

GMP BIOTECH PRODUCT

L-HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE, SYNTHETIC

EP, JP, BIOBURDEN AND ENDOTOXIN TESTED, GMP

CAS #: 5934-29-2 Formula: C₆H₉N₃O₂ HCl H₂O

F.W.: 209.63 g/mol

LHMM-6250

BIO QUALIFIED GRADE

Ammonium (EP/JP) Appearance and Color Appearance of Solution (EP) Assay, Dried Basis (EP) Assay, Anhydrous Basis (JP) Microbial Content TAMC Clarity and Color of Solution (EP) Identification A, Specific Optical Rotation (EP) Identification D (EP) Identification E (EP) Identification F (EP) Identification S, Chloride (JP) Identification S, Chloride (JP) Passes Test Identification S, Chloride (JP) Identification S, Chloride (JP) Identification S, Chloride (JP) Passes Test Identification S, Chloride (JP) Ninhydrin-positive Each Individual Impurity substances (EP) Total Impurities Specific Optical Rotation (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Frace Metals Iron (Fe) (EP/JP) Lead (Pb) Vasses Test 10,00% White Crystalline Powder or Crystals A = 200 ppm White Crystalline Powder or Crystals A = 200 CPT/g Basses Test Clear and Colorless Floor EU/g Clear and Colorless Floor EU/g H9.2° to +10.6° Standard Conforms to Reference Standard Conforms to Reference Standard Identification D (EP) Passes Test Identification E (EP) Passes Test Identification 2, Chloride (JP) Passes Test Identification 2, Chloride (JP) Passes Test Loss on Drying (EP) To - 10.0% Specific Optical Rotation (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (P) - 280 ppm Trace Metals Iron (Fe) (EP/JP) Lead (Pb) To - 10.0%	•		0
Appearance and Color Appearance of Solution (EP) Assay, Dried Basis (EP) Assay, Anhydrous Basis (JP) Microbial Content TAMC Clarity and Color of Solution (JP) Identification A, Specific Optical Rotation (EP) Identification J (EP) Identification E (EP) Identification E (EP) Identification E (EP) Identification F (EP) Identification E (EP) Identification E (EP) Identification E (EP) Identification B, pH (5%) (EP) Asses Test Identification E (EP) Identification E (EP) Passes Test Identification P (EP) Passes Test Identification P (EP) In Passes Test In I	Analysis		SPECIFICATIONS
Appearance and Color Appearance of Solution (EP) Assay, Dried Basis (EP) Assay, Anhydrous Basis (JP) Microbial Content TAMC Clarity and Color of Solution (JP) Identification A, Specific Optical Rotation (EP) Identification J (EP-C/JP-1) Identification E (EP) Identification E (EP) Identification F (EP) Identification F (EP) Identification J (SP) Identification P (SP) Identi	Ammonium (EP/JP)		< = 200 ppm
Assay, Dried Basis (EP) Assay, Anhydrous Basis (JP) Microbial Content TAMC TYMC Clarity and Color of Solution (JP) Endotoxin Identification A, Specific Optical Rotation (EP) Identification B, pH (5%) (EP) Identification D (EP) Identification D (EP) Identification E (EP) Identification F (EP) Identification P (EP) Passes Test In Passes Test Passes Test Specific Optical Rotation (JP) Passes Test Specific Optical Rotation (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (IP) Iron (Fe) (EP/JP) Lead (Pb) Iron (Fe) (EP/JP) Lead (Pb) I Dentification P (10.0%) In Passes Test In P	Appearance and Color		•
Assay, Anhydrous Basis (JP) Microbial Content TAMC TYMC Clarity and Color of Solution (JP) Clear and Colorless Endotoxin Function Eurore Identification B, pH (5%) (EP) Conforms to Reference Standard Identification D (EP) Passes Test Identification E (EP) Passes Test Identification F (EP) Passes Test Identification 2, Chloride (JP) Passes Test Identification 3, Chloride (JP) Passes Test Identification 4, Ferror Beach Individual Impurity Central Passes Fest Fest Specific Optical Rotation (JP) Phypases Test Fest Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (JP) Clear and Colorless Clear and Colorless Clear and Colorless Clear and Colorless Fest Conforms to Reference Standard Passes Test Fest Conforms to Reference Standard Passes Test Fest Fest Fest Fest Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (JP) Fest F	Appearance of Solution (EP)		Passes Test
