BIOSPECTRA

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

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|---|---|---|---|
| Effective Date: | 31-Jan-2025 | 31-Jan-2028 | : Date of Next Review |
| Prepared By: | Taylor Yurick | BSI-COA-0097 v.8.3 | : Supersedes |
| QA/QC Approval: | Jaron Hughes | Carissa Albert | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | |

# CERTIFICATE OF ANALYSIS

## TREHALOSE, DIHYDRATE

## BIO EXCIPIENT GRADE / TRED-3250

## LOT: TRED-N02-0924-0029

$C_{12}H_{22}O_{11} \cdot 2H_2O$ ⅄ F.W. 378.33 g/mol. ⅄ CAS# 6138-23-4

Manufacturing Date: 09/22/24 Retest Date: 09/30/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds NF, ChP, EP and JP Specifications

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Appearance and Color | | White to Almost White Crystalline Powder | White Crystalline Powder |
| Assay (NF/ChP/EP/JP) | | 98.0 – 101.0% | 99.5% |
| Appearance of Solution (EP) | | Clear, Colorless | Clear, Colorless |
| Chloride | Chloride (NF) | ≤ 0.0125% | < 0.0125% |
| | Chloride (ChP) | ≤ 0.0125% | < 0.0125% |
| | Chloride (EP) | ≤ 0.0125% | < 0.0125% |
| | Chloride (JP) | ≤ 0.018% | < 0.018% |
| Color and Clarity of Solution (NF) | A720 | ≤ 0.050 | 0.001 |
| | A420 – A720 | ≤ 0.100 | 0.014 |
| Clarity and Color of Solution (ChP) | A720 | ≤ 0.033 | 0.006 |
| | A420 – A720 | ≤ 0.067 | 0.016 |
| Dextrin, soluble starch, and sulfite (JP) | | Passes Test | Passes Test |
| Endotoxins (NF/ChP/EP) | | ≤ 2.4 EU/g | < 0.2 EU/g |
| Heavy Metals (ChP/JP) | | ≤ 5ppm | < 5 ppm |
| Identification, IR (NF-A/EP-A/JP-3/ChP-4) | | Conforms to Reference Standard | Conforms to Reference Standard |
| Identification B (NF-B/EP-B/JP-1/ChP-1) | | Passes Test | Passes Test |
| Identification C (NF-C/EP-C/JP-2/ChP-2) | | Passes Test | Passes Test |
| Identification 3 (JP) | | Conforms to Reference Standard | Conforms to Reference Standard |

| | | | |
|---|---|---|---|
| Identification 3 (ChP) | | Conforms to Reference Standard | Conforms to Reference Standard |
| ANALYSIS | | SPECIFICATION | TEST RESULT |
| Microbial Content (NF/ChP/EP) | *Escherichia coli* | Absent/g | Absent/g |
| | *Salmonella species* | Absent/10g | Absent/10g |
| | TAMC | ≤ 100 CFU/g | < 10 CFU/g |
| | TYMC | ≤ 100 CFU/g | < 10 CFU/g |
| Nitrogen Determination (NF/JP) | | ≤ 0.005% | < 0.005 % |
| Optical Rotation, Specific Rotation @ 20°C (NF/ChP/EP/JP) | | +197° to +201° | +199° |
| pH @ 25°C (NF/EP/JP), Acidity (ChP) | | 4.5 – 6.5 | 5.6 |
| Related Substances (NF/EP/JP) | Impurity A | ≤ 0.5% | < 0.10% |
| | Impurity B | ≤ 0.5% | < 0.10% |
| | Unspecified Impurities | ≤ 0.2% | 0.13% |
| | Total Impurities | ≤ 1.0% | 0.13% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | 0.13% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.01% |
| Related Substances (ChP) | | ≤ 0.5% | 0.13% |
| Residue on Ignition (NF/ChP/JP) | | ≤ 0.1% | < 0.1% |
| Residual Ethanol | | ≤ 200 ppm | < 95 ppm |
| Residual Isopropyl Alcohol | | ≤ 250 ppm | < 130 ppm |
| Residual Methanol | | ≤ 50 ppm | < 25 ppm |
| Soluble Starch (NF/ChP/EP) | | Passes Test | Passes Test |
| Sulfated Ash (EP) | | ≤ 0.1% | < 0.1% |
| Sulfate | Sulfate (NF) | ≤ 0.0200% | < 0.0200% |
| | Sulfate (ChP) | ≤ 0.020% | < 0.020% |
| | Sulfate (EP) | ≤ 0.0200% | < 0.0200% |
| | Sulfate (JP) | ≤ 0.024% | < 0.024% |
| Water Determination (NF/ChP/EP/JP) | | 9.0% to 11.0% | 9.6% |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

SPECIFICATION STATEMENT: When Applicable, the most stringent monograph specification will be referenced as the specification.

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 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. Ethanol and Methanol are not used in the manufacturing process.

Prepared by: Amil McCall Date: 7/21/25 Job Title: QA Tech III

Reviewed by: Cari Allen Date: 7/21/25 Job Title: Senior Quality Manager