



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 232701

Product:	TRANEXAMIC ACID
Lot:	232701
Expiry date:	03/03/2028
Reference:	Cumple PhEur11.1
Synonyms:	
Formula:	C8H15NO2
Molecular weight:	157.2 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform	PhEur	
pH	7,6	7,0 - 8,0	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,05 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Halides expressed as chlorides	< 140 ppm	<= 140 ppm	
Elemental impurities	Conform	Test PhEur	#
Assay	100,0 %	99,0 - 101,0 %	
Impurity B	< 0,03 %	<= 0,15 %	
Impurity C	0,00 %	<= 0,05 %	
Impurity D	< 0,03 %	<= 0,05 %	
Impurity E	< 0,03 %	<= 0,05 %	
Impurity F	0,00 %	<= 0,05 %	
Unspecified Impurities	< 0,03 %	<= 0,05 %	
Total impurities	< 0,03 %	<= 0,2 %	
Residual solvents	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 06/06/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00419 HUNAN DONGTING PHARMACEUTICAL Co., Ltd.

Manufacturer batch: X2303308M

Product	Name	Capacity	Batch
1130600	ACIDO TRANEXAMICO	10 g	232701-F-1
1130600	ACIDO TRANEXAMICO	10 g	232701-F-2
1130600	ACIDO TRANEXAMICO	10 g	232701-F-3
1130601	ACIDO TRANEXAMICO	25 g	232701-G-2
1130601	ACIDO TRANEXAMICO	25 g	232701-G-3
1130601	ACIDO TRANEXAMICO	25 g	232701-G-4
1130602	ACIDO TRANEXAMICO	100 g	232701-J-2
1130602	ACIDO TRANEXAMICO	100 g	232701-J-3
1130602	ACIDO TRANEXAMICO	100 g	232701-J-4
1130603	ACIDO TRANEXAMICO	250 g	232701-N-1
1130603	ACIDO TRANEXAMICO	250 g	232701-N-2
1130603	ACIDO TRANEXAMICO	250 g	232701-N-3
1130604	ACIDO TRANEXAMICO	1 kg	232701-P-1
1130604	ACIDO TRANEXAMICO	1 kg	232701-P-2
1130604	ACIDO TRANEXAMICO	1 kg	232701-P-3
1370254	ACIDO TRANEXAMICO (FLB)	25 g	232701-G-1
1370255	ACIDO TRANEXAMICO (FLB) (INACTIVO)	100 g	232701-J-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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