Certificate of Analysis

Product name: **Levocarnitinum**

Batch number / Weight: **23H09-B04-233563 / 200 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23H09-B04 / INS-23-6532**

Reference Code / No.: **V01706 / LC230717**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals, hygroscopic	Conform		
Identification A	-29,0 - -32,0	-30,0		
Identification B	Conform	Conform		
Appearance of solution	Clear, colourless	Conform		
pH	6,5 - 8,5	7,74		
Specific optical rotation	-29,0 - -32,0	-30,0		
Related substances	Conform	Conform		
Impurity A	<=0,3	<0,05	%	
Any impurity	<=0,10	0,060	%	
Total impurities A	<=0,5	0,06	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Water (Karl Fischer)	<=1,0	0,34	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Levocarnitine	98,0 - 102,0	99,66	%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 Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

04-12-2023

Expiration: 03-07-2026

Conclusion: APPROVED

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