

BIOSPECTRA

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

Effective Date:	7-Jan-2020	7-Jan-2023	: Date of Next Review
Prepared By:	Amy Hosein	16-001152 v3.0	: Supersedes
QA/QC Approval:	Carissa McCollan	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIO EXCIPIENT GRADE / GT3220-K010

LOT: GT3220-015-0720

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

Manufacturing Date: 7/9/20 Retest Date: 7/31/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 8/11/20

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance	280nm	0.300 a.u. max.	0.099 a.u.
	300nm	0.050 a.u. max.	0.013 a.u.
	340nm	0.030 a.u. max.	0.001 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	99.8%	
	DNase	None Detected	None Detected
Enzymes	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	5.3 @ 23.4°C	
Solubility (35%)	Passes Test	Passes Test	
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000043

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further manufacturing. 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: Cc Date: 8/12/20 Job Title: QA Supervisor

Reviewed by: Wendy Jatty Date: 08/12/20 Job Title: QA Manager