

Certificate of Analysis

Product name: **Methioninum (DL)**
Batch number / Weight: **21G10-B04-229499 / 100 G**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **21G10-B04 / INS-21-5126**
Reference Code / No.: **V01413 / 4541200812**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Identification A	Conform	Conform		
Identification C	-0,05 - +0,05	Conform	°	
Appearance of solution	Clear / colourless	Conform		
pH	5,4 - 6,1	6,1		
Optical rotation	-0,05 - +0,05	Conform	°	
Related substances	<=0,2	<0,2	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=200	<200	ppm	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,9	%m/m	
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 EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

13-06-2023

Expiration: 27-08-2026

Conclusion: APPROVED

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