

Sodium Citrate, Dihydrate, Granular, U.S.P.
Multi-Compendial



Material No.: 3647-01
Batch No.: 0000171900
Manufactured Date: 2017/02/09
Retest Date: 2022/02/08

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 – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Identification C	Passes Test	PT
USP – Alkalinity	Passes Test	PT
USP – Water (H ₂ O)	10.0 – 13.0 %	12.3
USP – Tartrate	Passes Test	PT
USP – Heavy Metals (as Pb)	<= 0.001 %	< 0.001
USP – Assay (C ₆ H ₅ Na ₃ O ₇) (calculated on the anhydrous basis)	99.0 – 100.5 %	100.5
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT
EP/BP – Readily Carbonizable Substances	Passes Test	PT
EP/BP – Chloride (Cl)	<= 50 ppm	< 50
EP/BP – Oxalate (C ₂ O ₄)	<= 300 ppm	< 300
EP/BP – Sulfate (SO ₄)	<= 150 ppm	< 150
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Water (H ₂ O)	11.0 – 13.0 %	12.2
EP/BP – Assay (C ₆ H ₅ Na ₃ O ₇) (calculated on the anhydrous basis)	99.0 – 101.0 %	100.5
EP/BP – Endotoxin Concentration (EU/g)	<= 2.5	< 1.3
JP – Assay (C ₆ H ₅ Na ₃ O ₇) (calculated on the anhydrous basis)	99.0 – 101.0 %	100.5

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
basis)		
JP - pH (1 in 20)	7.5 - 8.5	8.2
JP - Clarity and Color of Solution	Passes Test	PT
JP - Chloride (Cl)	<= 0.015 %	< 0.015
JP - Identification	Passes Test	PT
JP - Sulfate (SO ₄)	<= 0.048 %	< 0.048
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Arsenic (As)	<= 2 ppm	< 2
JP - Tartrate	Passes Test	PT
JP - Oxalate (C ₂ O ₄)	Passes Test	PT
JP - Readily Carbonizable Substances	Passes Test	PT
JP - Loss on Drying at 180°C	10.0 - 13.0 %	12.1
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. auresinosa	Negative	Negative

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Metallic Residues: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of this material.

Country of Origin: US
 Packaging Site: Paris Mfg Ctr & DC
 Manufacturer: P0033001
 Manufacturer source batch: S702094

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

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