

# TREHALOSE DIHYDRATE

MEETS EP/JP/ChP/NF, BET\*, GMP

CAS #: 6138-23-4

Formula:  $C_{12}H_{22}O_{11} \cdot 2H_2O$

F.W.: 378.33 g/mol

TRED-3250

BIO EXCIPIENT GRADE

| ANALYSIS                                        |                    | SPECIFICATIONS                           |
|-------------------------------------------------|--------------------|------------------------------------------|
| Appearance and Color                            |                    | White to Almost White Crystalline Powder |
| Assay, Anhydrous Basis (NF/ChP/EP/JP)           |                    | 98.0 – 101.0%                            |
| Appearance of Solution (EP)                     |                    | Clear, Colorless                         |
| Chloride                                        | Chloride (NF)      | < = 125 ppm                              |
|                                                 | Chloride (ChP)     | < = 125 ppm                              |
|                                                 | Chloride (EP)      | < = 125 ppm                              |
|                                                 | Chloride (JP)      | < = 180 ppm                              |
| Color and Clarity of Solution (NF)              | A720               | < = 0.050                                |
|                                                 | A420 - A720        | < = 0.100                                |
| Color and Clarity of Solution (ChP)             | A720               | < = 0.033                                |
|                                                 | A420 - A720        | < = 0.067                                |
| Dextrin, Soluble Starch, and Sulfite (JP)       |                    | Passes Test                              |
| Endotoxin (NF/ChP/EP)                           |                    | < = 2.4 EU/g                             |
| Heavy Metals (Pb) (ChP)                         |                    | < = 5 ppm                                |
| Identification, IR (NF-A/EP-A/JP-3/ChP-4)       |                    | Conforms to Reference Standard           |
| Identification B (NF-B/EP-B/JP-1/ChP-1)         |                    | Passes Test                              |
| Identification C (NF-C/EP-C/JP-2/ChP-2)         |                    | Passes Test                              |
| Identification 3 (ChP)                          |                    | Conforms to Reference Standard           |
| Microbial Content (NF/ChP/EP)                   | Escherichia coli   | Absent/g                                 |
|                                                 | Salmonella species | Absent/10g                               |
|                                                 | TAMC               | < = 100 CFU/g                            |
|                                                 | TYMC               | < = 100 CFU/g                            |
| Nitrogen (NF/JP)                                |                    | < = 50 ppm                               |
| Specific Optical Rotation, 20° C (NF/ChP/EP/JP) |                    | +197° to +201°                           |

| ANALYSIS                                        |                                        | SPECIFICATIONS |
|-------------------------------------------------|----------------------------------------|----------------|
| pH (NF/EP/JP), Acidity (ChP)                    |                                        | 4.5 – 6.5      |
| Related Substances                              | Impurity A (EP)                        | < = 0.5%       |
|                                                 | Impurity B (EP)                        | < = 0.5%       |
|                                                 | Any Unspecified Impurities (EP)        | < = 0.2%       |
|                                                 | Total Impurities (EP)                  | < = 1.0%       |
|                                                 | Total Impurities with RRT <1.0 (NF/JP) | < = 0.5%       |
|                                                 | Total Impurities with RRT >1.0 (NF/JP) | < = 0.5%       |
| Related Substances (ChP)                        |                                        | < = 0.5%       |
| Residue on Ignition/Sulfated Ash (NF/ChP/EP/JP) |                                        | < = 0.1%       |
| Residual Solvents                               | Ethanol                                | < = 200 ppm    |
|                                                 | Isopropyl Alcohol                      | < = 250 ppm    |
|                                                 | Methanol                               | < = 50 ppm     |
| Soluble Starch (NF/ChP/EP)                      |                                        | Passes Test    |
| Sulfate                                         | Sulfate (NF)                           | < = 200 ppm    |
|                                                 | Sulfate (ChP)                          | < = 200 ppm    |
|                                                 | Sulfate (EP)                           | < = 200 ppm    |
|                                                 | Sulfate (JP)                           | < = 240 ppm    |
| Water, KF (NF/ChP/EP/JP)                        |                                        | 9.0 – 11.0%    |

\*Bioburden and Endotoxin Tested

**Refer to page 2 for additional product details.**

*This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.*

### General Product Overview

Trehalose Dihydrate is a non-reducing disaccharide used as an excipient in biotherapeutic applications. Its primary purpose is to protect the protein drug substance both in the liquid and frozen state. It provides tonicity, stabilization, cryo-protection and lyo-protection. Trehalose is superior to other sugars due to the rigidity of the alpha 1,1 bond. Trehalose is also more stable under high temperature and acidic conditions. Due to its non-reducing end, Trehalose does not react with other excipients such as amino acids or aldehydes.

### Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

### Key Product Features

- The manufacturing of Trehalose Dihydrate, TRED-3250 is performed at BioSpectra's Bangor, PA facility.
- Appears as white to almost white crystalline powder
- Manufactured in accordance with ICH Q7
- Manufactured in a hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms:  $\alpha$ -D-Glucopyranosyl- $\alpha$ -D-glucopyranoside

### Storage and Shipping Conditions

Refer to SDS.

### Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

### Package Sizes

5kg, 10kg, 25kg, and 50kg

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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