

CERTIFICATE OF ANALYSIS

(Finish Product)

Product Name : TRANEXAMIC ACID Ph.Eur 10.1

Batch No : TRA/40340322

A.R No. : FP22/00333

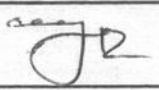
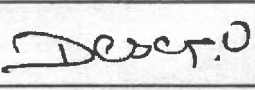
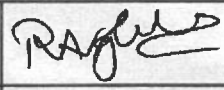
Mfg Date : MAR-22

Expiry/Retest Date : FEB-26

Approved Qty : 1010.40 Kg

Date of Analysis : 10.03.22

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	7.656
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	NMT : 0.15 %	BDL
	➤ Impurity C	NMT : 0.05 %	BDL
	➤ Impurity D	NMT : 0.05 %	BDL
	➤ Impurity E	NMT : 0.05 %	BDL
	➤ Impurity F	NMT : 0.05 %	ND
	➤ Unspecified Impurity	NMT : 0.05 %	BDL
	➤ Total Impurities	NMT : 0.2 %	BQL
9	Assay by Potentiometrically	99.0 % to 101.0 % on dried basis	100.7 %w/w

Prepared by		Checked by		Approved by	
Sign		Sign		Sign	
Date	19.03.22	Date	19.03.22	Date	19.03.22
Name	Vishnu Patel	Name	Pranav Desai	Name	Ranjit Vaghela
Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Sr.Manager Quality Control	Designation/ Department	Manager Quality Assurance

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Sr No.	Test	Specifications	Results
ADDITIONAL TEST			
10	Residual solvent* ➤ Methanol	NMT : 3000 ppm	41 ppm

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

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

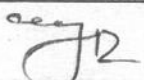
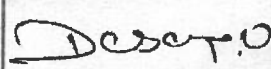
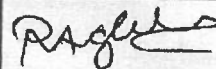
Impurity C : (4RS)-4-(aminomethyl)cyclohex-1-ene-1-carboxylic acid

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	19.03.22	Date	19.03.22	Date	19.03.22
Name	Vishnu Patel	Name	Pranav Desai	Name	Ranjit Vaghela
Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Sr.Manager Quality Control	Designation/ Department	Manager Quality Assurance