

Certificate of Analysis

Product name: Acidum tranexamicum
Batch number / Weight: 25C05-B05-010809 / 100 g
Producer / Producer Batch Number: Hunan Dongting Pharmaceutical Co., Ltd - Plant / X2411012M
Analyzed according to: Ph. Eur. 11.7
Number of Analysis / Certificate no.: 25C05-B05 / QO0016257

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
IR-spectrum	Conform	Conform		
pH	7,0 - 8,0	7,38		
Related substances	Conform	Conform		
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	0,043	%	
Total impurities	<= 0,2	0,043	%	
Halides express as chlorides	<= 140	<140	ppm	
Loss on drying	<=0,5	0,12	%	
Sulfated ash	<= 0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	99,77	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

5-6-2025
 Dominika Sołtysik
 Qualified Person

Expiration: 3-11-2029

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.