

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

Effective Date:	07-Jun-2023	07-Jun-2026	: Date of Next Review	
Prepared By:	Virginia Pena	BSI-COA-0131 v.6.1	: Supersedes	
QA/QC Approval:	Carissa Albert	Amy Yencho	: Management Approval	
Reason for Revision:	See Revision History in MasterControl.	*	10	

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / LCYS-4250-01

LOT: LCYS-0123-00015

C₆H₁₂N₂O₄S₂· 2HCl F.W. 313.22 g/mol. CAS# 30925-07-6

Retest Date: 04/15/25

Manufacturing/Packaging Date: 06/06/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis	SPECIFICATION	TEST RESULT
Appearance and Color	White to Slightly Yellow Crystalline Powder	White Crystalline Powder
Assay (Dried Basis)	98.0% - 102.0%	99.39%
Bioburden	$\leq 100 \text{ CFU/g}$	10 CFU/g
Chloride	22.2% - 23.5%	22.54%
Endotoxin	<0.02 EU/mg	Complies
Heavy Metals (Pb)	<10 ppm	0.482 ppm
Identification (IR Spectrum)	Passes Test	Complies
Loss on Drying @ 105°C	≤ 0.5%	0.14%
pH (0.1% soln.)	Report	2.268
Residue on Ignition	≤ 0.1%	0.05%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-220.07°
Solubility	Passes Test	Complies

COUNTRY OF ORIGIN: India

TEST RESULTS: Test Results are obtained from the approved supplier's certificate of analysis.

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.

<u>RETEST DATE:</u> The retest date is obtained from the approved supplier's certificate of analysis.

DCN: BSI-COA-0131 v.6.1

Prepared by: M. Alraffa Date: 06/16/23 Job Title: QA mater. Disp. Tech. III

Reviewed by: Job Title: QA Mater. Disp. Supervisor