

ACIDO TRANEXAMICO (EUR. PH.)

PRODUCT CODE: 000075	CAS Nº: 1197-18-8	ANALYSIS Nº: 019/24
MANUFACTURER BATCH: TRA/40340322	CERTIFICATE ID: 41.013	
SUPPLIER BATCH: 22F29-APR22317	MANUFACTURING DATE: 01/03/2022	
METAPH BATCH: 0070224	EXPIRY DATE: 28/02/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Identification	Complies	Complies (*)
pH	7.0 - 8.0	7.4
Related substances		
Impurity B	=< 0.15 %	< 0.03 %
Impurity C	=< 0.05 %	< 0.03 %
Impurity D	=< 0.05 %	< 0.03 %
Impurity E	=< 0.05 %	< 0.03 %
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 %	0.02 %
Sulfated ash	=< 0.1 %	0.09 %
Assay	99.0 - 101.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analysed inside the EU.

Product fully analyzed within the EU, in compliances with the currents 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 controlled by Metapharmaceutical Industrial SL.

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: 07/02/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001454
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