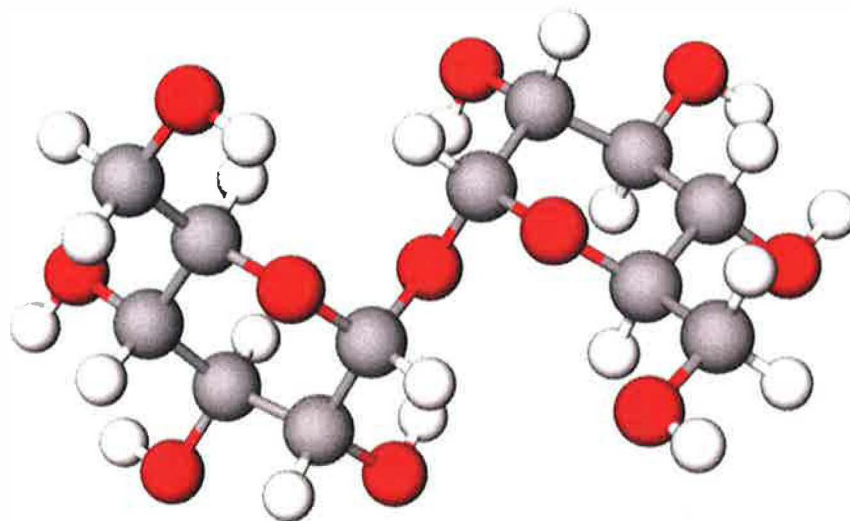




# TREHALOSE, DIHYDRATE



## BIO EXCIPIENT GRADE REGULATORY PACKET

**Signature/Date:**



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## 1. TREHALOSE, DIHYDRATE BIO EXCIPIENT GRADE:

### 1.1. General Product Information:

- 1.1.1. Product Name:
  - 1.1.1.1. Trehalose, Dihydrate
- 1.1.2. Product Code:
  - 1.1.2.1. Historic: TE3250, TE3251, TE3252, TE3253
  - 1.1.2.2. Current: TRED-3250, TRED-3251, TRED-3252, TRED-3253
- 1.1.3. Scope:
  - 1.1.3.1. This regulatory packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping and handling of Bio Excipient Grade Trehalose, Dihydrate manufactured by and at the BioSpectra, Bangor, PA facility.
- 1.1.4. Molecular Formula:
  - 1.1.4.1.  $C_{12}H_{22}O_{11} \cdot 2H_2O$
- 1.1.5. Molecular Weight:
  - 1.1.5.1. 378.33 g/mol.

### 1.2. Manufacturing, Packaging, Release Site, and Supplier Information:

- 1.2.1. General Information:
  - 1.2.1.1. BioSpectra manufactures Trehalose, Dihydrate in its Bangor, PA facility. Trehalose, Dihydrate is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
  - 1.2.1.2. Trehalose, Dihydrate is additionally stored and shipped at BioSpectra's Supply Chain Center: 51 North 3<sup>rd</sup> Street, Stroudsburg, PA 18360
- 1.2.2. Manufacturing:
  - 1.2.2.1. The manufacturing of Trehalose, Dihydrate is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Trehalose, Dihydrate is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
- 1.2.3. Packaging:
  - 1.2.3.1. The packaging of Trehalose, Dihydrate occurs in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013.
- 1.2.4. Testing for Release:
  - 1.2.4.1. Testing and release of Trehalose, Dihydrate is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013.
- 1.2.5. GMP Compliance Statement:
  - 1.2.5.1. Bio Excipient Grade Trehalose, Dihydrate is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This Grade of Trehalose, Dihydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

