

# BIO SPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	1-Mar-2021	1-Mar-2024	: Date of Next Review
Prepared By:	Carissa McCollan	19-002903 v.5.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### L-CYSTINE diHCl

### BIO PHARMA GRADE / NEW CODE LCYS-4250-25

#### (HISTORICAL CODE CY4250-K025)

#### LOT: LCYS-0121-00005

$C_6H_{12}N_2O_4S_2 \cdot 2HCl$  \* F.W. 313.22 g/mol. \* CAS# 30925-07-6

Manufacturing Date: 3/19/21      Retest Date: 3/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 7/27/21      Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to Slightly Yellow Crystalline Powder	White to Slightly Yellow Crystalline Powder
Assay (Dried Basis)	98.0% - 102.0%	99.9%
Bioburden	≤ 100 CFU/g	<10 CFU/g
Chloride	22.2% - 23.5%	22.6%
Endotoxin	<0.02 EU/mg	<0.02 EU/mg
Heavy Metals (Pb)	<10 ppm	<10 ppm
Identification (IR Spectrum)	Passes Test	Passes Test
Loss on Drying @ 105°C	1.0% max.	0.3%
pH (0.1% soln.)	Report	2.2
Residue on Ignition	0.1% max.	<0.1%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-221.3°
Solubility	Passes Test	Passes Test

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 17-002319

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. 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.

Prepared by: Jaron Hughes      Date: 8/2/21      Job Title: QA Specialist

Reviewed by: [Signature]      Date: 8/5/21      Job Title: QA Manager