BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

ICH-Q7 GMP Manufactured Product

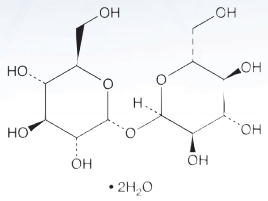
TREHALOSE Dihydrate, EP, JP, ChP, NF, LBLE*, GMP, Excipient Grade

***Low Bioburden, Low Endotoxin**

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.

Lead Time: Stock- 1 month / No Stock- 6 months
Minimum Order Quantity: 25kg



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-3250 | Previously: TE3250

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Made in the USA

ANALYSIS		SPECIFICATIONS
Appearance and Color		White to Almost White Crystalline Powder
Assay (NF/ChP/EP/JP)		98.0 – 101.0%
Appearance of Solution (EP)		Clear, colorless
Chloride	Chloride (NF) Chloride (ChP) Chloride (EP) Chloride (JP)	≤ 0.0125% ≤ 0.0125% ≤ 0.0125% ≤ 0.018%
Color and Clarity of Solution (NF)	A720 A420 – A720	≤ 0.050 ≤ 0.100
Clarity and Color of Solution (ChP)	A720 A420 – A720	≤ 0.033 ≤ 0.067
Dextrin, soluble starch, and sulfite (JP)		Passes Test
Endotoxins (NF/ChP/EP)		≤ 2.4 EU/g
Heavy Metals (ChP/JP)		≤ 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

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

TREHALOSE Dihydrate Excipient Grade

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

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

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.

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