

# 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-0124-00001

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

Retest Date: 10/13/25

Manufacturing/Packaging Date: MM/DD/YY 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)	98.5 – 101.0%	99.8 %
Assay (anhydrous basis)	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° to +10.6°	+9.9°
Identification B, pH (EP)	3.0 – 5.0	3.9
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)	$\leq 10$ ppm	<0.15 ppm
Iron (EP/JP)	$\leq 10$ ppm	<6.0 ppm
Loss on Drying (EP)	7.0 – 10.0%	8.3 %

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.

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° to +10.6°	+9.9°
	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)	$\leq 300\text{ppm}$	<300 ppm
	Sulfates (JP)	$\leq 280\text{ppm}$	<280 ppm
	Water (JP)	7.2 – 10.0%	8.3 %

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: Taylor Yunker Date: 7/8/24 Job Title: QA Tech III

Reviewed by: Car Albert Date: 7/8/24 Job Title: Senior Quality Manager