

Shilpa Pharma Lifesciences Limited




Unit-2: Plot No: 33, 33A & 40-47, Raichur Industrial Growth
Center, Chicksugur-584 134, Raichur District,
Karnataka State, India.

CIN No. U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: TRANEXAMIC ACID Ph.Eur	Drug license No.	: KTK/25/564/2009
Batch No.	: TXA8210179	Batch Quantity	: 556.500 Kg
Mfg. Date	: DEC-2021	A.R.No.	: 40000063804
Retest Date	: NOV-2026		

S.No.	Tests	Results	Specifications
1.	Appearance <Ph.Eur 1.4>	White crystalline powder	White or almost white, crystalline powder.
2.	Solubility <Ph.Eur 1.4>	Complies	Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and ethanol (96%)
3.	Identification by infrared absorption <Ph.Eur 2.2.24>	Complies	The infrared absorption spectrum of the substance being examined should be concordant with the spectrum of standard.
4.	pH <Ph.Eur 2.2.3>	7.39	Between 7.0 to 8.0
5.	Loss on drying (At 105°C for 2 hrs) <Ph.Eur 2.2.32>	0.27%	Not more than 0.5% w/w
6.	Sulphated ash <Ph.Eur 2.4.14>	0.05%	Not more than 0.1% w/w
7.	Halides expressed as chlorides <Ph.Eur 2.4.4>	Less than 140 ppm	Not more than 140 ppm
8.	Related substances (By HPLC) <Ph.Eur 2.2.29>		
	• Impurity-B	Not Detected	Not more than 0.15% w/w
	• Impurity-C	Below RT	Not more than 0.05% w/w
	• Impurity-D	Below RT	Not more than 0.05% w/w
	• Impurity-E	Below RT	Not more than 0.05% w/w
	• Impurity-F	Not Detected	Not more than 0.05% w/w
	• Unspecified impurity	Below RT	Not more than 0.05% w/w
	• Total impurities	Below RT	Not more than 0.2% w/w
9.	Assay by potentiometry (on dried basis) <Ph.Eur 2.2.20>	100.0%	Between 99.0% to 101.0% w/w
10.	Microbial limit tests		
	I) Microbial enumeration tests <Ph.Eur 2.6.12>		
	a) Total Aerobic Microbial Count	10 cfu/g	Not more than 1000 cfu/g
	b) Total combined Yeast and Mould Count	Less than 10 cfu/g	Not more than 100 cfu/g
	II) Test for specified microorganisms <Ph.Eur 2.6.13>		
	a) Enterobacteria	Absent	Should be absent
	b) Escherichia coli	Absent	Should be absent
	c) Salmonella species	Absent	Should be absent

	Prepared by	Checked by	Approved by
Name	B.Arvind	B.S.Petarge	K.Rajababu
Designation	Sr.Executive-QC	Sr.Manager-QC	Manager-QA
Sign & Date	 23/07/22	 23/07/22	 23/07/22

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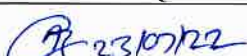


S.No.	Tests	Results	Specifications
	d) <i>Pseudomonas aeruginosa</i>	Absent	Should be absent
	e) <i>Staphylococcus aureus</i>	Absent	Should be absent
	f) <i>Clostridia</i>	Absent	Should be absent
	g) <i>Candida albicans</i>	Absent	Should be absent
11.	Bacterial Endotoxin test <Ph.Eur 2.6.14>	Less than 0.125 EU/mg	Not more than 0.125 EU/mg.
12.	Assay by HPLC (on dried basis) <In-House>	99.8%	Between 98.0% to 102.0% w/w

Storage condition: Preserve in tight containers and store at below 25°C temperature.

Remarks: The material complies with the above respective specifications. RT: Reporting Threshold (0.03%)

Chemical name of impurities:

- Impurity-B : (1*s*,4*s*)-4-(aminomethyl)cyclohexane-1-carboxylic acid
Impurity-C : (4*RS*)-4-(Aminomethyl)cyclohex-1-ene-1-carboxylic acid
Impurity-D : 4-(Aminomethyl) benzoic acid
Impurity-E : (1*r*,4*r*)-4-[(1*r*,4*r*)-4-(aminomethyl)cyclohexane-1-carboxamido]methyl]cyclohexane-1-carboxylic acid
Impurity-F : (1*r*,4*r*)-4-(formamidomethyl)cyclohexane-1-carboxylic acid

	Prepared by	Checked by	Approved by
Name	B.Arvind	B.S.Petarge	K.Rajababu
Designation	Sr.Executive-QC	Sr.Manager-QC	Manager-QA
Sign & Date	 23/07/22	 23/07/22	 23/07/22

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