

## Certificate of Analysis

**Product name:** **Methioninum apyrogen**

**Batch number / Weight:** **21L13-B09-217457 / 100 G**

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

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

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

11-03-2022

Expiration: 02-05-2025

Conclusion: APPROVED

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