

# BIOSPECTRA

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

|                      |                               |                |                       |
|----------------------|-------------------------------|----------------|-----------------------|
| Effective Date:      | 19-Dec-2019                   | 19-Dec-2022    | : Date of Next Review |
| Prepared By:         | Carissa McCollian             | 16-000062 v4.0 | : Supersedes          |
| QA/QC Approval:      | Hannah Bernier                | Amy Yenko      | : Management Approval |
| Reason for Revision: | See Revision History in ensur |                |                       |

## TRIS HCl

### CERTIFICATE OF ANALYSIS

### BIO EXCIPIENT GRADE / TH3220-K010

### LOT: TH3220-112-0320

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

Manufacturing Date: 2/21/2020 Retest Date: 2/28/2022

Packaging Date: 3/18/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

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 | White / Crystals |
| Assay                |                | 99.5% min.       | 99.6%            |
|                      | DNase          | None Detected    | None Detected    |
| Enzymes              | 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.        | 0.3%             |
| Melting Range        |                | 150 – 153 °C     | 151-152°C        |
| pH (0.5M)            |                | 4.0 – 5.0        | 4.2 @ 23.2°C     |
| pK <sub>a</sub>      |                | 8.0 – 8.4        | 8.2              |
| Residue on Ignition  |                | 0.1% max.        | <0.1%            |
| Solubility 35%       |                | Passes Test      | Passes Test      |
|                      | Arsenic (As)   | 1 ppm max.       | < 1 ppm          |
|                      | Calcium (Ca)   | 1 ppm max.       | < 1 ppm          |
|                      | Copper (Cu)    | 1 ppm max.       | < 1 ppm          |
| Trace Elements       | Iron (Fe)      | 1 ppm max.       | < 1 ppm          |
|                      | Lead (Pb)      | 1 ppm max.       | < 1 ppm          |
|                      | Magnesium (Mg) | 1 ppm max.       | < 1 ppm          |

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

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.

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: Kyle Snyder / QA Specialist Date: 3/27/20

Reviewed by: C. ~ / QA Supervisor Date: 3/30/20