

# BIOBUFFER SOLUTIONS

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

Effective Date:	23-Jul-2025	23-Jul-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0314 v.1.1	: Supersedes
QA/QC Approval:	Taylor Yurick	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### L-HISTIDINE MONOCHLORIDE MONOHYDRATE

### BIOTECH, MEETS EP, JP, LBLE, GMP

### BIO QUALIFIED GRADE / LHMM-6250

### LOT#: LHMM-L02-0625-0004

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

Retest Date: 10/13/25

Manufacturing Date: 06/04/25

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS	RESULT
Ammonium (EP/JP)	≤ 0.02 %	< 0.02 %
Appearance and Color	White crystalline powder or crystals	White crystalline powder or crystals
Appearance of Solution (EP)	Passes Test	Passes Test
Assay, Dried Substance (EP)	98.5 – 101.0 %	99.8 %
Assay, Anhydrous Basis (JP)	99.0 – 101.0 %	99.9 %
Bioburden	≤ 100 CFU/g	< 100 CFU/g
Clarity and Color of Solution (JP)	Clear and Colorless	Clear and Colorless
Endotoxin	≤ 100 EU/g	< 1 EU/g
Identification, Specific Optical Rotation (EP-A)	+9.2° to +10.6°	+ 9.9 °
Identification B, pH (EP)	3.0 – 5.0	3.9
Identification, IR (EP-C/JP-1)	Conforms to Reference Standard	Conforms to Reference Standard
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
Heavy Metals (JP)	≤ 10 ppm	< 0.15 ppm
Iron (EP/JP)	≤ 10 ppm	< 6.0 ppm
Loss on Drying (EP)	7.0 – 10.0%	8.3 %

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ANALYSIS		SPECIFICATIONS	RESULT
Ninhydrin-Positive Substances (EP)	Each Individual Impurity	$\leq 0.2 \%$	$< 0.2 \%$
	Total Impurities	$\leq 0.5 \%$	$< 0.5 \%$
Optical Rotation (JP)		$+9.2^{\circ}$ to $+10.6^{\circ}$	$+9.9^{\circ}$
pH (JP)		3.5 – 4.5	4.0
Related Substances (JP)		Passes Test	Passes Test
Residue on Ignition, Sulfated Ash (EP/JP)		$\leq 0.1 \%$	$< 0.1 \%$
Sulfates (EP)		$\leq 300$ ppm	$< 300$ ppm
Sulfates (JP)		$\leq 280$ ppm	$< 280$ 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. It is GMP manufactured by BioSpectra's approved supplier in accordance with the approved supplier's ISO 9001:2015 certified management system. The material represented by this Certificate of Analysis is not suitable to be used as an 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: Shirley McCall Date: 7/23/25 Job Title: QA Tech III

Reviewed by: Carla Alent Date: 7/23/25 Job Title: Senior Quality Manager