BIOBUFFER SOLUTIONS

GMP Biotech Product

HISTIDINE (L) MONOHYDROCHLORIDE, MONOHYDRATE BIOTECH
EP, JP, LBLE, GMP
LHMM-6250

$C_6H_9N_3O_2 \cdot HCl \cdot H_2O$ ⅄ 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)	≤ 0.02%
Appearance of Solution (EP)	Passes Test
Assay (Dried Substance) (EP)	98.5 – 101.0%
Identification A, Specific Optical Rotation (dried substance) (EP)	+9.2° to +10.6°
Identification B, pH (EP)	3.0 – 5.0
Identification C, IR (EP, JP)	Passes Test
Identification D (EP)	Passes Test
Identification E (EP)	Passes Test
Identification F (EP)	Passes Test
Iron (EP, JP)	≤ 10 ppm
Loss on Drying (EP)	7.0 – 10.0%
Ninhydrin-positive substances (EP) Any Individual Impurity	≤ 0.2%
Ninhydrin-positive substances (EP) Total Impurities	≤ 0.5%
Residue on Ignition / Sulfated Ash (EP, JP)	≤ 0.1 %
Sulphates (EP)	≤ 300 ppm
Assay (anhydrous basis) (JP)	99.0 – 101.0%
Clarity and Color of Solution (JP)	Clear and Colorless
Identification 2, Chloride (JP)	Passes Test
Heavy Metals (JP)	≤ 10 ppm
Optical Rotation (JP)	+9.2° to +10.6°
pH (JP)	3.5 – 4.5
Related Substances (JP)	Passes Test

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Sulfates (JP)	≤ 280 ppm
Water (JP)	7.2 – 10.0%
Appearance and Color	White or colorless crystalline powder crystals
Bioburden	< 100 CFU/g
Endotoxin	< 100 CFU/g

General Product Description:

Molecular Formula: $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$
Molecular Weight: 209.64 g/mol
CAS Number: 5934-29-2

L-Histidine Monohydrochloride, Monohydrate Biotech:

- 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

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