Certificate of Analysis

Product name: **Levocarnitinum**

Batch number / Weight: **21L02-B04-219896 / 200 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	7,53		
Specific optical rotation	-29,0 - -32,0	-30,2		
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Any impurity	<=0,10	0,06	%	
Total impurities A	<=0,5	0,06	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Water (Karl Fischer)	<=1,0	0,35	%	
Sulphated ash	<=0,1	0,07	%	
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	99,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

11-03-2022

Expiration: 23-10-2024

Conclusion: APPROVED

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Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl