# BIOSPECTRA

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

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|---|---|---|---|
| Effective Date: | 01-Jul-2022 | 01-Jul-2025 | : Date of Next Review |
| Prepared By: | Wendy Santay | Not Applicable | : Supersedes |
| QA/QC Approval: | Dora Meissner | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl | | |

# CERTIFICATE OF ANALYSIS

## TRIS / TROMETHAMINE

## BIO ACTIVE GRADE / CODE TRIS-2255-10

## LOT: TRIS-0122-00140

$NH_2C(CH_2OH)_3$ ⅄ F.W. 121.14 g/mol. ⅄ CAS# 77-86-1

Manufacturing Date: 6/10/22 Retest Date: 6/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/12/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Absorbance (40%) | 290nm | ≤ 0.2 a.u. | <0.2 a.u. |
| Appearance and Color | | White / Crystals | White / Crystals |
| Assay | | 99.0 – 101.0% | 99.8% |
| Bacterial Endotoxins | | ≤ 3.0 EU/g | <1.0 EU/g |
| Enzymes | DNase | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| Elemental Impurities | Cadmium (Cd) | ≤ 0.005 ppm | <0.002 ppm |
| | Lead (Pb) | ≤ 0.012 ppm | <0.005 ppm |
| | Arsenic (As) | ≤ 0.036 ppm | <0.015 ppm |
| | Mercury (Hg) | ≤0.007 ppm | <0.003 ppm |
| | Cobalt (Co) | ≤ 0.012 ppm | <0.005 ppm |
| | Vanadium (V) | ≤ 0.024 ppm | <0.01 ppm |
| | Nickel (Ni) | ≤ 0.079 ppm | 0.05 ppm |
| | Thallium (Tl) | ≤ 0.019 ppm | <0.008 ppm |
| | Gold (Au) | ≤ 0.238 ppm | <0.10 ppm |
| | Palladium (Pd) | ≤ 0.024 ppm | <0.01 ppm |
| | Iridium (Ir) | ≤ 0.024 ppm | <0.01 ppm |
| | Osmium (Os) | ≤ 0.024 ppm | <0.01 ppm |

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| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Elemental Impurities | Rhodium (Rh) | ≤ 0.024 ppm | <0.01 ppm |
| | Ruthenium (Ru) | ≤ 0.024 ppm | <0.01 ppm |
| | Selenium (Se) | ≤ 0.191 ppm | <0.05 ppm |
| | Silver (Ag) | ≤ 0.024 ppm | <0.01 ppm |
| | Platinum (Pt) | ≤ 0.024 ppm | <0.01 ppm |
| | Lithium (Li) | ≤ 0.595 ppm | <0.25 ppm |
| | Antimony (Sb) | ≤ 0.214 ppm | <0.09 ppm |
| | Barium (Ba) | ≤ 1.667 ppm | <0.70 ppm |
| | Molybdenum (Mo) | ≤ 3.572 ppm | <0.05 ppm |
| | Copper (Cu) | ≤ 0.714 ppm | <0.025 ppm |
| | Tin (Sn) | ≤ 1.429 ppm | <0.60 ppm |
| | Chromium (Cr) | ≤ 2.619 ppm | <0.05 ppm |
| Heavy Metals (as Pb) | | ≤ 0.012 ppm | <0.005 ppm |
| USP Identifications | A (IR) | Passes Test | Passes Test |
| | B | Passes Test | Passes Test |
| | C | Passes Test | Passes Test |
| Insoluble Matter | | ≤ 0.005% | <0.001% |
| Karl Fischer Water | | ≤ 2.0% | 0.2% |
| Loss on Drying | | ≤ 1.0% | 0.1% |
| Melting Range | | 168 – 172°C | 171-172 °C |
| Microbial Content | *Escherichia coli* | Negative | Negative |
| | *Pseudomonas aeruginosa* | Negative | Negative |
| | *Salmonella* | Negative | Negative |
| | *Staphylococcus aureus* | Negative | Negative |
| | TAMC | 100 CFU/g max. | < 100 CFU/g |
| | TYMC | 10 CFU/g max. | <10 CFU/g |
| Organic Impurities | 2-Nitropropane-1,3-diol | NMT 1 ppm | <1 ppm |
| | Tris(hydroxymethyl) nitromethane (EP Related Impurity) | NMT 1 ppm | <1 ppm |
| | 2-Nitroethanol | NMT 1 ppm | <1 ppm |
| | Formaldehyde | NMT 15ppm | 1 ppm |
| | Any Unspecified Impurities | NMT 300 ppm | <300 ppm |
| | Total Impurities | NMT 300 ppm | <300 ppm |

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| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| pH (1 in 20) | | 10.0 – 11.5 | 10.9 |
| Residue on Ignition | | ≤ 0.1% | <0.1% |
| Residual Solvents | Methanol | ≤ 300 ppm | <300 ppm |
| | Nitromethane | ≤ 15 ppm | <15 ppm |
| Trace Metals | Aluminum (Al) | ≤ 0.400 ppm | <0.40 ppm |
| | Calcium (Ca) | ≤ 1 ppm | <0.60 ppm |
| | Iron (Fe) | ≤ 1 ppm | <0.20 ppm |
| | Magnesium (Mg) | ≤ 1 ppm | <0.60 ppm |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

CAUTION: For manufacturing, processing, or repacking in the preparation of a new drug or new animal drug limited by Federal law to investigational use.

CAUTION: Rx only.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a non-Sterile Active Pharmaceutical Ingredient 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 a Sterile Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS STATEMENT: 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: 7/22/22 Job Title: QA Specialist

Reviewed by: _____ Date: 7/22/22 Job Title: QA Manager

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