

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-6350
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	< = 100 CFU/g
	TYMC	< = 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 is synthesized under cGMP conditions and meets multicompendial applications.

General Product Description

- Appears as white crystalline powder or crystals
- GMP manufactured in accordance with the certified management system
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains 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 or derivatives.
- Is not subject to genetic modification
- Synonyms: L-Histidine HCl hydrate, L-Histidine HCl Monohydrate
- Visit the product page on our website (www.biospectra.us) for additional information, supporting regulatory documents, and CoAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis (CoA) will contain a 2-year retest 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

2-4 weeks

Country of Origin: India

Blended, tested and packaged in Bangor, PA, USA under cGMP conditions.

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