DCN: 19-002903 v.1.0



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

Effective Date: 14-Jun-2019	14-Jun-2022	: Date of Next Review
Prepared By: Kyle Snyder	Not Applicable	: Supersedes
QA/QC Approval: Hannah Bernier	Dora Meissner	: Management Approval
Reason for Revision See Revision History in ensur		

## L-CYSTINE diHCl

CERTIFICATE OF ANALYSIS

## BIO PHARMA GRADE / CY4250-SAMPLE COA

LOT: CY4250-001-0719

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

Manufacture Date: 5/20/2018

Retest Date: 11/30/2019

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: Sample CoA Packaging Site: Sample CoA

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%	99.29%
Bioburden	50 CFU/g max.	<10 CFU/g
Chloride	22.2% - 23.5%	22.47%
Endotoxin (1% soln.)	<0.02 EU/mg	<0.02 EU/mg
Heavy Metals (Pb)	<10 ppm	<10 ppm
Identification	Passes Test	Passes Test
Loss on Drying @ 105°C	1.0% max.	0.0833%
pH (0.1% soln.)	Report	2.33 @ 22.3 °C
Residue on Ignition	0.1% max.	<0.0265%
Specific Rotation (Free Basis) @ 20°C	-225.0 to -210.0	-220.96 @ 20 °C
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 to be used only as the following: IPEC Compliant GMP Manufactured non-Sterile Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. The material represented by this Certificate of Analysis is not suitable to be used as a Sterile or Injectable Chemical, Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

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Prepared by:	Date: 7/24/19
Reviewed by: H. B.eurr	Date: 7/24/19