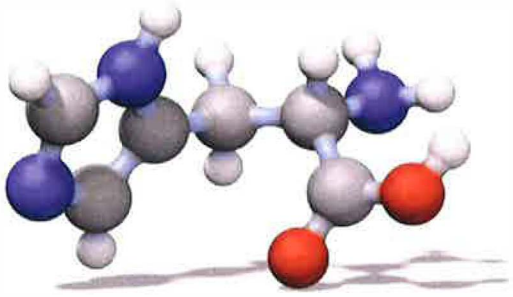
BIOSPECTRA
Premium Pharmaceutical Ingredients

DEXTRAN SULFATE



BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE REGULATORY PACKET

Signature/Date:

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1. DEXTRAN SULFATE BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE:

1.1. General Product Information:

1.1.1. Product Name:

1.1.1.1. Dextran Sulfate

1.1.2. Product Code:

1.1.2.1. Historic Code: DS4250

1.1.2.2. Current Code: DXSE-4250

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 Pharma Grade Dextran Sulfate 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 in its Bangor, PA facility. Dextran Sulfate is manufactured, packaged, stored, tested, and released at BioSpectra's Bangor, PA facility.

1.2.1.2. Dextran Sulfate is additionally stored and shipped at BioSpectra's Supply Chain Center: 51 North 3rd Street, Stroudsburg, PA 18360.

1.2.2. Manufacturing:

1.2.2.1. The manufacturing of Dextran Sulfate is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Dextran Sulfate is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.

1.2.3. Packaging:

1.2.3.1. The packaging of Dextran Sulfate 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 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 Pharma Grade Dextran Sulfate is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This grade of Dextran Sulfate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product, or Household Item.

1.3. Physico-Chemical Information:

1.3.1. CAS Number:

1.3.1.1. CAS # 9011-18-1

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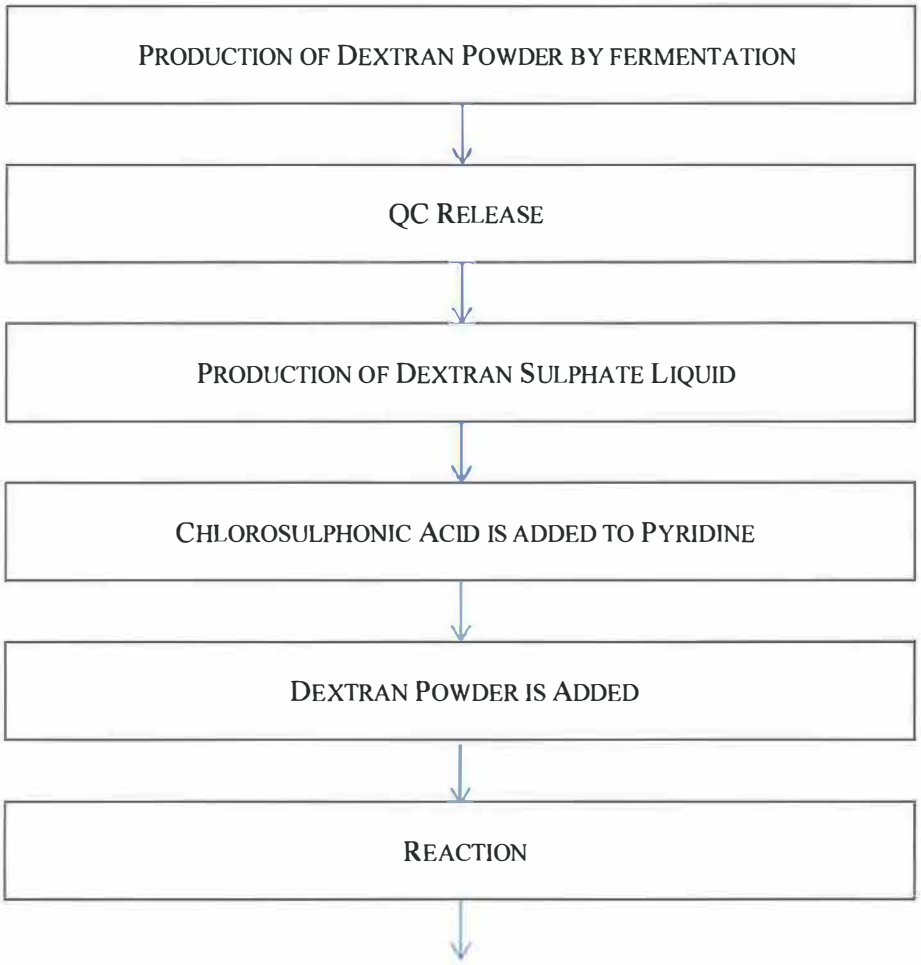
1.3.2. Origin:
1.3.2.1. The origin of Dextran Sulfate is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials which are derived by fermentation are used in the synthesis and purification of Dextran Sulfate.
1.3.3. Synonyms:
1.3.3.1. Dextran, hydrogen sulfate, sodium salt
1.3.4. Morphological Form:
1.3.4.1. White to Off-White Powder
1.3.5. Manufacturing Process:
1.3.5.1. The Dextran Sulfate, Bio Pharma Grade manufacturing process is performed by the following:

