

Dextrose, Anhydrous, Granular
U.S.P.



Material No.: 4908-20
Batch No.: 0000138324
Manufactured Date: 2015/12/18
Retest Date: 2020/12/16

Certificate of Analysis

Meets U.S.P Requirements,
GMP Manufactured Product

Test	Specification	Result
USP – Acidity (mL)	<= 0.30	< 0.30
USP – Arsenic (As)	<= 1 ppm	< 1
USP – Chloride (Cl)	<= 0.018 %	< 0.018
USP – Color of Aqueous Solution	Passes Test	PT
USP – Dextrin	Passes Test	PT
USP – Endotoxin Concentration (EU/g)	<= 2.5	< 0.1
USP – Heavy Metals (as Pb)	<= 0.0005 %	< 0.0005
USP – Identification	Passes Test	PT
USP – Residue on Ignition	<= 0.1 %	< 0.1
Solubility	Passes Test	PT
USP – Soluble Starch, Sulfites	Passes Test	PT
USP – Specific Rotation [α] _D ²⁵ (+)	52.6 – 53.2 Degree	52.6
USP – Sulfate (SO ₄)	<= 0.025 %	< 0.025
USP – Water (H ₂ O)	<= 0.5 %	< 0.5

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Appearance (white, granular powder)

Odorless

No Class 1,2,3 or other solvents are used or produced in the
manufacturing or purification of the product.

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.

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor TM Performance Materials Inc.

3477 Corporate Parkway, Suite #200, Center Valley, PA 18034, U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

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Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0003001
Manufacturer source batch: 1005352100

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
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008, 17025:2005
Panoli, India 9001:2008

James Ethier
Jamie Ethier
Vice President Global Quality

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