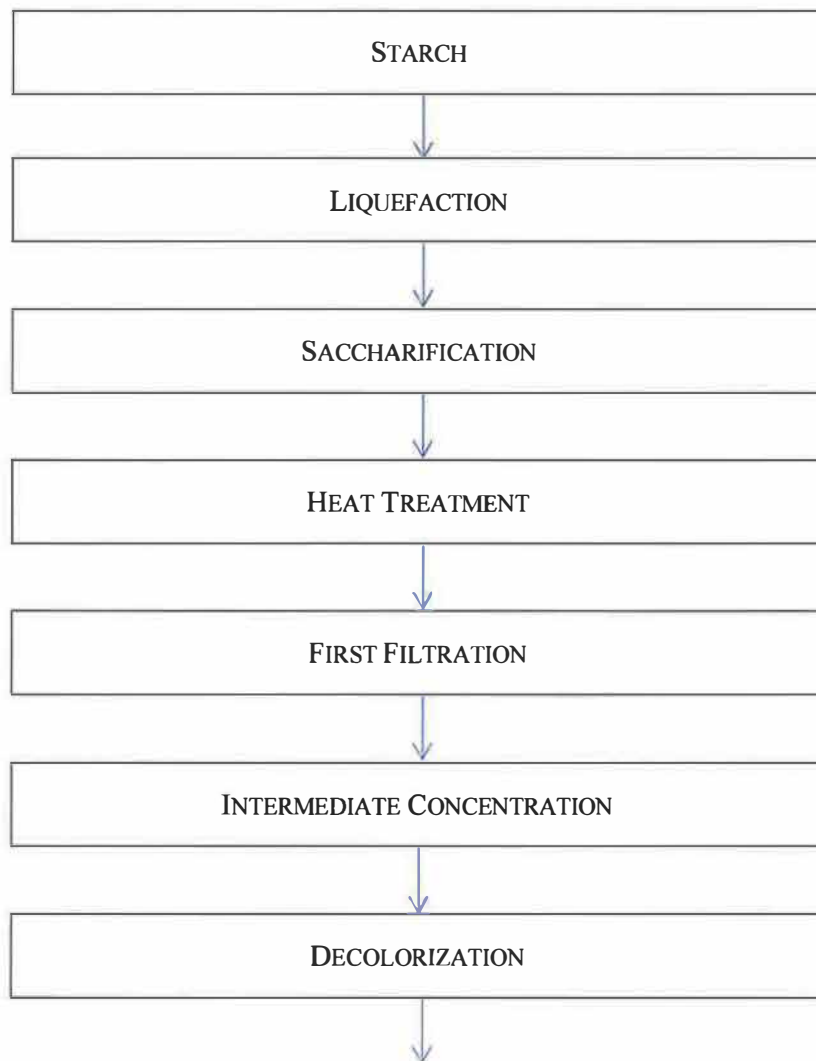
### 1.3. Physico-Chemical Information

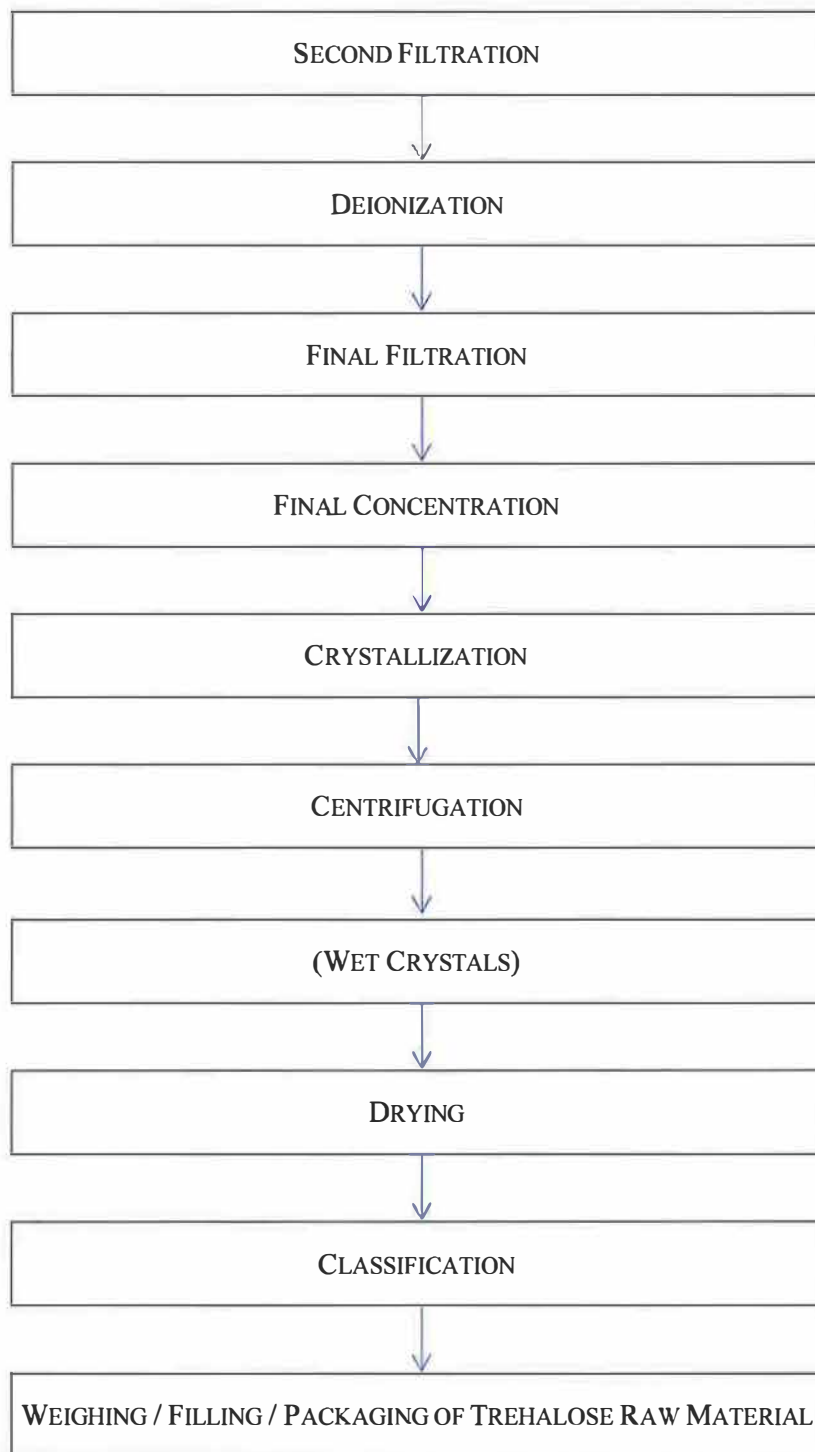
- 1.3.1. CAS Number:
  - 1.3.1.1. CAS# 6138-23-4



