L-(+)-Histidine
Multi-Compendial

Material No.: 4928-07
:
Revision No.: 0

Product Specification

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

Test	Specification
USP - Assay ($C_6H_9N_3O_2$) (dried basis)	98.5 - 101.5 %
USP - Identification	Passes Test
USP - Specific Rotation [Å]²5 ^D (+)	12.6 - 14.0 °
USP - pH	7.0 - 8.5
USP - Loss on Drying at 105°C	≤ 0.2 %
USP - Residue on Ignition	≤ 0.4 %
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 ($C_6H_9N_3O_2$) (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 [Å]²°^D (+)	11.4 - 12.4 °
EP/BP-Ninhydrin-Positive Substances-Each	≤ 0.2 %
EP/BP-Ninhydrin-Positive Substances-Total Impurities	≤ 0.5 %
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 (C6H9N3O2) (dried basis)	99.0 - 101.0 %
JP - Ammonium (NH_4)	≤ 0.02 %
JP - Chloride (Cl)	≤ 0.021 %
JP - Clarity and Color of Solution	Passes Test

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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
JP - Iron (Fe)	≤ 10 ppm
JP - Identification	Passes Test
JP - Loss on Drying at 105°C	≤ 0.30 %
JP- Optical Rotation [Å]²°^D (+)	11.8 - 12.8 °
JP - Related Substances	Passes Test
JP - pH	7.0 - 8.5
JP - Residue on Ignition	≤ 0.1 %
JP - Sulfate (SO_4)	≤ 0.028 %
ChP - Assay (dried basis)	99.0 - 101.0 %
ChP -Specific Rotation @ 20 °C (+)	12.0 - 12.8 °
ChP - Identification 1 (TLC)	Passes Test
ChP - Identification 2 (IR)	Passes Test
ChP - Acidity or alkalinity (pH)	7.0 - 8.5
ChP - Transmittance of solution	≥ 98.0 %
ChP - Chlorides	≤ 0.02 %
ChP - Sulfates	≤ 0.02 %
ChP - Ammonium	≤ 0.02 %
ChP - Other amino acids (TLC)(<=0.5%, one spot only)	Passes Test
ChP - Loss on drying @ 105 °C	≤ 0.2 %
ChP - Residue on ignition	≤ 0.1 %
ChP - Iron	≤ 0.001 %
ChP - Heavy metals	≤ 0.001 %
ChP - Arsenic	≤ 0.0001 %
ChP - Bacterial endotoxin, EU/g	≤ 6.0

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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