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: | Jaron Hughes | 21-003694 v.1.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollian | Wendy Santay | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

# CERTIFICATE OF ANALYSIS

## TRIS HYDROCHLORIDE

## BIO EXCIPIENT GRADE / NEW CODE THCL-3259-01

(HISTORICAL CODE TH3259-K001)

## LOT: THCL-0121-0249

$NH_2C(CH_2OH)_3 \cdot HCl$ ⅄ F.W. 157.60 g/mol. ⅄ CAS# 1185-53-1

Manufacturing Date: 1/2/21 Retest Date: 1/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 4/2/21 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 and Color | | White / Crystals | Passes Test |
| Assay, Dried | | 99.5% min. | 99.7% |
| Bioburden | | ≤ 100 CFU/g | <10 CFU/g |
| Endotoxin | | ≤ 2.5 EU/g | <2.0 EU/g |
| Enzymes | DNase | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| Heavy Metals | | 2 ppm max. | < 2 ppm |
| Identification | (IR) | Passes Test | Passes Test |
| | (Chloride) | Passes Test | Passes Test |
| Insoluble Matter | | 0.001% max. | <0.001% |
| Loss on Drying @ 105°C | | ≤ 0.5% | 0.1% |
| Melting Range | | 150 – 152 °C | 150-152°C |
| pH (1% Aqueous Solution) | | 4.0 – 5.0 | 4.7 |
| pH (0.5M) @ 25°C | | 3.5 – 5.0 | 4.2 |
| $pK_a$ | | 8.0 – 8.4 | 8.2 |
| Residue on Ignition | | 0.1% max. | <0.1% |

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Solubility 35% | | Passes Test | Passes Test |
| Sulfated Ash (EP) | | ≤ 300 ppm | <300 ppm |
| | Arsenic (As) | 1 ppm max. | <1 ppm |
| | Cadmium (Cd) | 1 ppm max. | <1 ppm |
| | Calcium (Ca) | 1 ppm max. | 1 ppm |
| Trace Metals | Copper (Cu) | 1 ppm max. | <1 ppm |
| | Iron (Fe) | 1 ppm max. | <1 ppm |
| | Lead (Pb) | 1 ppm max. | <1 ppm |
| | Magnesium (Mg) | 1 ppm max. | <1 ppm |
| Water (Karl Fischer) | | 0.5% max. | 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.

Prepared by: _____ Date: 4/7/21 Job Title: QA Specialist

Reviewed by: _____ Date: 4/8/21 Job Title: QA Manager