- 1.3.2. Origin:
  - 1.3.2.1. The origin of raw material Trehalose, Dihydrate is through fermentation. Trehalose, Dihydrate is then manufactured by BioSpectra using approved raw materials, which are purified in accordance with ICH Q7 guidelines.
- 1.3.3. Synonyms:
  - 1.3.3.1.  $\alpha$ -D-Glucopyranosyl- $\alpha$ -D-Glucopyranoside
- 1.3.4. Morphological Form:
  - 1.3.4.1. White Crystalline Powder
- 1.3.5. Manufacturing Process:
  - 1.3.5.1. The manufacturing process for Trehalose, Dihydrate, Bio Excipient Grade is performed by the following:

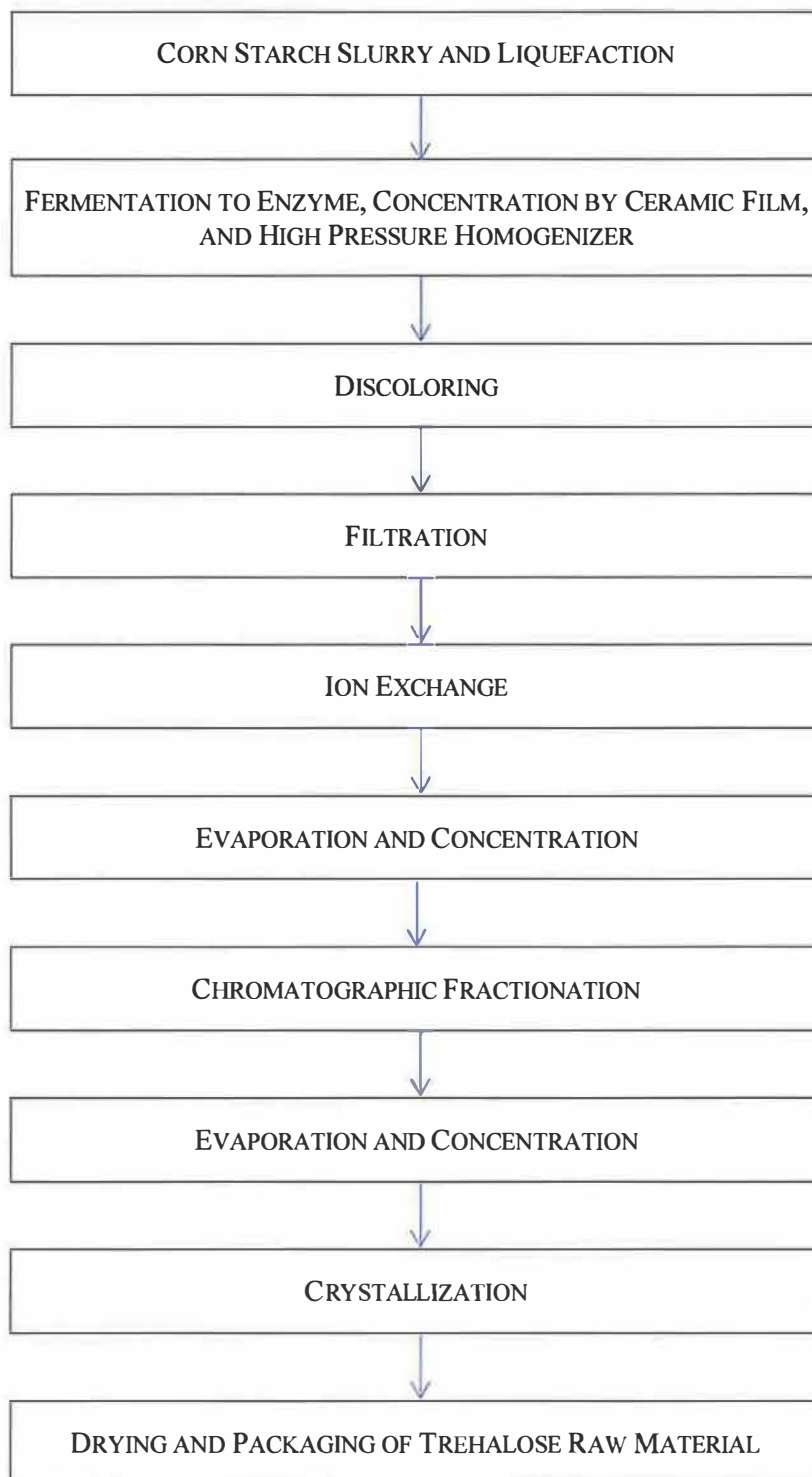
**Approved Supplier Raw Material Synthesis**