Microbial Content TAMC	Assay, Dried Basis (EP)		98.5 - 101.0%
Clarity and Color of Solution (JP) Clarity and Color of Solution (JP) Clear and Colorless Endotoxin Clear and Colorless Clear and Colorless Clear and Colorless Clear and Colorless Conforms Conforms to Reference Standard Identification D (EP) Passes Test Identification E (EP) Identification F (EP) Identification F (EP) Passes Test Identification 2, Chloride (JP) Ninhydrin-positive Each Individual Impurity substances (EP) Total Impurities Specific Optical Rotation (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Trace Metals Clear and Colorless Fest Ps.2° to +10.6° Total Impurities Candon Ellips Conforms to Reference Standard Conforms to Reference Standard Passes Test Identification Pieses Test Conforms to Reference Standard Passes Test Total Impurities Candon Conforms to Reference Standard Passes Test Conforms to Reference Standard Conforms to Reference Standard Passes Test Conforms to Reference Standard Passes Test Conforms to Reference Standard Passes Test Conforms to Pieses Fest Conformation Fest Pieses Fest Conformation Fest Pieses Fest Conformation Fest Pieses Fest Conformation Fest Pieses Fest Conformation	Assay, Anhydrous Basis (JP)		99.0 - 101.0%
Endotoxin < = 100 EU/g Identification A , Specific Optical Rotation (EP) Identification B, pH (5%) (EP) Identification, IR (EP-C/JP-1) Identification D (EP) Identification E (EP) Identification E (EP) Identification F (EP) Identification F (EP) Identification P (EP)	Microbial Content		,
Identification A , Specific Optical Rotation (EP) Identification B, pH (5%) (EP) Identification, IR (EP-C/JP-1) Identification D (EP) Identification D (EP) Identification E (EP) Identification E (EP) Identification F (EP) Identification F (EP) Identification 2, Chloride (JP) Loss on Drying (EP) Ninhydrin-positive Each Individual Impurity substances (EP) Total Impurities Specific Optical Rotation (JP) Passes Test 7.0 - 10.0% Ninhydrin-positive Each Individual Impurity < = 0.2% Specific Optical Rotation (JP) PH (10%) (JP) Related Substances (JP) Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (EP) Sulfate (EP) Sulfate (P) Frace Metals Iron (Fe) (EP/JP) Lead (Pb) Suppose to +10.6° Conforms to Reference Standard Passes Test 10 ppm - 10.0%	Clarity and Color of Solution (JP)		Clear and Colorless
Specific Optical Rotation (EP) F9.2° to +10.6° Identification B, pH (5%) (EP) 3.0 - 5.0 Identification, IR (EP-C/JP-1) Conforms to Reference Standard Identification D (EP) Passes Test Identification E (EP) Passes Test Identification F (EP) Passes Test Identification F (EP) Passes Test Identification 2, Chloride (JP) Passes Test Identification 3, Chloride (JP) Passes Test Identification 4, Chloride (JP) Passes Test Identification 5 (IP) Passes Test Identification 6 (IP) Passes Test Identification 7 (IP) Passes Test Identification 8, pH (5%) (IP) Passes Test Identification 9 (IP) Pas	Endotoxin		< = 100 EU/g
Identification, IR (EP-C/JP-1) Identification D (EP) Identification E (EP) Identification F (EP) Identification F (EP) Identification F (EP) Identification 2, Chloride (JP) Passes Test Identification 2, Chloride (JP) Passes Test Loss on Drying (EP) Ninhydrin-positive Each Individual Impurity <= 0.2% substances (EP) Total Impurities Specific Optical Rotation (JP) Ph (10%) (JP) Related Substances (JP) Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (EP) Sulfate (JP) Trace Metals Conforms to Reference Standard Passes Test Passes Test			+9.2° to +10.6°
