BIOBUFFER SOLUTIONS

GMP Amino Acid

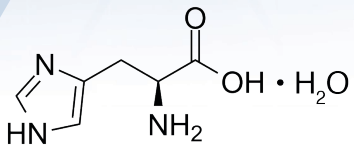
GMP Manufactured Product

HISTIDINE(L) Monohydrochloride, Monohydrate, EP, JP, LBLE* GMP, Excipient Grade

***Low Bioburden, Low Endotoxin**

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES AND PRODUCTS

L-Histidine Monohydrochloride, Monohydrate has been manufactured for use as a critical process chemical for downstream biological drug manufacturing. L-Histidine Monohydrochloride, Monohydrate has been manufactured and purified under strict ICH-Q7 guidelines for excipient materials and can be considered an excipient grade product.



Lead Time (If No Stock): 3-6 months
Minimum Order Quantity: 25kg

CAS #: 5934-29-2
Molecular Formula: $C_6H_9N_3O_2$ HCl • H_2O
F.W.: 209.64 g/mol
Solubility in Water (g/L): 149.55
pH @ 20°C: 4.38 - 4.48

BIO PHARMA GRADE | Product Code: LHMM-4250

$C_6H_9N_3O_2$ •HCl • H_2O F.W. 209.64 g/mol. CAS# 5934-29-2

EP Compendia

ANALYSIS		SPECIFICATIONS
Ammonium		≤ 0.02%
Appearance of Solution		Passes Test
Assay (Dried Substance)		98.5 - 101.0%
Identification A, Specific Optical Rotation (dried substance)		+9.2° to +10.6°
Identification B, pH		3.0-5.0
Identification C, IR		Passes Test
Identification D		Passes Test
Identification E		Passes Test
Identification F		Passes Test
Iron		≤ 10 ppm
Loss on Drying		7.0 – 10.0%
Ninhydrin- positive substances	Any Individual Impurity Total Impurities	≤0.2% ≤0.5%
Residue on Ignition/ Sulfated Ash		≤ 0.1%
Sulphates		≤300ppm

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

L-HISTIDINE Monohydrochloride Monohydrate Bio Excipient

JP Compendia

ANALYSIS	SPECIFICATIONS
Ammonium	≤ 0.02%
Assay (Anhydrous basis)	99.0-101.0%
Clarity and Color of Solution	Clear and colorless
Identification 1, IR	Passes Test
Identification 2, Chloride	Passes Test
Heavy Metals	≤ 10ppm
Iron	≤ 10ppm
Optical Rotation	+9.2° to +10.6°
pH	3.5-4.5
Related Substances	Passes Test
Residue on Ignition/ Sulfated Ash	≤0.1%
Sulfates	≤280ppm
Water	7.2-10.0%

Additional Analyses

ANALYSIS	SPECIFICATIONS
Appearance and Color	White or colorless crystalline powder crystals
Bioburden	≤100CFU/g
Endotoxin	≤100EU/g

General Product Description:

- L-Histidine Monohydrochloride Monohydrate, LHMM-4250, is produced at our cGMP platform in India and then shipped to our Bangor, PA facility where it is tested and repackaged under cGMP conditions.
- L-Histidine, Monohydrochloride, Monohydrate is a White Crystalline product.
- Molecular Formula: $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$
- Molecular Weight: 209.64 g/mol.
- CAS Number: 5934-29-2
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all L-Histidine Monohydrochloride, Monohydrate, LHMM-4250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- L-Histidine, Monohydrochloride, Monohydrate manufactured at our cGMP platform in India and any raw materials used in the manufacture of L-Histidine, Monohydrochloride, Monohydrate at BioSpectra are not subject to genetic modification.
- Synonyms: L-α-Amino-β-(4-imidazolyl)propionic acidmonochloride; 4-Hydroxy-2-methyl-1,1-dioxo-N-(pyridin-2-yl)-1, 2-dihydro-1lamb; da6,2-benzothiazine-3-carboxamide.

GMP Compliance:

Bio Pharma Grade L-Histidine Monohydrochloride Monohydrate, LHMM-4250, is suitable for use as an excipient. It is manufactured in accordance with International Organization for Standardization (ISO) registered Quality Managed Systems. This grade of L-Histidine Monohydrochloride Monohydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

The recommended retest period for L-Histidine, Monohydrochloride, Monohydrate is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and Store in ambient temperature.

Package Sizes:

10kg, 25 kg and 50 kg pails.

Country of Origin:

India

This product is then repacked and retested under cGMP at our Bangor USA cGMP FDA Regulated Facility.