

BIOSPECTRA

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

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|----------------------|--------------------------------|------------------|-----------------------|
| Effective Date: | 1-Mar-2021 | 1-Mar-2024 | : Date of Next Review |
| Prepared By: | Shana Geffken | 19-002949 v.10.0 | : Supersedes |
| QA/QC Approval: | Jess DeMaio | Hannah Bernier | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE THCL-3250-58

(HISTORICAL CODE TH3250-K050)

LOT: THCL-0222-00031

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

Manufacturing Date: 2/5/22 Expiration Date: 2/28/25

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 2/12/22 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

| ANALYSIS | SPECIFICATION | TEST RESULT | |
|------------------------|-----------------------|------------------|-------------|
| Absorbance (1M) | 260 nm | ≤ 0.06 a.u. | 0.01a.u. |
| | 280 nm | ≤ 0.06 a.u. | 0.01a.u. |
| | 400 nm | ≤ 0.01 a.u. | <0.01a.u. |
| Appearance | Passes Test | Passes Test | |
| Assay, Dried | $\geq 99.0\%$ | 99.9% | |
| Bioburden | ≤ 100 CFU/g | <100 CFU/g | |
| Endotoxin | ≤ 2.5 EU/g | <2.2 EU/g | |
| Identification | (IR) | Passes Test | Passes Test |
| | (Chloride) | Passes Test | Passes Test |
| Loss on Drying @ 105°C | $\leq 0.5\%$ | 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 | 4.1 |
| Trace Elements | Arsenic (As) | ≤ 10 ppm | <10 ppm |
| | Calcium (Ca) | ≤ 10 ppm | 1 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 | $\leq 2.0\%$ | 0.3% | |

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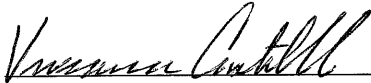
COUNTRY OF ORIGIN: U.S.A.

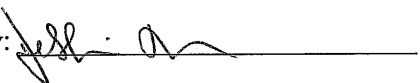
TEST METHOD REFERENCE: DCN: 16-000042

INTENDED USE: Material represented by this Certificate of Analysis is suitable 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:  Date: 3/7/22 Job Title: QA Technician

Reviewed by:  Date: 3/7/22 Job Title: QA Supervisor