

Certificate of Analysis

Product name: **Cellulosum microcristall. 102**

Batch number / Weight: **23C02-B11-228730 / 1 KG**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23C02-B11 / INS-23-3033**

Reference Code / No.: **V01759 / 225001704**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder slightly hygroscopic powder	Conform		
Particle size	>92% <250 µm	99,2		
Particle size	>45% >75 µm	47,0		
Apparent volume	280-330	328	g/l	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	5,0 - 7,5	6,62		
Conductivity	<=75	36,6	µS / cm	
Ether-soluble substances	<=0,05	0,008	%	
Water-soluble substances	<=0,25	0,244	%	
Loss on drying	<=7,0	4,32	%	
Sulphated ash	<=0,1	0,09	%	
Total aerobic microbial count (TA)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU/g	
E. coli	Negative / gram	Conform		
Ps. aeruginosa	Negative / gram	Conform		
S. aureus	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
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

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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, Eurofins

Release:

Ewelina Gadzinowska

Qualified Person

09-05-2023

Expiration: 22-09-2025

Conclusion: APPROVED

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