

BIOSPECTRA

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

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|----------------------|---------------------------------------|----------------|-----------------------|
| Effective Date: | 8-Nov-2022 | 8-Nov-2025 | : Date of Next Review |
| Prepared By: | Amy Hosein | Not Applicable | : Supersedes |
| QA/QC Approval: | Carissa Albert | Dora Meissner | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl | | |

CERTIFICATE OF ANALYSIS

GUANIDINE THIOCYANATE

BIO EXCIPIENT GRADE / GTHI-3220-14-76

LOT: GTHI-0122-00034

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

Manufacturing Date: 6/23/22 Retest Date: 6/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 11/2/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|----------------------|--------------|------------------|------------------|
| Absorbance | 280nm | 0.300 a.u. max. | 0.095 a.u. |
| | 300nm | 0.050 a.u. max. | 0.011 a.u. |
| | 340nm | 0.030 a.u. max. | 0.002 a.u. |
| Appearance and Color | | White / Crystals | White / Crystals |
| Assay | | 99.5% min. | 99.8% |
| 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 | 5.6 @ 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: BSI-ATM-0003

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. 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.

ADDITIONAL INFORMATION: The additional information below applies to the components and intermediate finished goods utilized for the packaging of the finished goods lot covered by this Certificate of Analysis.

EziDock Part Number 2000153, EziDock lot number 3504584.

BioSpectra bulk product code GTHI-3200, BioSpectra bulk lot number GTHI-0122-00009.

Prepared by: *Jan Rugh* Date: 11/11/22 Job Title: QA Specialist
Reviewed by: *Carrie Allert* Date: 11/11/22 Job Title: Assoc. Director of Quality