

## Certificate of Analysis

**Product name:** Lactosum monohyd. 200M  
**Batch number / Weight:** 21B03-B01-204494 / 5 KG  
**Analysed according to:** Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	4,5 - 5,5	Conform	%	
Appearance of solution	Clear / <=BY7	Conform		
Alcalinity	Conform	Conform	ml	
Specific optical rotation	+54,4 - +55,9	+54,8		
Absorbance	Conform	Conform		
at 400 nm	<= 0,04	0,01		
at 210 to 220 nm	<= 0,25	0,01		
at 270 to 300 nm	<= 0,07	0,01		
Water (Karl Fischer)	4,5 - 5,5	4,9	%	
Sulphated ash	<=0,1	0,08	%	
Total aerobic microbial count (TAMC)	<=100	Conform	CFU / g	
E. coli	Negative / 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
Particle size	X50 (D50) <=125 µm	51	µm	
Particle size	96%<150 µm	99	%	Data producer
Particle size	90%<100 µm	95	%	Data producer

Analysis performed by the authorized lab.

Release:  
Dominika Sołtysik  
Qualified Person

02-06-2021

Expiration: 28-02-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.