name of the Authorized Distributor Partner | Name of the Manufacture | Description of item | Batch No. / Mfg Date/Exp. date | Name of the Laboratory/ Report No. & Date | Reason of NSQ |
|---|--|--|---|----------------------------------|--|--|
| ESIC Super Speciality Hospital, Sanathnagar-Hyderabad | M/s Mahaveer Drugs Plus | M/s Zee Laboratories Ltd, Behind 47, Industrial Area, Paonta Sahib-H.P.-173025 | Tranexamic Acid Injection IP 500 mg/5ml | Z24-185 Feb.-2024 Jan-2026 | CDL, Kolkata Report No: KOL/LS/2025-26/282 dated: 28.05.2025. | The sample does not conform to IP with respect to the test for "Related Substances" and "Assay of Tranexamic Acid" |

In context to above, it is directed to:

- Stop use of the reported batch of the above mentioned item immediately which has been reported as "Not of Standard Quality"(copy enclosed).
- Replacement of supplies or cost of the material is to be recovered from the Authorized Distribution Channel partner as per MoU.
- Maintained record of action taken at in respective user units.

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

भवदीय,

संलग्नक: उपरोक्तानुसार

Digitally signed by
Sanjiv Kochhar
Date: 23-06-2025

13:49:54
उप चिकित्सा आयुक्त (दर संविदा)

Contd. to pre-page:

Copy to:-

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (dci@nic.in).
2. CDSCO Bhavan, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad - 500038, Telangana,with the request to take appropriate action on NSQ reported for the above said batch (copy of test report enclosed) (E m a i l : d d c h y d e r a b a d @ g m a i l . c o m , cdscohyd@gmail.com, hyderabad@cdsco.nic.in).
3. State Drug Controller, Controlling cum Licensing Authority, Baddi, Himachal Pradesh-173205 (Email:sd4hp@gmail.com).
4. M/s Zee Laboratories,Behind 47, Industrial Area , Paonta Sahib -173025, H.P. (INDIA),Email:zeeltd@zeelab.co.in.
5. M/s Mahaveer Drug Plus-Karnataka (Authorized Distributor Channel partner of PMBI) (Email Id:mahaveerdrugsplus@gmail.com).
6. Chief Executive Officer (CEO),PMBI,B-500, B-Tower, 5th Floor, Nauroji Nagar, World Trade Center, New Delhi-110029.(Email Id: ceo.office@ janaushadhi.gov. in.).
7. Website Content Manager with request for uploading on ESIC website.
8. Guard file.

क रा बी निगम मुख्यालय
VOIP No. 10011026

From: "Medical Supdt, ESIC Sanath Nagar, Telangana" <ms-sanathnagar.ts@esic.nic.in>
To: "Medical CommissionerSouth Zone" <mc-southzone@esic.nic.in>, "Medical CommissionerProcurement" <mc-procurement@esic.nic.in>, "DMC RC" <dmc-rc@esic.nic.in>, "ms esic-list" <ms.esic-list@ismgr.gov.in>, "dean esic-list" <dean.esic-list@ismgr.gov.in>, dimstsgovt@gmail.com, superesi63@gmail.com
Cc: "Padmavathi Bandi" <dr.padmavathi.band@esic.nic.in>
Sent: Saturday, June 14, 2025 12:11:10 PM
Subject: Inj Tranexemic acid, 500mg , Batch no Z24-185 - NSQ

महोदय/महोदया
Sir/Madam,

संबंधित पत्र/दस्तावेज इस मेल के साथ संलग्न कर/ नीचे उल्लिखित ट्रेयल मेल आपके सादर सूचनार्थ एवं आवश्यक कार्रवाई हेतु अग्रेषित किया जा रहा है।

Please find herewith the attachment/trail mail for your kind information & necessary action.

सादर/Regards,

चिकित्सा अधीक्षक कक्ष/MS Cell,
अति विसिष्टता अस्पताल/SSH,
कर्मचारी राज्य बीमा निगम/ESIC,
हैदराबाद/HYDERABAD.

Respected sir ,

Please find the attachment of the CDSCO report stating **Inj TRANEXAMIC ACID 500 mg / 5 ml** procured , Batch No : Z24-185 , Exp date : 01/26 , through PMJAY , has reported as **NOT OF STANDARD QUALITY.**

as per E-file approval we have called back all the stock from all departments of ESIC SSH .

Yours faithfully,

Dr. Padmavathi Bandi
CMO , Medical stores I/c
ESIC Super Speciality Hospital
Santhnagar,Hyderabad



Not of standard Quality Report-1.PDF

2 MB


FORM 17
(See rules 56)

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN

To
Dr. Arun Merry Theresa, Incharge Medical Store
ESI Superspeciality Hospital
Sanath Nagar, Telangana
Ph No: 9885795105
Email Id: NA

I have this day taken from the premises of ESI Superspeciality Hospital situated at Sanath Nagar, Telangana samples of the drugs specified below for the purpose of test or analysis.

