

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



Material No.: 0127-05
Batch No.: 0000171599
Manufactured Date: 2016/11/23
Retest Date: 2021/11/22

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 % | 99.8 |
| 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 – Identification C: Water (H ₂ O) | <= 1.0 % | < 0.1 |
| EP/BP – Assay (HOC(COOH)(CH ₂ COOH) ₂) (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 – 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 |

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 |
|--|----------------|----------|
| 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 % | 99.8 |
| 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 % | < 0.1 |
| JP – Water (H ₂ O) | <= 1.0 % | < 0.1 |
| Total Aerobic Microbial Count, For Information Only | cfu/g | < 10 |
| Total Yeasts and Molds Count, For Information Only | cfu/g | < 10 |
| 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: S611238

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

Jamie Ethier
 Vice President Global Quality

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