

## Product Specification

Meets U.S.P Requirements, Meets F.C.C. Requirements, GMP Manufactured Product

Test	Specification
USP – Assay (as $C_6H_8O_7$ ) (calculated on	99.5 – 100.5 %
USP – Clarity of Solution	Passes Test
USP – Color of Solution	Passes Test
USP – Identification (USP)	Passes Test
USP – Water ( $H_2O$ ) (U.S.P.)	7.5 – 9.0 %
USP – Residue on Ignition	$\leq 0.05$ %
USP – Oxalic Acid (USP)	$\leq 0.036$ %
USP – Sulfate ( $SO_4$ )	$\leq 0.015$ %
USP – Readily Carbonizable Substances	Passes Test
FCC – Assay (as $C_6H_8O_7$ ) (calculated on	99.5 – 100.5 %
FCC – Identification (FCC)	Passes Test
FCC – Water ( $H_2O$ ) (F.C.C.)	$\leq 8.8$ %
FCC – Residue on Ignition	$\leq 0.05$ %
FCC – Oxalate ( $C_2O_4$ ) (FCC)	$\leq 100$ mg/kg
FCC – Readily Carbonizable Substances	Passes Test
FCC – Lead (Pb)	$\leq 0.5$ mg/kg
Appearance (white, crystalline powder)	Passes Test

Citric Acid, Monohydrate  
U.S.P. – F.C.C.



Material No.: 0119-07

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Test

Specification

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GMP Manufactured Product  
Food GMP Manufactured Product  
Bulk Food Chemical  
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) – 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

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