

# BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

## DEXTRAN SULFATE 8000 SODIUM SALT



## BIO ULTRA GRADE REGULATORY PACKET

Signature/Date:

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## 1. DEXTRAN SULFATE 8000 SODIUM SALT BIO ULTRA GRADE:

### 1.1. General Product Information:

- 1.1.1. Product Name:
  - 1.1.1.1. Dextran Sulfate 8000 Sodium Salt
- 1.1.2. Product Code:
  - 1.1.2.1. Current Code: DXSE-5201
- 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 Ultra Grade Dextran Sulfate 8000 Sodium Salt manufactured by and at the BioSpectra Bangor, PA facility.
- 1.1.4. Molecular Formula:
  - 1.1.4.1.  $(C_6H_7Na_3O_{14}S_3)_n$
- 1.1.5. Molecular Weight:
  - 1.1.5.1. 8,000 g/mol

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

- 1.2.1. General Information:
  - 1.2.1.1. BioSpectra manufactures Dextran Sulfate 8000 Sodium Salt in its Bangor, PA facility. Dextran Sulfate 8000 Sodium Salt is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
  - 1.2.1.2. Dextran Sulfate 8000 Sodium Salt 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 Dextran Sulfate 8000 Sodium Salt is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Dextran Sulfate 8000 Sodium Salt is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
- 1.2.3. Packaging:
  - 1.2.3.1. The packaging of Dextran Sulfate 8000 Sodium Salt 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 Dextran Sulfate 8000 Sodium Salt is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013.
- 1.2.5. GMP Compliance Statement:
  - 1.2.5.1. Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade is suitable for use as a process chemical. This grade of Dextran Sulfate 8000 Sodium Salt is not suitable to be used as an Excipient, Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

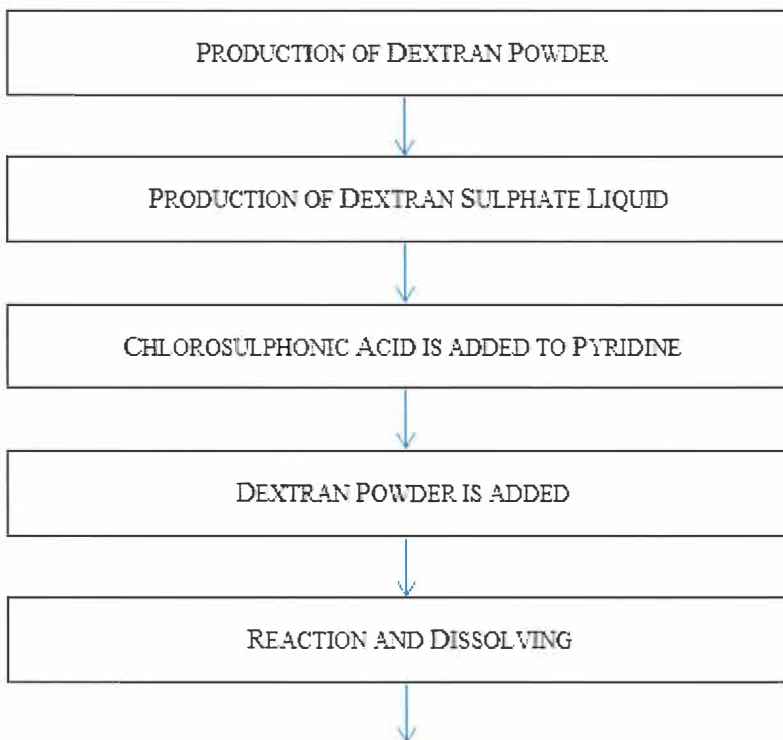
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### 1.3. Physico-Chemical Information:

- 1.3.1. CAS Number:
  - 1.3.1.1. CAS# 9011-18-1
- 1.3.2. Origin:
  - 1.3.2.1. The origin of Dextran Sulfate 8000 Sodium Salt is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials derived from fermentation are used in the synthesis and purification of Dextran Sulfate 8000 Sodium Salt.
- 1.3.3. Synonyms:
  - 1.3.3.1. Dextran, hydrogen sulfate, sodium salt
- 1.3.4. Morphological Form:
  - 1.3.4.1. Off White to Light Yellow Powder
- 1.3.5. Manufacturing Process:
  - 1.3.5.1. The Approved Supplier Raw Material Synthesis is summarized from Supplier SN000739.
  - 1.3.5.2. The BioSpectra Chemical Manufacturing Process is available in the Dextran Sulfate 8000 Sodium Salt Process Flow Diagram DCN: BSI-DGM-0202 v.1.2.
  - 1.3.5.3. The manufacturing process for Dextran Sulfate 8000 Sodium Salt is performed by the following:

