

## Certificate of Analysis

**Product name:** Acidum fusidicum  
**Batch number / Weight:** 21D12-B08-215415 / 50 G  
**Analysed according to:** Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Sodium
Related substances	Conform	Conform		HPLC
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	0,23	%	
Impurity I	<=0,2	<0,05	%	
Impurity K	<=0,2	<0,05	%	
Impurity L	<=0,5	<0,05	%	
Impurity M	<=1,0	0,29	%	
Impurity N	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=2,0	0,57	%	
Sulphated ash	<=0,2	0,1	%	
Water (Karl Fischer)	1,4 - 2,0	1,83	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Fusidic acid	97,5 - 101,0	100,4	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

11-09-2021

Expiration: 14-11-2023

Conclusion: APPROVED

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