

Product Specification

Meets E.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets ChP Chemical Specifications, GMP Manufactured Product

Test	Specification
EP/BP – Assay (C ₆ H ₉ N ₃ O ₂ · HCl) (dried basis)	98.5 – 101.0 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Identification C	Passes Test
EP/BP – Identification F	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – pH	3.0 – 5.0
EP/BP – Specific Rotation [α] _D ²⁰ (+)	9.2 – 10.6 °
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 at 150°C	7.0 – 10.0 %
EP/BP – Ash (sulfated)	≤ 0.1 %
JP – Identification	Passes Test
JP – Optical Rotation (+)	9.2 – 10.6
JP – pH	3.5 – 4.5
JP – Clarity and Color of Solution	Passes Test
JP – Sulfate (SO ₄)	≤ 0.028 %
JP – Ammonium (NH ₄)	≤ 0.02 %
JP – Iron (Fe)	≤ 10 ppm
JP – Related Substances	Passes Test
JP – Water	7.2 – 10.0 %
JP – Residue on Ignition	≤ 0.10 %
JP – Assay (anhydrous basis)	99.0 – 101.0 %
ChP – Specific Rotation @ 20 °C	8.5 – 10.5 °
ChP – Identification 1 (TLC)	Passes Test

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Test	Specification
ChP – Identification 2 (IR)	Passes Test
ChP – Acidity or alkalinity (pH)	3.5 – 4.5
ChP – Transmittance of solution	≥ 98.0 %
ChP – Chloride Content	16.7 – 17.1 %
ChP – Sulfates	≤ 0.02 %
ChP – Ammonium	≤ 0.02 %
ChP – Other amino acids (TLC)(≤0.2%, one spot only)	Passes Test
ChP – Loss on drying @ 105 °C	≤ 0.2 %
ChP – Residue on ignition	≤ 0.1 %
ChP – Heavy metals	≤ 0.001 %
ChP – Arsenic	≤ 0.0001 %
ChP – Bacterial endotoxin, EU/g	≤ 6.0
ChP – Assay, dried basis	99.0 – 100.5 %

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L-Histidine Monohydrochloride Monohydrate
Multi-Compendial



Material No.: 4938-07

Test

Specification

GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
Storage Condition: Store in airtight container.

Packaging Site: Paris Mfg Ctr & DC