# BI©BUFFER SOLUTIONS

## **GMP BIOTECH PRODUCT**

### HISTIDINE (L) MONOCHLORIDE MONOHYDRATE, SYNTHETIC BIOTECH, MEETS EP, JP, LBLE, GMP BIO QUALIFIED GRADE / LHMM-6350

C<sub>6</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub> · HCl · H<sub>2</sub>O ★ F.W. 209.64 g/mol ★ CAS# 5934-29-2

#### Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

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

### SPECIFICATIONS

Analysis	Specifications
Ammonium (EP/JP)	$\leq$ 0.02%
Appearance of Solution (EP)	Passes Test
Appearance and Color	White crystalline powder or crystals
Assay, Dried Substance (EP)	98.5 - 101.0%
Assay, Anhydrous Basis (JP)	99.0 - 101.0%
Bioburden	< 100 CFU/g
Endotoxin	< 100 CFU/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
Iron (EP/JP)	<u>≤</u> 10 ppm
Heavy Metals (JP)	$\leq 10 \text{ ppm}$
Loss on Drying (EP)	7.0 - 10.0%
Ninhydrin-positive Any Individual Impurity	$\leq 0.2\%$
substances (EP) Total Impurities	<u>≤</u> 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)	≤ 300 ppm
Sulfates (JP)	<u>≤</u> 280 ppm
Clarity and Color of Solution (JP)	Clear and Colorless
Water, KF (JP)	7.2 - 10.0%

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### **General Product Description:**

Molecular Formula: C<sub>6</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub> · HCl · H<sub>2</sub>O Molecular Weight: 209.64 g/mol CAS Number: 5934-29-2

### <u>L-Histidine Monohydrochloride,</u> <u>Monohydrate Biotech:</u>

- Appears as a white crystalline product.
- Is manufactured under an ISO Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: L-α-Amino-β-(4-imidazolyl) propionic acid monochloride

### **Shelf Life Policy:**

Three-year expiry from the date of manufacture.

### **Storage and Shipping Conditions:**

Please refer to the SDS for storage and shipping conditions.

### Package Size:

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