

BIOBUFFER SOLUTIONS

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

Effective Date:	04-Mar-2026	04-Mar-2029	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

L-ARGININE HYDROCHLORIDE

BIO ULTRA GRADE / LARH-5350

LOT: LARH-L03-0326-0000

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

Manufacturing Date: MM/DD/YY Retest Date: MM/DD/YY

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets USP, EP, JP Specifications

ANALYSIS	SPECIFICATIONS	RESULT
Appearance and Color	White or Almost White Crystalline Powder or Colorless Crystals	Passes Test
Ammonium (EP/JP)	< = 200 ppm	<200 ppm
Appearance of Solution (EP)	Clear, Colorless Solution	Passes Test
Assay, Dried Basis (USP/EP/JP)	98.5 – 101.0 %	99.9 %
Chloride Content (USP)	16.5 – 17.1 %	16.9 %
Clarity and Color of Solution (JP)	Passes Test	Passes Test
Endotoxin	< = 5 EU/g	<2 EU/g
Identification, IR (USP-A/EP-B/JP-1)	Conforms to Reference Standard	Passes Test
Identification, Specific Optical Rotation (EP-A/USP/JP)	+21.5° to +23.5°	+22.5 °
Identification C (EP)	Passes Test	Passes Test
Identification D (EP)	Passes Test	Passes Test
Identification, Chlorides (EP-E/JP-2)	Passes Test	Passes Test
Loss on Drying (USP/EP/JP)	< = 0.20 %	0.05 %

ANALYSIS		SPECIFICATIONS	RESULT
Microbial Content	TAMC	< = 100 CFU/g	<100 CFU/g
	TYMC	< = 10 CFU/g	<10 CFU/g
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)		< = 280 ppm	<280 ppm
Trace Metals	Arsenic (As)	< = 2 ppm	<0.45 ppm
	Iron (Fe)(EP)	< = 10 ppm	2 ppm
	Lead (Pb)	< = 20 ppm	<0.15 ppm

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

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. The material represented by this Certificate of Analysis is not suitable to be used as an Excipient, 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:  Date: 3/26/26 Job Title: QA Supervisor

Reviewed by:  Date: 3/26/26 Job Title: Senior QS Manager