GMP BIOTECH PRODUCT

TREHALOSE DIHYDRATE

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

CAS #: 6138-23-4

Formula: C₁₂H₂₂O₁₁ 2H₂O

F.W.: 378.33 g/mol

TRED-4250

BIO PHARMA GRADE

Appearance and Color Assay, Anhydrous Basis (NF/EP/JP) Appearance of Solution (EP) Chloride Chloride (NF/EP) Chloride (JP) Color and Clarity Of Solution (NF) At 20 Dextrin, soluble starch, and sulfite (JP) Lead (Pb) Identification, IR (NF-A/EP-A/JP-3) Identification B (NF-B/EP-B/JP-1) Identification C (NF-C/EP-C/JP-2) Microbial Content Salmonella species (NF/EP) Nitrogen (NF/JP) Specific Optical Rotation, 20°C (NF/EP/JP) Ph (NF/EP/JP) Impurity A (EP) Impurity A (EP) Impurity B (EP) Any Unspecified Impurities (EP) Substances Total Impurities with RRT Alo (NF/JP) Total Impurities with RRT Alo (NF/JP) Residue on Ignition / Sulfated Ash (NF/JP) Residual Solvents Reference Alonome Clear, coloroles Clear, colorles Clear, coloroles Ce 0.050 Ce 0.050 Conforms to Reference Standard Reference	Analysis	SPECIFICATIONS
Appearance of Solution (EP) Chloride Chloride (NF/EP) Chloride (JP) Color and Clarity Of Solution (NF) A420 – A720 Dextrin, soluble starch, and sulfite (JP) Lead (Pb) Identification, IR (NF-A/EP-A/JP-3) Identification B (NF-B/EP-B/JP-1) Identification C (NF-C/EP-C/JP-2) Microbial Content Salmonella species (NF/EP) Nitrogen (NF/JP) Specific Optical Rotation, 20°C (NF/EP/JP) PH (NF/EP/JP) Ph (NF/EP/JP) Total Impurities (EP) Total Impurities with RRT 1.0 (NF/JP) Residue on Ignition / Sulfated Ash (NF/JP) Residual Solvents Conforms to Reference Standard Conforms to Reference Standard Absent/g Absent/10g Absent/20 Conforms to Reference Standard Impuritia coli Absent/2g Absent/10g Absent/10g Absent/10g Absent/10g Absent/2g Absent/10g Absent/2g Absent/10g Absent/2g Absent/10g Absent/2g Absent/10g Absent/2g Absent/10g C= 100 CFU/g		White to Almost White
Chloride Chloride (NF/EP) Chloride (JP) < = 0.0125% Color and Clarity of Solution (NF) A720 < = 0.050	Assay, Anhydrous Basis (NF/EP/JP)	98.0 - 101.0%
Chloride	Appearance of Solution (EP)	Clear, colorless
of Solution (NF) A420 - A720 < = 0.100		
Endotoxin (NF/EP)		
Lead (Pb) Identification, IR (NF-A/EP-A/JP-3) Identification B (NF-B/EP-B/JP-1) Identification C (NF-C/EP-C/JP-2) Residuel On Ignition / Sulfated Ash (NF/JP) Residual Solvents Identification, IR (NF-A/EP-A/JP-3) Residual Solvents Conforms to Reference Standard Reference Standard Absent/S Absent/g Absent/10g Absent/10g <= 100 CFU/g Absent/10g <= 100 CFU/g <= 100 CFU/g <= 100 CFU/g Absent/10g <= 50 ppm +197° to +201° Hand of the point of the proposed o	Dextrin, soluble starch, and sulfite (JP)	Passes Test
Identification, IR (NF-A/EP-A/JP-3) Identification B (NF-B/EP-B/JP-1) Identification C (NF-C/EP-C/JP-2) Escherichia coli Microbial Content Salmonella species (NF/EP) TAMC TYMC Nitrogen (NF/JP) Specific Optical Rotation, 20°C (NF/EP/JP) Impurity A (EP) Impurity B (EP) Any Unspecified Substances Related Substances Total Impurities (EP) Total Impurities (EP) Total Impurities with RRT <1.0 (NF/JP) Residue on Ignition / Sulfated Ash (NF/JP) Residual Solvents Conforms to Reference Standard Absent/2 Absent/10g Absent/10g <= 100 CFU/g <= 100 CFU/g <= 50 ppm +197° to +201° <= 0.5% <= 0.2% <= 0.2% <= 0.2% <= 0.2% <= 0.2% <= 0.5% <= 0.2% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <= 0.5% <=	Endotoxin (NF/EP)	< = 2.4 EU/g
