

# TREHALOSE DIHYDRATE

## BIOTECH, MEETS NF, EP, JP, LBLE, GMP

### BIO PHARMA GRADE / TRED-4250

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

### Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

Trehalose Dihydrate is a high purity, GMP Reagent Grade, derived from plant not animal origins.

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.

### SPECIFICATIONS

ANALYSIS		SPECIFICATIONS
Assay, Anhydrous Basis (NF/EP/JP)		98.0 - 101.0%
Appearance and Color		White to Almost White Crystalline Powder
Appearance of Solution (EP)		Clear, colorless
Chloride	Chloride (NF)	$\leq 0.0125\%$
	Chloride (EP)	$\leq 0.0125\%$
	Chloride (JP)	$\leq 0.018\%$
Color and Clarity of Solution (NF)	A720	$\leq 0.050$
	A420 – A720	$\leq 0.100$
Endotoxin (EP/NF)		$\leq 2.4$ EU/g
Dextrin, soluble starch, and sulfite (JP)		Passes Test
Heavy Metals (JP)		$\leq 5$ ppm
Identification, IR (NF-A/EP-A/JP-3)		Conforms to Reference Standard
Identification B (NF-B/EP-B/JP-1)		Passes Test
Identification C (NF-C/EP-C/JP-2)		Passes Test
Microbial Content (NF/EP)	<i>Escherichia coli</i>	Absent/g
	<i>Salmonella species</i>	Absent/10g
	TAMC	$\leq 100$ CFU/g
	TYMC	$\leq 100$ CFU/g
Nitrogen Determination (NF/JP)		$\leq 0.005\%$

Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP)		+197° to +201°
pH @ 25°C (NF/EP/JP)		4.5 – 6.5
Related Substances (NF/EP/JP)	Impurity A	≤ 0.5 %
	Impurity B	≤ 0.5 %
	Unspecified Impurities	≤ 0.2 %
	Total Impurities	≤ 1.0 %
	Total Impurities with RRT < 1.0	≤ 0.5 %
	Total Impurities with RRT > 1.0	≤ 0.5 %
Residue on Ignition (NF/JP)		≤ 0.1%
Residual Ethanol		≤ 200 ppm
Residual Isopropyl Alcohol		≤ 250 ppm
Residual Methanol		≤ 50 ppm
Soluble Starch (NF/EP)		Passes Test
Sulfated Ash (EP)		≤ 0.1 %
Sulfate	Sulfate (NF)	≤ 0.0200%
	Sulfate (EP)	≤ 0.0200%
	Sulfate (JP)	≤ 0.024%
Water, KF (NF/EP/JP)		9.0 to 11.0%

### General Product Description:

Molecular Formula: C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · 2H<sub>2</sub>O  
 Molecular Weight: 378.33 g/mol  
 CAS Number: 6138-23-4

### Trehalose, Dihydrate Biotech:

- Trehalose is a white to off white crystalline powder
- Is manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: α-D-Glucopyranosyl 1-α-D-glucopyranoside

### Shelf Life Policy:

Three-year expiry from the date of manufacture.

### Storage and Shipping Conditions:

Please refer to the SDS for storage and shipping conditions.

### Package Size:

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg