

Product Specification

Meets E.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets J.P. 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] ²⁰ _D (+)	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 – Heavy Metals (as Pb)	≤ 10 ppm
JP – Iron (Fe)	≤ 10 ppm
JP – Related Substances	Passes Test
JP – Water	7.2 – 10.0 %
JP – Residue on Ignition	≤ 0.1 %
JP – Assay (anhydrous basis)	99.0 – 101.0 %
Endotoxin Concentration, IU/mg ,For Information Only	

L-Histidine Monohydrochloride
Multi-Compendial



Material No.: 2081-06

Test

Specification

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: Store in airtight container.

Packaging Site: Paris 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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