

ACIDUM TRANEXAMICUM 1 kg

Lot No.: 23D05-APR23220

Autorisation :	1890R06125	Date Of Analysis :	20/01/2023
Analytical Reference :	Ph. Eur. 10.7 [04/2020:0875]	Production Number :	110723-GS22175
CNK :	4433-207	Expiry Date :	03/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification	The spectrum complies with the spectrum obtained with tranexamic acid CRS	Complies
TESTS	SPECIFICATION	RESULT
pH	7.0 to 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%	0.041%
Total	≤ 0.2%	0.041%
Halides expressed as chlorides	≤ 140 ppm	Complies
Loss on drying	≤ 0.5%	0.06%
Sulfated ash	≤ 0.1%	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	99.3%
Manufacturer identification code: S/GS/157		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

Joran Smout
(Signature)

Digitally signed by Joran Smout (Signature)
Date: 2023.08.25 13:41:59 +02'00'

METAPHARMACEUTICAL

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