

Certificate of Analysis

Productname: **Acidum flufenamicum**
Number of analysis/Inspection Code: 1 / KEUR-179726B
Batchnumber: **19I13-F01-367081**
Reference code / No.: 4567 / FA1906021
Analysed according to: **MONOGR.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		UV-spectrum
Absorbance ratio	0,55 - 0,59	0,57		287nm; BP80
Absorbance	0,28 - 0,31	0,29		344 nm; BP80
Copper	<=20	Conform	ppm	
Related substances	<=0,2	<0,2	%	TLC
Loss on drying	<=0,5	0,3	%	In vacuo
Sulphated ash	<=0,1	<0,1	%	
3-Aminobenzotrifluoride	<=100	<100	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Flufenamic acid	99,0 - 101,0	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/17/20

Expiration: 06-2022

Conclusion: APPROVED

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