



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

|                      |                                        |                     |                       |
|----------------------|----------------------------------------|---------------------|-----------------------|
| Effective Date:      | 06-Feb-2025                            | 06-Feb-2028         | : Date of Next Review |
| Prepared By:         | Taylor Yurick                          | BSI-COA-0135 v.11.1 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                           | Carissa Albert      | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                     |                       |

**CERTIFICATE OF ANALYSIS**  
**TRIS HYDROCHLORIDE**  
**BIO EXCIPIENT GRADE / THCL-3250**  
**LOT: THCL-S03-1025-0152**

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

Manufacturing Date: 10/11/25      Expiration Date: 10/31/28

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS               | SPECIFICATION         | TEST RESULT      |
|------------------------|-----------------------|------------------|
| Absorbance (1M)        | 260 nm                | $\leq 0.06$ a.u. |
|                        | 280 nm                | $\leq 0.06$ a.u. |
|                        | 400 nm                | $\leq 0.01$ a.u. |
| Appearance             | Passes Test           | Passes Test      |
| Assay, Dried           | $\geq 99.0\%$         | 99.9%            |
| Bioburden              | $\leq 100$ CFU/g      | $< 100$ CFU/g    |
| Endotoxin              | $\leq 2.5$ EU/g       | $< 1.9$ EU/g     |
| Identification         | (IR)                  | Passes Test      |
|                        | (Chloride)            | Passes Test      |
| Loss on Drying @ 105°C | $\leq 0.5\%$          | 0.1%             |
| Melting Range          | 147 – 152 °C          | 151-152°C        |
| pH                     | (1% Aqueous Solution) | 4.7              |
|                        | (0.5M) @ 25°C         | 4.3              |
| Trace Elements         | Arsenic (As)          | $\leq 10$ ppm    |
|                        | Calcium (Ca)          | $\leq 10$ ppm    |
|                        | Copper (Cu)           | $\leq 10$ ppm    |
|                        | Iron (Fe)             | $\leq 10$ ppm    |
|                        | Lead (Pb)             | $\leq 10$ ppm    |
|                        | Magnesium (Mg)        | $\leq 10$ ppm    |
| Water                  | $\leq 2.0\%$          | 0.3%             |

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0002

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.

ANIMAL ORIGIN: Tris Hydrochloride manufactured at BioSpectra is not derived from and does not come in contact with animal parts, products and/or byproducts.

Prepared by: Shail McCall Date: 11/10/25 Job Title: QA Tech III

Reviewed by: Joan Bingham Date: 11/10/25 Job Title: QA Supervisor