

TREHALOSE DIHYDRATE

BIOTECH, 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

ANALYSISSPECIFICATIONSAppearance and ColorWhite to Almost White Crystalline PowderAssay, Anhydrous Basis (NF/EP/JP) $98.0 - 101.0\%$ Appearance of Solution (EP)Clear, colorlessChlorideChloride (NF/EP) Choride (JP) $\leq 0.0125\%$ $\leq 0.0125\%$ Color and ClarityA720 A120 ≤ 0.050 of Solution (NF)A420 - A720 A420 - A720 ≤ 0.000 Dextrin, soluble starch, sulfite (JP)Passes TestEndotoxin (NF/EP) ≤ 2.4 EU/gHeavy Metals (JP) ≤ 5 ppmIdentification, IR (NF-A/EP-A/JP-3)Conforms to Reference StandardIdentification G (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification S (NF-C/EP-C/JP-2)Passes TestIdentification S (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification S pecific Rotation @ 20°C (NF/EP/JP) $+197^{\circ}$ to $+201^{\circ}$ PH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity B Related SubstancesTotal Impurities RRT <1.0Related SubstancesTotal Impurities with RRT <1.0Residual Ethanol ≤ 200 ppmResidual Ethanol ≤ 200 ppmResidual Isopropyl Alcohol ≤ 250 ppmResidual Methanol ≤ 50 ppmSoluble Starch (NF/EP)Passes TestSulfated Ash (EP) $\leq 0.1\%$		
Appearance and ColorCrystalline PowderAssay, Anhydrous Basis (NF/EP/JP) $98.0 - 101.0\%$ Appearance of Solution (EP)Clear, colorlessChlorideChloride (NF/EP) Chloride (JP) $\leq 0.0125\%$ $\leq 0.018\%$ Color and ClarityA720 Chloride (JP) ≤ 0.0100 Dextrin, soluble starch, sulfite (JP)Passes TestEndotoxin (NF/EP) ≤ 2.4 EU/gHeavy Metals (JP) ≤ 5 ppmIdentification, IR (NF-A/EP-A/JP-3)Conforms to Reference StandardIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIntrogen Determination (NF/JP) $\leq 0.005\%$ Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP) $+197^{\circ}$ to $+201^{\circ}$ PH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity A (NF/EP/JP) $\leq 0.5\%$ Related SubstancesTotal Impurities RRT <1.0Residue on Ignition (NF/JP) $\leq 0.5\%$ Residue on Ignition (NF/JP) $\leq 0.1\%$ Residual Ethanol ≤ 200 ppmResidual Isopropyl A	ANALYSIS	SPECIFICATIONS
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Appearance of Solution (EP)Clear, colorlessChlorideChloride (NF/EP) Chloride (JP) $\leq 0.0125\%$ $\leq 0.0125\%$ $\leq 0.0125\%$ Color and ClarityA720 A420 – A720 ≤ 0.050 ≤ 0.100 Dextrin, soluble starch, sulfite (JP)Passes TestEndotoxin (NF/EP) ≤ 2.4 EU/gHeavy Metals (JP) ≤ 5 ppmIdentification, IR (NF-A/EP-A/JP-3)Conforms to Reference StandardIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF/EP) $\leq 0.005\%$ Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP) $+197^{\circ}$ to $+201^{\circ}$ PH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity A Substances $< 0.5\%$ Related SubstancesTotal Impurities RRT <1.0		
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Heavy Metals (JP) $\leq 5 \text{ ppm}$ Identification, IR (NF-A/EP-A/JP-3)Conforms to Reference StandardIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestMicrobialSalmonella species Absent/10gContent (NF/EP)TAMCYMC $\leq 100 \text{ CFU/g}$ TYMC $\leq 100 \text{ CFU/g}$ Nitrogen Determination (NF/JP) $\leq 0.005\%$ Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP) $+197^{\circ} \text{ to } +201^{\circ}$ pH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity B Substances $\leq 0.5\%$ Inspecified Impurities Substances $\leq 1.0\%$ Nitrofen Ignition (NF/JP) $\leq 0.5\%$ Related SubstancesTotal Impurities with RRT <1.0	Dextrin, soluble starch, sulfite (JP)	Passes Test
Identification, IR (NF-A/EP-A/JP-3)Conforms to Reference StandardIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestEscherichia coliAbsent/gMicrobialSalmonella speciesContent (NF/EP)TAMCTYMC ≤ 100 CFU/gNitrogen Determination (NF/JP) $\leq 0.005\%$ Optical Rotation, Specific Rotation $+197^{\circ}$ to $+201^{\circ}$ PH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity A $\leq 0.5\%$ RelatedTotal ImpuritiesSubstancesTotal Impurities with RRT <1.0	Endotoxin (NF/EP)	<u><</u> 2.4 EU/g