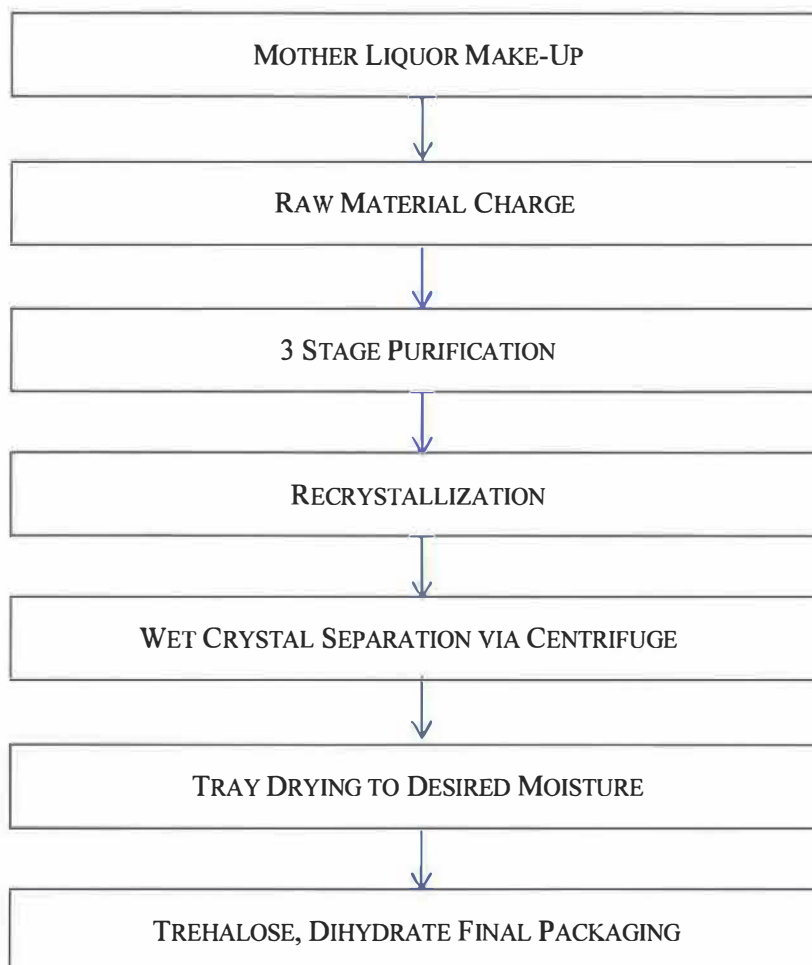


### Approved Supplier Raw Material Synthesis





## BioSpectra Excipient Manufacturing Process



### 1.3.6. Specifications:

1.3.6.1. Available upon request.

### 1.4. Regulatory Information:

#### 1.4.1. Compendial Compliance:

1.4.1.1. EP, CP, JP, NF – Trehalose based on the specific product code purchased.

#### 1.4.2. Master File:

1.4.2.1. Drug Master File (DMF) is available for this product.

1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.

#### 1.4.3. REACH:

1.4.3.1. Refer to the Trehalose, Dihydrate Safety Data Sheet for the REACH Number or contact your Commercial Team Representative for further information.





