



Specification

Lactose Monohydrate USP-NF/EP/JP

Catalog Number:	LM1001
CAS Number:	64044-51-5
Molecular Formula:	$C_{12}H_{22}O_{11} \cdot H_2O$
Molecular Weight:	360.32
Storage:	15°C – 30°C
Retest Period:	Three years from the date of manufacture

Test	Specification
Appearance	White powder
Identification A (FTIR) ¹	To match reference spectra
Identification B (TLC) ¹	To meet requirements
Specific Rotation ¹	+54.4° to + 55.9°
Clarity & Color of Solution ¹	Clear & nearly colorless
Absorbance (400nm) ¹	≤ 0.04
Appearance of Solution ²	To meet requirements
PLAI Absorbance ¹	
210-220nm	≤ 0.25
270-300nm	≤ 0.07
Acidity/Alkalinity ¹	≤ 0.4 mL
Acidity/Alkalinity Color ¹	Solution is colorless
Moisture (LOD) ¹	≤ 0.5%
Water Determination ¹	4.5 – 5.5%
Residue on Ignition ¹	≤ 0.1%
Heavy Metals ¹	To meet requirements
Heavy Metals ³	To meet requirements
Particle Size	
#100 (non-cumulative) ¹	0.0 – 10.0%
#200 (non-cumulative) ¹	10.0 – 30.0%
#80 (non-cumulative) ¹	0.0 – 5.0%
Total Aerobic Count ¹	≤ 100cfu/g
Total Mold & Yeast ¹	≤ 50cfu/g
E. coli ¹	Negative
Salmonella ¹	Negative

¹ Meets USP-NF specifications, ² Meets EP specification, ³ Meets JP specification.

Approved:

John Grubb, PhD
Gojira Fine Chemicals

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