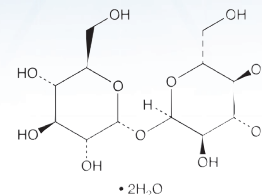


# TREHALOSE Dihydrate, LBLE, EP, JP, NF, GMP

Low Bioburden, Low Endotoxin, EP, JP, NF, GMP Manufactured, Excipient Grade Product

### INTENDED FOR USE AS AN EXCIPIENT IN BIOLOGICAL DRUG PRODUCTS

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.



**CAS #:** 6138-23-4

**Formula:** C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · 2H<sub>2</sub>O

**Solubility in Water (g/L):** 689

**F.W.:** 378.33 g/mol

**BIO EXCIPIENT GRADE | Product Code: TRED-3250** | Previously: TE3250

C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · 2H<sub>2</sub>O F.W.: 378.33 g/mol • CAS# 6138-23-4



### NF Compendia

ANALYSIS		SPECIFICATIONS
<sup>1</sup> Assay		<sup>3</sup> 98.0 – 101.0%
Chloride and Sulfate, <i>Chloride</i>		≤ 0.0125%
Color and Clarity of Solution	A720 A420 – A720	≤ 0.050 ≤ 0.100
<sup>2</sup> Endotoxins		<sup>3</sup> ≤ 2.4 EU/g
<sup>2</sup> Identification A		Conforms to Standard
<sup>2</sup> Identification B		Passes Test
<sup>2</sup> Identification C		Passes Test
<sup>2</sup> Microbial Content	<i>Escherichia coli</i> <i>Salmonella species</i> TAMC TYMC	Absent/g Absent/10g ≤ 100 CFU/g ≤ 100 CFU/g
<sup>2</sup> Nitrogen Determination		≤ 0.005%
<sup>2</sup> Optical Rotation, Specific Rotation @ 20°C		+197° to +201°
<sup>2</sup> pH @ 25°C		4.5 – 6.5
<sup>1</sup> Related Substances	Total Impurities with RRT <1.0 Total Impurities with RRT >1.0	≤ 0.5% ≤ 0.5%
<sup>2</sup> Residue on Ignition		≤ 0.1%
<sup>2</sup> Soluble Starch		Passes Test
Chloride and Sulfate, <i>Sulfate</i>		≤ 0.0200%
<sup>2</sup> Water Determination		9.0% to 11.0%



## EP Compendia

ANALYSIS		SPECIFICATIONS
<sup>1</sup> Assay		<sup>3</sup> 98.0 – 101.0%
Appearance of Solution		Clear, colorless
Chlorides		≤ 0.0125%
<sup>2</sup> Endotoxins		<sup>3</sup> ≤ 2.4 EU/g
<sup>2</sup> Identification A		Conforms to Standard
<sup>2</sup> Identification B		Passes Test
<sup>2</sup> Identification C		Passes Test
<sup>1</sup> Related Substances	Impurity A Impurity B Unspecified Impurities Total Impurities	≤ 0.5% ≤ 0.5% ≤ 0.2% ≤ 1.0%
<sup>2</sup> Microbial Content	<i>Escherichia coli</i> <i>Salmonella species</i> TAMC TYMC	Absent/g Absent/10g ≤ 100 CFU/g ≤ 100 CFU/g
<sup>2</sup> pH @ 25°C		4.5 – 6.5
<sup>2</sup> Soluble Starch		Passes Test
<sup>2</sup> Specific Optical Rotation @ 20°C		+197° to +201°
Sulfated Ash		≤ 0.1%
Sulfates		≤ 0.0200%
<sup>2</sup> Water		9.0% to 11.0%

## JP Compendia

ANALYSIS		SPECIFICATIONS
<sup>1</sup> Assay		98.0 – 101.0%
Chloride		≤ 0.018%
<sup>2</sup> Dextrin, soluble starch, and sulfite		Passes Test
Heavy Metals (as Pb)		≤ 5 ppm
<sup>2</sup> Identification 1		Passes Test
<sup>2</sup> Identification 2		Passes Test
<sup>2</sup> Identification 3		Conforms to Standard
<sup>2</sup> Nitrogen		≤ 0.005%
<sup>2</sup> Optical Rotation @ 20°C		+197° to +201°
<sup>2</sup> pH @ 25°C		4.5 – 6.5
<sup>2</sup> Residue on Ignition		≤ 0.1%
<sup>1</sup> Related Substances	Total Impurities with RRT <1.0 Total Impurities with RRT >1.0	≤0.5% ≤0.5%
Sulfate		≤ 0.024%
<sup>2</sup> Water		9.0% to 11.0%

## Non-Compendial Analyses

ANALYSIS	SPECIFICATIONS
Appearance and Color	White to Almost White Crystalline Powder
<sup>1</sup> Residual Ethanol	≤ 5000 ppm
<sup>1</sup> Residual Methanol	≤ 3000ppm

<sup>1</sup>Alternate Validated Method

<sup>2</sup>Analyses are Harmonized

<sup>3</sup>Specifications is more stringent than Compendia Monograph

## GMP Compliance:

Bio Excipient Grade Trehalose Dihydrate TRED-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Trehalose Dihydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

## Retest Date:

The recommended retest period for Trehalose, Dihydrate TRED-3250 is based on current available stability data in accordance with the Stability Testing Program.

## Storage and Shipping Conditions:

Ship and Store in ambient conditions.

Store in a clean, dry and well-ventilated area.

Store in the original container.

## Package Sizes:

10kg and 25kg pails.

## General Product Description:

- The Manufacturing of Trehalose, Dihydrate TRED-3250 is performed at BioSpectra's Bangor, PA facility
- Trehalose is a White to off white Crystalline powder
- Molecular Formula:  $C_{12}H_{22}O_{11} \cdot 2H_2O$
- Molecular Weight: 378.33 g/mol
- CAS Number: 6138-23-4
- Trehalose, Dihydrate is not manufactured with or using any of the following substances: Melamine, Latex and Glycerine.
- BioSpectra certifies that all Trehalose, Dihydrate TRED-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Trehalose, Dihydrate manufactured at BioSpectra and any raw materials used in the manufacture of Trehalose, Dihydrate at BioSpectra are not subject to genetic modification.