Identification, IR (NF-A/EP-A/JP-3) Identification B (NF-B/EP-B/JP-1) Identification C (NF-C/EP-C/JP-2) Reference Standard Identification C (NF-C/EP-C/JP-2) Passes Test Escherichia coli	Lead (Pb)	< = 5 ppm
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Identification, IR (NF-A/EP-A/JP-3)	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Identification B (NF-B/EP-B/JP-1)	Passes Test
Microbial Content (NF/EP) TAMC (NF/EP) TAMC TYMC C = 100 CFU/g C = 0.5%	Identification C (NF-C/EP-C/JP-2)	Passes Test
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Microbial Content Salmonella species (NF/EP) TAMC	Absent/10g < = 100 CFU/g
NF/EP/JP	Nitrogen (NF/JP)	< = 50 ppm
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	I	+197° to +201°
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	pH (NF/EP/JP)	4.5 - 6.5
Related Substances Total Impurities (EP) Substances Total Impurities with RRT $<1.0 \text{ (NF/JP)}$ Total Impurities with RRT $<1.0 \text{ (NF/JP)}$ Total Impurities with RRT $>1.0 \text{ (NF/JP)}$ $<=0.5\%$ Residue on Ignition / Sulfated Ash (NF/JP) $<=0.1\%$ Residual Solvents Isopropyl Alcohol $<=200 \text{ ppm}$ Residual Solvents $=200 \text{ ppm}$ $=250 \text{ ppm}$ $=250 \text{ ppm}$		
Total Impurities with RRT $<1.0 \text{ (NF/JP)}$ Total Impurities with RRT $<1.0 \text{ (NF/JP)}$ Total Impurities with RRT $>1.0 \text{ (NF/JP)}$ Residue on Ignition / Sulfated Ash (NF/JP) $<=0.1\%$ Ethanol $<=200 \text{ ppm}$ Residual Solvents Isopropyl Alcohol $<=250 \text{ ppm}$ Methanol $<=50 \text{ ppm}$	Related Impurities (EP)	
Total Impurities with RRT >1.0 (NF/JP) Residue on Ignition / Sulfated Ash (NF/JP) <= 0.1% Ethanol	Total Impurities with RRT	
Residual Solvents Ethanol <= 200 ppm <= 250 ppm <= 250 ppm <= 50 pp	Total Impurities with RRT	< = 0.5%
Residual Solvents Isopropyl Alcohol <= 250 ppm Methanol <= 50 ppm	<u> </u>	
Colubia Starah (FD/NF)	Residual Solvents Isopropyl Alcohol	< = 250 ppm
Soluble Statch (EP/NF) Passes Test	Soluble Starch (EP/NF)	Passes Test

ANALYSIS		SPECIFICATIONS
Appearance and Color		White to Almost White Crystalline Powder
Assay, Anhydrous Basis (NF/EP/JP)		98.0 - 101.0%
Appearance of Soluti	on (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 stard	ch, 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
	Impurity A (EP)	< = 0.5%
	Impurity B (EP)	< = 0.5%
Related Substances	Any Unspecified Impurities (EP)	< = 0.2%
	Total Impurities (EP)	< = 1.0%
	tal Impurities with RRT <1.0 (NF/JP)	< = 0.5%
То	tal Impurities with RRT >1.0 (NF/JP)	< = 0.5%
Residue on Ignition / Sulfated Ash (NF/JP)		< = 0.1%
Residual Solvents	Ethanol Isopropyl Alcohol	< = 200 ppm < = 250 ppm

ANALYSIS		SPECIFICATIONS
	Sulfate (NF)	< = 200 ppm
Sulfate	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 nonreducing 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

This is not considered a controlled document. We are not responsible for any errors or omissions.

Country of Origin: USA