BIOSPECTRA
Premium Pharmaceutical Ingredients

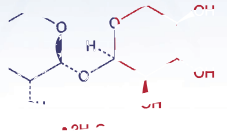
Excipient

ICH-Q7 GMP Manufactured Product

TREHALOSE Dihydrate, USP, EP, JP, Ultra Low Endotoxin, GMP, 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-3252 | Previously: TE3252

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

Made in the USA

NF Compendia

ANALYSIS		SPECIFICATIONS
[1]Assay		[3]98.0% – 101.0%
Chloride and Sulfate, *Chloride*		≤ 0.0125%
Color and Clarity of Solution	A720 A420-A720	≤ 0.033 ≤ 0.067
[2]Endotoxins		[3]≤ 0.3 EU/g
[2]Identification A		Conforms to Standard
[2]Identification B		Passes Test
[2]Identification C		Passes Test
[2]Microbial Content	*Escherichia coli* *Salmonella species* TAMC TYMC	Absent/g Absent/10g ≤ 50 CFU/g ≤ 20 CFU/g
[2]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	Total Impurities with RRT <1.0 Total Impurities with RRT >1.0	≤ 0.5% ≤ 0.5%
[2]Residue on Ignition		≤ 0.1%
[2]Soluble Starch		Passes Test
Chloride and Sulfate, *Sulfate*		≤ 0.0200%
[2]Water Determination		9.0% to 11.0%

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

TREHALOSE Dihydrate Excipient Grade

EP Compendia

ANALYSIS		SPECIFICATIONS
[1]Assay		[3]98.0% – 101.0%
Appearance of Solution		Clear, colorless
Chlorides		≤ 0.0125%
[2]Endotoxins		[3]≤ 0.3 EU/g
[2]Identification A		Conforms to Standard
[2]Identification B		Passes Test
[2]Identification C		Passes Test
[1]Related Substances	Impurity A Impurity B Unspecified Impurities Total Impurities	≤ 0.5% ≤ 0.2% ≤ 0.2% ≤ 1.0%
[2]Microbial Content	*Escherichia coli* *Salmonella species* Staphylococcus aureus Pseudomonas aeruginosa TAMC TYMC	Absent/g Absent/10g Absent Absent ≤ 50 CFU/g ≤ 20 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%

JP Compendia

ANALYSIS		SPECIFICATIONS
[1]Assay		98.0% – 101.0%
Chloride		≤ 0.018%
[2]Dextrin, Soluble Starch, Sulfite		Passes Test
Heavy Metals (as Pb)		≤ 5 ppm
[2]Identification 1		Passes Test
[2]Identification 2		Passes Test
[2]Identification 3		Conforms to Standard
[2]Nitrogen		≤ 0.005%
[2]Optical Rotation @ 20°C		+197° to +201°
[2]pH @ 25°C		4.5 - 6.5
[2]Residue on Ignition		≤ 0.1%
[1]Related Substances	Total Impurities with RRT <1.0 Total Impurities with RRT >1.0	≤ 0.5% ≤ 0.5%
Sulfate		≤ 0.0200%
[2]Water		9.0% to 11.0%

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

TREHALOSE Dihydrate Excipient Grade

Non-Compendial Analyses

ANALYSIS	SPECIFICATIONS
Appearance and Color	White to Off-White Crystalline Powder
[1]Residual Ethanol	≤ 200 ppm
[1]Residual Isopropyl Alcohol	≤ 250 ppm
[1]Residual Methanol	≤ 50 ppm

ANALYSIS	SPECIFICATIONS
Cadmium (Cd)	≤ 50 ppb
Arsenic (As)	≤ 50 ppb
Mercury (Hg)	≤ 50 ppb
Lead (Pb)	≤ 50 ppb
Nickel (Ni)	≤ 100 ppb
Molybdenum (Mo)	≤ 100 ppb
Copper (Cu)	≤ 100 ppb
Chromium (Cr)	≤ 100 ppb
Iron (Fe)	≤ 100 ppb
Aluminum (Al)	≤ 100 ppb
Zinc (Zn)	≤ 100 ppb

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

General Product Description:

- The Manufacturing of Trehalose, Dihydrate TRED-3252 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-3252 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-3252 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-3252 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.

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