Sucrose, NF
Multi-Compendial
High Purity, Low Endotoxin, Cane Derived
HPLE, Parenteral Grade

Material No.: 6320-05
Batch No.: 0000169025
Manufactured Date: 2016/10/28
Retest Date: 2021/10/27

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 – Identification	Passes Test	PT
NF – Appearance of Solution	Passes Test	PT
NF – Color Value	<= 45	< 10
NF – Conductivity	<= 35 µS/cm	< 1
NF – Optical Rotation (+)	66.3 – 67.0 Degree	66.4
NF – Reducing Sugars	Passes Test	PT
NF – Sulfite (SO2)	<= 10 ppm	< 10
NF – Loss on Drying at 105 °C	<= 0.1 %	< 0.1
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Conductivity, uS cm-1	<= 35	< 1
EP/BP – Optical Rotation (+)	66.3 – 67.0 Degree	66.4
EP/BP – Colour Value	<= 45	< 10
EP/BP – Reducing Sugars	Passes Test	PT
EP/BP – Sulfite (SO_2)	<= 10 ppm	< 10
EP/BP – Loss on Drying at 105°C	<= 0.1 %	< 0.1
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	66.3 – 67.0 Degree	66.4
JP – Color Value	<= 45	< 10
JP – Clarity of Solution	Passes Test	PT
JP – Dextrins	Passes Test	PT

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

Material No.: 6320-05
Batch No.: 0000169025

Test	Specification	Result
JP - Sulfite (SO_2)	<= 10 ppm	< 10
JP - Conductivity, uS cm-1	<= 35	< 1
JP - Loss on Drying at 105°C	<= 0.1 %	< 0.1
JP - Reducing Sugars	Passes Test	PT
Assay (HPLC)	>= 99 %	101
Endotoxin Concentration (EU/g)	<= 0.6	0.2
Microbial Testing - Salmonella (USP)	None Detected	None Detected
Microbial Testing - E. coli (USP)	None Detected	None Detected
Microbial Testing - Staphylococcus aureus (USP)	None Detected	None Detected
Microbial Testing - Pseudomonas aeruginosa (USP)	None Detected	None Detected
Microbial Testing - Total Yeast and Molds (USP)	<= 100 cfu/g	< 10
Microbial Testing - Total Aerobic Microbial Count (USP)	<= 100 cfu/g	< 10
Microbial Testing -Bile tolerant gram-negative bacteria	None Detected	None Detected
Microbial Testing - Clostridia	None Detected	None Detected
Microbial Testing - Candida albicans	None Detected	None Detected
Trace Impurities - Aluminum (Al), For Information Only	ppb	15.0
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	15.0
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

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Test	Specification	Result
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
Trace Impurities - Vanadium (V), For Information Only	ppb	< 10.0
Trace Impurities - Zinc (Zn), For Information Only	ppb	< 10.0
Residual Methanol	<= 3000 ppm	56
Residual Ethanol	<= 5000 ppm	655
Residual Isopropanol	<= 5000 ppm	31

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.

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:	0000157543

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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