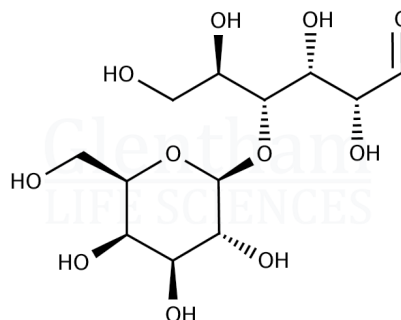


Certificate of Analysis

Product Name	Lactose, anhydrous, Ph. Eur., USP grade
Glentham Code	GC1111
CAS Number	63-42-3
EINECS	200-559-2
MDL Number	MFCD00151251
Additional CAS	64044-51-5
Additional CAS	10039-26-6
Additional CAS	14641-93-1
Additional CAS	5989-81-1
Batch Number	039QUN

Molecular Weight	342.30
Molecular Formula	C ₁₂ H ₂₂ O ₁₁
Storage Temp.	+20°C



Property	Specification	Batch 039QUN
Physical Description	White or almost white crystalline powder	White crystalline powder
Identification	According to Ph. Eur., USP	Conforms
Solubility (10% in water)	Clear, colourless solution (boiling water)	Clear, colourless solution
Acidity or Alkalinity	≤ 0.4ml (of 0.1M NaOH)	Conforms
Specific Optical Rotation	+54.4 - +55.9 ° (anhydrous substance)	+54.5°
Absorbance	≤ 0.04 (400nm)	0.03
	≤ 0.07 (270 - 300 nm)	0.01
	≤ 0.25 (210 - 220 nm)	0.05
Heavy Metals	≤ 5ppm	Conforms
Water	≤ 1.0%	0.2%
Loss on Drying	≤ 0.5%	0.1%
Residue on Ignition	≤ 0.1%	0.03%
Total Aerobic Microbial Count	≤ 100CFU/g	≤ 10CFU/g
Total Combined Yeast and Mould Count	≤ 50CFU/g	≤ 10CFU/g
E. Coli	Absent in 10g	Conforms
Assay (GC)	≥ 99.5% (C ₁₂ H ₂₂ O ₁₁)	99.9%
Pharmacopoeia Specification(s)	Conforms to Ph. Eur., USP	Conforms

Specification Version	v1.1
Manufacture Date	2023-10-25
Re-Test Date	2031-01-08

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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