

Sorbitol
Multi-Compendial



Material No.: 3449-09

Revision No.: 0

Product Specification

Meets J.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets N.F. Requirements, Meets B.P. Chemical Specifications, GMP Manufactured Product

Test	Specification
NF - Assay (anhydrous basis)	91.0 - 100.5 %
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - pH of 10% solution	3.5 - 7.0
NF - Reducing Sugars	≤ 0.3 %
NF - Residue on Ignition	≤ 0.1 %
NF - Sulfate (SO ₄)	≤ 0.01 %
NF - Chloride (Cl)	≤ 0.0050 %
NF - Nickel (Ni)	≤ 1 ppm
NF - Water	≤ 1.5 %
NF - Total Aerobic Microbial Count, cfu/g	≤ 1000
NF - Total Yeast and Mold Count, cfu/g	≤ 100
EP/BP - Assay (anhydrous basis)	97.0 - 102.0 %
EP/BP - Identification A	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP - Conductivity, uS cm-1	≤ 20
EP/BP - Reducing Sugars	≤ 0.2 %
EP/BP - Related Substances - Any impurity, each	≤ 2.0 %
EP/BP - Related Substances - Total	≤ 3.0 %
EP/BP - Water	≤ 1.5 %
Total Viable Aerobic Count - Total Aerobic Microbial Count, cfu/g	≤ 100
Total Viable Aerobic Count - Total Yeast and Mold Count, cfu/g	≤ 100
Total Viable Aerobic Count - Escherichia coli (negative)	Passes Test
Salmonella (negative)	Passes Test
Endotoxin Concentration, <2.5 IU/g	Passes Test
JP - Assay (dried basis)	≥ 97.0 %
JP - Identification A	Passes Test
JP - Identification B	Passes Test

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

Avantor Performance Materials, LLC

100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
JP - Identification C	Passes Test
JP - Clarity and Color	Passes Test
JP - Acidity or Alkalinity	Passes Test
JP - Chloride (Cl)	$\leq 0.005 \%$
JP - Sulfate (SO ₄)	$\leq 0.006 \%$
JP - Heavy Metals (as Pb)	≤ 5 ppm
JP - Nickel (Ni)	Passes Test
JP - Arsenic (As)	≤ 1.3 ppm
JP - Glucose	Passes Test
JP - Sugars	Passes Test
JP - Loss on Drying	$\leq 2.0 \%$
JP - Residue on Ignition	$\leq 0.02 \%$

GMP Manufactured Product
Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only Class 2 solvents (Ethylene Glycol) are likely to be present. All are below Option 1 limits.

Packaging Site: Paris Mfg Ctr & DC


Jamie Ethier
Vice President Global Quality

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