

Certificate of Analysis

Productname: Levocarnitini tartras
Number of analysis/Inspection Code: 1 / KEUR-187199B
Batchnumber: 20J01-F01-375011
Reference code / No.: 3344 / LT200714
Analysed according to: INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	White cristal powder	Conform		
Melting point	About 173	173	°C	
Specific optical rotation	-11,0 - -9,5	-10,1		1% <i>m/V</i>
Identification A	Conform	Conform		IR-spectrum
Identification B	Blue / red	Conform		Colour reaction
Appearance of solution	Clear / colourless	Conform		10% <i>m/V</i>
pH	3,0 - 4,5	3,7		5% <i>m/V</i>
Chlorides	<=200	Conform	ppm	
Sulphates	<=200	Conform	ppm	
Heavy metals	<=10	Conform	ppm	
Water (Karl Fischer)	<=0,5	0,1	%	
Sulphated ash	<=0,1	0,1	%	2 h 600°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Levocarnitine tartrate	99,0 - 101,0	99,9	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Remark	Qualified as Food	.		

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

11/20/20

Expiration: 06-2023

Conclusion: APPROVED

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