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-0201 v.1.4	: Supersedes
QA/QC Approval:	Taylor Yurick	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

L-ARGININE HCL

GMP MANUFACTURED, USP, EP, JP

BIO PHARMA GRADE / LARH-4220-93

LOT#: LARH-0124-00007

$C_6H_{14}N_4O_2 \cdot HCl$ ⅄ F.W. 210.66 g/mol. ⅄ CAS# 1119-34-2

Retest Date: 10/01/25

Manufacturing/Packaging Date: 04/25/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White or almost white crystalline powder or colourless crystals	White crystalline powder
Ammonium (EP/JP)	≤ 0.02%	<0.02 %
Appearance of Solution (EP)	Clear, Colourless Solution	Clear, Colourless Solution
Arsenic (JP)	≤ 2 ppm	<0.45 ppm
Assay (dried basis) (USP/EP/JP)	98.5 – 101.0%	100.0 %
Chloride Content (USP)	16.5 – 17.1%	16.9 %
Clarity and Color of Solution (JP)	Passes Test	Passes Test
Heavy Metals (JP)	≤ 20 ppm	<0.15 ppm
Identification, IR (USP-A/EP-B/JP-1)	Conforms to Reference Standard	Conforms to Reference Standard
Identification, Specific Optical Rotation (EP-A/USP/JP)	+21.5° to +23.5°	+22.6 °
Identification C, TLC (EP)	Passes Test	Passes Test
Identification D, Color (EP)	Passes Test	Passes Test
Identification, Chlorides (EP-E/JP-2)	Passes Test	Passes Test
Iron (EP)	≤ 10 ppm	2.4 ppm
Loss on Drying (USP/EP/JP)	≤ 0.20%	0.05 %

ANALYSIS		SPECIFICATIONS	RESULT
Ninhydrin-Positive Substances (USP/EP)	Each Individual Impurity	≤ 0.2%	<0.2 %
	Total Impurities	≤ 0.5%	<0.5 %
pH (1 in 10) (JP)		4.7 – 6.2	5.6
Related Substances (USP/JP)		Passes Test	Passes Test
Residue on Ignition, Sulfated Ash (USP/EP/JP)		≤ 0.1%	0.1 %
Sulfate (USP/EP/JP)		≤ 0.028%	<0.028 %

COUNTRY OF ORIGIN: India

SPECIFICATION STATEMENT: When applicable, the most stringent monograph specification will be referenced as the specification.

TEST METHOD REFERENCE: DCN: BSI-ATM-0114

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

Prepared by: Zaire Rorgin Date: 6/21/24 Job Title: QA Tech I

Reviewed by: Can Alut Date: 6/21/24 Job Title: Senior Quality Manager