

Certificate of Analysis

Productname: Lithii carbonas
Number of analysis/Inspection Code MON-196597B / KEUR-183974B
Batchnumber: 20F04-F07
Reference code / No.: 1229 / B542111AA
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White powder	Conform		
Apparent volume		8,0	ml / 5 g	
Identification A	Red	Conform		Lithium
Identification B	Conform	Conform		
Identification C	Conform	Conform		Carbonate
Appearance of solution	Clear and colourless	Conform		10%m/V
Chlorides	<=200	Conform	ppm	
Sulphates	<=200	Conform	ppm	
Arsenic	<=2	Conform	ppm	
Calcium	<=200	Conform	ppm	
Iron	<=20	Conform	ppm	
Magnesium	<=150	Conform	ppm	
Potassium	<=300	Conform	ppm	
Sodium	<=300	Conform	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Lithium carbonate	98,5 - 100,5	100,0	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Release:
Paul Hofman
Pharmacist - Qualified Person

16-07-20

Expiration: 10-2024

Conclusion: APPROVED

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