BIOSPECTRA
Premium Pharmaceutical Ingredients

July 22nd, 2025
Revision 1

DEXTRAN POWDER MW 10,000, BIO EXCIPIENT GRADE

REGULATORY PACKET PRODUCT CODES

Dextran Powder MW 10,000 GMP

The Dextran Powder MW 10,000, Bio Excipient Grade Regulatory Packet BSI-RPT-2263 applies to all Dextran Powder MW 10,000, Bio Excipient Grade Product Codes listed in Table 1 below.

Table 1. Dextran Powder Product Codes

Current Product Number
D010-3201

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Senior Compliance Specialist

BIOSPECTRA
Premium Pharmaceutical Ingredients

DEXTRAN POWDER, MW 10,000

BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date: Cassie Baun 7/22/25

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1. DEXTRAN POWDER, MW 10,000 BIO EXCIPIENT GRADE:

1.1. General Product Information:

1.1.1. Product Name:

1.1.1.1. Dextran Powder, MW 10,000

1.1.2. Product Code:

1.1.2.1. Reference Cover Sheet.

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 Dextran Powder, MW 10,000 manufactured by and at the BioSpectra Bangor, PA facility.

1.1.4. Molecular Formula:

1.1.4.1. $(C_6H_{10}O_5)_n$

1.1.5. Molecular Weight:

1.1.5.1. 10,000 g/mol

1.2. Manufacturing, Packaging Release Site and Supplier Information:

1.2.1. General Information:

1.2.1.1. BioSpectra manufactures Dextran Powder, MW 10,000 in its Bangor, PA facility. Dextran Powder MW 10,000 is manufactured, packaged, stored, tested, and released at BioSpectra's Bangor, PA facility.

1.2.1.2. Dextran Powder, MW 10,000 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 Powder, MW 10,000 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Dextran Powder, MW 10,000 is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.

1.2.3. Packaging:

1.2.3.1. The packaging of Dextran Powder, MW 10,000 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 Powder, MW 10,000 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 Dextran Powder, MW 10,000 is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This grade of Dextran Powder, MW 10,000 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 # 9004-54-0

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1.3.2. Origin:

1.3.2.1. The origin of Dextran Powder, MW 10,000 is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials which are produced through fermentation are used in the synthesis and purification of Dextran Powder, MW 10,000.

1.3.3. Synonyms:

1.3.3.1. 2,3,4,5-tetrahydroxy-6-[3,4,5-trihydroxy-6-[[3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxymethyl]oxan-2-yl]oxyhexanal

1.3.4. Morphological Form:

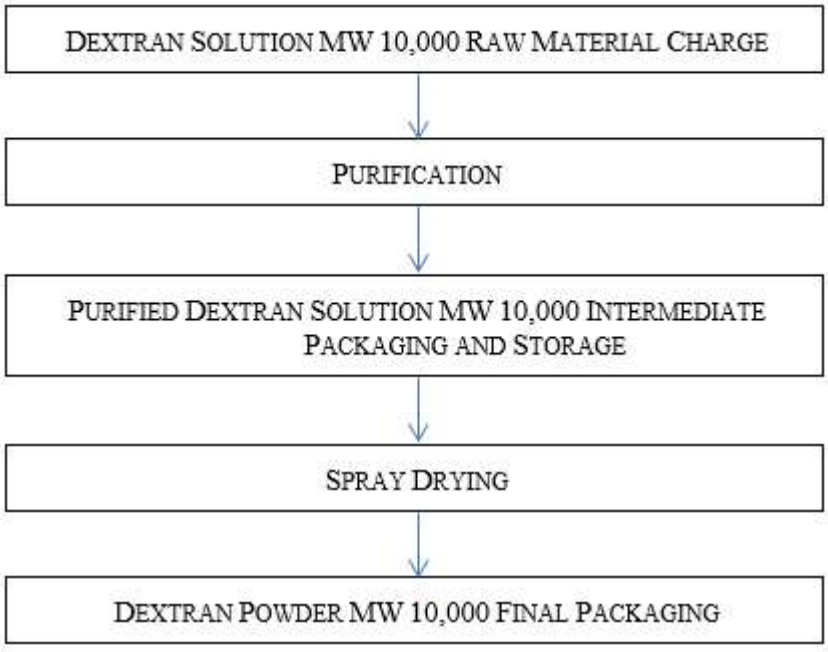
1.3.4.1. White to slightly off-white powder

1.3.5. Manufacturing Process:

1.3.5.1. The BioSpectra Excipient Manufacturing Process is available in the Dextran Powder, MW 10,000 Process Flow Diagram DCN: BSI-DGM-0286 v.1.0.

1.3.5.2. The manufacturing process for Dextran Powder, MW 10,000, Bio Excipient Grade is performed by the following:

BioSpectra Dextran Powder, MW 10,000 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. Not Applicable.

