



F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D-46286 Dorsten • Germany
Phone: +49 (0) 2369-9261947 • Fax: +49 (0) 2369-9261950

Innovating for
affordable healthcare

Shilpa Medicare Limited

(Unit-2: 100% Export Oriented Unit)

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

CIN No. L85110KA1987PLC008739

CERTIFICATE OF ANALYSIS

Material Name	: TRANEXAMIC ACID Ph.Eur		
Batch No.	: TXAK210413	Drug License No.	: KTK/25/564/2009
Source Batch No.	: TXA8210135	Batch Quantity	: 504.400 KG
Mfg. Date	: SEP-2021	Dispatch Quantity	: 50.000 KG
Retest Date	: AUG-2026	A.R.No.	: 40000059766
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>	7.62	Between 7.0 to 8.0
5	Loss on drying (At 105°C for 2 hrs) <Ph.Eur 2.2.32>	0.26%w/w	Not more than 0.5% w/w
6	Sulphated ash <Ph.Eur 2.4.14>	0.05%w/w	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>		
8.1	Impurity-B	Below RT	Not more than 0.15%
8.2	Impurity-C	Below RT	Not more than 0.05%
8.3	Impurity-D	Below RT	Not more than 0.05%
8.4	Impurity-E	Below RT	Not more than 0.05%
8.5	Impurity-F	Not Detected	Not more than 0.05%
8.6	Unspecified impurities	Below RT	Not more than 0.05%
8.7	Total impurities	Below RT	Not more than 0.2%
9	Assay by potentiometry (on dried basis) <Ph.Eur 2.2.20>	99.9%w/w	Between 99.0% to 101.0% w/w
10	Microbial limit tests		
10.1	Microbial enumeration tests <Ph.Eur 2.6.12>		
10.1.1	Total Aerobic Microbial Count	Less than 10 cfu/g	Not more than 1000 cfu/g
10.1.2	Total combined Yeast and Mould Count	Less than 10 cfu/g	Not more than 100 cfu/g

Checked by :
KRISHNA . 16.10.2021

Approved by :
Suresh Babu G 16.10.2021



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Page No : 1 / 2

Corporate & Admin Office : "Shilpa House", #12-6-214/A-1, Hyderabad Road, Raichur-584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +8532-238876, Email: info@vbshilpa.com, Web: www.vbshilpa.com



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Source Batch No.	: TXA8210135	Dispatch Quantity	: 50.000 KG
Mfg. Date	: SEP-2021	A.R.No.	: 40000059766
Retest Date	: AUG-2026		
S.No.	Tests	Results	Specifications
10.2	Test for specified microorganisms <Ph.Eur 2.6.13>		
10.2.1	Enterobacteria	Absent	Should be absent
10.2.2	Escherichia coli	Absent	Should be absent
10.2.3	Salmonella species	Absent	Should be absent
10.2.4	Pseudomonas aeruginosa	Absent	Should be absent
10.2.5	Staphylococcus aureus	Absent	Should be absent
10.2.6	Clostridia	Absent	Should be absent
10.2.7	Candida albicans	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) <IH>	99.5%w/w	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%); CEP No.: R0-CEP 2018-048-Rev 00

Fecha Entrada: 08-11-2021

25kg

11017

ACIDO TRANEXAMICO 25Kg



Lote: 0106615



QC-00236967

PRODUCTO ACTIVO FARMACEUTICO

Guinama S.L.U.
C/Praga, s/n. P.I. Ouzenberg
46185 La Pobla de Valbona (Spain)
Tel.: +34 96 158 90 90 - www.guinama.com

Guinama S.L.U.
C/Praga, s/n. P.I. Ouzenberg
46185 La Pobla de Valbona (Spain)
Tel.: +34 96 158 90 90 - www.guinama.com



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