DCN: BSI-COA-0316 v.1.0



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

Effective Date:	21-Jan-2025	21-Jan-2028	: Date of Next Review
Prepared By:	Amy Yencho	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-0124-00004

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

Manufacturing Date: 7/25/24 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	
	280 nm	≤ 0.300 a.u.	0.096 a.u.	
Absorbance (1.7M)	300 nm	≤ 0.050 a.u.	0.012 a.u.	
	340 nm	\leq 0.030 a.u.	0.003 a.u.	
Appearance and Color		White / Crystals	White / Crystals	
Assay		99.0 - 101.0 %	100.2 %	
	DNase	None Detected	None Detected	
Enzymes	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 %	0.2 %	
Melting Range		115 - 121 °C	119 - 120 °C	
pH (5% solution)		5.0 - 7.0	5.5	
Sulfated Ash		≤ 0.5 %	< 0.5 %	
Sulfate		≤ 50 ppm < 50 ppm		
	Arsenic (As)	≤ 5 ppm	< 0.45 ppm	
A	luminum (Al)	≤ 5 ppm	< 1,5 ppm	
Trace	Barium (Ba)	≤ 5 ppm	< 4.2 ppm	
Metals	Bismuth (Bi)	≤ 5 ppm	< 3.0 ppm	
	Calcium (Ca)	≤ 10 ppm	< 1.5 ppm	
C	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	2.3 ppm
	Potassium (K)	≤ 50 ppm	< 15 ppm
	Lead (Pb)	≤ 5 ppm	< 0.15 ppm
Trace	Lithium (Li)	≤ 5 ppm	< 1.5 ppm
Metals	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.

	Date: 2/17/25	_ Job Title: QA	Tech	
Reviewed by: Allut	_Date: _ 2 17 25	_Job Title: Senior	Quality	Manager