

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

|                      |                                |                 |                       |
|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date:      | 23-Mar-2021                    | 23-Mar-2024     | : Date of Next Review |
| Prepared By:         | Jared L Lobb                   | 19-002973 v.8.0 | : Supersedes          |
| QA/QC Approval:      | Carissa McCollian              | Wendy Santay    | : Management Approval |
| Reason for Revision: | See Revision History in ensur. |                 |                       |

## CERTIFICATE OF ANALYSIS

### TRIS

### BIO EXCIPIENT GRADE / NEW CODE TRIS-3255-05

(HISTORICAL CODE TR3255-K005)

LOT: TRIS-0122-00100

NH<sub>2</sub>C(CH<sub>2</sub>OH)<sub>3</sub> \* F.W. 121.14 g/mol. \* CAS# 77-86-1

Manufacturing Date: 10/13/21 Expiration Date: 10/31/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 4/6/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP, EP and JPC Specifications

#### USP COMPENDIA

| ANALYSIS            | SPECIFICATION | TEST RESULT  |
|---------------------|---------------|--------------|
| Assay (Dried Basis) | 99.0-101.0%   | 100.1%       |
| Identification A    | Passes Test   | Passes Test  |
| Identification B    | Passes Test   | Passes Test  |
| Identification C    | Passes Test   | Passes Test  |
| Loss on Drying      | 1.0% max.     | 0.2%         |
| Melting Range       | 168-172°C     | 169 - 171 °C |
| pH (1 in 20)        | 10.0 – 11.5   | 10.9         |
| Residue on Ignition | 0.1% max.     | < 0.1%       |

#### EP COMPENDIA

| ANALYSIS                         | SPECIFICATION | TEST RESULT  |
|----------------------------------|---------------|--------------|
| Appearance of Solution           | Passes Test   | Passes Test  |
| Assay (Dried Basis)              | 99.0-100.5%   | 100.1%       |
| Chloride (Cl)                    | ≤ 100 ppm     | < 100 ppm    |
| Identification A                 | Passes Test   | Passes Test  |
| Identification B (Melting Range) | 168-172°C     | 169 - 171 °C |
| Identification C                 | Passes Test   | Passes Test  |
| Identification D                 | Passes Test   | Passes Test  |
| Iron (Fe)                        | 10 ppm max.   | < 10 ppm     |
| Loss on Drying @105°C            | 0.5% max.     | 0.2%         |
| pH (5%)                          | 10.0-11.5     | 10.9         |
| Related Substances               | ≤ 1.0%        | 0.1%         |

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| ANALYSIS     | SPECIFICATION | TEST RESULT |
|--------------|---------------|-------------|
| Sulfated Ash | 0.1% max.     | < 0.1%      |

## JPC ANALYSIS

| ANALYSIS                      | SPECIFICATION | TEST RESULT  |
|-------------------------------|---------------|--------------|
| Arsenic (As)                  | 1.6 ppm max.  | ≤ 1.6 ppm    |
| Assay (Dried Basis)           | 99.0-101.0%   | 100.1%       |
| Clarity and Color of Solution | Passes Test   | Passes Test  |
| Heavy Metals                  | 8 ppm max.    | ≤ 8 ppm      |
| Identification A              | Passes Test   | Passes Test  |
| Identification B              | Passes Test   | Passes Test  |
| Loss on Drying                | 0.5% max.     | 0.2%         |
| Melting Point                 | 168-172°C     | 169 - 171 °C |
| pH                            | 10.3 – 10.7   | 10.4         |
| Residue on Ignition           | 0.1% max.     | < 0.1%       |

## ADDITIONAL ANALYSES

| ANALYSIS                       | SPECIFICATION                                     | TEST RESULT                                       |
|--------------------------------|---|---|
| Appearance and Color           | White, crystalline powder to needle-like crystals | White, crystalline powder to needle-like crystals |
| Absorbance (1M)                | 0.06 a.u. max                                     | 0.01 a.u.   |
|                                | 0.06 a.u. max                                     | < 0.06 a.u.                                       |
|                                | 0.01 a.u. max                                     | < 0.01 a.u.                                       |
| Absorbance (10%)               | 0.03 a.u. max.                                    | 0.01 a.u.   |
|                                | 0.02 a.u. max.                                    | < 0.02 a.u.                                       |
|                                | 0.004 a.u. max.                                   | < 0.004 a.u.                                      |
| Absorbance (40%)               | 0.2 a.u. max.                                     | < 0.2 a.u.  |
| APHA Color, 20% Solution       | 20 APHA max.                                      | < 20 APHA   |
| Assay (Ultrapure, Dried Basis) | 99.9% min   | 100.1%  |
| Endotoxins                     | ≤ 2.5 EU/g  | < 1.0 EU/g  |
|                                | None  | None  |
| Enzymes                        | None  | None  |
|                                | None  | None  |
| Heavy Metals (As Pb)           | 1 ppm max.  | ≤ 1 ppm   |
| Insoluble Matter               | 0.005% max.                                       | < 0.005%  |
| Karl Fischer Water             | 1.0% max.   | 0.1%  |
| Loss on Drying                 | 0.3% max.   | 0.2%  |
| Microbial Content              | ≤ 100 CFU/g                                       | < 10 CFU/g  |
|                                | ≤ 100 CFU/g                                       | < 10 CFU/g  |
| Related Substances             | 0.1% max.   | 0.1%  |

| ANALYSIS               | SPECIFICATION | TEST RESULT |
|------------------------|---------------|-------------|
| Residue on Ignition    | 0.05% max.    | 0.02%       |
| Arsenic (As)           | ≤ 1.6 ppm     | ≤ 1.6 ppm   |
| Calcium (Ca)           | ≤ 1 ppm       | ≤ 1 ppm     |
| Copper (Cu)            | ≤ 1 ppm       | ≤ 1 ppm     |
| Trace Metals Iron (Fe) | ≤ 1 ppm       | ≤ 1 ppm     |
| Lead (Pb)              | ≤ 1 ppm       | ≤ 1 ppm     |
| Magnesium (Mg)         | ≤ 5 ppm       | ≤ 5 ppm     |
| Manganese (Mn)         | ≤ 1 ppm       | ≤ 1 ppm     |
| Zinc (Zn)              | ≤ 1 ppm       | ≤ 1 ppm     |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

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: B B Date: 4/11/22 Job Title: QA specialist

Reviewed by: C Date: 4/11/22 Job Title: QA Manager