BIOSPECTRA
Premium Pharmaceutical Ingredients

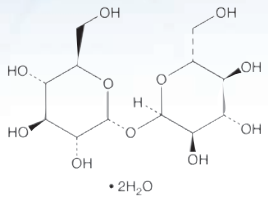
Bio Excipient Grade

TREHALOSE DIHYDRATE LBLE

TECHNICAL PRODUCT SHEET

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 / TE3250

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

Meets or exceeds EP/BP, JP and NF specifications.

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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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%

General Product Description:

- The Manufacturing of Trehalose, Dihydrate TE3250 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 TE3250 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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Quality Assurance / Regulatory Support / Quality Control

Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH Q7 Compliant Manufactured
Suitable for Research and Diagnostic	Yes
Each Batch 100% Analyzed	Yes
Management of Change	Yes
Validated Analytical Methods	Yes
Compendial Testing	Yes
Trace Metals Analyzed	Yes
Two Year Stability	Yes
BioSpectra Supply Chain Audit Trail	Yes
Product Origin Statement	Yes
Customer Quality Audits	Yes
Customized Additional Specifications	Yes
Multi-Compendial Testing	Yes
Enzyme Tested	Yes
Validated Manufacturing Process	Yes
US Manufactured at BioSpectra	Yes
IPEC cGMP Compliant Manufactured	Yes
Suitable for use as Excipient	Yes
Microbial / Endotoxin Tested	Yes
Manufactured in FDA Registered Facility	Available
Customized Manufacturing Schedule	Available
Custom Regulatory Packet	Available
Accelerated Stability	Available
Type IV Drug Master File	Available
Video Conference access to BioSpectra Sites	Available
Complete access to Product Traceability	Available
Access to Supply Chain Information	Yes
ICH Q7 Qualified Utilities	Yes
ICH Q7 Compliant Manufactured	Yes

GMP Compliance:

Bio Excipient Grade Trehalose, Dihydrate TE3250 is manufactured in accordance with cGMP guidelines and is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured non-Sterile Excipient for use in further Manufacturing. This Grade of Trehalose, Dihydrate is not suitable to be used as a Sterile or Injectable Excipient, Active Pharmaceutical Ingredient, Drug Product or Household Item.

Expiration/Retest Date:

The recommended retest period for Trehalose, Dihydrate TE3250 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.