

TREHALOSE DIHYDRATE

NF, EP, JP, ULTRA LOW ENDOTOXIN, GMP, EXCIPIENT
CAS #: 6138-23-4
Formula: C₁₂H₂₂O₁₁ • 2H₂O
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.

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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.](#)

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