



Material No.: 0115-07
Batch No.: 0000171596
Manufactured Date: 2016/11/24
Expiration Date: 2018/11/24

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets U.S.P Requirements,
GMP Manufactured Product

Test	Specification	Result
USP – Clarity of Solution	Passes Test	PT
USP – Color of Solution	Passes Test	PT
USP – Identification	Passes Test	PT
USP – Water (H ₂ O)	7.5 – 9.0 %	8.3
USP – Readily Carbonizable Substances	Passes Test	PT
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Sulfate (SO ₄)	<= 0.015 %	< 0.015
USP – Oxalic Acid	<= 0.036 %	< 0.036
USP – Assay (C ₆ H ₈ O ₇) (anhydrous basis)	99.5 – 100.5 %	99.8
EP/BP – Assay (C ₆ H ₈ O ₇) (anhydrous basis)	99.5 – 100.5 %	99.8
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Readily Carbonizable Substances	Passes Test	PT
EP/BP – Oxalic Acid	<= 360 ppm	< 360
EP/BP – Sulfate (SO ₄)	<= 150 ppm	< 150
EP/BP – Water (H ₂ O)	7.5 – 9.0 %	8.3
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1
EP/BP – Endotoxin Concentration, IU/mg	<= 0.5	< 0.1
JP – Assay (C ₆ H ₈ O ₇) (anhydrous basis)	99.5 – 100.5 %	99.8
JP – Identification	Passes Test	PT
JP – Sulfate (SO ₄)	<= 150 ppm	< 150

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
JP - Oxalic Acid	<= 360 ppm	< 360
JP - Clarity and Color of Solution	Passes Test	PT
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Water (H ₂ O)	7.5 - 9.0 %	8.3
JP - Readily Carbonizable Substances	Passes Test	PT
JP - Residue on Ignition	<= 0.1 %	<0.01

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging
Must be subjected to further processing during the preparation of
injectable dosage forms.

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

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.

Storage Conditions: Preserve in Tight Containers

Country of Origin: AT

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0008001

Manufacturer source batch: 1213072



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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