Certificate of Analysis

Product name: **Levocarnitinum**

Batch number / Weight: **21I02-B07-213229 / 50 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals, hygroscopic	Conform		
Identification A	-29,0 - -32,0	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear, colourless	Conform		
pH	6,5 - 8,5	7,47		
Specific optical rotation	-29,0 - -32,0	-31,2		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,01	%	
Any impurity	<=0,10	<0,05	%	
Total impurities A		0,00	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Water (Karl Fischer)	<=1,0	0,42	%	
Sulphated ash	<=0,1	0,02	%	
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	99,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

29-11-2021

Expiration: 08-08-2024

Conclusion: APPROVED

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