

BIOSPECTRA

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

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|----------------------|-------------------------------|----------------|-----------------------|
| Effective Date: | 17-Feb-2017 | 17-Feb-2020 | : Date of Next Review |
| Prepared By: | Jamie Storm | 16-000062 v3.0 | : Supersedes |
| QA/QC Approval: | Nicole Fisher | Dora Meissner | : Management Approval |
| Reason for Revision: | See Revision History in ensur | | |

TRIS HCl

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TH3220-K012

LOT: TH3220-062-1018

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

Manufacturing Date: 06/09/2018 Retest Date: 06/30/2020

Packaging Date: 10/14/2018

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT |
|-----------------------------|------------------|------------------|
| Absorbance 280 nm | 0.06 a.u. max. | 0.0058a.u. |
| Appearance and Color | White / Crystals | White / Crystals |
| Assay | 99.5% min. | 99.79% |
| DNase | None Detected | None Detected |
| Enzymes RNase | None Detected | None Detected |
| Protease | None Detected | None Detected |
| Heavy Metals | 2 ppm max. | < 2 ppm |
| Identification (IR) | Passes Test | Passes Test |
| Insoluble Matter | 0.001% max. | <0.0005% |
| Karl Fischer | 0.5% max. | 0.31% |
| Melting Range | 150 – 153 °C | 150.3-151.3°C |
| pH (0.5M) | 4.0 – 5.0 | 4.208 @ 22.39°C |
| pK _a | 8.0 – 8.4 | 8.2 |
| Residue on Ignition | 0.1% max. | <0.0300% |
| Solubility | Passes Test | Passes Test |
| Trace Elements Arsenic (As) | 1 ppm max. | < 1 ppm |
| Calcium (Ca) | 1 ppm max. | < 1 ppm |
| 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 |

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further manufacturing. 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 and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: H. Bennett Date: 10/16/18

Reviewed by: Jana Miller Date: 10/16/18