



Specification

1.07660.0250 Lactose monohydrate for biochemistry

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

Corresponds to Ph Eur and USP/NF

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Responsible laboratory manager quality control

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