

Certificate of Analysis

Product name: Carmellosum natricum 1000mPa.s

Batch number / Weight: 22K03-B17-225299 / 100 G

Analysed according to: Ph. Eur. 10.8

Number of analysis / Inspection Code 22K03-B17 / INS-22-9964

Reference Code / No.: V01480 / AA6140361

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, granular powder	Conform		
Appearance	hygroscopic after drying			
Identification A	Blue	Conform		
Identification B	No precipitate	Conform		
Identification C	Conform	Conform		
Appearance of solution	<ref. susp. III <=Y6	Conform		
pH	6,0 - 8,0	6,97		
Viscosity	750 - 1400	924	mPa.s	
Sodium glycollate	<=0,4	Conform	%	
Chlorides	<=0,25	Conform	%	
Loss on drying	<=10,0	7,00	%	
Sulphated ash	20,0 - 33,3	24,53	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Ethanol	<= 5000	<5000	ppm	
2-Propanol	<= 5000	<5000	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

27-12-2022

Expiration: 27-09-2024

Conclusion: APPROVED

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