DCN: 16-000923 v.2.1

## **BIOSPECTRA**

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

Effective Date:	23-Jun-2017	23-Jun-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-000923 v.2.0	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		•

## **GUANIDINE THIOCYANATE**

**CERTIFICATE OF ANALYSIS** 

## BIO PHARMA GRADE / GT4220-K025

LOT: GT4220-114-0219

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

Retest Date: 4/30/2020

Manufacturing Date: 4/30/2018

Relest Date: 4/30/202

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 2/17/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis		SPECIFICATION	TEST RESULT
	280 nm	0.300 a.u. maximum	0.0925 a.u.
Absorbance	300 nm	0.050 a.u. maximum	0.0135 a.u.
	340 nm	0.030 a.u. maximum	0.0037 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% minimum	99.74%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification (IR)		Passes Test	Passes Test
Loss on Drying		0.5% maximum	0.1364%
Melting Range		115-121°C	119.4 − 120.5°C
pH (5% solution)		5.0-7.0	6.992 @ 19.46°C
Solubility (35%)	•	Clear	Clear
Trace Metals	Arsenic (As)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	Iron (Fe)	5 ppm maximum	< 5 ppm
	Lead (Pb)	5 ppm maximum	< 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: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. 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.

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RESIDUAL SOLVENTS: Based on the manufacturing process and the controlled handling and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by:	Date: 2/18/19
Reviewed by: H. Bourn	Date: 2/18/19