

Certificate of Analysis

Productname: Amifampridinum
Number of analysis/Inspection Code: 1 / KEUR-187621B
Batchnumber: 20J13-F01-375361
Reference code / No.: 3490 / 33-20-I-46P4323
Analysed according to: DAC 2020/1

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or light brown, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=B5	Conform		1 g / 20 ml MeOH
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	<0,01	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Water (Karl Fischer)	<=1,0	0,1	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Amifampridin	99,0 - 101,0	100,3	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/10/20

Expiration: 09-2023

Conclusion: APPROVED

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