

Certificate of Analysis

Productname: Acidum flufenamicum
Number of analysis/Inspection Code: 1 / KEUR-185867B
Batchnumber: 20G29-F02-373449
Reference code / No.: 4567 / FA2005019
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		
Absorbance ratio	0,55 - 0,59	0,57		287nm; BP80
Absorbance	0,28 - 0,31	0,29		344 nm; BP80
Copper	<=20	<1	ppm	
Related substances	<=0,2	<0,2	%	TLC
Loss on drying	<=0,5	0,1	%	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	99,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/23/20

Expiration: 05-2023

Conclusion: APPROVED

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