

Certificate of Analysis

Product name: Acidum fusidicum
Batch number / Weight: 24D18-B07-008391 / 5 g
Producer / Producer Batch Number: Ercros SA - Aranjuez / FS 1242
Analyzed according to: Ph. Eur. 11.6
Number of Analysis / Certificate no.: 24D18-B07 / QO0013464

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A, B	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,3	<0,05	%	
Impurity B	<=0,4	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity F	<=0,2	<0,05	%	
Impurity G	<=0,7	0,09	%	
Impurity I	<=0,2	0,07	%	
Impurity K	<=0,2	<0,05	%	
Impurity L	<=0,5	0,06	%	
Impurity M	<=1,0	0,45	%	
Impurity N	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	0,058	%	
Total impurities	<=2,0	0,73	%	
Sulfated ash	<=0,2	0,00	%	
Water (Karl Fischer)	1,4 - 2,0	1,81	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	97,5 - 101,0	98,10	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	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:

31-3-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 3-12-2026

Conclusion: APPROVED

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Requirement	Result	Unit	Standard remark
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