



Shilpa Pharma Lifesciences 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. U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Material Name	: TRANEXAMIC ACID Ph.Eur		
Batch No.	: TXAJ220509	Drug License No.	: KTK/25/564/2009
Source Batch No.	: TXA8220090	Batch Quantity	: 551.700 KG
Mfg. Date	: JUL-2022	Dispatch Quantity	: 75.000 KG
Retest Date	: JUN-2027	A.R.No.	: 40000074664
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>	7.28	Between 7.0 to 8.0
5	Loss on drying (At 105°C for 2 hrs) <Ph.Eur 2.2.32>	0.23%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	0.04%	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	0.04%	Not more than 0.2%
9	Assay by potentiometry (on dried basis) <Ph.Eur 2.2.20>	100.1%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	10cfu/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 . 09.09.2022

Approved by :

Chinna Bheemaraju V.V 09.09.2022

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Corporate & Admin Office: "Shilpa House", #12-6-214/A-1, Hyderabad Road, Raichur- 584 135, Karnataka, India

Tel: +91-8532-238704, Fax: +91-8532-238876, Email: info@vbshilpa.com, Web: www.vbshilpa.com

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Mfg. Date	: JUL-2022	A.R.No.	: 40000074664
Retest Date	: JUN-2027		

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>	100.5%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 01

Fecha Entrada: 29-09-2022

10871

ACIDO TRANEXAMICO GRANEL



Lote: 0113671



QC-00246212

[1x87-10-9]
15720
CBH15N02

H315 Provoca irritación cutánea. H319 Provoca irritación ocular grave. H335 Puede irritar las vías respiratorias. P261 Evitar respirar el polvo/aerosol/gas/vapor/aerosol. P280 Usar guantes/ropa de protección. P301+P312 En caso de ingestión, beber agua. P302+P352 En caso de contacto con la piel, lavar abundantemente con agua y jabón. P303+P361+P353 En caso de contacto con los ojos, lavar abundantemente con agua y jabón. P304+P340 Si se respira el polvo/aerosol/gas/vapor, salir al aire fresco. P305+P351+P338 En caso de contacto con los ojos, levantar los párpados y lavar abundantemente con agua corriente durante al menos 15 minutos. P308+P313 En caso de exposición, consultar a un médico. P309+P311 En caso de exposición, evacuar la zona. P403+P233 Almacenar en un lugar bien ventilado. Mantener el recipiente cerrado herméticamente. P501 Eliminar el contenido en el recipiente.

Guinana S.L.U.
C/Praga, s/n, P.I. Guinana
40105 La Pobla de Valbona (Spain)
Tel: +34 96 186 90 00 - www.guinana.com

Bultos: 1

Guinana S.L.U.
C/Praga, s/n, P.I. Guinana
40105 La Pobla de Valbona (Spain)
Tel: +34 96 186 90 00 - www.guinana.com

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ATENCION AL CLIENTE

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