



## TECHNICAL DATA SHEET

000075-TDS-ENG-2023

ACIDO TRANEXAMICO EP		
DESCRIPTION DCI: TRANEXAMIC ACID		DESCRIPTION DOE: ACIDO TRANEXAMICO
CAS Nº: 1197-18-8	EC Nº: 214-818-2	AEMPS CODE: 3157A
MOL. WEIGHT: 157.21	MOL. FORMULA: C8H15NO2	ARTICLE CODE: 000075

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96 %)
Identification	Complies
pH	7.0 - 8.0
Related substances	
Impurity B	=< 0.15 %
Impurity C	=< 0.05 %
Impurity D	=< 0.05 %
Impurity E	=< 0.05 %
Impurity F	=< 0.05 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.2 %
Halides expressed as chlorides	=< 140 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep container tightly closed in a dry and well-ventilated place.

### REMARKS

Tranexamic Acid is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.