

Trehalose, Dihydrate, NF
Multi-Compendial
High Purity, Low Endotoxin
HPLE, Parenteral Grade



Material No.: 6324-05

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 (HPLC)	97.0 - 102.0 %
NF - Chloride (Cl)	≤ 0.0125 %
NF - Color and Clarity of Solution: Absorbance @ 720 nm	≤ 0.050
NF - Color and Clarity of Solution, Absorption difference	≤ 0.100
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - Identification C	Passes Test
NF - Microbial Limits: TAMC (cfu/g)	≤ 100 CFU/g
NF - Microbial Limits: TYMC (cfu/g)	≤ 100 CFU/g
NF - Microbial Limits: E. coli	None Detected
NF - Microbial Limits: Salmonella	None Detected
NF - Nitrogen content	≤ 0.005 %
NF - pH of 10% solution	4.5 - 6.5
NF - Related Substances - total peaks eluting before trehalose	≤ 0.5 %
NF - Related Substances - total peaks eluting after trehalose	≤ 0.5 %
NF - Residue on Ignition	≤ 0.10 %
NF - Soluble starch	Passes Test
NF - Specific Optical Rotation, anhydrous [α] _D ²⁰ (+)	197 - 201 °
NF - Sulfate (SO ₄)	≤ 0.0200 %
NF - Water (by Karl Fischer titration)	9.0 - 11.0 %
EP/BP - Appearance of Solution	Passes Test
EP/BP - Assay (LC)	97.0 - 102.0 %
EP/BP - Chloride (Cl)	≤ 125 ppm
EP/BP - Identification A	Passes Test
EP/BP - Identification B	Passes Test
EP/BP - Identification C	Passes Test
EP/BP - Microbial Limits: TAMC (cfu/g)	≤ 100 CFU/g
EP/BP - Microbial Limits: TYMC (cfu/g)	≤ 100 CFU/g

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

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Test	Specification
EP/BP - Microbial Limits: E. coli	None Detected
EP/BP - Microbial Limits: Salmonella	None Detected
EP/BP - pH of 10% solution	4.5 - 6.5
EP/BP - Related Substances - Impurity A	≤ 0.5 %
EP/BP - Related Substances - Impurity B	≤ 0.5 %
EP/BP - Related Substances - Unspecified Impurities, each	≤ 0.2 %
EP/BP - Related Substances - Total Impurities	≤ 1.0 %
EP/BP - Soluble starch	Passes Test
EP/BP - Specific Optical Rotation, anhydrous $[\alpha]^{20}_D (+)$	197 - 201 °
EP/BP - Sulfate (SO ₄)	≤ 200 ppm
EP/BP - Sulfated ash	≤ 0.1 %
EP/BP - Water (by Karl Fischer	9.0 - 11.0 %
JP - Assay (LC)	98.0 - 101.0 %
JP - Chloride (Cl)	≤ 0.018 %
JP - Dextrin, soluble starch and sulfite	Passes Test
JP - Heavy Metals (as Pb)	≤ 5 ppm
JP - Identification 1	Passes Test
JP - Identification 2	Passes Test
JP - Identification 3	Passes Test
JP - Nitrogen	≤ 0.005 %
JP - pH of 10% solution	4.5 - 6.5
JP - Related Substances - total peaks eluting before trehalose	≤ 0.5 %
JP - Related Substances - total peaks eluting after trehalose	≤ 0.5 %
JP - Residue on Ignition	≤ 0.1 %
JP - Specific Optical Rotation, anhydrous $[\alpha]^{20}_D (+)$	197 - 201 °
JP - Sulfate (SO ₄)	≤ 0.024 %
JP - Water (by Karl Fischer titration)	9.0 - 11.0 %
Appearance (white to off white powder)	Passes Test
Conductivity, uS cm ⁻¹	≤ 15
Reducing Sugars	Passes Test
Glucose Area%	≤ 0.5 %
Microbial Testing - Staphylococcus aureus (USP)	None Detected
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Microbial Testing - Pseudomonas aeruginosa (USP)	None Detected
Specific Optical Rotation, dihydrate $[\alpha]^{20}_D (+)$	177.5 - 180.5 °
Endotoxin Concentration, EU/g	≤ 0.6
Trace Impurities - Aluminum (Al), For Information Only	ppb
Trace Impurities - Arsenic (As), For Information Only	ppb
Trace Impurities - Cadmium (Cd), For Information Only	ppb
Trace Impurities - Chromium (Cr), For Information Only	ppb
Trace Impurities - Copper (Cu), For Information Only	ppb
Trace Impurities - Iridium (Ir), For Information Only	ppb
Trace Impurities - Iron (Fe), For Information Only	ppb
Trace Impurities - Lead (Pb), For Information Only	ppb
Trace Impurities - Manganese (Mn), For Information Only	ppb
Trace Impurities - Mercury (Hg), For Information Only	ppb
Trace Impurities - Molybdenum (Mo), For Information Only	ppb
Trace Impurities - Nickel (Ni), For Information Only	ppb
Trace Impurities - Osmium (Os), For Information Only	ppb
Trace Impurities - Palladium (Pd), For Information Only	ppb
Trace Impurities - Platinum (Pt), For Information Only	ppb
Trace Impurities - Rhodium (Rh), For Information Only	ppb
Trace Impurities - Ruthenium (Ru), For Information Only	ppb
Trace Impurities - Vanadium (V), For Information Only	ppb
Trace Impurities - Zinc (Zn), For Information Only	ppb
Residual Methanol	≤ 3000 ppm
Residual Ethanol	≤ 5000 ppm
Residual Isopropanol	≤ 5000 ppm
Cyanide (CN)	≤ 100 ppb

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Test	Specification
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GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
Residual Solvents: Only the Class 2 solvent Methanol and the Class 3 Solvents Ethanol and Isopropanol are likely to be present.
Each is tested and the concentration reported for each batch.
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.
Plant Derived.
Suitable for use in the manufacture of parenteral dosage forms.

Packaging Site: Phillipsburg Mfg Ctr & DC


Jamie Ethier
Vice President Global Quality

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