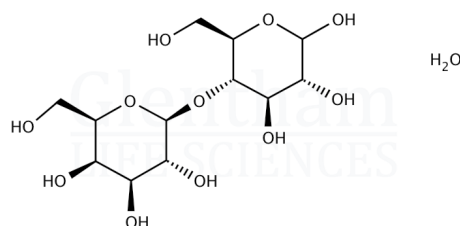


Certificate of Analysis

Product Name D(+)-Lactose monohydrate, 99.5%, Ph. Eur. grade

Glentham Code GC9081
CAS Number 64044-51-5
EINECS 200-559-2
Numéro MDL MFCD00166994
CAS supplémentaire 10039-26-6
CAS supplémentaire 14641-93-1
CAS supplémentaire 5989-81-1
CAS supplémentaire 63-42-3 (anhydrous)
Batch Number 472IKP

Molecular Weight 360.32
Molecular Formula $C_{12}H_{22}O_{11} \cdot H_2O$
Storage Temp. +20°C



Property	Specification	Batch 472IKP
Physical Description	White or almost white crystalline powder	Conforms
Identification	A, B, C, D according to Ph. Eur.	Conforms
Solubility (10% in water)	Clear, colourless solution	Clear, colourless solution
Acidity or Alkalinity	≤ 0.4ml (0.1M NaOH required)	0.2ml
Absorbance	10% in water at 400nm: ≤ 0.04	0.00
	1% in water at 270 - 300nm: ≤ 0.07	0.01
	1% in water at 210 - 220nm: ≤ 0.25	0.03
Specific Optical Rotation	+54.4 - +55.9 ° (anhydrous substance)	+55.4°
Heavy Metals	≤ 5ppm	≤ 5ppm
Water	4.5 - 5.5 %	5.1%
Sulphated Ash	≤ 0.1%	≤ 0.1%
Arsenic (As)	≤ 0.5ppm	≤ 0.5ppm
Lead (Pb)	≤ 0.01ppm	≤ 0.01ppm
Cadmium (Cd)	≤ 0.1ppm	≤ 0.01ppm
Mercury (Hg)	≤ 0.01ppm	≤ 0.01ppm
Cobalt (Co)	≤ 1ppm	≤ 1ppm
Vanadium (V)	≤ 1ppm	≤ 1ppm
Nickel (Ni)	≤ 1ppm	≤ 1ppm
Lithium (Li)	≤ 1ppm	≤ 1ppm
Antimony (Sb)	≤ 1ppm	≤ 1ppm
Barium (Ba)	≤ 1ppm	≤ 1ppm
Molybdenum (Mo)	≤ 1ppm	≤ 1ppm
Copper (Cu)	≤ 0.1ppm	≤ 0.1ppm
Tin (Sn)	≤ 1ppm	≤ 1ppm
Chromium (Cr)	≤ 1ppm	≤ 1ppm

Certificate of Analysis

Purity	≥ 99.5% (anhydrous basis)	99.8%
Pharmacopoeia Specification(s)	Ph. Eur.	Conforms
Specification Version	v1.0	
Manufacture Date	2023-05-29	
Re-Test Date	2032-07-28	

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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