

Lactose, Monohydrate, Powder  
N.F.



Material No.: 2249-07  
Revision No.: 0

## Product Specification

Meets N.F. Requirements, GMP Manufactured Product

Test	Specification
NF - Clarity and Color of Solution	Passes Test
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - Specific Rotation $[\alpha]^{20}_D (+)$	54.4 - 55.9 °
Microbial Limits - Total Aerobic Count (per g)	≤ 100
Microbial Limits - Total Combined Molds and Yeasts Count (per g)	≤ 50
Microbial Limits - Escherichia coli	Passes Test
NF - Acidity or Alkalinity	Passes Test
NF - Loss on Drying at 80°C	≤ 0.5 %
NF - Water (H <sub>2</sub> O)	4.5 - 5.5 %
NF - Residue on Ignition	≤ 0.1 %
NF - Protein and Light-Absorbing Impurities	Passes Test

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Paris Mfg Ctr & DC

  
Jamie Ethier  
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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