

Certificate of Analysis

Product name: **Methylcellulosum 400 mPa.s**

Batch number / Weight: **23E16-B01-233644 / 100 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23E16-B01 / INS-23-4893**

Reference Code / No.: **V01346 / 2095765**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, yellowish-white or greyish-white granular po	Conform		
	or granules, hygroscopic after drying			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	<=ref. susp.III / <=Y6	Conform		
pH	5,0 - 8,0	6,11		
Loss on drying	<=5,0	1,71	%	
Sulphated ash	<=1,5	0,17	%	
Viscosity	320 - 480	406	mPa.s	
Viscosity		101,5	%	
Degree of substitution	26,0 - 33,0	29,2	%	
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
TotalAerobicMicrob.Count(TAMC	<=10 ³	<10	CFU/g	
Total yeasts and moulds (TYMC)		<10	CFU/g	

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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, EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

29-11-2023

Expiration: 23-09-2025

Conclusion: APPROVED

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