

Citric Acid, Anhydrous, Powder, U.S.P.
Multi-Compendial



Material No.: 0127-05
Batch No.: 0000147323
Manufactured Date: 2016/03/18
Retest Date: 2021/03/17

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 – Assay (HOC(COOH)(CH ₂ COOH) ₂) (anhydrous basis)	99.5 – 100.5 %	100.5
USP – Clarity of Solution	Passes Test	PT
USP – Color of Solution	Passes Test	PT
USP – Identification	Passes Test	PT
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Heavy Metals (as Pb)	<= 0.001 %	< 0.001
USP – Oxalic Acid	<= 0.036 %	< 0.036
USP – Sulfate (SO ₄)	<= 0.015 %	< 0.015
USP – Readily Carbonizable Substances	Passes Test	PT
USP – Water (H ₂ O)	<= 1.0 %	< 0.1
EP/BP – Assay (HOC(COOH)(CH ₂ COOH) ₂) (anhydrous basis)	99.5 – 100.5 %	100.5
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 – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Water (H ₂ O)	<= 1.0 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

Test	Specification	Result
EP/BP – Endotoxin Concentration, <0.5 IU/mg	Passes Test	PT
JP – Assay (HOC(COOH)(CH ₂ COOH) ₂) (anhydrous basis)	99.5 – 100.5 %	100.5
JP – Clarity and Color of Solution	Passes Test	PT
JP – Identification	Passes Test	PT
JP – Sulfate (SO ₄)	<= 150 ppm	< 150
JP – Oxalic Acid	<= 360 ppm	< 360
JP – Heavy Metals (as Pb)	<= 10 ppm	< 10
JP – Readily Carbonizable Substances	Passes Test	PT
JP – Residue on Ignition	<= 0.1 %	<0.01
JP – Water (H ₂ O)	<= 1.0 %	< 0.1
Total Aerobic Microbial Count, For Information Only	cfu/g	< 1
Total Yeasts and Molds Count, For Information Only	cfu/g	< 1
E. coli	Negative	Negative
P. aureginosa	Negative	Negative

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.

Storage Conditions: Preserve in Tight Containers

Country of Origin: US

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0033001

Manufacturer source batch: S603188



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

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