

ACIDO TRANEXAMICO (EUR. PH.)

PRODUCT CODE: 000075	CAS Nº: 1197-18-8	ANALYSIS Nº: 060/25
MANUFACTURER BATCH: 7605924C01	CERTIFICATE ID: 45.527	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/08/2024	
METAPH BATCH: 0130325	RETEST DATE: 31/07/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification	Complies	Complies
pH	7.0 - 8.0	7.6
Related substances		
Impurity B	=< 0.15 %	0.03 %
Impurity C	=< 0.05 %	< 0.03 %
Impurity D	=< 0.05 %	< 0.03 %
Impurity E	=< 0.05 %	Not Detected
Impurity F	=< 0.05 %	< 0.03 %
Unspecified impurities	=< 0.05 %	< 0.03 %
Total impurities	=< 0.2 %	0.03 %
Halides expressed as chlorides	=< 140 ppm	< 140 ppm
Loss on drying	=< 0.5 %	0.08 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	99.0 - 101.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 02/04/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001543
 MALLADI DRUGS & PHARMACEUTICALS LIMITED
 Plot No.7B & 7C, SIPCOT Industrial Complex,
 Ranipet, Ranipet District
 632 403 TAMIL NADU