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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 Powder 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 Powder, MW 10,000, Bio Excipient Grade is not of animal or human origin. BioSpectra can state that BSE/TSE is not a concern based on this evaluation.
1.4.5. Allergens Statement:
1.4.5.1. BioSpectra can state that Dextran Powder, MW 10,000, Bio Excipient Grade manufactured by BioSpectra is 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.
1.4.6. Genetically Modified Organisms (GMO) Statement:
1.4.6.1. BioSpectra does not use genetically modified organisms (GMO) in the manufacturing process of Dextran Powder MW 10,000, Bio Excipient Grade.
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 Dextran Powder MW 10,000, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline, and USP <467> Residual Solvents. 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 raw material supplied to BioSpectra, which complies with the <5000 ppm specification. BioSpectra does not specifically analyze Dextran Powder MW 10,000, Bio Excipient Grade for Residual Solvents, as solvents are not utilized in the BioSpectra manufacturing process.

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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 Powder, MW 10,000, Bio Excipient 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 Powder, MW 10,000, Bio Excipient Grade manufactured at BioSpectra are ISPM 15 compliant.
1.4.10. Elemental Impurities Statement:
1.4.10.1. BioSpectra does not intentionally add or introduce elemental impurities into the BioSpectra manufacturing process of Dextran Powder MW 10,000, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that elemental impurities are not expected to be present based on this evaluation.
1.4.11. Melamine Statement:
1.4.11.1. BioSpectra does not use Melamine in the manufacturing process of Dextran Powder MW 10,000, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the raw materials are not expected to contain melamine based on this evaluation. BioSpectra does not analyze Dextran Powder MW 10,000, Bio Excipient Grade or its raw materials for melamine.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:
1.5.1.1. The Dextran Powder MW 10,000 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 per BSI-DMG-0009 BioSpectra Lot Number Identification:
1.5.2.2. A sample lot number would appear as:
1.5.2.2.1. QS7: D010-L10-0125-0001
1.5.2.2.1.1. The first four digits are alpha digits which indicate the material, where D010 represents Dextran Powder, MW 10,000. 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 25 represents 2025.

The final four digits are numerical digits, which indicate the sequential batch number, where 0001 represents the first Dextran Powder, MW 10,000 batch of 2025 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. Dextran Powder MW 10,000 Bio Excipient Grade will undergo stability testing in accordance with BioSpectra's Stability Testing Program. Retest and/or expiry dates are assigned based on available data and are present on the Certificate of Analysis, as applicable.

1.5.4. Storage and Shipping Conditions:

1.5.4.1. Refer to the Dextran Powder SDS, DCN: BSI-SDS-0052.

1.5.5. Packaging:

1.5.5.1. Packaging information is available through the following: https://Biospectra.us/package-pics-dims/

1.6. Contact Information:

1.6.1. https://www.biospectra.us/commercial-team/#

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100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

BioSpectra Quality Management System Regulatory Packet

Signature/Date:

Cassie Baun 12/30/24

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1. SITE QUALITY OVERVIEW:

1.1. Facility Overview:

1.1.1. BioSpectra Facilities

Table 1. BioSpectra Facility Names and Addresses

Name	Address	Activity
Jacobsburg	1349 Jacobsburg Road Wind Gap, PA 18091	Commercial, IT, HR, & Finance Offices, Training Center, and Small Warehouse for applicable materials
Majestic	100 Majestic Way Bangor, PA 18013	Bulk Manufacturing Facility & Head Corporate Offices: Administration, Regulatory Affairs, Quality Assurance & Quality Control
Rockdale	1474 Rockdale Lane Stroudsburg, PA 18360	Bulk Manufacturing Facility, Quality Control and Assurance
McConnell	51 North 3rd Street Stroudsburg, PA 18360	Shipping and Receiving & Security Headquarters

1.1.2. Customer Audit Policy:

1.1.2.1. BioSpectra welcomes auditors and visitors. Our customers and business partners are assured access to our facilities based on purchased product grade attributes and/or Supply/Quality Agreements. BioSpectra allows scheduled audits to maintain assurance of current information related to the systems, equipment, utilities and operations at each site. Potential customers and potential business partners may be provided with appropriate access while establishing business relationships. Audits may be restricted in the absence of a current commercial relationship.

1.1.2.2. To request an audit, please complete the Audit Request Form:

1.1.2.2.1. https://biospectra.us/audit-request-form/

1.1.3. Site Details:

1.1.3.1. General Site Information

1.1.3.1.1. BioSpectra was founded in 1994 and was officially incorporated in the State of Pennsylvania in 1995. The first BioSpectra manufacturing facility was opened in Sciota, PA in March of 1996. This facility was created for the cGMP manufacturing of Biological Buffers. BioSpectra opened the Stroudsburg, PA facility (Rockdale) in December of 2000. Between 2000 and 2003, BioSpectra moved its processes from the Sciota, PA facility to its Stroudsburg, PA facility. This site is registered with the US Food and Drug Administration. The processes were initially validated in the Stroudsburg facility throughout 2000 and 2003 and revalidated in accordance with BioSpectra's approved Manufacturing Process Validation Master Plan. The manufacturing operations at this site operate 24 hours per day 7 days per week.

