

BIO SPECTRA

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

Effective Date:	8-Nov-2022	8-Nov-2025	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Carissa Albert	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIO EXCIPIENT GRADE / GTHI-3220-14-76

LOT: GTHI-0123-00004

 $\text{NH}_2\text{C}(\text{NH})\text{NH}_2\text{-HSCN}$ * F.W. 118.16 g/mol * CAS#: 593-84-0

Manufacturing Date: 8/1/22 Retest Date: 8/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 2/11/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance	280nm	0.300 a.u. max.	0.091 a.u.
	300nm	0.050 a.u. max.	0.012 a.u.
	340nm	0.030 a.u. max.	0.003 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	99.6%	
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Identification (IR)	Passes Test	Passes Test	
Loss on Drying	0.5% max.	0.1%	
Melting Range	115-121°C	119 - 120°C	
pH (5% Solution)	5.0 – 7.0	5.5 @ 23.5°C	
Solubility (35%)	Passes Test	Passes Test	
Trace Metals	Arsenic (As)	5 ppm max.	<0.45 ppm
	Copper (Cu)	5 ppm max.	<0.90 ppm
	Iron (Fe)	5 ppm max.	<0.90 ppm
	Lead (Pb)	5 ppm max.	<0.15 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0003

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

OVI STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

ADDITIONAL INFORMATION: The additional information below applies to the components and intermediate finished goods utilized for the packaging of the finished goods lot covered by this Certificate of Analysis.

EziDock Part Number 2000153, EziDock lot number 3504584.

BioSpectra bulk product code GTHI-3200, BioSpectra bulk lot number GTHI-0122-00022.

Prepared by: Cassie Albert Date: 2/28/23 Job Title: Assoc. Director of Quality

Reviewed by: Janet Humphreys Date: 2/28/23 Job Title: QA Specialist