DCN: BSI-COA-0131 v.6.2



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:	ion: See Revision History in MasterControl.			-

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / LCYS-4250-25

LOT: LCYS-0124-00016

C₆H₁₂N₂O₄S₂·2HC1 Å F.W. 313.22 g/mol. Å CAS# 30925-07-6

Retest Date: 05/22/25

Manufacturing/Packaging Date: 06/19/24 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%	100.86%
Bioburden	$\leq 100 \text{ CFU/g}$	5 CFU/g
Chloride	22.2% - 23.5%	22.83%
Endotoxin	<0.02 EU/mg	Complies
Heavy Metals (Pb)	<10 ppm	Complies
Identification (IR Spectrum)	Passes Test	Complies
Loss on Drying @ 105°C	≤ 0.5%	0.27%
pH (0.1% soln.)	Report	2.518
Residue on Ignition	≤ 0.1%	0.02%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-219.48°
Solubility	Passes Test	Complies

COUNTRY OF ORIGIN: India

<u>TEST RESULTS:</u> 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.

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

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Prepared by: Date: 6/25/24 Job Title: QA Tech I

Reviewed by: Date: 6/25/24 Job Title: QA Supervisor