

# L-HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE, SYNTHETIC

## EP, JP, BIOBURDEN AND ENDOTOXIN TESTED, GMP

CAS #: 5934-29-2

Formula:  $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$ 

F.W.: 209.63 g/mol

LHMM-6250

BIO QUALIFIED GRADE

ANALYSIS		SPECIFICATIONS
Ammonium (EP/JP)		< = 200 ppm
Appearance and Color		White Crystalline Powder or Crystals
Appearance of Solution (EP)		Passes Test
Assay, Dried Basis (EP)		98.5 – 101.0%
Assay, Anhydrous Basis (JP)		99.0 – 101.0%
Microbial Content	TAMC TYMC	< = 100 CFU/g < = 100 CFU/g
Clarity and Color of Solution (JP)		Clear and Colorless
Endotoxin		< = 100 EU/g
Identification A , Specific Optical Rotation (EP)		+9.2° 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 2, Chloride (JP)		Passes Test
Loss on Drying (EP)		7.0 – 10.0%
Ninhydrin-positive substances (EP)	Each Individual Impurity	< = 0.2%
	Total Impurities	< = 0.5%
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)	< = 300 ppm
	Sulfate (JP)	< = 280 ppm
Trace Metals	Iron (Fe) (EP/JP)	< = 10 ppm
	Lead (Pb)	< = 10 ppm
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- $\alpha$ -Amino- $\beta$ -(4-imidazolyl) propionic acid monochloride
- Visit the product page on our website ([www.biospectra.us](http://www.biospectra.us)) 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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