Citric Acid, Monohydrate, Granular, U.S.P.
Multi-Compendial

Material No.: 0115-05
Revision No.: 0

Product Specification

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

Test	Specification
USP - Clarity of Solution	Passes Test
USP - Color of Solution	Passes Test
USP - Identification	Passes Test
USP - Water (H_2O)	7.5 - 9.0 %
USP - Readily Carbonizable Substances	Passes Test
USP - Residue on Ignition	≤ 0.1 %
USP - Sulfate (SO_4)	≤ 0.015 %
USP - Oxalic Acid	≤ 0.036 %
USP - Assay ($C_6H_8O_7$) (anhydrous basis)	99.5 - 100.5 %
EP/BP - Assay ($C_6H_8O_7$) (anhydrous basi	99.5 - 100.5 %
EP/BP - Identification B	Passes Test
EP/BP - Identification E	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP - Readily Carbonizable Substances	Passes Test
EP/BP - Oxalic Acid	≤ 360 ppm
EP/BP - Sulfate (SO_4)	≤ 150 ppm
EP/BP - Water (H_2O)	7.5 - 9.0 %
EP/BP - Ash (sulfated)	≤ 0.1 %
EP/BP - Endotoxin Concentration, IU/mg	≤ 0.5
JP - Assay ($C_6H_8O_7$) (anhydrous basis)	99.5 - 100.5 %
JP - Identification	Passes Test
JP - Sulfate (SO_4)	≤ 150 ppm
JP - Oxalic Acid	≤ 360 ppm
JP - Clarity and Color of Solution	Passes Test
JP - Heavy Metals (as Pb)	≤ 10 ppm
JP - Water (H_2O)	7.5 - 9.0 %
JP - Readily Carbonizable Substances	Passes Test
JP - Residue on Ignition	≤ 0.1 %

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GMP Manufactured Product
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 Condition: Preserve in Tight Containers

Packaging Site: Paris Mfg Ctr & DC

Jamie Ethier
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700