BIOSPECTRA
Premium Pharmaceutical Ingredients

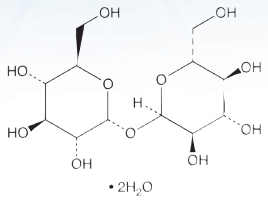
Excipient
ICH-Q7 GMP Manufactured Product

TREHALOSE Dihydrate, EP, BP, NF, GMP, LBLE

Low Bioburden, Low Endotoxin, EP, BP, 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: $C_{12}H_{22}O_{11} \cdot 2H_2O$
Solubility in Water (g/L): 689
F.W.: 378.33 g/mol

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

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

Made in the USA

ANALYSIS		SPECIFICATIONS
Appearance and Color		White to Off-White Crystalline Powder
Appearance of Solution (EP)		Clear, Colorless
Assay % w/w		98.0% – 101.0%
Chloride	(NF)	≤ 0.0125%
	(EP)	≤ 0.0125%
	(JP)	< 0.018%
Color and Clarity of Solution (NF)	A720	≤ 0.050
	A420 – A720	≤ 0.100
Dextrin, Soluble Starch, Sulfite (JP)		Passes Test
Endotoxins		≤ 2.4 EU/g
Heavy Metals (as Pb)		≤ 5 ppm
Identification A		Conforms to Standard
Identification B		Passes Test
Identification C		Passes Test
Identification 1	(JP)	Passes Test
Identification 2	(JP)	Passes Test
Identification 3	(JP)	Passes Test

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Made in the USA

ANALYSIS		SPECIFICATIONS
Impurities	Maltotriose (Impurity B)	≤ 0.5%
	Total Impurities with RRT <1.0	≤ 0.5%
	Total Impurities with RRT >1.0	≤ 0.5%
	Glucose (Impurity A)	≤ 0.5%
	Any other Impurities	≤ 0.2%
	Sum of Glucose, Maltotriose and Other Impurities	≤ 1.0%
Microbial Content	*Escherichia coli*	Absent
	Salmonella species	Absent
	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Nitrogen Content		≤ 0.005%
pH @ 25°C		4.5 – 6.5
Residual Ethanol		≤ 5000 ppm
Residual Isopropyl Alcohol		≤ 5000 ppm
Residual Methanol		≤ 3000 ppm
Residue on Ignition		≤ 0.1%
Soluble Starch		Passes Test
Specific Optical Rotation @ 20°C		+197° to +201°
Sulfate	(NF)	≤ 0.0200%
	(EP)	≤ 0.0200%
	(JP)	≤ 0.024%
Water (Karl Fischer)		9.0% to 11.0%

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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