

TREHALOSE DIHYDRATE BIOTECH
USP, EP, JP, LBLE, GMP
TRED-4250

$C_{12}H_{22}O_{11} \cdot 2H_2O$ F.W. 378.33 g/mol 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 (EP, JP, NF)		98.0 -101.0%
Chloride and Sulfate, <i>Chloride</i> (NF)		≤ 0.0125%
Color and Clarity of Solution (NF)	A720	≤ 0.050
	A420 – A720	≤ 0.100
Endotoxins (NF)		≤ 2.4 EU/g
Identification A (NF)		Conforms to Standard
Identification B (NF)		Passes Test
Identification C (NF)		Passes Test
Microbial Content (NF)	<i>Escherichia coli</i>	Absent/g
	<i>Salmonella species</i>	Absent/10g
	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Nitrogen Determination (NF)		≤ 0.005%
Optical Rotation, Specific Rotation @ 20°C (NF)		+197° to +201°
pH @ 25°C (NF)		4.5 – 6.5
Related Substances (NF)		
	Total Impurities with RRT <1.0	≤ 0.5%
	Total Impurities with RRT >1.0	≤ 0.5%
Residue on Ignition (JP, NF)		≤ 0.1%
Soluble Starch (NF)		Passes Test
Chloride and Sulfate, <i>Sulfate</i> (NF)		≤ 0.0200%

Water (JP, EP, NF)	9.0% to 11.0%
Appearance of Solution (EP)	Clear, Colorless
Endotoxins (EP)	≤ 2.4 EU/g
Identification A (EP)	Conforms to Standard
Identification B (EP)	Passes Test
Identification C (EP)	Passes Test
Microbial Content (EP)	
<i>Escherichia coli</i>	Absent/g
<i>Salmonella species</i>	Absent/g
TAMC	≤ 100 CFU/g
TYMC	≤ 100 CFU/g
pH @ 25°C (JP, EP)	4.5 – 6.5
Related Substances (EP)	
Impurity A	Absent/g
Impurity B	Absent/10g
Unspecified Impurities	≤ 100 CFU/g
Total Impurities	≤ 100 CFU/g
Soluble Starch (EP)	Passes Test
Sulfates (EP)	≤ 0.0200%
Chloride (JP)	≤ 0.018%
Dextrin, soluble starch, and sulfate (JP)	Passes Test
Heavy Metals (as Pb) (JP)	≤ 5 ppm
Identification 1 (JP)	Passes Test
Identification 2 (JP)	Passes Test
Identification 3 (JP)	Conforms to Standard
Nitrogen (JP)	≤ 0.005%
Optical Rotation @ 20°C (JP)	+197° to +201°
Related Substances (JP)	
Total Impurities with RRT < 1.0	≤ 0.5%
Total Impurities with RRT > 1.0	≤ 0.5%
Sulfate (JP)	≤ 0.024%
Appearance and Color	White to Almost White Crystalline Powder
Residual Ethanol	≤ 200 ppm
Residual Isopropyl Alcohol	≤ 250 ppm
Residual Methanol	≤ 50 ppm

General Product Description:

Molecular Formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$

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