

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

NH₂C(NH)NH₂·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 300nm 340nm	0.300 a.u. max. 0.050 a.u. max. 0.030 a.u. max.	0.096 a.u. 0.012 a.u. 0.003 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	100.2%	
Enzymes	DNase RNase Protease	None Detected None Detected None Detected	None Detected 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) Copper (Cu) Iron (Fe) Lead (Pb)	5 ppm max. 5 ppm max. 5 ppm max. 5 ppm max.	< 0.45 ppm < 0.90 ppm 2.3 ppm < 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.

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.

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 McCall Date: 8/28/24 Job Title: QA Tech I

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