

Specification

Technical Data Sheet

CAS

5989-81-1

STORAGE

Ambient

MOLECULAR WEIGHT

360.31

PRODUCT

alpha-D-Lactose monohydrate USP

Product number 90037408

CAS number 5989-81-1

Molecular formula C₁₂H₂₂O₁₁·H₂O

Molecular weight 360.31 g/mol

PARAMETER

SPECIFICATION

Appearance

White to Off-white powder

Assay

98.0 - 102.0%

Heavy metals

≤ 5.0µg

Loss on Drying

≤ 0.5% (80°C, 2hours)

Water

4.5 - 5.5%

Acidity / Alkalinity

Add 0.3ml of phenolphthalein TS: the solution is colourless and ≤ 0.4 ml of 0.1N sodium hydroxide is required to produce a pink or red colour.

Clarity and colour of solution

The solution(1g in 10ml of boiling water) is clear and nearly colorless. Determine the absorbance of this solution at a wavelength of 400 nm. The absorbance divided by the path length, in cm, is ≤ 0.04

Escherichia coli

Absent in 10g

Identification A

FT-IR Conforms to USP reference

Optical Rotation

+54.4 to +55.9°

Residue on Ignition

≤ 0.1%

Solubility

Free soluble in water, practically insoluble in ethanol (96%)

Identification B

The principal spot obtained from the Test solution corresponds in appearance and RF value to that obtained from Standard solution A. The test is not valid unless the chromatogram

PARAMETER	SPECIFICATION
	obtained with Standard solution B shows four clearly discernible spots, disregarding any spots at the origin.
Mould & Yeast	≤ 50cfu/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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