

Certificate of Analysis

Productname: Lactosum monohyd. 200M
Number of analysis/Inspection Code: 1 / KEUR-182935B
Batchnumber: 20D02-F01-370222
Reference code / No.: 3779 / 105360Z
Analysed according to: PHEUR10.1+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Appearance	poeder	Conform		
Particle size	$\geq 96\%$ $< 150\ \mu\text{m}$	99	%	Sieve analysis; data producer
Particle size	$\geq 90\%$ $< 100\ \mu\text{m}$	93	%	Sieve analysis; data producer
Particle size	X50 (D50) ≤ 125	46	μm	Laser
Identification A	Conform	Conform		IR-spectrum
Identification D	4,5 - 5,5	Conform	%	Water
Appearance of solution	Clear / $\leq \text{BY7}$	Conform		10% m/V
Acidity or alkalinity	Conform	Conform		Data producer
Specific optical rotation	+54,4 - +55,9	+55,0		10% m/V + ammonia; anhydr.; data producer
Absorbance	Conform	Conform		Data producer
Water (Karl Fischer)	4,5 - 5,5	4,8	%	
Sulphated ash	$\leq 0,1$	$\leq 0,1$	%	Data producer
Total aerobic microbial count (TAMC)	$\leq 10^2$	Conform	CFU / g	
E. coli	Negative	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

06/02/20

Expiration: 10-2022

Conclusion: APPROVED

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