

Certificate of Analysis

Productname: Carbocisteinum
Number of analysis/Inspection Code: 1 / KEUR-187982B
Batchnumber: 20117-F08-374442
Reference code / No.: 3328 / C101-202007006
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-32,5 - -35,5	Conform		Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear and colourless	Conform		10% <i>m/V</i> ; pH 6.3
pH	2,8 - 3,0	2,9		1% <i>m/V</i> suspension
Specific optical rotation	-32,5 - -35,5	-35,2		10% <i>m/V</i> ; pH 6.3; dried
Ninhydrin-positive substances	<=0,5	Conform	%	TLC
Chlorides	<=0,15	Conform	%	
Sulphates	<=300	Conform	ppm	
Loss on drying	<=0,5	0,2	%	2 h 105 °C
Sulphated ash	<=0,3	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Carbocisteine	98,5 - 101,0	99,9	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/30/20

Expiration: 07-2022

Conclusion: APPROVED

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