

BIOSPECTRA

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

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|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 6-Jul-2020 | 6-Jul-2023 | : Date of Next Review |
| Prepared By: | Amy Hosein | 16-000062 v.5.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

TRIS HCl

BIO EXCIPIENT GRADE / TH3220-K025

LOT: TH3220-135-1020

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3 \cdot \text{HCl}$ ^ F.W. 157.60 g mol. ^ CAS# 1185-53-1

Manufacturing Date: 8/30/20 Retest Date: 8/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 10/1/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|----------------------|----------------|------------------|---------------|
| Absorbance (1M) | 280 nm | 0.06 a.u. max. | 0.01 a.u. |
| Appearance and Color | | White / Crystals | Passes Test |
| Assay | | 99.5% min. | 99.9% |
| Enzymes | DNase | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| Heavy Metals | | 2 ppm max. | < 2 ppm |
| Identification (IR) | | Passes Test | Passes Test |
| Insoluble Matter | | 0.001% max. | <0.001% |
| Karl Fischer | | 0.5% max. | <0.5% |
| Melting Range | | 150 – 153 °C | 150-152°C |
| pH (0.5M) | | 4.0 – 5.0 | 4.2 @ 25.0°C |
| pK _a | | 8.0 – 8.4 | 8.2 |
| Residue on Ignition | | 0.1% max. | <0.1% |
| Solubility 35% | | Passes Test | Passes Test |
| Trace Metals | Arsenic (As) | 1 ppm max. | < 1 ppm |
| | Calcium (Ca) | 1 ppm max. | 1 ppm |
| | Copper (Cu) | 1 ppm max. | < 1 ppm |
| | Iron (Fe) | 1 ppm max. | < 1 ppm |
| | Lead (Pb) | 1 ppm max. | < 1 ppm |
| | Magnesium (Mg) | 1 ppm max. | < 1 ppm |

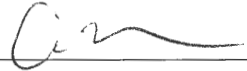
COUNTRY OF ORIGIN: U.S.A.


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TEST METHOD REFERENCE: DCN: 16-000042

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.

RESIDUAL SOLVENTS: 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:  Date: 10/9/20 Job Title: QA Supervisor

Reviewed by:  Date: 10/09/20 Job Title: QI Manager