

## Product Specification

Meets N.F. Requirements, Meets J.P. Chemical Specifications, Meets E.P. Chemical Specifications, 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 $[\alpha]^{20\text{D}} (+)$	54.4 – 55.9 °
NF – Microbial Limits – Total Aerobic Mi	$\leq 100$
NF – Microbial Limits – Total Combined M	$\leq 50$
NF – Microbial Limits – Escherichia Coli	Passes Test
NF – Acidity or Alkalinity	Passes Test
NF – Loss on Drying at 80°C	$\leq 0.5 \%$
NF – Water (H <sub>2</sub> O)	4.5 – 5.5 %
NF – Residue on Ignition	$\leq 0.1 \%$
NF – Protein and Light-Absorbing Impuriti	Passes Test
EP – Identification A	Passes Test
EP – Identification B	Passes Test
EP – Identification C	Passes Test
EP – Identification D	Passes Test
EP – Specific Rotation $[\alpha]^{20\text{D}} (+)$	54.4 – 55.9 °
EP – Sulfated Ash	$\leq 0.1 \%$
EP – Microbial Limits – Total Aerobic Mi	$\leq 100$
EP – Microbial Limits – Total Combined Mo	$\leq 50$
EP – Microbial Limits – Escherichia coli	Passes Test
EP – Acidity or Alkalinity	Passes Test
EP – Water (H <sub>2</sub> O)	4.5 – 5.5 %
EP – Protein and Light-Absorbing Impuriti	Passes Test
EP – Appearance of Solution	Passes Test
JP – Clarity and Color of Solution	Passes Test
JP – Identification A	Passes Test
JP – Specific Rotation $[\alpha]^{20\text{D}} (+)$	54.4 – 55.9 °

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Lactose, Monohydrate, Powder, N.F.  
Multi-Compendial



Material No.: 2250-07

Test	Specification
JP – Microbial Limits – Total Aerobic Mi	≤ 100
JP – Microbial Limits – Total Combined M	≤ 50
JP – Microbial Limits – Escherichia Coli	Passes Test
JP – Acidity or Alkalinity	Passes Test
JP – Water (H <sub>2</sub> O)	4.5 – 5.5 %
JP – Loss on Drying at 80°C	≤ 0.5 %
JP – Residue on Ignition	≤ 0.10 %
JP – Heavy Metals (as Pb)	≤ 5 ppm
JP – Protein and Light-Absorbing Impurit	Passes Test
Endotoxin Concentration (EU/g), For Info	

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.

Internationally Harmonized

Storage Condition: Store in airtight container.

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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