Approved Supplier Raw Material Synthesis



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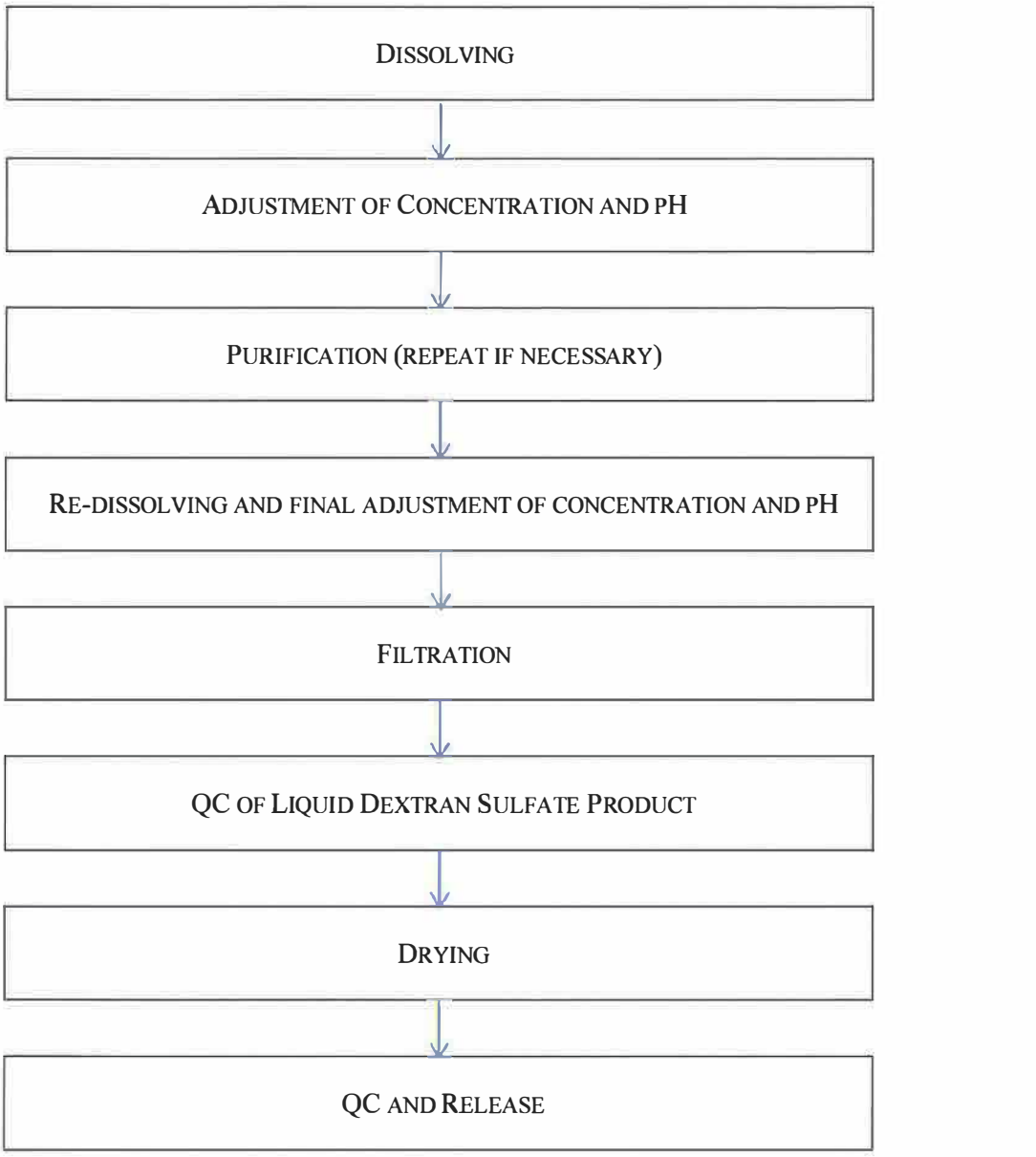

