BIOSPECTRA

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

Effective Date:	17-Jul-2024	17-Jul-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0020 v 5.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIO EXCIPIENT GRADE / GTHI-3220-25

LOT: GTHI-0124-00008

$NH_2C(NH)NH_2 \cdot HSCN$ ▲ F.W. 118.16 g/mol ▲ CAS#: 593-84-0

Manufacturing Date: 07/25/24 Retest Date: 07/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 08/26/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance	280nm	0.300 a.u. max.	0.096 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.	100.2%
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.	0.2%
Melting Range		115-121°C	119 - 120°C
pH (5% Solution)		5.0 – 7.0	5.5
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.	2.3 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.

Prepared by: Anil McLall Date: 8/28/24 Job Title: QA Tech I

Reviewed by: Joan Bingham Date: 8/28/24 Job Title: QA Supervisor