

BIOSPECTRA

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

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|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 15-Jul-2020 | 15-Jul-2023 | : Date of Next Review |
| Prepared By: | Amy Hosein | 19-002949 v.9.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / TH3250-G500

LOT: TH3250-024-0820

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

Manufacturing Date: 11/27/19 Retest Date: 11/30/21

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 8/25/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT |
|------------------------|----------------------------|---|
| Absorbance (1M) | 260 nm 280 nm 400 nm | ≤ 0.06 a.u. ≤ 0.06 a.u. ≤ 0.01 a.u. |
| Appearance | Passes Test | 0.01 a.u. 0.01 a.u. <0.01 a.u. |
| Assay, Dried | ≥ 99.0% | Passes Test |
| Bioburden | ≤ 100 CFU/g | 99.9% |
| Endotoxin | ≤ 2.5 EU/g | ≤ 100 CFU/g |
| Identification | (IR) | ≤ 1.9 EU/g |
| | (Chloride) | Passes Test |
| Loss on Drying @ 105°C | ≤ 0.5% | Passes Test |
| Melting Range | 147 – 152 °C | 0.2% |
| pH | (1% Aqueous Solution) | 4.0 – 5.0 |
| | (0.5M) @ 25°C | 3.5 – 5.0 |
| Trace Elements | Arsenic (As) | ≤ 10 ppm |
| | Calcium (Ca) | ≤ 10 ppm |
| | Copper (Cu) | ≤ 10 ppm |
| | Iron (Fe) | ≤ 10 ppm |
| | Lead (Pb) | ≤ 10 ppm |
| | Magnesium (Mg) | ≤ 10 ppm |
| Water | ≤ 2.0% | 0.2% |

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: Cir Date: 8/25/20 Job Title: QA Supervisor

Reviewed by: Wendy Jantz Date: 08/25/20 Job Title: QA Manager