

BIOSPECTRA

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

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|----------------------|-------------------------------|----------------|-----------------------|
| 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: GT3220-018-0720

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

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

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 7/22/20

Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT | |
|----------------------|------------------|------------------|---------------|
| Absorbance | 280nm | 0.300 a.u. max. | 0.096 a.u. |
| | 300nm | 0.050 a.u. max. | 0.014 a.u. |
| | 340nm | 0.030 a.u. max. | 0.003 a.u. |
| Appearance and Color | White / Crystals | White / Crystals | |
| Assay | 99.5% min. | 99.7% | |
| Enzymes | DNase | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| | Protease | 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 @ 23.1°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: Cin Date: 8/11/20 Job Title: QA Supervisor
Reviewed by: Wendy Smith Date: 08/12/20 Job Title: QA Manager