



Sophix Natural
And Agro Products Ltd
RC-1615742

Importers and dealers of
- Natural and Organic Oils
- Essential Oils
- Natural Powders
- Clays, etc
- Agro Products
- General Contracts

Certificate of Analysis

Product Name	Tranexamic Acid		
INCI Name:	TRANEXAMIC ACID		
CAS	701-54-2		
MF	C8H15NO2		
EINECS	622-133-9		
Batch Number	20260609	Manufacture Date	20260609
Report Date	20260609		

Items Tested	Specifications	Results	Test Method
Physical and Chemical Analysis			
Assay	≥99.0%	99.5%	HPLC
Appearance	White powder or crystalline powder	Complies	Organoleptic examination
Identity (IR-spectrum)	Corresponds to the reference	Conforms	FT-IR / USP <197>
Odor	Odorless	Conforms	Organoleptic examination
Solubility	Freely soluble in water and glacial Acetic acid, very slightly soluble in ethanol.	Conforms	Visual inspection
PH	7.0—8.0	7.7	USP <791>
Physical Characteristics			
Chloride	≤140ppm	<140ppm	USP <221> / Limit Test
Residue on ignition	≤0.10%	0.01%	USP <281> / Ph.Eur. 2.4.14
Loss on drying	≤0.5%	0.13%	USP <731> / Ph.Eur. 2.2.32
Heavy metals	≤10ppm	<10ppm	ICP-MS
Related Substances			
Impurity A	≤0.10%	Not Detected	HPLC
Impurity B	≤0.20%	0.02%	HPLC
Impurity C	≤0.10%	0.001%	HPLC
Impurity D	≤0.10%	Not Detected	HPLC
Unspecified impurities	≤0.10%	0.01%	HPLC / USP <621>
Sum of unspecified impurities	≤0.20%	0.04%	HPLC / USP <621>
Heavy Metals (ICP-MS)			
Lead (Pb)	≤ 10 ppm	<0.5 ppm	ICP-MS
Arsenic (As)	≤ 2 ppm	<0.1 ppm	ICP-MS
Cadmium (Cd)	≤ 1 ppm	<0.1 ppm	ICP-MS
Mercury (Hg)	≤ 1 ppm	<0.05 ppm	ICP-MS
Microbial Limits			
Total Aerobic Microbial Count	≤ 1000 CFU/g	<10 CFU/g	USP <61> / Ph. Eur. 2.6.12
Total Yeast and Mold Count	≤ 100 CFU/g	<10 CFU/g	USP <61> / Ph. Eur. 2.6.12
E. coli	Absent in 1g	Absent	USP <62> / Ph. Eur. 2.6.13
Salmonella spp.	Absent in 10g	Absent	USP <62> / Ph. Eur. 2.6.13
Pseudomonas aeruginosa	Absent in 1g	Absent	USP <62> / Ph. Eur. 2.6.13

Quality Statement: This product is manufactured under a quality system compliant with cGMP principles for both food and cosmetic applications. Specifications and test methods are established with reference to the relevant ISO Standards, Chinese National Standards (GB), United States Pharmacopeia (USP), and European Pharmacopoeia (Ph. Eur.).

For cosmetic use, the batch fully complies with the requirements of EU Cosmetic Regulation (EC) No 1223/2009, China's Safety Technical Standards for Cosmetics (2015 Edition), and U.S. FDA cosmetic GMP guidelines. For food use, the batch meets the applicable requirements of China's national food safety standards (including GB 2762, GB 2763, GB 7101) and the U.S. FDA Food Safety Modernization Act (FSMA) and applicable food additive regulations.

Storage: Store in tight, light-resistant containers. Avoid exposure to direct sunlight, moisture, and excessive heat.

Shelf Life: 24 months if stored under the above conditions and remains in original packaging.



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