L-Histidine Monohydrochloride
Multi-Compendial

Material No.: 2081-07
Revision No.: 0

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 ($C_6H_9N_3O_2 \cdot HCl$) (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 [Å]²°^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	

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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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