

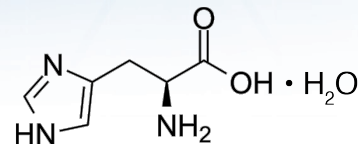
L-HISTIDINE Monochloride, Monohydrate, LBLE, EP, JP, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

L-Histidine Monochloride, Monohydrate has been manufactured for use as a critical process chemical for downstream biological drug manufacturing. L-Histidine Monochloride, 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: $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$

F.W.: 209.64 g/mol

Solubility in Water (g/L): 149.55

pH @ 20°C: 4.38 - 4.48

BIO EXCIPIENT GRADE | Product Code: LHMM-3250

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

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

EP Compendia

ANALYSIS	SPECIFICATIONS
Ammonium	$\leq 0.02\%$
Appearance of Solution	Passes Test
Assay (Dried Substance)	99.0 - 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 $\leq 0.2\%$ Total Impurities $\leq 0.5\%$
Sulphated Ash	$\leq 0.1\%$
Sulphates	≤ 300 ppm



L-HISTIDINE Monochloride 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	≤0.1%
Sulfate	≤0.028%
Water	7.2-10.0%

Additional
Analyses

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

GMP Compliance:

Bio Excipient Grade L-Histidine, Monochloride, Monohydrate, LHMM-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of L-Histidine, Monochloride, Monohydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for L-Histidine, Monochloride, 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

General Product Description:

- L-Histidine Monochloride Monohydrate 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, Monochloride, 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, Monochloride, Monohydrate, LHMM-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- L-Histidine, Monochloride, Monohydrate manufactured at our cGMP platform in India and any raw materials used in the manufacture of L-Histidine, Monochloride, Monohydrate at BioSpectra are not subject to genetic modification.
- Synonyms: L-α-Amino-β-(4-imidazolyl)propionic acid monochloride; 4-Hydroxy-2-methyl-1,1-dioxo-N-(pyridin-2-yl)-1, 2-dihydro-1λ⁶; da6,2-benzothiazine-3-carboxamide.