MALLADI

METAPHARMACEUTICAL

N DE LOTE: 0231025

20/10/2025

MALLADI
DRUGS & 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. : 7603025
3. Quantity Manufactured : 40 kg
4. Date of Manufacture : Aug'2025
5. Retest Date : Jul' 2030

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	7.7	7.0 to 8.0
5	Chlorides	Less than 140ppm	Not more than 140ppm
6	Sulphated ash	0.03%	Not more than 0.1%
7	Loss on drying (at 105°C for 2hrs.)	0.19%	Not more than 0.5%
8	Related substances by HPLC (%w/w)*		
	a. Impurity -B	0.10%	Not more than 0.15%
	b. Impurity -C	0.0006%	Not more than 0.05%
	c. Impurity -D	BQL	Not more than 0.05%
	d. Impurity –E	Not detected	Not more than 0.05%
	e. Impurity –F	Not detected	Not more than 0.05%
	f. Unspecified impurity	Not detected	Not more than 0.05%
	g. Total impurities	0.10%	Not more than 0.2%

*Below quantification limit (BQL) for Impurity -B is 0.079%, Impurity -C is 0.0002%, Impurity -D is 0.001% , Impurity -E is 0.005% and Impurity -F is 0.001% .

Prepared by (Q.C) Date: 24/09/25

Checked by (Q.A) Date: 25/09/25

Approved by (In- charge Q.C) Date: 25/09/25

Regd. Off. : SKCL Tech Square, 7th Floor, Plot No. South Phase 14, Thiru Vi Ka Industrial Estate, Guindy, Chennai - 600 032. Tamil Nadu, India. Phone : 91-44-66876999 Fax : 91-44-66876998

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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 BQL Not detected	 Not more than 5000 ppm Not more than 5000 ppm Not more than 890 ppm Not more than 360 ppm

** Below quantification limit (BQL) for Toluene is 8.97ppm.

Status: The sample referred above COMPLIES with EP 11.8 and In-House specification

J. Sel
Prepared by (Q.C)
Date: 24/09/25

Checked by (Q.A)
Date: 25/09/25

S. Murugesh
Approved by (In- charge Q.C)
Date: 25/09/25

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