

Certificate of Analysis

Product name: Acidum fusidicum
Batch number / Weight: 21D12-B08-215414 / 10 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	$\leq 0,3$	0,05	%	
Impurity B	$\leq 0,4$	$< 0,05$	%	
Impurity C	$\leq 0,2$	$< 0,05$	%	
Impurity D	$\leq 0,2$	$< 0,05$	%	
Impurity F	$\leq 0,2$	$< 0,05$	%	
Impurity G	$\leq 0,7$	0,23	%	
Impurity I	$\leq 0,2$	$< 0,05$	%	
Impurity K	$\leq 0,2$	$< 0,05$	%	
Impurity L	$\leq 0,5$	$< 0,05$	%	
Impurity M	$\leq 1,0$	0,29	%	
Impurity N	$\leq 0,2$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 2,0$	0,57	%	
Sulphated ash	$\leq 0,2$	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

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