Identification, IR (NF-A/EP-A/JP-3)Reference StandardIdentification B (NF-B/EP-B/JP-1)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestIdentification C (NF-C/EP-C/JP-2)Passes TestMicrobialSalmonella speciesAbsent/10gContent (NF/EP)TAMC ≤ 100 CFU/gTYMC ≤ 100 CFU/gTYMCNitrogen Determination (NF/JP) $\leq 0.005\%$ Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP) $+197^{\circ}$ to $+201^{\circ}$ pH @ 25°C (NF/EP/JP) $4.5 - 6.5$ Impurity A Impurity B Substances Notal Impurities Total Impurities with RRT <1.0 Total Impurities with RRT >1.0 $\leq 0.5\%$ Residue on Ignition (NF/JP) $\leq 0.1\%$ Residual Ethanol ≤ 200 ppmResidual Isopropyl Alcohol ≤ 250 ppmResidual Methanol ≤ 50 ppmSoluble Starch (NF/EP)Passes Test	Heavy Metals (JP)	<u><</u> 5 ppm
Identification C (NF-C/EP-C/JP-2)Passes TestEscherichia coliAbsent/gMicrobialSalmonella speciesContent (NF/EP)TAMCTYMC ≤ 100 CFU/gTYMC ≤ 100 CFU/gNitrogen Determination (NF/JP) $\leq 0.005\%$ Optical Rotation, Specific Rotation $+197^{\circ}$ to $+201^{\circ}$ $@ 20^{\circ}C$ (NF/EP/JP) $4.5 - 6.5$ Impurity A $\leq 0.5\%$ RelatedImpuritiesSubstancesTotal Impurities(NF/EP/JP)Total Impurities with RRT <1.0	Identification, IR (NF-A/EP-A/JP-3)	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Identification B (NF-B/EP-B/JP-1)	Passes Test
$\begin{array}{c c} \mbox{Microbial} & Salmonella species} & Absent/10g \\ \mbox{Content (NF/EP)} & TAMC & \leq 100 \mbox{CFU/g} \\ \hline TYMC & \leq 100 \mbox{CFU/g} \\ \hline Substances & C(NF/EP/JP) & \leq 0.005\% \\ \mbox{Optical Rotation, Specific Rotation} & +197^{\circ} \ to +201^{\circ} \\ \hline pH @ 25^{\circ}C (NF/EP/JP) & 4.5 - 6.5 \\ \hline Impurity A & \leq 0.5\% \\ \hline Unspecified Impurities & \leq 0.2\% \\ \hline Unspecified Impurities & \leq 0.2\% \\ \hline Substances & Total Impurities & \leq 1.0\% \\ \hline (NF/EP/JP) & Total Impurities with \\ RRT < 1.0 & \\ \hline Total Impurities with \\ RRT > 1.0 & \\ \hline Residue \ on Ignition (NF/JP) & \leq 0.1\% \\ \hline Residual Ethanol & \leq 200 \ ppm \\ \hline Residual Isopropyl Alcohol & \leq 250 \ ppm \\ \hline Soluble Starch (NF/EP) & \hline Passes Test \\ \hline \end{array}$	Identification C (NF-C/EP-C/JP-2)	Passes Test
Optical Rotation, Specific Rotation @ $20^{\circ}C$ (NF/EP/JP) $+197^{\circ}$ to $+201^{\circ}$ pH @ $25^{\circ}C$ (NF/EP/JP) $4.5 - 6.5$ Impurity A Impurity B $\leq 0.5\%$ Related Substances (NF/EP/JP)Total Impurities Total Impurities with RRT <1.0 Total Impurities with RRT >1.0 $\leq 0.5\%$ Residue on Ignition (NF/JP) $\leq 0.1\%$ Residual Ethanol ≤ 200 ppmResidual Isopropyl Alcohol ≤ 50 ppmSoluble Starch (NF/EP)Passes Test	Microbial Salmonella species Content (NF/EP) TAMC	Absent/10g <u><</u> 100 CFU/g
$@ 20 \circ C (NF/EP/JP)$ $+197^{\circ}$ to $+201^{\circ}$ pH @ 25 \circ C (NF/EP/JP) $4.5 - 6.5$ Impurity A Impurity B Substances $\leq 0.5\%$ Unspecified Impurities Substances $\leq 0.2\%$ Total Impurities NF/EP/JP) $\leq 1.0\%$ Total Impurities with RRT < 1.0	Nitrogen Determination (NF/JP)	<u><</u> 0.005%
$\begin{array}{r c c c c c c c c c c c c c c c c c c c$		+197º to +201º
Impurity B $\leq 0.5\%$ RelatedUnspecified Impurities $\leq 0.2\%$ SubstancesTotal Impurities $\leq 1.0\%$ SubstancesTotal Impurities with RRT <1.0	pH @ 25°C (NF/EP/JP)	4.5 - 6.5
Residual Ethanol< 200 ppmResidual Isopropyl Alcohol< 250 ppm	Impurity B Related Substances (NF/EP/JP) Impurities Unspecified Impurities Total Impurities with RRT <1.0 Total Impurities with	 ≤ 0.5% ≤ 0.2% ≤ 1.0% ≤ 0.5%
Residual Isopropyl Alcohol ≤ 250 ppm Residual Methanol ≤ 50 ppm Soluble Starch (NF/EP) Passes Test	Residue on Ignition (NF/JP)	<u><</u> 0.1%
Residual Methanol< 50 ppmSoluble Starch (NF/EP)Passes Test	Residual Ethanol	<u><</u> 200 ppm
Soluble Starch (NF/EP) Passes Test	Residual Isopropyl Alcohol	<u><</u> 250 ppm
	Residual Methanol	<u><</u> 50 ppm
Sulfated Ash (EP) $\leq 0.1\%$	Soluble Starch (NF/EP)	Passes Test
	Sulfated Ash (EP)	<u><</u> 0.1%

Country of Origin: USA

	Analysis	SPECIFICATIONS
Sulfate	Sulfate (NF/EP) Sulfate (JP)	<u><</u> 0.0200% <u><</u> 0.024%
Water, KF (N	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 ICH-Q7 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 (<u>www.biospectra.us</u>) for additional information, supporting regulatory

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

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks