

## Certificate of Analysis

**Product name:** **Lactosum monoh. modeste parvum**

**Batch number / Weight:** **23C14-B21-229766 / 5 KG**

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

**Number of analysis / Inspection Code** **23C14-B21 / INS-23-2950**

**Reference Code / No.:** **V01359 / L103833622**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	acc. to Ph. Eur.	Conform		
Acidity or alkalinity	acc. to Ph. Eur.	0,25	ml NaOH	
Specific optical rotation	+54,4 - +55,9(anhydrous substance)	+55,3		
Absorbance: proteins and light-absorbing impurities	max.0,04 at 400 nm	0,007		
- from 210 nm to 220 nm	max. 0,25	<0,25		
- from 270 nm to 300 nm	max.0.07	<0,07		
Water	4,5 - 5,5	5,03	%	
Sulphated ash	<=0,1	0,05	%	
Total aerobic microbial count	<=10 <sup>2</sup>	<1	CFU/g	
E. coli	Negative / 1 gram	Conform		
Particle size, X50 (D50)	180-355	216	µm	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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 lab

Release:

Agnieszka Pszczółka

Qualified Person

26-05-2023

Expiration: 31-08-2025

Conclusion: APPROVED

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