BIOSPECTRA
Premium Pharmaceutical Ingredients

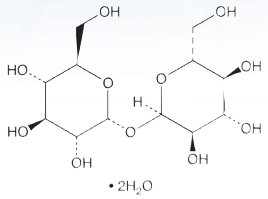
**Excipient**
**ICH-Q7 GMP Manufactured Product**

# TREHALOSE Dihydrate, Ch.P., LBLE

**Low Bioburden, Low Endotoxin, GMP Manufactured, Excipient Grade**

## 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:** $C_{12}H_{22}O_{11} \cdot 2H_2O$
**Solubility in Water (g/L):** 689
**F.W.:** 378.33 g/mol

## BIO EXCIPIENT GRADE | Product Code: TRED-3251 | Previously: TE3251

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

Made in the USA

### NF COMPENDIA

| ANALYSIS | SPECIFICATIONS |
|---|---|
| [1]Assay | [3]98.0% – 102.0% |
| Chloride and Sulfate, *Chloride* | ≤ 0.0125% |
| Color and Clarity of Solution | A720 ≤ 0.050<br>A420 – A720 ≤ 0.100 |
| [2]Endotoxins | [3]≤ 2.4 EU/g |
| [2]Identification A | Conforms to standard |
| [2]Identification B | Passes Test |
| [2]Identification C | Passes Test |
| [2]Microbial Content<br>*Escherichia coli*<br>*Salmonella Species*<br>TAMC<br>TYMC | Absent/g<br>Absent/10g<br>≤ 100 CFU/g<br>≤ 100 CFU/g |
| Nitrogen Determination | ≤ 0.005% |
| [2]Optical Rotation, Specific Rotation @ 20°C | +197° to +201° |
| [2]pH @ 25°C | 4.5 – 6.5 |
| [1]Related Substances | ≤ 0.5% |
| [2]Residue on Ignition | ≤ 0.1% |
| [2]Soluble Starch | Passes Test |
| Chloride and Sulfate, *Sulfate* | ≤ 0.0200% |
| [2]Water Determination | 9.0 – 11.0% |

[1]Alternate Validated Method [2]Analyses are Harmonized [3]Specification is more stringent than Compendia Monograph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## EP COMPENDIA

| ANALYSIS | | SPECIFICATIONS |
|---|---|---|
| [1]Assay | | [3]98.0% – 102.0% |
| Appearance of Solution | | Clear, colorless |
| Chlorides | | ≤ 0.0125% |
| [2]Endotoxins | | [3]≤ 2.4 EU/g |
| [2]Identification A | | Conforms to Standard |
| [2]Identification B | | Passes Test |
| [2]Identification C | | Passes Test |
| [1]Related Substances | Impurities A and B<br>Unspecified Impurities<br>Total Impurities | ≤ 0.5%<br>≤ 0.2%<br>≤ 1.0% |
| [2]Microbial Content | *Escherichia coli*<br>*Salmonella species*<br>TAMC<br>TYMC | Absent/g<br>Absent/10g<br>≤ 100 CFU/g<br>≤ 100 CFU/g |
| [2]pH @ 25°C | | 4.5 – 6.5 |
| [2]Soluble Starch | | Passes Test |
| [2]Specific Optical Rotation @ 20°C | | +197° to +201° |
| Sulfated Ash | | ≤ 0.1% |
| Sulfates | | ≤ 0.0200% |
| [2]Water | | 9.0% to 11.0% |

## CP COMPENDIA

| ANALYSIS | | SPECIFICATIONS |
|---|---|---|
| [2]Acidity | | 4.5 – 6.5 |
| [1]Assay | | 98.0 – 102.0% |
| Color and Clarity of Solution | | A720 ≤ 0.033<br>A420 – A720 ≤ 0.067 |
| Chloride | | ≤ 0.0125% |
| [2]Endotoxins | | [3]≤ 2.4 EU/g |
| Heavy Metals | | ≤ 0.0005% |
| [2]Identification 1 | | Passes Test |
| [2]Identification 2 | | Passes Test |
| [1]Identification 3 | | Passes Test |
| [2]Identification 4 | | Conforms to Standard |
| [2]Microbial Content | *Escherichia coli*<br>*Salmonella species*<br>TAMC<br>TYMC | Absent/g<br>Absent/10g<br>[3]≤100 CFU/g<br>≤100 CFU/g |
| [1]Related Substances | | ≤ 0.5% |
| [2]Residue on Ignition | | ≤ 0.1% |
| [2]Soluble Starch | | Passes Test |
| [2]Specific Optical Rotation @ 20°C | | +197 to +201° |
| Sulfate | | ≤0.020% |
| [2]Water | | 9.0 – 11.0% |

## General Product Description:

- The Manufacturing of Trehalose, Dihydrate TRED-3251 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-3251 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.

## GMP Compliance:

Bio Excipient Grade Trehalose Dihydrate TRED-3251 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-3251 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.

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


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