Identification, IR (EP-C/JP-1) Identification D (EP) Identification E (EP) Identification F (EP) Identification F (EP) Identification 2, Chloride (JP) Loss on Drying (EP) Ninhydrin-positive Each Individual Impurity <= 0.2%	Identification B, pH (5%) (EP)		3.0 - 5.0
Identification E (EP)Passes TestIdentification F (EP)Passes TestIdentification 2, Chloride (JP)Passes TestLoss on Drying (EP)7.0 - 10.0%Ninhydrin-positive substances (EP)Total Impurity substances (EP)< = 0.2%	Identification, IR (EP-C/JP-1)		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Identification D (EP)		Passes Test
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Identification E (EP)		Passes Test
$\begin{array}{llllllllllllllllllllllllllllllllllll$	Identification F (EP)		Passes Test
Ninhydrin-positive substances (EP) Total Impurity < = 0.2% Specific Optical Rotation (JP) +9.2° to +10.6° pH (10%) (JP) 3.5 - 4.5 Related Substances (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) <= 0.1% Sulfate Sulfate (EP) Sulfate (JP) <= 300 ppm <= 280 ppm Trace Metals Iron (Fe) (EP/JP) <= 10 ppm <= 10 ppm	Identification 2, Chloride (JP)		Passes Test
substances (EP) Total Impurities < = 0.5% Specific Optical Rotation (JP) pH (10%) (JP) Related Substances (JP) Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (JP) Trace Metals Total Impurities < = 0.5% +9.2° to +10.6° Passes Test < = 0.1% < = 0.1% < = 300 ppm < = 280 ppm < = 280 ppm < = 10 ppm < = 10 ppm < = 10 ppm	Loss on Drying (EP)		7.0 - 10.0%
Specific Optical Rotation (JP) +9.2° to +10.6° pH (10%) (JP) 3.5 - 4.5 Related Substances (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) < = 0.1%	7		<= 0.2%
pH (10%) (JP) 3.5 - 4.5 Related Substances (JP) Passes Test Residue on Ignition/Sulfated Ash (EP/JP) < = 0.1%	substances (EP) Total Impurities		< = 0.5%
Related Substances (JP) Residue on Ignition/Sulfated Ash (EP/JP) Sulfate Sulfate (EP) Sulfate (JP) Trace Metals Passes Test <= 0.1% <= 300 ppm <= 280 ppm <= 280 ppm <= 10 ppm <= 10 ppm <= 10 ppm	Specific Optical Rotation (JP)		+9.2° to +10.6°
Residue on Ignition/Sulfated Ash (EP/JP) < = 0.1%	pH (10%) (JP)		3.5 - 4.5
Sulfate Sulfate (EP) Sulfate (JP) < = 300 ppm Trace Metals Iron (Fe) (EP/JP) Lead (Pb) < = 10 ppm	Related Substances (JP)		Passes Test
Sulfate Sulfate (JP) < = 280 ppm Trace Metals Iron (Fe) (EP/JP) < = 10 ppm	Residue on Ignition/Sulfated Ash (EP/JP)		< = 0.1%
Lead (Pb) <= 10 ppm	I SIIITATA		• •
Water, KF (JP) 7.2 – 10.0%	I Trace Metals		• •
	Water, KF (JP)		7.2 - 10.0%

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Histidine Monohydrochloride, Monohydrate has been synthesized under full GMP conditions and meets multicompendial applications.

General Product Description

- Appears as white crystalline powder or crystals
- Manufactured under a Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- No known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts/derivatives.
- Is not subject to genetic modification
- Synonyms: L-α-Amino-β-(4-imidazolyl) propionic acid monochloride
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CofAs.

Storage and Shipping Conditions Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis (CofA) will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks

Country of Origin: India

Blended, Tested, Packaged in Bangor, PA, USA under full GMP conditions.

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