BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer

GMP BIOTECH PRODUCT

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) Chloride (EP) Chloride (JP)	< = 125 ppm < = 125 ppm < = 180 ppm
Color and Clarity of Solution (NF)	A720 A420 – A720	< = 0.050 < = 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)	*Escherichia coli* *Salmonella species* TAMC TYMC	Absent/g Absent/10g < = 100 CFU/g < = 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) Impurity B (EP) Any Unspecified Impurities (EP) Total Impurities (EP) Total Impurities with RRT <1.0 (NF/JP) Total Impurities with RRT >1.0 (NF/JP)	< = 0.5% < = 0.5% < = 0.2% < = 1.0% < = 0.5% < = 0.5%
Residue on Ignition / Sulfated Ash (NF/EP/JP)		< = 0.1%
Residual Solvents	Ethanol Isopropyl Alcohol Methanol	< = 200 ppm < = 250 ppm < = 50 ppm
Soluble Starch (NF/EP)		Passes Test
Sulfate	Sulfate (NF) Sulfate (EP) Sulfate (JP)	< = 200 ppm < = 200 ppm < = 240 ppm
Water, KF (NF/EP/JP)		9.0 – 11.0%

General Product Overview

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.

Industry Application

Suitable for use in biological and biotech chemical process applications from R&D through scale cGMP production.

Key Product Features

- Appears as a white to almost white crystalline powder
- Manufactured in accordance with IPEC
- Manufactured in a hormone 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

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

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