

Product Specification

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
USP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis)	98.5 – 101.5 %
USP – Identification	Passes Test
USP – Specific Rotation [α] ²⁵ ^{AD} (+)	20.4 – 21.4 °
USP – Loss on Drying at 105°C	≤ 0.4 %
USP – Residue on Ignition	≤ 0.1 %
USP – Sulfate (SO ₄)	≤ 0.03 %
USP – Iron (Fe)	≤ 0.003 %
USP – Related Compounds – Individual Imp	≤ 0.5 %
USP – Related Compounds – Total Impuriti	≤ 2.0 %
USP – Chloride (Cl)	19.0 – 19.6 %
EP/BP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried bas	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 ^{AD} (+)	21.0 – 22.5 °
EP/BP–Ninhydrin–Positive Substances–Each	≤ 0.2 %
EP/BP–Ninhydrin–Positive Substances–Tota	≤ 1.0 %
EP/BP – Sulfate (SO ₄)	≤ 300 ppm
EP/BP – Ammonium (NH ₄)	≤ 0.02 %
EP/BP – Iron (Fe)	≤ 30 ppm
EP/BP – Loss on Drying at 105°C	≤ 0.5 %
EP/BP – Ash (sulfated)	≤ 0.1 %
JP – Assay (C ₆ H ₁₄ N ₂ O ₂ · HCl) (dried basis)	98.5 – 101.0 %
JP – Identification A	Passes Test
JP – Identification B	Passes Test
JP – Optical Rotation (+)	19.0 – 21.5 °
JP – pH (1 in 10)	5.0 – 6.0

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Test	Specification
JP - Clarity and Color of Solution	Passes Test
JP - Sulfate (SO ₄)	≤ 0.028 %
JP - Ammonium (NH ₄)	≤ 0.02 %
JP - Heavy Metals (as Pb)	≤ 10 ppm
JP - Arsenic (As)	≤ 2 ppm
JP - Related Substances	Passes Test
JP - Loss on Drying at 105°C	≤ 1.0 %
JP - Residue on Ignition	≤ 0.10 %
Endotoxin Concentration, IU/mg, For	

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.

Packaging Site: Paris Mfg Ctr & DC



Jamie Ethier
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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