TREHALOSE DIHYDRATE

NF, EP, JP, ULTRA LOW ENDOTOXIN, GMP, EXCIPIENT

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

TRED-3252

BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Appearance and Color		White to Off White Crystalline Powder
Assay, Anhydrous Basis (NF/EP/JP)		98.0 – 101.0%
Appearance of Solution (EP)		Clear, Colorless
Chloride	Chloride (NF)	< = 125 ppm
	Chloride (EP)	< = 125 ppm
	Chloride (JP)	< = 180 ppm
Color and Clarity of Solution (NF)	A720	< = 0.050
	A420 - A720	< = 0.100
Dextrin, Soluble Starch, Sulfite (JP)		Passes Test
Endotoxin (NF/EP)		< = 0.3 EU/g
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)	TAMC	< = 50 CFU/g
	TYMC	< = 20 CFU/g
	Escherichia coli	Absent/g
	Salmonella species	Absent/10g
	Staphylococcus aureus	Absent/g
	Pseudomonas aeruginosa	Absent/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

ANALYSIS		SPECIFICATIONS
Related Substances	Impurity A (EP)	< = 0.5%
	Impurity B (EP)	< = 0.2%
	Any Unspecified Impurities (EP)	< = 0.2%
	Total Impurities (EP)	< = 1.0%
	Total Impurities with RRT <1.0 (NF/JP)	< = 0.5%
	Total Impurities with RRT >1.0 (NF/JP)	< = 0.5%
Residue on Ignition/Sulfated Ash (NF/EP/JP)		< = 0.1%
Residual Solvents	Ethanol	< = 200 ppm
	Isopropyl Alcohol	< = 250 ppm
	Methanol	< = 50 ppm
Soluble Starch (NF/EP)		Passes Test
Sulfate	Sulfate (NF)	< = 200 ppm
	Sulfate (EP)	< = 200 ppm
	Sulfate (JP)	< = 240 ppm
Trace Metals	Cadmium (Cd)	< = 0.050 ppm
	Arsenic (As)	< = 0.050 ppm
	Mercury (Hg)	< = 0.050 ppm
	Lead (Pb)	< = 0.050 ppm
	Nickel (Ni)	< = 0.100 ppm
	Molybdenum (Mo)	< = 0.100 ppm
	Copper (Cu)	< = 0.100 ppm
	Chromium (Cr)	< = 0.100 ppm
	Iron (Fe)	< = 0.100 ppm
	Aluminum (Al)	< = 0.100 ppm
	Zinc (Zn)	< = 0.100 ppm
Water, KF (NF/EP/JP)		9.0 – 11.0%

Refer to page 2 for additional product details.

General Product Overview

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.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Trehalose Dihydrate, TRED-3252 is performed at BioSpectra's Bangor, PA facility.
- Appears as white to off-white crystalline powder
- Manufactured in accordance with ICH Q7
- Manufactured in a hormone free and animal free environment.
- Contains 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 or derivatives.
- Is not subject to genetic modification
- Synonyms: α-D-Glucopyranosyl-α-D-glucopyranoside

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

5kg, 10kg and 25kg pails

Click here to view SDS, CoAs and other supporting regulatory documents on our website.