

Certificate of Analysis

Productname: **Methioninum apyrogen**
Number of analysis/Inspection Code: 1 / KEUR-180615B
Batchnumber: **19L20-F03-367929**
Reference code / No.: 2746 / 1601190311
Analysed according to: **PH.EUR10.0**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification A	+22,5 - +24,0	Conform		Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		2,5% <i>m/V</i>
pH	5,5 - 6,5	5,9		2,5% <i>m/V</i>
Specific optical rotation	+22,5 - +24,0	+23,5		2% <i>m/V</i> in HCl 20%; dried
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Ammonium	<=200	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay L-Methionine	99,0 - 101,0	100,0	% <i>m/m</i>	Dried
Endotoxins	<=6	Conform	IU / g	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs+Microb..

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

02/21/20

Expiration: 03-2023

Conclusion: APPROVED

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