

Certificate of Analysis

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

Batch number / Weight: **21I15-B04-214980 / 5 KG**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white, crystalline powder	Conform		
Identification A	acc. to Ph. Eur.	Conform		
Identification D	4,5 - 5,5	Conform		
Appearance of solution	acc. to Ph. Eur.	Conform		
Alcalinity	acc. to Ph. Eur.	0,21	ml NaOH	
Specific optical rotation	+54,4 - +55,9	+55,2		
Absorbance	acc. to Ph. Eur.	Conform		
Water (Karl Fischer)	4,5 - 5,5	5,09	%	
Sulphated ash	<=0,1	0,06	%	
Total aerobic microbial count	<=10 ²	<1	CFU/g	
E. coli	Negative / 1 gram	Conform		
Particle size, X50 (D50)	180-355	195	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		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

25-02-2022

Expiration: 17-03-2024

Conclusion: APPROVED

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