



Certificate of Analysis

1.07660.0000 Lactose monohydrate for biochemistry
Batch K56121460

	Spec. Values		Batch Values	
Appearance	White or almost white, fine powder.		White or almost white, fine powder.	
Identity (IR)	passes test		passes test	
Identity (TLC)	passes test		passes test	
Identity (water)	passes test		passes test	
Appearance of solution	passes test		passes test	
Acidity or alkalinity	passes test		passes test	
Spec. rotation (α 20/D; 10 %; water; calc. on anhydrous substance)	+54.4 - +55.9	°	+55.3	°
Heavy metals (as Pb)	≤ 5	ppm	≤ 5	ppm
Proteins and UV-absorbing impurities	passes test		passes test	
Sulfated ash	≤ 0.1	%	≤ 0.1	%
Loss on drying (80 °C, 2 h)	≤ 0.5	%	0.1	%
Residual solvents (ICH Q3C)	excluded by the production process		excluded by the production process	
Water	4.5 - 5.5	%	5.0	%
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 200	CFU/g	≤ 200	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 100	CFU/g	≤ 100	CFU/g
Escherichia coli (absent in 1 g)	passes test		passes test	

Corresponds to Ph Eur and USP/NF

Minimum shelf life (DD.MM.YYYY) 31.05.2026

Julian Hofmann

Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.