

## 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 <sub>4</sub> )	≤ 0.01 %
NF – Chloride (Cl)	≤ 0.0050 %
NF – Nickel (Ni)	≤ 1 ppm
NF – Water	≤ 1.5 %
NF – Total Aerobic Microbial Count, cfu/	≤ 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 <sup>-1</sup>	≤ 20
EP/BP – Reducing Sugars	≤ 0.2 %
EP/BP – Related Substances – Any impurit	≤ 2.0 %
EP/BP – Related Substances – Total	≤ 3.0 %
EP/BP – Water	≤ 1.5 %
Total Viable Aerobic Count – Total Aerob	≤ 100
Total Viable Aerobic Count – Total Yeast	≤ 100
Total Viable Aerobic Count – Escherichia	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

>>> Continued on page 2 >>>

Sorbitol  
Multi-Compendial



Material No.: 3449-06

Test	Specification
JP - Identification C	Passes Test
JP - Clarity and Color	Passes Test
JP - Acidity or Alkalinity	Passes Test
JP - Chloride (Cl)	≤ 0.005 %
JP - Sulfate (SO <sub>4</sub> )	≤ 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	≤ 2.0 %
JP - Residue on Ignition	≤ 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

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