



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

Product No. 2250
Specifications current as of: Feb
28 2017

TEST	SPECIFICATION
GMP Manufactured Product	
Meets E.P. Chemical Specifications	
Meets J.P. Chemical Specifications	
Meets N.F. Requirements	
Store in airtight container.	
CAUTION: For Manufacturing, processing or repackaging	
Bulk Pharmaceutical Chemical	
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 Degree
NF - Microbial Limits - Total Aerobic Microbial Counts, cfu/g	≤ 100
NF - Microbial Limits - Total Combined Molds and Yeasts Count (per g)	≤ 50
NF - Microbial Limits - Escherichia Coli and Salmonella	Passes Test
NF - Acidity or Alkalinity	Passes Test
NF - Loss on Drying at 80°C	$\leq 0.5 \%$
NF - Water (H ₂ O)	4.5 - 5.5 %
NF - Residue on Ignition	$\leq 0.1 \%$
NF - Heavy Metals (as Pb)	≤ 5 ppm
NF - Protein and Light-Absorbing Impurities	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 $[\alpha]^{20}_D (+)$	54.4 - 55.9 Degree
EP - Sulfated Ash	$\leq 0.1 \%$
EP - Microbial Limits - Total Aerobic Microbial Count, cfu/g	≤ 100
EP- Microbial Limits - Total Combined Molds and Yeasts Count (per g)	≤ 50
EP - Microbial Limits - Escherichia coli (absent)	Passes Test
EP - Acidity or Alkalinity	Passes Test
EP - Water (H ₂ O)	4.5 - 5.5 %
EP - Heavy Metals (as Pb)	≤ 5 ppm
EP - Protein and Light-Absorbing Impurities	Passes Test

EP - Appearance of Solution	Passes Test
JP - Clarity and Color of Solution	Passes Test
JP - Identification A	Passes Test
JP - Specific Rotation [α] _D ²⁰ (+)	54.4 - 55.9 Degree
JP - Microbial Limits - Total Aerobic Microbial Count, cfu/g	<= 100
JP - Microbial Limits - Total Combined Molds and Yeasts Count (per g)	<= 50
JP - Microbial Limits - Escherichia Coli and Salmonella	Passes Test
JP - Acidity or Alkalinity	Passes Test
JP - Water (H ₂ 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 Impurities	Passes Test
Endotoxin Concentration (EU/g), For Information Only	
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.	
Internationally Harmonized	