

D-(+)-Galactose
 Multi-Compendial
 High Purity, Low Endotoxin
 HPLC, Tested to meet NF monograph specifications



Material No.: 6322-05
 Batch No.: 0000188113
 Manufactured Date: 2017/09/08
 Expiration Date: 2019/09/08

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications,
 GMP Manufactured Product

Test	Specification	Result
NF - Appearance of Solution	Passes Test	PT
NF - Acidity	Passes Test	PT
NF - Identification A (IR)	Passes Test	PT
NF - Identification B (TLC)	Passes Test	PT
NF - Optical Rotation $[\alpha]^{20\text{D}} (+)$	78.0 - 81.5 Degree	81.0
NF - Barium (Ba)	Passes Test	PT
NF - Lead (Pb)	≤ 0.5 ppm	0.2
NF - Water (H ₂ O)	≤ 1.0 %	0.2
NF - Residue on Ignition	≤ 0.1 %	< 0.1
EP/BP - Assay (C ₆ H ₁₂ O ₆)(anhydrous basis)	97.0 - 102.0 %	99.1
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - Acidity or Alkalinity	Passes Test	PT
EP/BP - Identification A (IR)	Passes Test	PT
EP/BP - Proteins	≤ 0.1 %	< 0.1
EP/BP - Related Substances: Sum of Impurities A and B	≤ 1.0 %	< 0.2
EP/BP - Related Substances: Unspecified impurities, each	≤ 0.3 %	< 0.2
EP/BP - Related Substances: Total impurities	≤ 2.0 %	1.1
EP/BP - Specific Optical Rotation $[\alpha]^{20\text{D}} (+)$	78.0 - 81.5 Degree	81.0
EP/BP - Barium (Ba)	Passes Test	PT
EP/BP - Lead (Pb)	≤ 0.5 ppm	0.2
EP/BP - Water (H ₂ O)	≤ 1.0 %	0.2

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
EP/BP – Sulfated Ash	<= 0.1 %	0.1
EP/BP – TAMC (cfu/g)	<= 100 cfu/g	< 10
Appearance	Passes Test	PT
Endotoxin Concentration (EU/g)	<= 2.5	< 0.1
Glucose	<= 0.1 %	< 0.1
Purity (HPLC)	>= 99 %	100
Residue on Ignition	<= 0.05 %	0.02
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 Mold (USP)	<= 100 cfu/g	< 10
Microbial Testing – Total Aerobic Microbial Count (USP)	<= 100 cfu/g	< 10
Solution Clarity (300 mg/mL)	Passes Test	PT
Solution Color, APHA – For Information Only		10
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	43.0
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

Test	Specification	Result
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	34.0
Residual Methanol	<= 3000 ppm	28
Residual Ethanol	<= 5000 ppm	74
Residual Isopropanol	<= 5000 ppm	2


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.


Metallic Residues: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of this material.

Plant Derived

Storage Conditions: Preserve in well-closed containers.
 Country of Origin: US
 Packaging Site: Phillipsburg Mfg Ctr & DC
 Manufacturer: PBG
 Manufacturer source batch: 0000182555



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



Jamie Ethier
 Vice President Global Quality

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