1.4.4. BSE/TSE Statement:

1.4.4.1. Trehalose, Dihydrate, Bio Excipient Grade manufactured by BioSpectra is animal origin free through the tertiary level, where the primary level is defined as BioSpectra's Trehalose, Dihydrate Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that BSE/TSE is not a concern based on this evaluation.

1.4.5. Allergens Statement:

1.4.5.1. Trehalose, Dihydrate manufactured by BioSpectra and its raw materials are not manufactured with or using, and do not contain any of the following allergenic substances: Cereals containing gluten, i.e.: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof, including lactose, Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulfites at >10 mg/kg as SO<sub>2</sub>, Nuts and products thereof, i.e.: Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*) Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia or Queensland nuts (*Macadamia ternifolia*), Beef, Chicken, Pork, Azo Dyes, Benzoic Acid, Tartrazine, Vanillin, Cocoa, Cinnamon, Coriander, Yeast, Glutamate, Legumes, and Corn. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. Trehalose, Dihydrate has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.

1.4.7. Residual Solvents Statement:

1.4.7.1. BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product, that the Trehalose, Dihydrate manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. The Class 3 solvent Isopropyl Alcohol is used by BioSpectra in the manufacture of the Trehalose, Dihydrate finished good and the product adheres to the specification of <5000ppm.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. Trehalose, Dihydrate manufactured by BioSpectra is manufactured without the use of metal catalysts and metal reagents. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.





- 1.4.9. Pallet Statement:
  - 1.4.9.1. BioSpectra can state that the wooden pallets used in the packaging and shipping of Trehalose, Dihydrate manufactured at BioSpectra are ISPM 15 compliant.
- 1.4.10. Elemental Impurities Statement:
  - 1.4.10.1. BioSpectra's Trehalose, Dihydrate material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.
- 1.4.11. Melamine Statement:
  - 1.4.11.1. Trehalose, Dihydrate Bio Excipient Grade has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that Melamine is not a risk based on this evaluation. BioSpectra additionally analyzes Trehalose, Dihydrate annually for melamine, with a specification of <2.5 mg/kg.
- 1.4.12. Latex Statement:
  - 1.4.12.1. BioSpectra can state that all Trehalose, Dihydrate manufactured at BioSpectra is Latex free. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.
- 1.4.13. Glycerine Statement:
  - 1.4.13.1. BioSpectra can state that all Trehalose, Dihydrate manufactured at BioSpectra is Glycerine free. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.
- 1.4.14. Radionuclide Statement:
  - 1.4.14.1. BioSpectra does not test for radionuclides, however, BioSpectra can state that radionuclides are not intentionally added to Trehalose, Dihydrate manufactured at BioSpectra.
- 1.4.15. Genotoxic Statement:
  - 1.4.15.1. BioSpectra does not test for mutagens, however, BioSpectra can state that mutagens are not intentionally added to Trehalose, Dihydrate manufactured at BioSpectra.
- 1.4.16. Plasticizer Statement:
  - 1.4.16.1. BioSpectra does not test for plasticizers, however, BioSpectra can state that plasticizers are not intentionally added to Trehalose, Dihydrate manufactured at BioSpectra.
- 1.4.17. Pesticide Statement:
  - 1.4.17.1. BioSpectra does not test for pesticides, however, BioSpectra can state that pesticides are not intentionally added to Trehalose, Dihydrate manufactured at BioSpectra. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.

## **1.5. Miscellaneous Product Information:**

- 1.5.1. Description of Batch:
  - 1.5.1.1. The Trehalose, Dihydrate process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.

1.5.2. Lot/Batch Numbering System:

1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumeric digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: TRED-0123-00001.

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where TRED represents Trehalose, Dihydrate. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 01 represents the Bangor, PA facility. The seventh and eighth digits are numeric digits which indicate the year the batch record was issued, where 23 represents 2023. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Trehalose, Dihydrate batch of 2023 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.

1.5.3. Expiration Date and/or Recommended Re-Evaluation Interval:

1.5.3.1. The current recommended Retest or Expiration Date for Trehalose, Dihydrate, Bio Excipient Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended Retest or Expiration Date will be available on the Product Specific Certificate of Analysis, as applicable.

1.5.4. Storage and Shipping Conditions:

1.5.4.1. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep containers tightly closed.

1.5.5. Packaging:

1.5.5.1. Packaging information is available through the following:  
<https://biospectra.us/packaging>

**1.6. Contact Information:**

1.6.1. <https://www.biospectra.us/about-us/commercial-marketing-team>