Date : 27-MAR-2025


 सतिंदर पाल सिंग / SATINDER PAL S
 औषधि निरीक्षक / Drugs Inspector
 सी.डी.एस.सी.ओ. अंचलिक कार्यालय / CDSCO Zone Office
 स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services
 एम.आर.नगर, हैदराबाद-५०००३८/S.R. Nagar, Hyderabad, 500 038.
Mr. Satinder Pal Singh
 (Inspector)

| S. No. | Sample No. | Details of Samples taken | Quantity & Unit |
|--------|-----------------------|--|-----------------------|
| 1 | LS/SPS/HZ/20 25/10 | Name Of Product : TRANEXAMIC ACID INJECTION IP 500 mg/5 ml Composition : Each ml is purported to contain Tranexamic Acid IP 100 mg Brand Name : NA Batch No : Z24-185 Mfg. Date : 02/2024 Exp. Date : 01/2026 Mfg. By : M/s Zee Laboratories Ltd., Behind 47, Industrial Area, Paonta sahib-173025. Mfg. Lic. No.: S-MB/10/68 Mkt. By. : Pharmaceutical & Medical Device Bureau of India (PBMI), 8th Floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 Imported By. : NA | 40 10X5ML Ampoules |
| 2 | LS/SPS/HZ/20 25/14 | Name Of Product : Paracetamol Paediatric Oral Suspension IP Composition : Each 5ml is purported to contains: Paracetamol IP 250 mg Brand Name : NA Batch No : GMK-240002 Mfg. Date : 02/2024 Exp. Date : 01/2026 Mfg. By : GMH Laboratories, Plot No. 3 & 4, Industrial Township Bhatoli Kalan, Baddi-173205, Dist. Solan (H.P) Mfg. Lic. No.: L/23/309/MNB Mkt. By. : GMH Laboratories, plot no. 3 & 4, Industrial Township Bhatoli Kalan, Baddi-173205, dist. Solan (H.P) Imported By. : NA | 16 60ml Bottle |
| 3 | LS/SPS/HZ/20 25/13 | Name Of Product : Disodium Hydrogen Citrate Syrup (1.53gm) Composition : Each 5 ml contains Disodium Hydrogen Citrate B.P 1.53gm Brand Name : NA Batch No : DG1LE002 Mfg. Date : 09/2024 Exp. Date : 08/2026 Mfg. By : M/s. Unicare India Ltd., Plot No. 46(B),/49B, Vill. Raipur, Bhagwanpur, Roorkee, Distt. Haridwar, Uttarakhand Mfg. Lic. No.: 30/UA/2006 Mkt. By. : Pharmaceutical & Medical Device Bureau of India (PBMI), 8th Floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 Imported By. : NA | 8 100ml bottle |

| | | | |
|---|-----------------------|---|----------------------|
| 4 | SPS/HZ/20 25/12 | Name Of Product : Midodrine Hydrochloride Tablets USP 2.5mg Composition : Each uncoated tablet contains midodrine hydrochloride USP 2.5mg Brand Name : NA Batch No : PWOF01 Mfg. Date : 07/2024 Exp. Date : 06/2026 Mfg. By : M/s. Pure and Cure Healthcare Pvt. Ltd. ...Plot No. 26A, 27-30, Sector-8A, I.I.E., SIDCUL, Ranipur, Haridwar-249 403, (Uttarakhand) Mfg. Lic. No.: 31/UA/2013 Mkt. By. : Pharmaceutical & Medical Device Bureau of India (PBMI),B-500, Tower-B, 5th floor, World Trade Centre, Naurojl Nagar, New Delhi-110029 Imported By. : NA | 200 10 tablets/strip |
| 5 | LS/SPS/HZ/20 25/11 | Name Of Product : Metoclopramide Hydrochloride Injection I.P 5mg/ml Composition : each ml contains metoclopramide hydrochloride I.P eq. to anhydrous metoclopramide hydrochloride 5.00mg Brand Name : NA Batch No : OMCI-001 Mfg. Date : 07/2024 Exp. Date : 06/2026 Mfg. By : Laborate Pharmaceuticals India Ltd.,#31, Rajban Road, Nariwala Paonta Sahib (H.P.) Mfg. Lic. No.: S-MB/10/66 Mkt. By. : Pharmaceutical & Medical Device Bureau of India (PBMI), 8th Floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 Imported By. : NA | 40 5X2ML Ampoules |

Date : 27-MAR-2025

Mr. Satinder Pal Singh
(Inspector)

END OF FORM

सतिंदर पाल सिंग / SATINDER PAL SINGH
 औषधि निरीक्षक / Drugs Inspector
 सी.डी.एस.सी.ओ. आंचनिक कार्यालय / CDSCO Zonal Office
 स्वास्थ्य सेवा प्रदानिदेशालय / Directorate General of Health Services
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय/Ministry of Health & Family Welfare
 प्लाट नगर, हैदराबाद-५००३८/S.R. Nagar, Hyderabad - 500 038.

