

BIOSPECTRA

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

Effective Date:	21-Jan-2025	21-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIOTECH, GMP

BIO PHARMA GRADE / GTHI-4221

LOT: GTHI-0124-00003

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

Manufacturing Date: 7/22/24 Retest Date: 7/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1.7M)	280 nm	≤ 0.300 a.u.	0.096 a.u.
	300 nm	≤ 0.050 a.u.	0.013 a.u.
	340 nm	≤ 0.030 a.u.	0.003 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0 %	100.1 %
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification, IR		Conforms to Reference Standard	Conforms to Reference Standard
Loss on Drying		≤ 0.5 %	0.1 %
Melting Range		115 - 121 °C	119 - 121 °C
pH (5% solution)		5.0 - 7.0	5.8
Sulfated Ash		≤ 0.5 %	< 0.5 %
Sulfate		≤ 50 ppm	< 50 ppm
Arsenic (As)		≤ 5 ppm	< 0.45 ppm
Aluminum (Al)		≤ 5 ppm	< 1.5 ppm
Trace Metals	Barium (Ba)	≤ 5 ppm	< 4.2 ppm
	Bismuth (Bi)	≤ 5 ppm	< 3.0 ppm
	Calcium (Ca)	≤ 10 ppm	< 1.5 ppm
	Cadmium (Cd)	≤ 5 ppm	< 0.06 ppm


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ANALYSIS	SPECIFICATION	TEST RESULT	
Chromium (Cr)	≤ 5 ppm	< 1.5 ppm	
Cobalt (Co)	≤ 5 ppm	< 0.15 ppm	
Copper (Cu)	≤ 5 ppm	< 0.90 ppm	
Iron (Fe)	≤ 5 ppm	< 0.90 ppm	
Potassium (K)	≤ 50 ppm	< 15 ppm	
Lead (Pb)	≤ 5 ppm	< 0.15 ppm	
Trace Metals	Lithium (Li)	≤ 5 ppm	< 1.5 ppm
	Magnesium (Mg)	≤ 5 ppm	< 1.5 ppm
	Manganese (Mn)	≤ 5 ppm	< 1.5 ppm
	Molybdenum (Mo)	≤ 5 ppm	< 4.5 ppm
	Sodium (Na)	≤ 5000 ppm	< 15 ppm
	Nickel (Ni)	≤ 5 ppm	< 0.60 ppm
	Strontium (Sr)	≤ 5 ppm	< 1.5 ppm
	Zinc (Zn)	≤ 5 ppm	< 1.5 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 a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by:  Date: 2/17/25 Job Title: QA Tech I

Reviewed by:  Date: 2/17/25 Job Title: Senior Quality Manager