

BIOSPECTRA

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

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|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 24-Jul-2020 | 24-Jul-2023 | : Date of Next Review |
| Prepared By: | Amy Hosein | 19-002973 v.7.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollian | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3255-K050

LOT: TR3255-020-1220

NH₂C(CH₂OH)₃ * F.W. 121.14 g mol. * CAS# 77-86-1
 Manufacturing Date: 10/13/20 Retest Date: 10/31/22
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Date: 12/8/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013
 Meets or Exceeds USP, EP and JPC Specifications

USP COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|----------------------|---|---|
| Appearance and Color | White, crystalline powder to needle-like crystals | White, crystalline powder to needle-like crystals |
| Assay (Dried Basis) | 99.0-101.0% | 100.0% |
| 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 | 170 - 172 °C |
| pH (1 in 20) | 10.0 – 11.5 | 10.7 |
| 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% | 100.0% |
| Chloride (Cl) | ≤ 100 ppm | <100 ppm |
| Identification A | Passes Test | Passes Test |
| Identification B (Melting Range) | 168-172°C | 170 - 172 °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 | 10.7 |
| Related Substances | ≤ 1.0% | <1.0% |

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| | | |
|--------------|-----------|-------|
| Sulfated Ash | 0.1% max. | <0.1% |
|--------------|-----------|-------|

| JPC ANALYSIS | | |
|-------------------------------|---------------|--------------|
| ANALYSIS | SPECIFICATION | TEST RESULT |
| Arsenic (As) | 1.6 ppm max. | ≤ 1.6ppm |
| Assay (Dried Basis) | 99.0-101.0% | 100.0% |
| Clarity and Color of Solution | Passes Test | Passes Test |
| Heavy Metals | 8 ppm max. | ≤ 8ppm |
| 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 | 170 - 172 °C |
| pH | 10.3 – 10.7 | 10.5 |
| Residue on Ignition | 0.1% max. | <0.1% |

| ANALYSIS | SPECIFICATION | TEST RESULT |
|-------------------------------|---------------|--------------|
| Arsenic (As) | 1.6 ppm max. | ≤ 1.6ppm |
| Assay (Dried Basis) | 99.0-101.0% | 100.0% |
| Clarity and Color of Solution | Passes Test | Passes Test |
| Heavy Metals | 8 ppm max. | ≤ 8ppm |
| 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 | 170 - 172 °C |
| pH | 10.3 – 10.7 | 10.5 |
| Residue on Ignition | 0.1% max. | <0.1% |

| ANALYSIS | SPECIFICATION | TEST RESULT |
|--------------------------------|---------------|-----------------|
| | 260nm | 0.06 a.u. max |
| Absorbance (1M) | 280nm | 0.06 a.u. max |
| | 430nm | 0.01 a.u. max |
| | 260nm | 0.03 a.u. max. |
| Absorbance (10%) | 280nm | 0.02 a.u. max. |
| | 430nm | 0.004 a.u. max. |
| Absorbance (40%) | 290nm | 0.2 a.u. max. |
| APHA Color, 20% Solution | 20 APHA max. | <20 |
| Assay (Ultrapure, Dried Basis) | 99.9% min | 100.2% |
| Endotoxins | ≤ 2.5 EU/g | <1.1 EU/g |
| | DNase | None |
| Enzymes | Protease | None |
| | RNase | None |
| Heavy Metals (As Pb) | 1 ppm max. | ≤ 1 ppm |
| Insoluble Matter | 0.005% max. | 0.001% |
| Karl Fischer Water | 1.0% max. | 0.1% |
| Loss on Drying | 0.3% max. | 0.2% |
| Microbial Content | TAMC | ≤ 100 CFU/g |
| | TYMC | ≤ 100 CFU/g |
| Related Substances | 0.1% max. | <0.1% |
| Residue on Ignition | 0.05% max. | <0.05% |
| | Arsenic (As) | < 1.6 ppm |
| | Calcium (Ca) | < 1 ppm |
| Trace Metals | Copper (Cu) | < 1 ppm |
| | Iron (Fe) | < 1 ppm |
| | Lead (Pb) | < 1 ppm |

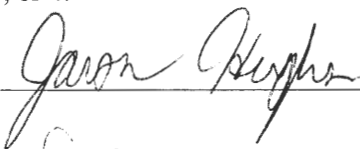
| | ANALYSIS | SPECIFICATION | TEST RESULT |
|-----------------|----------------|---------------|-------------|
| Trace Metals | Magnesium (Mg) | < 5 ppm | < 5ppm |
| | Manganese (Mn) | < 1 ppm | < 1ppm |
| | Zinc (Zn) | < 1 ppm | < 1ppm |

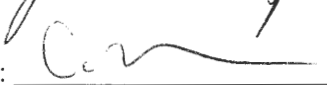
COUNTRY OF ORIGIN: U.S.A.

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:  Date: 12/9/20 Job Title: QA Specialist

Reviewed by:  Date: 12/9/20 Job Title: QA Supervisor