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

Material No.: 6324-05
Batch No.: 0000191208
Manufactured Date: 2017/10/12
Expiration Date: 2019/10/12

Certificate of Analysis

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

Test	Specification	Result
NF – Assay (HPLC)	97.0 – 102.0 %	98.9
NF – Chloride (Cl)	<= 0.0125 %	< 0.0125
NF – Color and Clarity of Solution: Absorbance @ 720 nm	<= 0.050	< 0.001
NF – Color and Clarity of Solution, Absorption difference	<= 0.100	0.013
NF – Identification A	Passes Test	PT
NF – Identification B	Passes Test	PT
NF – Identification C	Passes Test	PT
NF – Microbial Limits: TAMC (cfu/g)	<= 100 cfu/g	< 10
NF – Microbial Limits: TYMC (cfu/g)	<= 100 cfu/g	< 10
NF – Microbial Limits: E. coli	None Detected	None Detected
NF – Microbial Limits: Salmonella	None Detected	None Detected
NF – Nitrogen content	<= 0.005 %	< 0.005
NF – pH of 10% solution	4.5 – 6.5	5.8
NF – Related Substances – total peaks eluting before trehalose	<= 0.5 %	0.2
NF – Related Substances – total peaks eluting after trehalose	<= 0.5 %	< 0.1
NF – Residue on Ignition	<= 0.10 %	0.02
NF – Soluble starch	Passes Test	PT
NF – Specific Optical Rotation, anhydrous [Å]²°^D (+)	197 – 201 Degree	198
NF – Sulfate (SO_4)	<= 0.0200 %	< 0.0200

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.
3477 Corporate Parkway. Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
NF - Water (by Karl Fischer titration)	9.0 - 11.0 %	9.6
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - Assay (LC)	97.0 - 102.0 %	99.0
EP/BP - Chloride (Cl)	<= 125 ppm	< 125
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification C	Passes Test	PT
EP/BP - Microbial Limits: TAMC (cfu/g)	<= 100 cfu/g	< 10
EP/BP - Microbial Limits: TYMC (cfu/g)	<= 100 cfu/g	< 10
EP/BP - Microbial Limits: E. coli	None Detected	None Detected
EP/BP - Microbial Limits: Salmonella	None Detected	None Detected
EP/BP - pH of 10% solution	4.5 - 6.5	5.8
EP/BP - Related Substances - Impurity A	<= 0.5 %	< 0.1
EP/BP - Related Substances - Impurity B	<= 0.5 %	0.2
EP/BP - Related Substances - Unspecified Impurities, each	<= 0.2 %	< 0.1
EP/BP - Related Substances - Total Impurities	<= 1.0 %	0.3
EP/BP - Soluble starch	Passes Test	PT
EP/BP - Specific Optical Rotation, anhydrous [Å]²°^D (+)	197 - 201 Degree	198
EP/BP - Sulfate (SO_4)	<= 200 ppm	< 200
EP/BP - Sulfated ash	<= 0.1 %	< 0.1
EP/BP - Water (by Karl Fischer	9.0 - 11.0 %	9.3
JP - Assay (LC)	98.0 - 101.0 %	100.3
JP - Chloride (Cl)	<= 0.018 %	< 0.018
JP - Dextrin, soluble starch and sulfite	Passes Test	PT
JP - Heavy Metals (as Pb)	<= 5 ppm	< 5
JP - Identification 1	Passes Test	PT
JP - Identification 2	Passes Test	PT
JP - Identification 3	Passes Test	PT
JP - Nitrogen	<= 0.005 %	< 0.005
JP - pH of 10% solution	4.5 - 6.5	5.8
JP - Related Substances - total peaks eluting before trehalose	<= 0.5 %	0.2
JP - Related Substances - total peaks eluting after	<= 0.5 %	0.2

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Test	Specification	Result
trehalose		
JP - Residue on Ignition	<= 0.1 %	< 0.1
JP - Specific Optical Rotation, anhydrous [Å]²°^D (+)	197 - 201 Degree	198
JP - Sulfate (SO_4)	<= 0.024 %	< 0.024
JP - Water (by Karl Fischer titration)	9.0 - 11.0 %	9.3
Appearance (white to off white powder)	Passes Test	PT
Conductivity, uS cm-1	<= 15	< 15
Reducing Sugars	Passes Test	PT
Glucose Area%	<= 0.5 %	< 0.1
Microbial Testing - Staphylococcus aureus (USP)	None Detected	None Detected
Microbial Testing - Pseudomonas aeruginosa (USP)	None Detected	None Detected
Specific Optical Rotation, dihydrate [Å]²°^D (+)	177.5 - 180.5 Degree	179.2
Endotoxin Concentration, EU/g	<= 0.6	< 0.1
Trace Impurities - Aluminum (Al), For Information Only	ppb	< 10.0
Trace Impurities - Arsenic (As), For Information Only	ppb	< 10.0
Trace Impurities - Cadmium (Cd), For Information Only	ppb	< 10.0
Trace Impurities - Chromium (Cr), For Information Only	ppb	< 10.0
Trace Impurities - Copper (Cu), For Information Only	ppb	< 10.0
Trace Impurities - Iridium (Ir), For Information Only	ppb	< 10
Trace Impurities - Iron (Fe), For Information Only	ppb	< 10.0
Trace Impurities - Lead (Pb), For Information Only	ppb	< 10.0
Trace Impurities - Manganese (Mn), For Information Only	ppb	< 10.0
Trace Impurities - Mercury (Hg), For Information Only	ppb	< 10.0
Trace Impurities - Molybdenum (Mo), For Information Only	ppb	< 10.0
Trace Impurities - Nickel (Ni), For Information Only	ppb	< 10.0
Trace Impurities - Osmium (Os), For Information Only	ppb	< 10
Trace Impurities - Palladium (Pd), For Information Only	ppb	< 10.0
Trace Impurities - Platinum (Pt), For Information Only	ppb	< 10.0
Trace Impurities - Rhodium (Rh), For Information Only	ppb	< 10.0
Trace Impurities - Ruthenium (Ru), For Information Only	ppb	< 10.0

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Test	Specification	Result
Trace Impurities - Vanadium (V), For Information Only	ppb	< 10.0
Trace Impurities - Zinc (Zn), For Information Only	ppb	11.0
Residual Methanol	<= 3000 ppm	62
Residual Ethanol	<= 5000 ppm	331
Residual Isopropanol	<= 5000 ppm	18
Cyanide (CN)	<= 100 ppb	< 100

Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
Residual Solvents: Only the Class 2 solvent Methanol and the Class 3 Solvent Ethanol 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.

Country of Origin:	US
Packaging Site:	Phillipsburg Mfg Ctr & DC
Manufacturer:	PBG
Manufacturer source batch:	0000185336

ISO
Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
Gliwice, Poland 9001:2008, 13485:2012
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008
Panoli, India 9001:2008

James Ethier
Jamie Ethier
Vice President Global Quality

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