Fagron

Certificate of Analysis

Productname: **Levocarnitinum**

Number of analysis/Inspection Code: 2 / KEUR-187506B

Batchnumber: **20G31-F05-373306**

Reference code / No.: 3344 / LC200715

Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		Hygroscopic
	or colourless crystals	Conform		
Identification A	-29,0 - -32,0	Conform		Strongly alkaline
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear, colourless	Conform		10%m/V
pH	6,5 - 8,5	7,5		5%m/V
Specific optical rotation	-29,0 - -32,0	-31,2		10%m/V; anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,3	0,0	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities (Ex.Onz.A)	<=0,5	0,1	%	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Water (Karl Fischer)	<=1,0	0,5	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Levocarnitine	98,0 - 102,0	99,9	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/03/20

Expiration: 07-2023

Conclusion: APPROVED

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