BIOBUFFER SOLUTIONS

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

Effective Date:	21-Jun-2024	21-Jun-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0290 v.1.1	: Supersedes
QA/QC Approval:	Taylor Yurick	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

L-HISTIDINE MONOCHLORIDE MONOHYDRATE

EP, JP, GMP

BIO PHARMA GRADE / LHMM-4250-93

LOT#: LHMM-0124-00002

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

Retest Date: 10/15/25

Manufacturing/Packaging Date: MM/DD/YY 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)	98.5 – 101.0%	100.3 %
Assay (anhydrous basis)	99.0 – 101.0%	99.7 %
Bioburden	≤ 100CFU/g	<100 CFU/g
Clarity and Color of Solution (JP)	Clear and Colorless	Clear and Colorless
Endotoxin	≤ 100EU/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	4.0
Identification, IR (EP-C/JP-1)	Passes Test	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
Heavy Metals (JP)	≤ 10 ppm	<0.15 ppm
Iron (EP/JP)	≤ 10 ppm	<6.0 ppm
Loss on Drying (EP)	7.0 – 10.0%	8.7 %

ANALYSIS		SPECIFICATIONS	RESULT
Ninhydrin-Positive Substances (EP)	Each Individual Impurity	≤ 0.2%	<0.2 %
	Total Impurities	≤ 0.5%	<0.5 %
Optical Rotation (JP)		+9.2° to +10.6°	+10.0°
pH (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 (EP)		≤300ppm	<300 ppm
Sulfates (JP)		≤280ppm	<280 ppm
Water (JP)		7.2 – 10.0%	8.2 %

COUNTRY OF ORIGIN: India

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is GMP manufactured by the 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: Jaylon Spence Date: 7/8/24 Job Title: QA Tech III

Reviewed by: Cari Allen Date: 7/8/24 Job Title: Senior Quality Manager