

TREHALOSE DIHYDRATE

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)	$\leq 0.0125\%$
	Chloride (JP)	$\leq 0.018\%$
Color and Clarity of Solution (NF)	A720	≤ 0.050
	A420 – A720	≤ 0.100
Dextrin, soluble starch, and sulfite (JP)		Passes Test
Endotoxin (NF/EP)		≤ 2.4 EU/g
Lead (Pb)		≤ 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	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Nitrogen (NF/JP)		≤ 50 ppm
Specific Optical Rotation, 20°C (NF/EP/JP)		+197° to +201°
pH (NF/EP/JP)		4.5 – 6.5
Related Substances	Impurity A (EP)	$\leq 0.5\%$
	Impurity B (EP)	$\leq 0.5\%$
	Any Unspecified Impurities (EP)	$\leq 0.2\%$
	Total Impurities (EP)	$\leq 1.0\%$
	Total Impurities with RRT ≤ 1.0 (NF/JP)	$\leq 0.5\%$
	Total Impurities with RRT ≤ 1.0 (NF/JP)	$\leq 0.5\%$
	Total Impurities with RRT > 1.0 (NF/JP)	$\leq 0.5\%$
Residue on Ignition / Sulfated Ash (NF/JP)		$\leq 0.1\%$
Residual Solvents	Ethanol	≤ 200 ppm
	Isopropyl Alcohol	≤ 250 ppm
	Methanol	≤ 50 ppm
Soluble Starch (EP/NF)		Passes Test

Country of Origin: USA

ANALYSIS		SPECIFICATIONS
Sulfate	Sulfate (NF)	≤ 200 ppm
	Sulfate (EP)	≤ 200 ppm
	Sulfate (JP)	≤ 240 ppm
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 IPEC 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 documents, and CofAs.

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

1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks

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