

Certificate of Analysis

Product name: **Methioninum apyrogen**
Batch number / Weight: **21F01-B04-212193 / 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	+23,0		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	5,5 - 6,5	5,84		
Specific optical rotation	+22,5 - +24,0	+23,0		
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	0,00	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	<=100	ppm	
Ammonium	<=200	Conform	ppm	
Iron	<=10	<=10	ppm	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,97	%m/m	
Endotoxins	<=6	Conform	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

12-07-2021

Expiration: 22-12-2024

Conclusion: APPROVED

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