

Product Specification

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

Test	Specification
USP - Assay (C ₆ H ₁₄ N ₄ O ₂ ·HCl) (dried basis)	98.5 - 101.5 %
USP - Identification	Passes Test
USP - Specific Rotation [α] ²⁰ _D (+)	21.4 - 23.6 °
USP - Loss on Drying at 105°C	≤ 0.2 %
USP - Residue on Ignition	≤ 0.1 %
USP - Sulfate (SO ₄)	≤ 0.03 %
USP - Related Compounds - Individual Impurities	≤ 0.5 %
USP - Related Compounds - Total Impurities	≤ 2.0 %
USP - Chloride (Cl)	16.5 - 17.1 %
EP/BP - Assay (C ₆ H ₁₄ N ₄ O ₂ ·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 [α] ²⁰ _D (+)	21.0 - 23.5 °
EP/BP-Ninhydrin-Positive Substances-Each	≤ 0.2 %
EP/BP-Ninhydrin-Positive Substances-Total Impurities	≤ 0.5 %
EP/BP - Sulfate (SO ₄)	≤ 300 ppm
EP/BP - Ammonium (NH ₄)	≤ 0.02 %
EP/BP - Iron (Fe)	≤ 10 ppm
EP/BP - Loss on Drying	≤ 0.5 %
EP/BP - Ash (sulfated)	≤ 0.1 %
JP - Assay (C ₆ H ₁₄ N ₄ O ₂ ·HCl) (dried basis)	98.5 - 101.0 %
JP - Identification	Passes Test
JP - Optical Rotation (+)	21.5 - 23.5 °
JP - pH (1 in 10)	4.7 - 6.2
JP - Clarity and Color of Solution	Passes Test
JP - Sulfate (SO ₄)	≤ 0.028 %

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Mansford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

L-Arginine Hydrochloride
Multi-Compendial



Material No.: 4930-07

Test	Specification
JP - Ammonium (NH ₄)	≤ 0.02 %
JP - Heavy Metals (as Pb)	≤ 20 ppm
JP - Arsenic (As)	≤ 2 ppm
JP - Related Substances	Passes Test
JP - Loss on Drying at 105°C	≤ 0.20 %
JP - Residue after Ignition	≤ 0.10 %
Endotoxin Concentration, IU/mg, For Information Only	
ChP - Proteins	Passes Test
ChP - Sulfates	≤ 0.02 %
ChP - Other amino acids (TLC)(≤0.2%, one spot only)	Passes Test
ChP - Phosphates	≤ 0.02 %
ChP - Residue on ignition	≤ 0.1 %
ChP - Identification 1 (TLC)	Passes Test
ChP - Assay (dried basis)	98.5 - 101.0 %
ChP - Iron	≤ 0.001 %
ChP - Ammonium	≤ 0.02 %
ChP - Loss on drying @ 105 °C	≤ 0.2 %
ChP - Arsenic	≤ 0.0001 %
ChP - Specific Rotation @ 20 °C (+)	21.5 - 23.5
ChP - Chloride Content	16.7 - 17.1 %
ChP - Heavy metals	≤ 0.001 %
ChP - Transmittance of solution	≥ 98.0 %
ChP - Identification 2 (IR)	Passes Test

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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.

Elemental Impurities (USP (232), EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Store in well-closed, light-resistant containers

Packaging Site: Paris Mfg Ctr & DC

Jamie Ethier
Vice President Global Quality

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