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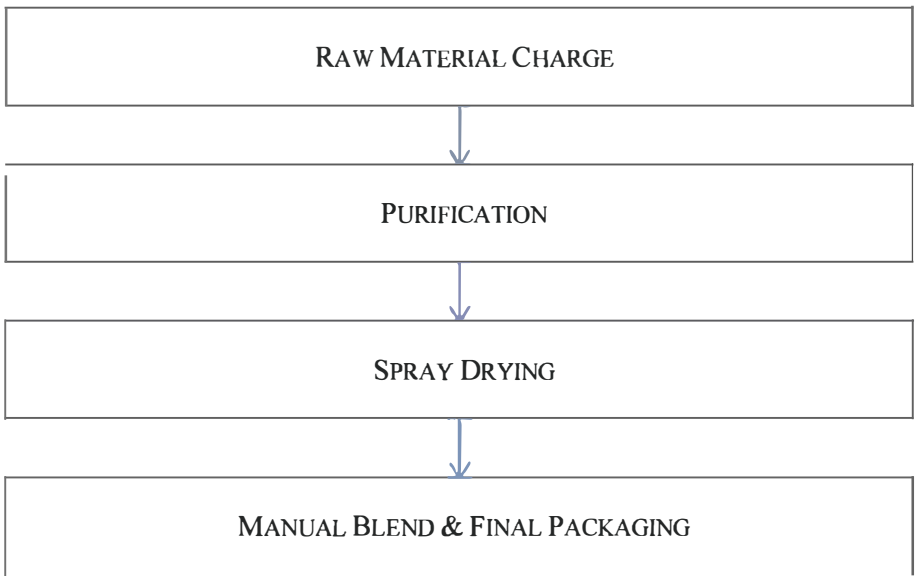
BioSpectra Dextran Sulfate Chemical Manufacturing Process



1.3.6. Specifications: Available upon request.

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 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 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. Dextran Sulfate, Bio Pharma Grade 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, Bio Pharma Grade and its raw materials are not of animal origin.

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1.4.5. Allergens Statement:

1.4.5.1. BioSpectra can state that Dextran Sulfate, Bio Pharma Grade manufactured by BioSpectra 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 sulphites at >10 mg/kg as SO, Nuts, i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoinensis* (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. Dextran Sulfate, Bio Pharma 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 genetic modification is not a concern based on this evaluation.

1.4.7. Residual Solvents Statement:

1.4.7.1. BioSpectra does not intentionally add or use any solvents in the manufacturing process of Dextran Sulfate, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 3 solvent Isopropyl Alcohol is used in the manufacture of the starting Dextran Powder material, which contains quantities well below the <5000 ppm Specification. Subsequently, the Class 2 solvent Methanol is used in the manufacture of the Dextran Sulfate raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has stated that the Dextran Sulfate raw material is controlled to conform to the ICH Q3C requirements of <3000 ppm Methanol. BioSpectra has additionally analyzed Dextran Sulfate for Methanol and Isopropyl Alcohol during degradation and impurity profiling for manufacturing process validation and confirmed that the material complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. BioSpectra can state that metal catalysts and metal reagents are not intentionally added or introduced to the BioSpectra manufacturing process for Dextran Sulfate, Bio Pharma 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.

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1.4.9. Pallet Statement:

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

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Dextran Sulfate, Bio Pharma 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. Dextran Sulfate, Bio Pharma 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 has not specifically analyzed Dextran Sulfate, Bio Pharma 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 manufacturing 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 alphanumerical digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: DXSE-0123-00001

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, 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 23 represents 2023. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Dextran Sulfate 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 date or expiration date for Dextran Sulfate, Bio Pharma 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.

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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