

# BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	13-Mar-2026	13-Mar-2029	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### L-HISTIDINE MONOHYDROCHLORIDE MONOHYDRATE

### BIO ULTRA GRADE / LHMM-5250

LOT: LHMM-L02-0326-0000

$C_6H_9N_3O_2 \cdot HCl \cdot H_2O$  \* F.W. 209.63 g/mol. \* CAS# 5934-29-2

Manufacturing Date: MM/DD/YY Retest Date: MM/DD/YY

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets EP, JP Specifications

ANALYSIS	SPECIFICATIONS	RESULT
Ammonium (EP/JP)	< = 200 ppm	<200 ppm
Appearance and Color	White Crystalline Powder or Crystals	Passes Test
Appearance of Solution (EP)	Passes Test	Passes Test
Assay, Dried Basis (EP)	98.5 – 101.0 %	99.8 %
Assay, Anhydrous Basis (JP)	99.0 – 101.0 %	99.9 %
Microbial Content	TAMC < = 100 CFU/g TYMC < = 100 CFU/g	<100 CFU/g <10 CFU/g
Clarity and Color of Solution (JP)	Clear and Colorless	Passes Test
Endotoxin	< = 100 EU/g	<1 EU/g
Identification A, Specific Optical Rotation (EP)	+9.2° to +10.6°	+9.9 °
Identification B, pH (5%) (EP)	3.0 – 5.0	3.9
Identification, IR (EP-C/JP-1)	Conforms to Reference Standard	Passes Test
Identification D (EP)	Passes Test	Passes Test
Identification E (EP)	Passes Test	Passes Test
Identification F (EP)	Passes Test	Passes Test
Identification 2, Chloride (JP)	Passes Test	Passes Test
Loss on Drying (EP)	7.0 – 10.0%	8.3 %

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ANALYSIS		SPECIFICATIONS	RESULT
Ninhydrin- Positive Substances (EP)	Each Individual Impurity Total Impurities	< = 0.2 % < = 0.5 %	<0.2 % <0.5 %
Specific Optical Rotation (JP)		+9.2° to +10.6°	+9.9 °
pH (10%) (JP)		3.5 – 4.5	4.0
Related Substances (JP)		Passes Test	Passes Test
Residue on Ignition, Sulfated Ash (EP/JP)		< = 0.1 %	<0.1 %
Sulfates	Sulfate (EP)	< = 300 ppm	<300 ppm
	Sulfate (JP)	< = 280 ppm	<280 ppm
Trace Metals	Iron (Fe) (EP/JP)	< = 10 ppm	<6.0 ppm
	Lead (Pb)	< = 10 ppm	<0.15 ppm
Water, KF (JP)		7.2 – 10.0 %	8.3 %

COUNTRY OF ORIGIN: India

TEST METHOD REFERENCE: DCN: BSI-ATM-0119

MANUFACTURING DATE: The manufacturing date is representative of the final packaging date at BioSpectra.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. The material represented by this Certificate of Analysis is not suitable to be used as an Excipient, Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

RETEST DATE: A 24-month retest date is assigned based on available industry information.

Prepared by: *Jaron D'Almeida* Date: 3/26/26 Job Title: QA Supervisor

Reviewed by: *Jill* Date: 3/26/26 Job Title: Senior QS Manager