

# METAPHARMACEUTICAL



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11/03/2025

MALLADI

DRUGS &amp; PHARMACEUTICALS LIMITED

UNIT - 3

Factory : Plot No. 7B & 7C, SIPCOT Industrial Complex,  
Ranipet, Ranipet Dist. Tamil Nadu, India. Pin - 632 403.

☎ : 91-4172-244290 / 244653 Fax : 91-4172-244853

## CERTIFICATE OF ANALYSIS

1. Name of the Product : Tranexamic Acid EP  
2. Batch No. : 7605924C01  
3. Quantity Manufactured : 20 Kg  
4. Date of Manufacture : Aug'2024  
5. Retest Date : Jul' 2029

S. No.	TEST	RESULT	LIMIT
1	Appearance	White crystalline powder	White or almost white, crystalline powder
2	Solubility	Freely soluble in water and in glacial acetic acid; practically insoluble in acetone and in ethanol(96%)	Freely soluble in water and in glacial acetic acid; practically insoluble in acetone and in ethanol(96%)
3	Identification Infrared absorption spectrophotometry	Sample spectrum matches with standard spectrum	The test IR spectrum should be concordant with reference IR spectrum
4	pH of 5.0%w/v solution in carbon dioxide free water	7.53	7.0 to 8.0
5	Chlorides	Less than 140ppm	Not more than 140ppm
6	Sulphated ash	0.04%	Not more than 0.1%
7	Loss on drying (at 105°C for 2hrs. )	0.21%	Not more than 0.5%
8	Related substances by HPLC (%w/w) a. Impurity -B b. Impurity -C c. Impurity -D d. Impurity -E e. Impurity -F f. Unspecified impurity g. Total impurities	0.04% 0.0003% 0.0005% 0.0003% Not detected 0.007% 0.05%	Not more than 0.15% Not more than 0.05% Not more than 0.05% Not more than 0.05% Not more than 0.05% Not more than 0.05% Not more than 0.2%

T. S. C. S.  
Prepared by (Q.C)  
Date: 14/02/25

Checked by (Q.A)  
Date: 14/02/25

P. V. V. V.  
Approved by (In-charge Q.C)  
Date: 14/02/2025

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S. No.	TEST	RESULT	LIMIT
9	Assay by potentiometric titration (on dried basis)	100.1%	99.0% and 101.0%
10	Residual solvents by GC a. Ethanol b. Isopropyl alcohol (IPA) c. Toluene d. Monochlorobenzene	Not detected Not detected Not detected Not detected	Not more than 5000 ppm Not more than 5000 ppm Not more than 890 ppm Not more than 360 ppm
11	Particle size D(90)	107 µm	200 µm
12	Customer specification Microbiological Test a) Total Aerobic Microbial Count b) Total Combined Moulds and Yeasts Count c) Tests for Absence of following Pathogens: i. Enterobacteriaceae ii. Pseudomonas aeruginosa iii Staphylococcus aureus	<10 CFU/g <10 CFU/g Absent/g Absent/g Absent/g	Not more than 100 CFU/g Not more than 10 CFU/g Absent/g Absent/g Absent/g

Status: The sample referred above COMPLIES with EP 11.5 and In-House specification

T. 801  
Prepared by (Q.C)  
Date: 14/02/25

Checked by (Q.A)  
Date: 14/02/25

Approved by (In-charge Q.C)  
Date: 14/02/25

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