

Product/sample name : Acidum flufenamicum; 503912
 Client-code : 129
 Project-code : 0119361
 Batch number : 20G29-F02
 Analysis : BP80 add. 86 and Client specification
 Version : 1

Test	Test method	Specification	Result	Complies
Characters	Appearance	Pale yellow, crystalline powder	Pale yellow crystalline powder	Yes
Identity A	App. II A	Compared to reference	Conform (2x)	Yes
Identity B	Monograph	Strong bluish-white fluorescence under UV-light	Conform	Yes
		Strong greenish-yellow fluorescence under UV-light	Conform	Yes
Light absorption*	Monograph	287 nm: 0.55 - 0.59	0.57	Yes
		344 nm: 0.28 - 0.31	0.29	Yes
Copper	Monograph	≤ 20 ppm	< 1 ppm	Yes
Related substances	Monograph	≤ 0.2 %	< 0.2 %	Yes
Loss on drying	Monograph	≤ 0.5 %	0.1 %	Yes
Sulfated ash	App. IX A (I)	≤ 0.1 %	0.1 %	Yes
Assay	Monograph	99.0 - 101.0 %	99.5 %	Yes
3-Aminobenzotrifluoride	Monograph	≤ 100 ppm	< 100 ppm	Yes

* Remark: according to BP80



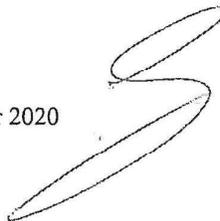
QA-statement:

This study met the criteria for a valid test and was performed in compliance with the Good control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community. The reported results adequately reflect the raw data of the study.

Conclusion:

The results do comply with the specifications

This certificate is approved by Manager QA on 11 September 2020



11 Sep 2020

Product/sample name : Acidum flufenamicum; 503912
 Client-code : 129
 Project-code : 0119361-RS
 Batch number : 20G29-F02
 Analysis : BP2020
 Version : 1

Test	Test method	Specification	Result	Complies
Residual solvents	2.4.24	Toluene ≤ 890 ppm	711	Yes



QA-statement:

This study met the criteria for a valid test and was performed in compliance with the Good control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community. The reported results adequately reflect the raw data of the study.

Conclusion:

The results do comply with the specifications

This certificate is approved by Manager QA on 25 August 2020

25 aug 2020

Enclosure with label 20G29-F02



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Certificate of Analysis

Product/sample name : Acidum flufenamicum; 503912
Client-code : 129
Project-code : 0116880
Batch number : 19I13-F01
Analysis : BP80 add. 86 and Client specification
Version : 1

Test	Test method	Specification	Result	Complies
Characters	Appearance	Pale yellow, crystalline powder	Pale yellow crystalline powder	Yes
Identity A	App. II A	Compared to reference	Conform (2x)	Yes
Identity B	Monograph	Strong bluish-white fluorescence under UV-light	Conform	Yes
		Strong greenish-yellow fluorescence under UV-light	Conform	Yes
Light absorbtion*	Monograph	287 nm: 0.55 - 0.59	0.57	Yes
		344 nm: 0.28 - 0.31	0.29	Yes
Copper	Monograph	≤ 20 ppm	0 ppm	Yes
Related substances	Monograph	≤ 0.2 %	< 0.2 %	Yes
Loss on drying	Monograph	≤ 0.5 %	0.3 %	Yes
Sulfated ash	App. IX A (I)	≤ 0.1 %	< 0.1 %	Yes
Assay	Monograph	99.0 - 101.0 %	100.0 %	Yes
3-Aminobenzotrifluoride	Monograph	≤ 100 ppm	< 100 ppm	Yes

* Remark: according to BP80

Additional test for label 20G29-F02:

- Toluene ≤ 890 ppm

HLW
31.07.20.

SPECIFICATIONS RECOMPLIANCE EN CONFORM	
DATE	PARAS
22-10-19	Y/S

QA-statement:

This study met the criteria for a valid test and was performed in compliance with the Good control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community. The reported results adequately reflect the raw data of the study.

Conclusion:

The results do comply with the specifications

This certificate is approved by Manager QA on 16 October 2019

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