

L-Cysteine Hydrochloride, Monohydrate, U.S.P.
Multi-Compendial



Material No.: 2071-05
Batch No.: 0000171121
Manufactured Date: 2015/11/13
Retest Date: 2020/11/11

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets F.C.C. Requirements, Meets U.S.P Requirements,
GMP Manufactured Product, Food GMP Manufactured Product

Test	Specification	Result
USP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.5 %	99.7
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D (+)	5.7 – 6.8 Degree	6.1
USP – Loss on Drying	8.0 – 12.0 %	8.9
USP – Residue on Ignition	<= 0.1 %	0.1
USP – Sulfate (SO ₄)	<= 0.03 %	< 0.03
USP – Iron (Fe)	<= 0.003 %	< 0.003
USP – Heavy Metals (as Pb)	<= 0.0015 %	< 0.0015
USP – Related Compounds – Individual Impurities	<= 0.5 %	< 0.5
USP – Related Compounds – Total Impurities	<= 2.0 %	< 0.5
FCC – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.0 – 101.5 %	98.2
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	8.0 – 12.0 %	8.9
FCC – Residue on Ignition	<= 0.1 %	0.1
FCC – Specific Rotation [α] ²⁰ ^D (+)	5.0 – 8.0 Degree	6.8
EP/BP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.0 %	98.7
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] ²⁰ ^D (+)	5.5 – 7.0 Degree	6.6

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 – Ninhydrin-Positive Substances – Impurity A	<= 0.5 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.2
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 1.0 %	< 0.1
EP/BP – Sulfate (SO ₄)	<= 300 ppm	< 300
EP/BP – Ammonium (NH ₄)	<= 0.02 %	< 0.02
EP/BP – Iron (Fe)	<= 20 ppm	< 20
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Loss on Drying	8.0 – 12.0 %	8.9
EP/BP – Ash (sulfated)	<= 0.1 %	0.1
Endotoxin Concentration, IU/mg, For Information Only		< 0.005

Bulk Food Chemical

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: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0063001
Manufacturer source batch: 169072



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

James Ethier
Jamie Ethier
Vice President Global Quality

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