

Product Specification

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

Test	Specification
USP – Assay ($C_3H_7NO_2S \cdot HCl$) (dried basis)	98.5 – 101.5 %
USP – Identification	Passes Test
USP – Specific Rotation $[\alpha]^{25}_D (+)$	5.7 – 6.8 °
USP – Loss on Drying	8.0 – 12.0 %
USP – Residue on Ignition	≤ 0.1 %
USP – Sulfate (SO_4)	≤ 0.03 %
USP – Iron (Fe)	≤ 0.003 %
USP – Related Compounds – Individual Impurities	≤ 0.5 %
USP – Related Compounds – Total Impurities	≤ 2.0 %
EP/BP – Assay ($C_3H_7NO_2S \cdot HCl$) (dried basis)	98.5 – 101.0 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Identification E	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – Specific Rotation $[\alpha]^{20}_D (+)$	5.5 – 7.0 °
EP/BP – Ninhydrin-Positive Substances – Impurity A	≤ 0.5 %
EP/BP-Ninhydrin-Positive Substances-Each	≤ 0.2 %
EP/BP-Ninhydrin-Positive Substances-Total Impurities	≤ 1.0 %
EP/BP – Sulfate (SO_4)	≤ 300 ppm
EP/BP – Ammonium (NH_4)	≤ 0.02 %
EP/BP – Iron (Fe)	≤ 20 ppm
EP/BP – Loss on Drying	8.0 – 12.0 %
EP/BP – Ash (sulfated)	≤ 0.1 %
Endotoxin Concentration, IU/mg, For Information Only	

L-Cysteine Hydrochloride, Monohydrate
Multi-Compendial



Material No.: 2071-06

Test	Specification
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GMP Manufactured Product
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.

Packaging Site: Paris Mfg Ctr & DC