

BIO SPECTRA

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

Effective Date:	13-Aug-2021	13-Aug-2024	: Date of Next Review
Prepared By:	Jared Lobb	16-001152 v4.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIO EXCIPIENT GRADE / NEW CODE GTHI-3220-25

(HISTORICAL CODE GT3220-K025)

LOT: GTHI-0123-00013

NH₂C(NH)NH₂·HSCN * F.W. 118.16 g/mol * CAS#: 593-84-0

Manufacturing Date: 09/11/22 Retest Date: 09/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 07/13/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance	280nm	0.300 a.u. max.
	300nm	0.050 a.u. max.
	340nm	0.030 a.u. max.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.5% min.	99.9%
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Identification (IR)	Passes Test	Passes Test
Loss on Drying	0.5% max.	0.2%
Melting Range	115 – 121 °C	119 – 120 °C
pH (5% Solution)	5.0 – 7.0	5.6 @ 23.0 °C
Solubility (35%)	Passes Test	Passes Test
Trace Metals	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000043

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.

Prepared by: M. Akafu Date: 07/17/23 Job Title: QA Mater. Disp. Tech. III
Reviewed by: Jason Rugh Date: 7/17/23 Job Title: QA Mater. Disp. Supervisor