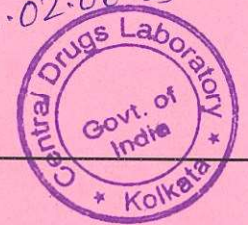
डॉ. एम. अरुण मेरी थेरेसा / Dr.M.Arun Mary Theresa
 मुख्य चिकित्सा अधिकारी / Chief Medical Officer
 ईएसआईसी सुपर स्पेशियलिटी अस्पताल
 ESIC Super Speciality Hospital
 सनतनगर - हैदराबाद Sanathnagar, Hyderabad-38

सत्यमेव जयते

Validity
unknown

Signed by Mr. Satinder Pal Singh
 Drug Inspector Thu Mar 27
 13:16:17 IST 2025





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. Satinder Pal Singh ,Drugs Inspector
Mr. Satinder Pal Singh
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/2024-25/2154 , 27-MAR-2025
3. Number of Sample : LS/SPS/HZ/2025/10
4. Date of receipt : 01-APR-2025
5. Names of drugs purporting to be contained in the sample : TRANEXAMIC ACID INJECTION IP 500 mg/5 ml

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. & Exp | Marketed By | Mfg. By |
|----------------------|--------------------|-----------|--------------------|---|--|
| LSD/KOL/2025-26/0179 | KOL/LS/2025-26/282 | Z24-185 | 02/2024 01/2026 | Pharmaceutical & Medical Device Bureau of India (PBMI), 8th Floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 | M/s Zee Laboratories Ltd., Behind 47,Industrial Area, Paonta sahib-173025. |

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 14-May-2025 To 27-May-2025

COMPOSITION : Each ml is purported to contain Tranexamic Acid IP 100 mg

Protocol Applied : IP 2022

| Sr No. | Test Name | Result | Limits |
|--------|----------------------|---|------------|
| 1 | Description | Clear, colorless liquid supplied in sealed transparent glass ampoule. | NA |
| 2 | Identification | Gives positive test for Tranexamic Acid. | NA |
| 3 | pH | Found: 6.80 | 6.5 to 8 . |
| 4 | Related Substances | Does not comply. | NA |
| 5 | Bacterial endotoxins | Complies. | NA |
| 6 | Sterility | Complies. | NA |

| | | | |
|---|--------------------|-----------|----|
| 7 | Particulate matter | Complies | NA |
| 8 | Extractable volume | Complies. | NA |


Assay

| Sr.No | Ingredient Name | Found | Claim | % of claim | Limits | Procedure / Method |
|-------|-----------------|------------|-----------|------------|---------------|--------------------|
| 1 | Tranexamic Acid | 85.6 mg/ml | 100 mg/ml | 85.6 | 90 % to 110 % | IP 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:-

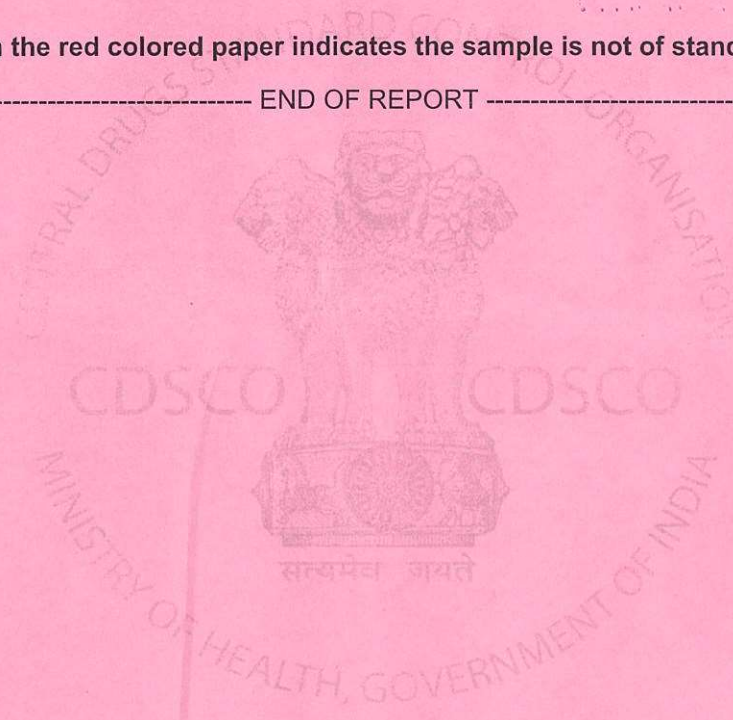
The sample does not conform to IP with respect to the test for "Related Substances" and "Assay of Tranexamic Acid"

