

TREHALOSE DIHYDRATE

BIOTECH, PLANT DERIVED, NF, EP, JP, LBLE, GMP

CAS #: 6138-23-4

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

F.W.: 378.33 g/mol

TRED-4250

BIO PHARMA GRADE

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

ANALYSIS		SPECIFICATIONS
Sulfate	Sulfate (NF/EP)	$\leq 0.0200\%$
	Sulfate (JP)	$\leq 0.024\%$
Water, KF (NF/EP/JP)		9.0 – 11.0%

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

High purity, GMP, Reagent grade Trehalose Dihydrate is derived from plant, not animal origins. Trehalose Dihydrate is a non-reducing disaccharide. Its primary purpose is to protect the protein drug substance, both in the liquid and frozen state. It provides tonicity, stabilization, cyro-protection and lyo-protection. Trehalose is superior to other sugars due to the rigidity of the alpha 1,1 bond and it is 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.

General Product Description

- Appears as a white to off-white crystalline powder
- Manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in a hormone and animal free environment and is not subject to genetic modification
- Has no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts/derivatives.
- Visit the product page on our website (www.biospectra.us) for additional information, supporting regulatory

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

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

Standard Lead Time

1-2 weeks

Country of Origin: USA

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