

# BIOBUFFER SOLUTIONS

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

Effective Date:	23-Jan-2025	23-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: 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

Manufacturing Date: 10/14/23

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS	RESULT
Ammonium (EP/JP)	$\leq 0.02 \%$	$< 0.02 \%$
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	$\leq 100$ CFU/g	$< 100$ CFU/g
Clarity and Color of Solution (JP)	Clear and Colorless	Clear and Colorless
Endotoxin	$\leq 100$ EU/g	$< 1$ EU/g
Identification, Specific Optical Rotation (EP-A)	$+9.2^\circ$ to $+10.6^\circ$	$+9.9^\circ$
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)	$\leq 10$ ppm	$< 0.15$ ppm
Iron (EP/JP)	$\leq 10$ 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

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: The retest date is obtained from the approved supplier's certificate of analysis.

Prepared by: *David McCall* Date: 6/14/25 Job Title: QA Technician

Reviewed by: *Jim Singh* Date: 6/15/25 Job Title: QA Supervisor