

Certificate of Analysis

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

Batch number / Weight: **22A17-B02-217542 / 5 KG**

Analysed according to: **Ph.Eur. + Monogr.**

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	0,2 ml NaOH ml		
Specific optical rotation	+54,4 - +55,9	+55,2		
Absorbance	Conform	Conform		
400 nm	<= 0,04	0,039		
at 210 to 220 nm	<= 0,25	<0,07		
at 270 to 300 nm	<= 0,07	<0,07		
Water (Karl Fischer)	4,5 - 5,5	5,24	%	
Sulphated ash	<=0,1	0,02	%	
Total aerobic microbial count (TA)	<=100	<1	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	50,7	µm	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

27-05-2022

Expiration: 31-10-2024

Conclusion: APPROVED

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