

L-HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE, SYNTHETIC BIOTECH, EP, JP, LBLE, GMP

CAS #: 5934-29-2

Formula: $C_6H_9N_3O_2 \text{ HCl H}_2O$

F.W.: 209.64 g/mol

LHMM-6350

BIO QUALIFIED GRADE

ANALYSIS	SPECIFICATIONS
Ammonium (EP/JP)	$\leq 0.02\%$
Appearance and Color	White crystalline powder or crystals
Appearance of Solution (EP)	Passes Test
Assay, Dried Substance (EP)	98.5 – 101.0%
Assay, Anhydrous Basis (JP)	99.0 – 101.0%
Bioburden	$\leq 100 \text{ CFU/g}$
Clarity and Color of Solution (JP)	Clear and Colorless
Endotoxin	$\leq 100 \text{ EU/g}$
Identification, Specific Optical Rotation (EP-A)	+9.2° to +10.6°
Identification B, pH (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
Heavy Metals (JP)	$\leq 10 \text{ ppm}$
Iron (EP/JP)	$\leq 10 \text{ ppm}$
Loss on Drying (EP)	7.0 – 10.0%
Ninhydrin-positive substances (EP)	Any Individual Impurity $\leq 0.2\%$ Total Impurities $\leq 0.5\%$
Optical Rotation (JP)	+9.2° to +10.6°
pH (JP)	3.5 – 4.5
Related Substances (JP)	Passes Test
Residue on Ignition/Sulfated Ash (EP/JP)	$\leq 0.1\%$
Sulfates (EP)	$\leq 300 \text{ ppm}$
Sulfates (JP)	$\leq 280 \text{ ppm}$
Water, KF (JP)	7.2 – 10.0%

Country of Origin: India

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

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

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

General Product Description

- Appears as a white crystalline product
- 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 (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

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