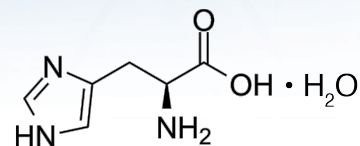


L-HISTIDINE Monohydrochloride, Monohydrate, LBLE, EP, JP, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

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.



CAS #: 5934-29-2

Molecular Formula: C₆H₉N₃O₂ · HCl · H₂O

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

C₆H₉N₃O₂ · HCl · H₂O 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.

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

ANALYSIS	SPECIFICATIONS
Identity – IR	Conforms to Reference Standard
Specific Optical Rotation @ 20°C	+9.2° to +10.6° (on dried basis)
Ninhydrin – Positive Substances	For each impurity: ≤ 0.2% Total: ≤ 0.5%
Ammonium	Passes Test
Iron	≤ 10 ppm
Loss on Drying	7.0 – 10.0%
Sulphated Ash	≤ 0.1%


EP Compendia



L-HISTIDINE Monohydrochloride Monohydrate Bio Excipient

JP Compendia

ANALYSIS	SPECIFICATIONS
Clarity and Color of Solution	Clear and colorless
pH	3.5 – 4.5
Sulfate	≤ 0.028%
Heavy Metals	≤ 10 ppm
Water	7.2 – 10.0%
Assay (Anhydrous Basis)	99.0 – 101.0%

 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

General Product Description:

- The manufacturing of Bio Excipient Grade L-Histidine, Monohydrochloride, Monohydrate, LHMM-3250 is performed at BioSpectra's Bangor, PA facility and BioSpectra's Rensselaer, NY facility utilizing multiuse equipment. Equipment used in the manufacturing of Bio Pharma Grade L-Histidine, Monohydrochloride, Monohydrate is cleaned in accordance with BioSpectra's Cleaning Validation Plan.
- 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-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, Monohydrochloride, Monohydrate manufactured at BioSpectra 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 acid monohydrochloride; 4-Hydroxy-2-methyl-1,1-dioxo-N-(pyridin-2-yl)-1, 2-dihydro-1 λ b; da6,2-benzothiazine-3-carboxamide

GMP Compliance:

Bio Excipient Grade L-Histidine, Monohydrochloride, 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, Monohydrochloride, 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, 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.