

Certificate of Analysis

Product name: **Amifampridinum**

Batch number / Weight: **23E10-B10-229104 / 5 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **23E10-B10 / INS-23-4292**

Reference Code / No.: **V01521 / 33-21-II-36P4709**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or light brown, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / $\leq B5$	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,1$	$< 0,01$	%	
Any other impurity	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,5$	$< 0,05$	%	
Water (Karl Fischer)	$\leq 1,0$	0,08	%	
Sulphated ash	$\leq 0,1$	0,08	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Amifampridin	99,0 - 101,0	100,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	not more than 1500 ppm	72	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:

Ewelina Gadzinowska

Qualified Person

25-06-2023

Expiration: 13-12-2024

Conclusion: APPROVED

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