



陕西宝新药业有限公司
SHAANXI BAONIN PHARMACEUTICAL CO., LTD

CERTIFICATE OF ANALYSIS

Product name: Flufenamic Acid

Batch No. FA1906021

Manufacturing date	Jun 10, 2019	Release date	Jun 12, 2019
Expiry date	Jun 9, 2022	Article No.	20101
Package	25 kg per drum	Package	Φ310 × 470 (mm)
Ref. pharmacopoeia(s)	In-house standards	Quantity	100 kg

Test Item	Specification	Result
Appearance	White to pale yellow crystalline compacted; odorless	Comply
Solubility	In 4 parts of ethanol 96% In 7 parts of chloroform In 3 parts of ether	Comply
Identification	Meet the requirements	Comply
Melting pointing	133.0 ~ 135.0℃	134.1~134.6℃
Copper	≤10ppm	≤10ppm
Loss on drying	≤0.5%	0.02%
Sulphated ash	≤0.1%	0.03%
Related substances		
2-chlorobenzoic acid	≤0.1%	Not detected
3-Aminobenzotrifluoride	≤100ppm	Not detected
Unspecified impurities	≤0.1%	0.01%
Total impurities	≤0.2%	0.02%
Heavy metals	≤20ppm	<20pm
Assay (dried substance)	99.0% ~ 101.0%	99.8%

Conclusion: *This batch complies with the specification of In-house standards.*

Remark: For exportation and processing only.

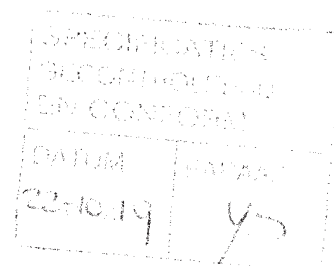
Reported by: [Signature]

QA Manager: [Signature]

Product/sample name : Acidum flufenamicum; 503912
Client-code : 129
Project-code : 0116880
Batch number : 19113-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



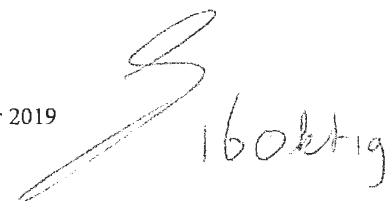
QA-statement:

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:

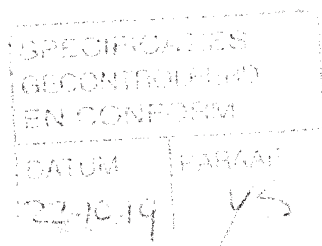
The results do comply with the specifications

This certificate is approved by Manager QA on 16 October 2019



Product/sample name : Acidum flufenamicum; 503912
Client-code : 129
Project-code : 0116880-RS
Batch number : 19I13-F01
Analysis : BP 2019
Version : 1

Test	Test method	Specification	Result	Complies
Residual solvents	2.4.24	N,N- dimethylformamide: ≤ 880 ppm Toluene ≤ 890 ppm	Not detectable with this method 420 ppm	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 17 October 2019

 17 Oct 19