

Certificate of Analysis

Product name: **Levocarnitini tartras**

Batch number / Weight: **23L14-B02-231636 / 100 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **23L14-B02 / INS-24-1096**

Reference Code / No.: **V01706 / LT231128**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White cristal powder	Conform		
Identification A	Conform	Conform		
Identification B	Blue / red	Conform		
Melting point	About 173	175,3	°C	
Specific optical rotation	-11,0 - -9,5	-9,8		
Appearance of solution	Clear / colourless	Conform		
pH	3,0 - 4,5	3,69		
Chlorides	<=200	<200	ppm	
Sulphates	<=200	<200	ppm	
Heavy metals	<=10	<10	ppm	
Water (Karl Fischer)	<=0,5	0,07	%	
Sulphated ash	<=0,1	0,04	%	
Tartaric acid	30,8-32,8	31,49	%	
L-Carnitine	67,2-69,2	67,89	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		

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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, EI Spol

Release:
Dominika Soltysik
Qualified Person

27-02-2024

Expiration: 16-11-2026

Conclusion: APPROVED

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