

BIO SPECTRA

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

| | | | |
|----------------------|--|---------------------|-----------------------|
| Effective Date: | 8-Aug-2022 | 8-Aug-2025 | : Date of Next Review |
| Prepared By: | Amy Hosein | BSI-COA-0135 v.11.0 | : Supersedes |
| QA/QC Approval: | Brett Brink | Carissa McCollan | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | |

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE THCL-3250-25

(HISTORICAL CODE TH3250-K025)

LOT: THCL-0121-0001

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

Manufacturing Date: 2/10/21 Expiration Date: 2/29/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 4/19/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT | |
|------------------------|-----------------------|-------------|-------------|
| Absorbance (1M) | 260 nm | ≤ 0.06 a.u. | 0.01 a.u. |
| | 280 nm | ≤ 0.06 a.u. | 0.01 a.u. |
| | 400 nm | ≤ 0.01 a.u. | <0.01 a.u. |
| Appearance | Passes Test | Passes Test | |
| Assay, Dried | ≥ 99.0% | 99.7% | |
| Bioburden | ≤ 100 CFU/g | ≤ 10 CFU/g | |
| Endotoxin | ≤ 2.5 EU/g | ≤ 2.0 EU/g | |
| Identification | (IR) | Passes Test | Passes Test |
| | (Chloride) | Passes Test | Passes Test |
| Loss on Drying @ 105°C | ≤ 0.5% | 0.1% | |
| Melting Range | 147 – 152 °C | 150-151°C | |
| pH | (1% Aqueous Solution) | 4.0 – 5.0 | 4.7 |
| | (0.5M) @ 25°C | 3.5 – 5.0 | 4.2 |
| Trace Elements | Arsenic (As) | ≤ 10 ppm | ≤ 10 ppm |
| | Calcium (Ca) | ≤ 10 ppm | ≤ 10 ppm |
| | Copper (Cu) | ≤ 10 ppm | ≤ 10 ppm |
| | Iron (Fe) | ≤ 10 ppm | ≤ 10 ppm |
| | Lead (Pb) | ≤ 10 ppm | ≤ 10 ppm |
| | Magnesium (Mg) | ≤ 10 ppm | ≤ 10 ppm |
| Water | ≤ 2.0% | 0.4% | |

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

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: John Rugh Date: 1/5/23 Job Title: QA Specialist
Reviewed by: Carm Allert Date: 1/5/23 Job Title: Assoc. Director of Quality