

Specification

Technical Data Sheet

CAS

64044-51-5

STORAGE

Ambient

MOLECULAR WEIGHT

360.32

PRODUCT

D-Lactose monohydrate

Product number	16091931
CAS number	64044-51-5
Molecular formula	C ₁₂ H ₂₂ O ₁₁ · H ₂ O
Molecular weight	360.32 g/mol

PARAMETER

SPECIFICATION

Appearance	White, crystalline powder
Molecular Weight	360.31
Assay (HPLC)	(HPLC) 98% to 102%
Grade	BP2009
Heavy metals	≤ 5ppm
Identification	The infrared absorption spectrum of the sample is concordant with that of the standard.
Specific rotation	+54.4° to +55.9°
Water	4.5% to 5.5%
Absorbance	The absorbance of the solution measured at 400 nm is not greater than 0.04. Dilute 1.0 ml of solution A to 10.0 ml with water R. Examine the solution from 210 nm to 300 nm. At wavelengths from 210 nm to 220 nm, the absorbance is not greater than 0.25. At wavelengths from 270 nm to 300nm, the absorbance is not greater than 0.07.
Acidity / Alkalinity	Add 0.3 ml of phenolphthalein solution R. The solution is colorless. Not more than 0.4 ml of 0.1 N sodium hydroxide is required to change the color of the indicator to pink.
Appearance of Solution	The solution is clear and not more intensely colored than reference solution BY7.

PARAMETER	SPECIFICATION
Escherichia coli	Absence
Identification A	The infrared absorption spectrum of the sample is concordant with that of the standard.
Specific optical rotation	+54.4° to +55.9°, calculated with reference to the anhydrous substance.
Sulphated Ash	≤0.1%
TPC	<100cfu/g

SPECIFICATION STATEMENT	The values stated above represent the standard specification for this product, issued under Molekula Ltd 's quality management system. Batch-specific results are provided on the Certificate of Analysis.
STORAGE	Store as indicated on the product label, away from light, moisture and incompatible materials.

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