

## Certificate of Analysis

**Product name:** **Methioninum apyrogeen**

**Batch number / Weight:** **21L13-B09-221778 / 100 G**

**Analysed according to:** **Ph.Eur.10**

**Number of analysis / Inspection Code** **21L13-B09 / INS-22-1281**

**Reference Code / No.:** **V01413 / 1601210503**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Identification A	+22,5 - +24,0	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	5,5 - 6,5	6,0		
Specific optical rotation	+22,5 - +24,0	+23,0		
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Ammonium	<=200	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,04	%	
Sulphated ash	<=0,1	0,08	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,5	%m/m	
Endotoxins	<=6	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 Fagron PL, ElSpol

Release:  
Dominika Soltysik  
Qualified Person

26-08-2022

Expiration: 02-05-2025

Conclusion: APPROVED

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