Date: 28-MAY-2025


GOVERNMENT ANALYST
 Dr. Dinesh S. Harel
 Jr. Scientific Officer & Govt. Analyst.
 Central Drugs Laboratory
 Govt of India
 Fol - 16

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
आंचलिक कार्यालय. 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)

No. 6-2(1)/SPS/NSQ-01/HZ/2025-26/ 336

Dated: 13 Jun - 2025

To

Dr. Padmavathi Bandi, Incharge medical Store
ESIC Superspeciality Hospital
Sanath Nagar, Hyderabad, Telangana
Ph.No: 9246226849

Subject: Drugs and Cosmetics Act, 1940 and Rules made there under-Sample of drug drawn for test/ analysis:
- Form-13 forwarding for Sample No. LS/SPS/HZ/2025/10—named as “Tranexamic Acid Injection IP 500 mg/5ml bearing B. No: Z24-185, Mfg. Date: 02/2024 ,Exp. Date : 01/2026 manufactured by M/s Zee Laboratories Ltd, Behind 47, Industrial Area, Paonta Sahib-173025, marketed by M/s Pharmaceutical & medical Device Bureau of India (PMBI), 8th floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 is declared as “Not of Standard Quality” by Govt. Analyst, Central Drugs Laboratory, Kolkata – Regarding.

Ref: 1) Form 17 dated 27.03.2025 for Sample No. LS/SPS/HZ/2025/10 named as “Tranexamic Acid Injection IP 500 mg/5 ml bearing B. No: Z24-185, Mfg. Date: 02/2024 ,Exp. Date : 01/2026 manufactured by M/s Zee Laboratories Ltd, Behind 47, Industrial Area, Paonta Sahib-173025, marketed by M/s Pharmaceutical & medical Device Bureau of India (PMBI), 8th floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 drawn from the premises of M/s. ESIC Superspeciality Hospital, Sanath Nagar, Hyderabad, Telangana, India

2) Test report in Form-13 issued by Govt. Analyst, CDL, Kolkata vide report No. KOL/LS/2025-26/282 dated 02-JUN-2025.

Madam/Sir,

With reference to the subject cited above, it is to state that the Drug Sample “Tranexamic Acid Injection IP 500 mg/5ml bearing B. No: Z24-185, Mfg. Date: 02/2024 ,Exp. Date : 01/2026 manufactured by M/s Zee Laboratories Ltd, Behind 47, Industrial Area, Paonta Sahib-173025, marketed by M/s Pharmaceutical & medical Device Bureau of India (PMBI), 8th floor, Videocon tower, E-1, Jhandewalan Extension, New Delhi-110055 was drawn under Section 23 of the Drugs & Cosmetics Act, 1940 on 27-03-2025 from your premises M/s. ESIC Superspeciality Hospital, Sanath Nagar, Hyderabad, Telangana and sent to the Government Analyst, Central Drugs Laboratory, Kolkata for test/analysis under Form-18 vide Serial No. of Memorandum: 6-2(1)/HZ/2024-25/2154 dated 27.03.2025.

The sample was declared as **Not of Standard Quality** by the Government Analyst at Central Drugs Laboratory, Kolkata vide test report No. KOL/LS/2025-26/282 dated 02-JUN-2025 for the reasons that the **sample does not conform to IP specification with respect to test for “Related Substances, Assay of Tranexamic Acid”**

As required under Section 25(2) of Drugs & Cosmetics Act 1940, please find enclosed one set of above mentioned Test Report in **Original**.

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 along with relevant documents as per Section 18B of the Drugs and Cosmetics Act, 1940 and Rules:

1. The total quantity of the subject Drug procured, distributed, used and stocks available with you.
2. Name, address and other particulars like contact number/official e-mail id of the firm/person from whom the said 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.).
3. The circumstances under which you have obtained the said drug.
4. Details regarding date of receipt of the subject 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 the receipt of this letter and to forward **the required details in covering letter duly signed and stamped by the Authorized person, indicating name and Designation of the Authorized Signatory at the earliest.**

This is to be treated as most urgent.

Yours Faithfully,



Bhukya Vijay Nayak,
Drugs Inspector,

CDSCO, Hyderabad Zonal Office, Telangana.

Encl: Copy of Form 17 & one original test report in Form 13 from CDL, Kolkata

डॉ. भुक्या विजय नायक / Dr. BHUKYA VIJAY NAYAK
औषधि निरीक्षक / Drugs Inspector
(सी.डी.एस.सी.ओ) आंचलिक कार्यालय / CDSCO Zonal Office
स्वास्थ्य सेवा मंत्रालय / Directorate General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
एस.आर.नगर, हैदराबाद-५०००३८ / S.R. Nagar, Hyderabad - 500038.