Citric Acid, Monohydrate, Granular
USP - GenAR®
Suitable for Use in Biotechnology

Material No.: 7788-06
:
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 - Assay (as $C_6H_8O_7$) (calculated on anhydrous basis)	99.5 - 100.5 %
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 - Residue on Ignition	≤ 0.1 %
USP - Readily Carbonizable Substances	Passes Test
USP - Oxalic Acid	≤ 0.036 %
USP - Sulfate (SO_4)	≤ 0.015 %
EP/BP - Assay (as $C_6H_8O_7$) (calculated on anhydrous basis)	99.5 - 100.5 %
EP/BP - Identification B	Passes Test
EP/BP - Identification E	Passes Test
EP/BP - Oxalic Acid	≤ 360 ppm
EP/BP - Sulfate (SO_4)	≤ 150 ppm
EP/BP - Ash (sulfated)	≤ 0.1 %
EP/BP - Appearance of Solution	Passes Test
EP/BP - Readily Carbonizable Substances	Passes Test
EP/BP - Water (H_2O)	7.5 - 9.0 %
JP - Assay ($C_6H_8O_7$) (anhydrous basis)	99.5 - 100.5 %
JP - Clarity and Color of Solution	Passes Test
JP - Identification	Passes Test
JP - Oxalic Acid	≤ 360 ppm
JP - Readily Carbonizable Substances	Passes Test
JP - Residue on Ignition	≤ 0.10 %
JP - Sulfate (SO_4)	≤ 150 ppm
JP - Water (H_2O)	7.5 - 9.0 %
Endotoxin Concentration (IU/mg)	≤ 0.5

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Test	Specification

GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
Appearance (white to colorless crystals, granules or white crystalline powder; efflorescent)
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.
Must be subjected to further processing during the preparation of injectable dosage forms.
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