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-0197 v.4.3 | : 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-3252

## LOT: TRED-N02-0925-0026

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

Manufacturing Date: 9/9/25 Expiration Date: 9/30/28

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds NF, EP, and JP Specifications

### NF COMPENDIA

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Assay[1] | | 98.0 - 101.0%[3] | 99.6% |
| Chloride and Sulfate, *Chloride* | | ≤ 0.0125% | ≤ 0.0125 % |
| Color and Clarity of Solution | A720 | ≤ 0.050 | <0.003 |
| | A420 – A720 | ≤ 0.100 | 0.011 |
| Endotoxins[2] | | ≤ 0.3 EU/g[3] | ≤ 0.2 EU/g |
| Identification A[2] | | Conforms to Standard | Conforms to standard |
| Identification B[2] | | Passes Test | Passes Test |
| Identification C[2] | | Passes Test | Passes Test |
| Microbial Content[2] | *Escherichia coli* | Absent/g | Absent |
| | *Salmonella species* | Absent/10g | Absent |
| | TAMC | ≤ 50 CFU/g | <10 CFU/g |
| | TYMC | ≤ 20 CFU/g | <10 CFU/g |
| Nitrogen Determination[2] | | ≤ 0.005% | ≤ 0.005% |
| Optical Rotation, Specific Rotation @ 20°C[2] | | +197° to +201° | +200° |
| pH @ 25°C[2] | | 4.5 - 6.5 | 5.8 |
| Related Substances[1] | Total Impurities with RRT <1.0 | ≤ 0.5% | 0.21% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | <0.01% |
| Residue on Ignition[2] | | ≤ 0.1% | <0.1% |

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---|---|---|
| Soluble Starch[2] | Passes Test | Passes Test |
| Chloride and Sulfate, *Sulfate* | ≤ 0.0200% | <0.0200% |
| Water Determination[2] | 9.0% to 11.0% | 9.9% |

## EP COMPENDIA

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Assay[1] | | 98.0 – 101.0%[3] | 99.6% |
| Appearance of Solution | | Clear, colorless | Clear, colorless |
| Chlorides | | ≤ 0.0125% | <0.0125% |
| Endotoxins[2] | | ≤ 0.3 EU/g[3] | <0.2 EU/g |
| Identification A[2] | | Conforms to Standard | Conforms to standard |
| Identification B[2] | | Passes Test | Passes Test |
| Identification C[2] | | Passes Test | Passes Test |
| Related Substances[1] | Impurity A | ≤ 0.5% | <0.10% |
| | Impurity B | ≤ 0.2% | <0.10% |
| | Unspecified Impurities | ≤ 0.2% | 0.21% |
| | Total Impurities | ≤ 1.0% | 0.21% |
| Microbial Content[2] | *Escherichia coli* | Absent/g | Absent |
| | *Salmonella species* | Absent/10g | Absent |
| | TAMC | ≤ 50 CFU/g | <10 CFU/g |
| | TYMC | ≤ 20 CFU/g | <10 CFU/g |
| pH @ 25°C[2] | | 4.5 – 6.5 | 5.8 |
| Soluble Starch[2] | | Passes Test | Passes Test |
| Specific, Optical Rotation @ 20°C[2] | | +197° to +201° | +200° |
| Sulfated Ash | | ≤ 0.1% | <0.1% |
| Sulfate | | ≤ 0.0200% | <0.0200% |
| Water[2] | | 9.0% to 11.0% | 9.9% |

## JP COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---|---|---|
| Assay[1] | 98.0 – 101.0% | 99.6% |
| Chloride | ≤ 0.018% | <0.018% |
| Dextrin, Soluble Starch, Sulfite[2] | Passes Test | Passes Test |

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Heavy Metals (as Pb) | | ≤ 5 ppm | <5 ppm |
| Identification 1[2] | | Passes Test | Passes Test |
| Identification 2[2] | | Passes Test | Passes Test |
| Identification 3[2] | | Conforms to Standard | Conforms to standard |
| Nitrogen[2] | | ≤ 0.005% | <0.005% |
| Optical Rotation @ 20°C[2] | | +197° to +201° | +200° |
| pH @ 25°C[2] | | 4.5 - 6.5 | 5.8 |
| Residue on Ignition[2] | | ≤ 0.1% | <0.1% |
| Related Substances[1] | Total Impurities with RRT <1.0 | ≤ 0.5% | 0.21% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | <0.01% |
| Sulfate | | ≤ 0.024% | <0.024% |
| Water[2] | | 9.0% to 11.0% | 9.9% |

## NON-COMPENDIAL ANALYSES

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Appearance and Color | | White to Off White Crystalline Powder | White to Off White Crystalline Powder |
| Microbial Content | *Staphylococcus aureus* | Absent/g | Absent |
| | *Pseudomonas aeruginosa* | Absent/g | Absent |
| Residual Ethanol[1] | | ≤ 200 ppm | <95ppm |
| Residual Isopropyl Alcohol[1] | | ≤ 250 ppm | <130ppm |
| Residual Methanol[1] | | ≤ 50 ppm | <25ppm |
| Trace Metals | Cadmium (Cd) | ≤50 ppb | <2 ppb |
| | Arsenic (As) | ≤50 ppb | <15 ppb |
| | Mercury (Hg) | ≤50 ppb | <3 ppb |
| | Lead (Pb) | ≤50 ppb | <5 ppb |
| | Nickel (Ni) | ≤100 ppb | <20 ppb |
| | Molybdenum (Mo) | ≤100 ppb | <50 ppb |
| | Copper (Cu) | ≤100 ppb | <50 ppb |
| | Chromium (Cr) | ≤100 ppb | <50 ppb |
| | Iron (Fe) | ≤100 ppb | <50 ppb |
| | Aluminum (Al) | ≤100 ppb | <50 ppb |
| | Zinc (Zn) | ≤100 ppb | <50 ppb |

[1]Alternate Validated Method [2]Analyses are Harmonized [3]Specifications is more stringent than Compendia Monograph

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

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.

Prepared by: Cari Allen Date: 9/30/25 Job Title: Senior Quality Manager

Reviewed by: Anil McCall Date: 10/1/25 Job Title: QA Tech III