



Certificate of Analysis

Lactose Monohydrate USP-NF/EP/JP

Catalog Number: LM1001
Lot Number: 0622804
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
Date of Manufacture: October 7, 2017
Retest Date: October 6, 2020

Test	Specification	Result
Appearance	White powder	Conforms
Identification A (FTIR) ¹	To match reference spectra	Conforms
Identification B (TLC) ¹	To meet requirements	Conforms
Specific Rotation ¹	+54.4° to + 55.9°	+55.2°
Clarity & Color of Solution ¹	Clear & nearly colorless	Conforms
Absorbance (400nm) ¹	≤ 0.04	0.00
Appearance of Solution ²	To meet requirements	Conforms
PLAI Absorbance ¹		
210-220nm	≤ 0.25	0.03
270-300nm	≤ 0.07	0.00
Acidity/Alkalinity ¹	≤ 0.4 mL	0.1mL
Acidity/Alkalinity Color ¹	Solution is colorless	Conforms
Moisture (LOD) ¹	≤ 0.5%	0.1%
Water Determination ¹	4.5 – 5.5%	5.0%
Residue on Ignition ¹	≤ 0.1%	0.02%
Heavy Metals ¹	To meet requirements	Conforms
Heavy Metals ³	To meet requirements	Conforms
Particle Size		
#100 (non-cumulative) ¹	0.0 – 10.0%	0.1%
#200 (non-cumulative) ¹	10.0 – 30.0%	20.1%
#80 (non-cumulative) ¹	0.0 – 5.0%	0.0%
Total Aerobic Count ¹	≤ 100cfu/g	3cfu/g
Total Mold & Yeast ¹	≤ 50cfu/g	3cfu/g
E. coli ¹	Negative	Negative
Salmonella ¹	Negative	Negative

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



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Approved by:

Date: June 28, 2018

A handwritten signature in blue ink that reads "John Grubb". The signature is written in a cursive, flowing style.

John Grubb, PhD
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