

CERTIFICATE OF ANALYSIS

(Finish Product)

Product Name : TRANEXAMIC ACID Ph.Eur 10.8

Batch No. : TRA/40580422

A.R. No. : FP22/00486

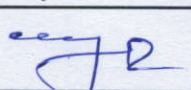
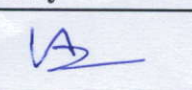
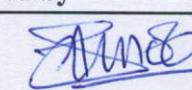
Mfg. Date : APR-22

Expiry/Retest Date : MAR-26

Approved Qty. : 1123.70 Kg

Date of analysis : 10.04.22

Sr. No.	Test	Specifications	Results
1	Description	A White or almost white, crystalline powder.	A 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 By IR	The IR absorption spectrum of Tranexamic Acid must be concordant with that of spectrum obtained from Tranexamic Acid CRS/ working standard.	The IR absorption spectrum of Tranexamic Acid concordant with that of spectrum obtained from Tranexamic Acid working standard.
4	pH	7.0 to 8.0	7.435
5	Halides expressed as chlorides	NMT : 140 ppm	Less than 140 ppm
6	Loss on Drying	NMT : 0.5 %	0.20 %w/w
7	Sulphated ash	NMT : 0.1 %	0.07 %w/w
8	Related substances by HPLC ➤ Impurity B ➤ Impurity C ➤ Impurity D ➤ Impurity E ➤ Impurity F ➤ Unspecified Impurity ➤ Total Impurities	NMT : 0.15 % NMT : 0.05 % NMT : 0.05 % NMT : 0.05 % NMT : 0.05 % NMT : 0.05 % NMT : 0.2 %	0.05 % BDL BDL BDL ND 0.03 % BQL
9	Assay by Potentiometrically	99.0 % to 101.0 % on dried basis	100.2 %w/w

Prepared by		Checked by		Approved by	
Sign		Sign		Sign	
Date	18.11.22	Date	18.11.22	Date	18.11.22
Name	Vishnu Patel	Name	Ashish Patel	Name	Arabinda Sahoo
Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Sr.Manager Quality Control	Designation/ Department	Manager Quality Assurance

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ADDITIONAL TEST			
10	Residual solvent* ➤ Methanol	NMT : 3000 ppm	ND

Remarks: The product conforms as per Specification No.: FPS/TRA/05/01.

Impurity B : (1s,4s)-4-(aminomethyl)cyclohexane-1-carboxylic acid

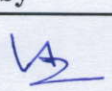
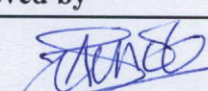
Impurity C : (4RS)-4-(aminomethyl)cyclohex-1-ene-1-carboxylic acid

Impurity D : 4-(aminomethyl)benzoic acid

Impurity E : (1r,4r)-4-[[[(1r,4r)-4-(aminomethyl)cyclohexane-1-carboxamido]methyl] cyclohexane-1-carboxylic acid

Impurity F : (1r,4r)-4-(formamidomethyl)cyclohexane-1-carboxylic acid

“*” indicates in-house method

Prepared by		Checked by		Approved by	
Sign		Sign		Sign	
Date	18.11.22	Date	18.11.22	Date	18.11.22
Name	Vishnu Patel	Name	Ashish Patel	Name	Arabinda Sahoo
Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Sr.Manager Quality Control	Designation/ Department	Manager Quality Assurance