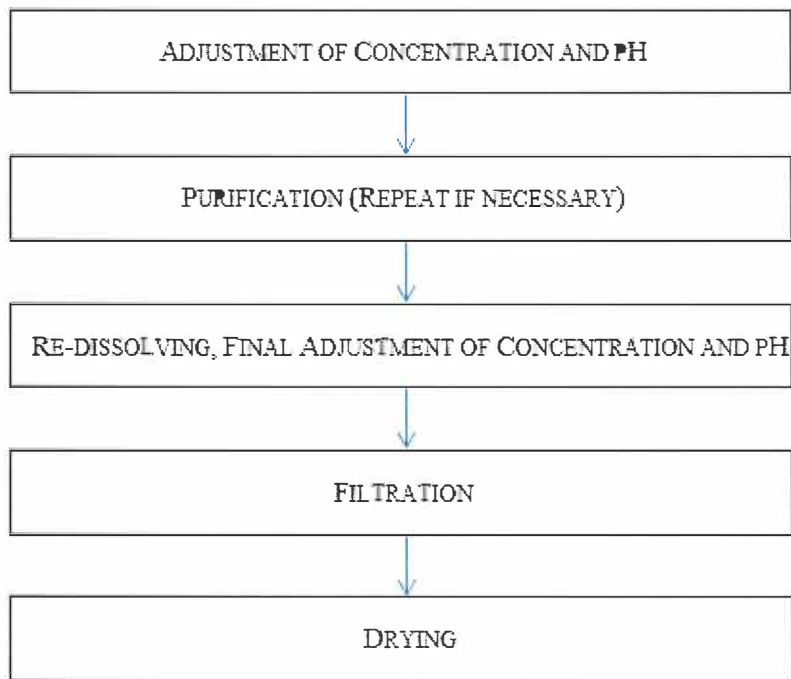
### Approved Supplier Raw Material Synthesis



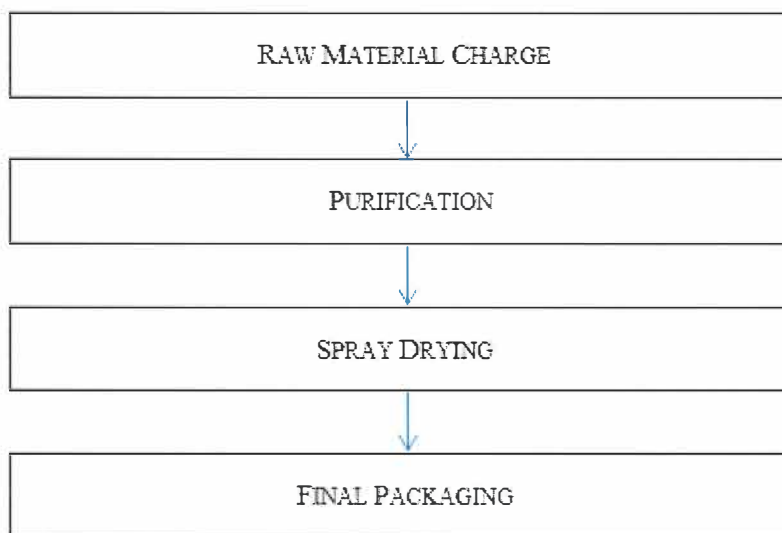
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## BioSpectra Chemical Manufacturing Process



- 1.3.6. Specifications:
  - 1.3.6.1. Available upon request.

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## 1.4. Regulatory Information:

### 1.4.1. Compendial Compliance:

1.4.1.1. Not Applicable

### 1.4.2. Master File:

1.4.2.1. Drug Master File (DMF) is currently not 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 Dextran Sulfate 8000 Sodium Salt Safety Data Sheet for the REACH Number, if applicable, or contact your Commercial Team Representative for further information.

### 1.4.4. BSE/TSE Statement:

1.4.4.1. Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade manufactured by BioSpectra has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation. Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade and its raw materials are not of animal origin.

### 1.4.5. Allergens Statement:

1.4.5.1. Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade and its raw materials are not manufactured with or using 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, 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*) and products thereof, 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. BioSpectra does not use genetically modified organisms in the manufacturing process of Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that genetic modification is not a concern based on this evaluation.

### 1.4.7. Residual Solvents Statement:

1.4.7.1. Based on the manufacturing process and the controlled handling, storage and analysis of this product, Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.



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## 1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. BioSpectra does not use metal catalysts or metal reagents in the manufacturing process of Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that catalysts are not used in the raw material manufacturing process based on this evaluation.

## 1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that the pallets used in the packaging and shipping of Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade manufactured at BioSpectra are ISPM 15 compliant.

## 1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade 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. BioSpectra does not use Melamine in the manufacturing process of Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade and its raw materials are not expected to contain Melamine based on this evaluation. BioSpectra does not analyze Dextran Sulfate 8000 Sodium Salt, Bio Ultra Grade or its raw materials for melamine.

## 1.5. Miscellaneous Product Information:

### 1.5.1. Description of Batch:

1.5.1.1. The Dextran Sulfate 8000 Sodium Salt 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 per BSI-DGM-0009 BioSpectra Lot Number Identification:

1.5.2.2. A sample lot number would appear as:

1.5.2.2.1. **QS6: DXSE-0124-00001**

1.5.2.2.1.1. The first four digits are alpha digits which indicate the material, where DXSE represents Dextran Sulfate. 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 24 represents 2024. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Dextran Sulfate batch of 2024 that is automatically generated by the ERP system.

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The sequential batch number automatically resets on the first of the new calendar year.

1.5.2.2.2. **QS7: DXSE-G13-0124-0001**

1.5.2.2.2.1. The first four digits are alpha digits which indicate the material, where DXSE represents Dextran Sulfate. The fifth, sixth, and seventh digits are alphanumeric digits which indicate the location of manufacturing. The eighth and ninth digits are numerical digits which indicate the month of work order issuance, where 01 represents January. The tenth and eleventh digits are numerical digits which indicate the year of work order issuance, where 24 represents 2024. The final four digits are numerical digits which indicate the sequential batch number, where 0001 represents the first Dextran Sulfate batch of 2024 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first day of each 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 Dextran Sulfate 8000 Sodium Salt, Bio Ultra 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 tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances.

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>