

## Certificate of Analysis

**Product name:** **Lactosum monohyd. 200M**

**Batch number / Weight:** **21I20-B13-215678 / 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	+55,3		
Absorbance	Conform	Conform		
400 nm	<= 0,04	0,017		
at 210 to 220 nm	<= 0,25	<0,25		
at 270 to 300 nm	<= 0,07	<0,07		
Water (Karl Fischer)	4,5 - 5,5	4,91	%	
Sulphated ash	<=0,1	0,09	%	
Total aerobic microbial count (TA)	<=100	0,2x10 <sup>1</sup>	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) <=125µm	44	µm	

Analysis performed by the authorized lab.

Release:  
Dominika Sołtysik  
Qualified Person

29-12-2021

Expiration: 31-05-2024

Conclusion: APPROVED

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