

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 ₁₃ NO ₂) (dried basis)	98.5 – 101.5 %
USP – Identification	Passes Test
USP – Specific Rotation [A] ²⁵ ^D (+)	14.9 – 17.3 °
USP – pH	5.5 – 7.0
USP – Loss on Drying at 105°C	≤ 0.2 %
USP – Residue on Ignition	≤ 0.4 %
USP – Chloride (Cl)	≤ 0.05 %
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 ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.0 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – Specific Rotation [A] ²⁰ ^D (+)	14.5 – 16.5 °
EP/BP–Ninhydrin–Positive Substances–Impurity A	≤ 0.8 %
EP/BP–Ninhydrin–Positive Substances–Each	≤ 0.2 %
EP/BP–Ninhydrin–Positive Substances–Total Impurities	≤ 1.0 %
EP/BP – Chloride (Cl)	≤ 200 ppm
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 at 105°C	≤ 0.5 %
EP/BP – Ash (sulfated)	≤ 0.1 %
JP – Assay (C ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.0 %
JP – Identification	Passes Test
JP – Optical Rotation (+)	14.5 – 16.0 °

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Test	Specification
JP – pH	5.5 – 6.5
JP – Clarity and Color of Solution	Passes Test
JP – Chloride (Cl)	≤ 0.021 %
JP – Sulfate (SO ₄)	≤ 0.028 %
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	≤ 0.30 %
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

Only Class 2 Solvents (Methanol) are likely to be present. All are below Option 1 limits.

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