

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 ₄ O ₂ · HCl) (dried basis)	98.5 – 101.5 %
USP – Identification	Passes Test
USP – Specific Rotation [A] 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 [A] 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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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	

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.

Storage Condition: Preserve in well-closed containers. Store in well-closed, light-resistant containers

Packaging Site: Paris Mfg Ctr & DC