

Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets U.S.P Requirements, Meets J.P. Chemical Specifications, 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 [α] ²⁵ ^{AD} (+)	38.9 – 41.8 °
USP – pH	5.5 – 7.0
USP – Loss on Drying at 105°C	≤ 0.3 %
USP – Residue on Ignition	≤ 0.3 %
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 [α] ²⁰ ^{AD} (+)	40.0 – 43.0 °
EP/BP–Ninhydrin–Positive Substances–Impurity A	≤ 0.3 %
EP/BP–Ninhydrin–Positive Substances–Impurity C	≤ 0.3 %
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	≤ 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

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Test	Specification
JP – Optical Rotation (+)	39.5 – 41.5 °
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 on 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 impuri
profile report.

Packaging Site: Paris Mfg Ctr & DC