

Certificate of Analysis

Product name: **Acidum flufenamicum**

Batch number / Weight: **22A14-B06-220770 / 100 G**

Analysed according to: **Monograph/EP (for Res.Solv.)**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Absorbance ratio	0,55 - 0,59	0,58		
Absorbance	0,28 - 0,31	0,30		
Copper	<=20	Conform	ppm	
Related substances	<=0,2	Conform	%	
Loss on drying	<=0,5	0,01	%	
Sulphated ash	<=0,1	<0,01	%	
3-Aminobenzotrifluoride	<=100	Conform	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Toluen	<= 880 ppm	141	ppm	
N,N-Dimethylformamide	<= 890 ppm	<15	ppm	
Assay Flufenamic acid	99,0 - 101,0	100,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

25-05-2022

Expiration: 01-09-2024

Conclusion: APPROVED

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