

## Certificate of Analysis

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

**Batch number / Weight:** **23F12-B06-234214 / 5 KG**

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

**Number of analysis / Inspection Code** **23F12-B06 / INS-23-5514**

**Reference Code / No.:** **V01072 / 10B22RR**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	4,5 - 5,5	4,96	%	
Appearance of solution	Clear / <=BY7	Conform		
Alcalinity	Conform	0,35	ml	
Specific optical rotation	+54,4 - +55,9	+54,9		
Absorbance	Conform	Conform		
400 nm	<= 0,04	0,010		
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	4,96	%	
Sulphated ash	<=0,1	0,05	%	
Total aerobic microbial count (TA)	<=10 <sup>2</sup>	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=10 <sup>2</sup>	<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	49	µm	
Particle size	> 96% <150µm	98	% (d.p.)	
Particle size	> 90% <100µm	91	% (d.p.)	

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Fagron Services Northern Europe Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.  
 ul. Pasternik 26, 31-354 Kraków, Poland  
 tel.: +48 12 3343 512  
 e-mail: biuro@fagron.pl

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, Novasome, CBM

Release:  
Dominika Soltysik  
Qualified Person

24-11-2023

Expiration: 31-10-2025

Conclusion: APPROVED

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