

Product Specification

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

Test	Specification
USP – Assay ($\text{CH}_3\text{CHOHCOOH}$)	88.0 – 92.0 %
USP – Chloride (Cl)	Passes Test
USP – Citric, Oxalic, Phosphoric, or Tartaric Acids	Passes Test
USP – Identification	Passes Test
USP – Readily Carbonizable Substances	Passes Test
USP – Residue on Ignition	≤ 0.05 %
USP – Sugars	Passes Test
USP – Sulfate (SO_4)	Passes Test
EP – Assay ($\text{CH}_3\text{CHOHCOOH}$)	88.0 – 92.0 %
EP – Appearance	Passes Test
EP – (S)-enantiomer	≥ 95.0 %
EP – Calcium (Ca)	≤ 200 ppm
EP – Citric, Oxalic, and Phosphoric Acids	Passes Test
EP – Endotoxin Concentration, <5 IU/g	Passes Test
EP – Ether-Insoluble Substances	Passes Test
EP – Identification A	Passes Test
EP – Identification B	Passes Test
EP – Identification C	Passes Test
EP – Methanol (by GC)	≤ 50 ppm
EP – Sugars and Other Reducing Substances	Passes Test
EP – Sulfate (SO_4)	≤ 200 ppm
EP – Sulfated Ash	≤ 0.1 %
JP – Assay ($\text{CH}_3\text{CHOHCOOH}$)	85.0 – 92.0 %
JP – Chloride (Cl)	≤ 0.036 %
JP – Citric, Oxalic, Phosphoric, or Tartaric Acids	Passes Test
JP – Cyanide (CN)	Passes Test
JP – Glycerin and Mannitol	Passes Test
JP – Heavy Metals (as Pb)	≤ 10 ppm

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L-Lactic Acid
Multi-Compendial
(levorotatory)



Material No.: 0200-07

Test	Specification
JP – Identification	Passes Test
JP – Iron (Fe)	≤ 5 ppm
JP – Readily Carbonizable Substances	Passes Test
JP – Residue on Ignition	≤ 0.1 %
JP – Sugars	Passes Test
JP – Sulfate (SO ₄)	≤ 0.010 %
JP – Volatile Fatty Acids	Passes Test
JP – Optical Rotation	-52 – -46 °

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

This product is pyrogen free.

Only Class 3 Solvents are likely to be present. Residual concentration of all Class 3 Solvents is <0.5%.

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: Phillipsburg 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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