

Certificate of Analysis

Product name: Carmellosum natricum 550 mPa.s

Batch number / Weight: 22I19-B04-220917 / 250 G

Analysed according to: Ph.Eur.10.8

Number of analysis / Inspection Code 22I19-B04 / INS-22-8279

Reference Code / No.: V01388 / C213947

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, granular powder	Conform		
Appearance	hygroscopic after drying			
Identification A	Blue, cotton like precipitate is formed	Conform		
Identification B	No precipitate is formed	Conform		
Identification C	Conform - reactions of sodium	Conform		
Appearance of solution	<ref. susp. III / <=Y6	Conform		
pH	6,0 - 8,0	7,26		
Viscosity	375 - 700	648	mPa.s	
Sodium glycollate	<=0,4	<0,4	%	
Chlorides	<=0,25	<0,25	%	
Loss on drying	<=10,0	9,5	%	
Sulphated ash	20,0 - 33,3	25,11	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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, ElSpol

Release:

Agnieszka Pszczółka

Qualified Person

25-11-2022

Expiration: 14-11-2023

Conclusion: APPROVED

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