1.1.3.1.2. BioSpectra purchased the Bangor, PA facility (Majestic) in December of 2012. This facility develops new processes, conducts research and development, and manufactures Active Pharmaceutical Ingredients, Excipients, and Life Science Intermediates, as well as Custom Buffers and Blends. This site is registered with the US Food and Drug Administration. The manufacturing operations at this site operate 24 hours per day 7 days per week.

1.1.3.1.3. In April of 2021 BioSpectra opened the Wind Gap Corporate Center (Jacobsburg), which houses office and warehousing space. The warehouse consists of multiple push-back racking systems and additional pallet positions designated on the warehouse floor. This facility is the Corporate Center with office locations for Commercial, IT, Human Resources, and Finance. Additionally, this facility is the training center. There are no products currently manufactured at this site.

1.1.3.1.4. In 2023, BioSpectra opened the Supply Chain Center (McConnell) in Stroudsburg, PA, which houses offices, security headquarters and warehousing space for sampling and storage of raw materials and components as well as storage, release, and shipment of finished goods in accordance with cGMP guidelines. There are no products manufactured at this site.

1.1.3.2. Facility Size and Composition

1.1.3.2.1. The BioSpectra Majestic facility is approximately 150,000 square feet in size and is comprised of various Zones. Each Zone represents a particular geographical portion of the facility. Any one zone may include multiple operational areas, which include manufacturing, packaging, storage, or further processing areas. The map of the facility contains details of each zone. Detailed site information is available in DCN: BSI-SOP-0218.

1.1.3.2.2. There are multiple processing rooms, packaging rooms, and drying rooms within BioSpectra's 25,000 square foot Rockdale facility, as well as a warehouse with a push-back racking system, and a Quality Control Laboratory. Detailed site information is available in DCN: BSI-SOP-0078.

1.1.3.2.3. The BioSpectra Jacobsburg facility is 25,000 square feet. Detailed site information is available in DCN: BSI-SOP-0425.

1.1.3.2.4. The BioSpectra McConnell Facility is approximately 52,000 square feet. Detailed site information is available in DCN: BSI-SOP-0557.

1.1.3.3. Site Activities Conducted

1.1.3.3.1. The activities conducted at BioSpectra include but are not limited to the following:

1.1.3.3.1.1. Chemical Manufacturing
1.1.3.3.1.2. Blending
1.1.3.3.1.3. Particle Manipulation
1.1.3.3.1.4. USP/EP Purified Water System Generation, at minimum
1.1.3.3.1.5. Analytical Method Validation
1.1.3.3.1.6. Analytical Method Verification
1.1.3.3.1.7. Supplier Qualification and Approval
1.1.3.3.1.8. Stability Program
1.1.3.3.1.9. Impurity and Degradation Profiling
1.1.3.3.1.10. Multi-Compendial Analysis
1.1.3.3.1.11. Custom Analytical Methods and Specifications
1.1.3.3.1.12. Bioburden Reporting
1.1.3.3.1.13. Endotoxin Testing
1.1.3.3.1.14. Elemental Impurities
1.1.3.3.1.15. Residual Solvents
1.1.3.3.1.16. Rinse/Swab Analysis/Sampling
1.1.3.3.1.17. Environmental Monitoring

1.1.4. Primary applications of products produced at this site:

1.1.4.1. Bio FUISA Grade material is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This grade of material is not suitable to be used as a Sterile Active Pharmaceutical Ingredient, Drug Product or Household Item.

1.1.4.2. Bio Active Grade material is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This grade of material is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product, or Household Item.

1.1.4.3. Bio Excipient Grade material is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This grade of material is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product, or Household Item.

1.1.4.4. Bio Pharma Grade BSI material 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 material is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product, or Household Item.

1.1.5. Facility production of antibiotics, steroids, or hormone products:

1.1.5.1. There is no production of antibiotics, steroids, or hormones conducted at any BioSpectra facility.

1.1.6. Product Release:

1.1.6.1. Products manufactured by BioSpectra are tested to ensure each batch conforms to assigned specifications. Quality Control performs all analytical testing of each batch of product. Quality Assurance reviews all batch documentation for release. All packaged and prepared materials are inspected before final shipment.

1.1.7. Service Providers:

1.1.7.1. Service Providers are approved and qualified in accordance with BioSpectra's Supplier, Manufacturer, and Service Provider Qualification Master Plan. This includes completion of appropriate questionnaires and verification of quality, capabilities and performance via audits and inspections.

1.2. **Compliance Evidence:**

1.2.1. Reference the BioSpectra Quality Manual DCN: BSI-SOP-0302 for further details on how BioSpectra, as a manufacturer of Active Pharmaceutical Ingredients, Excipients and Process Chemicals, complies with ICH Q7 Good Manufacturing Practice Guidelines for Active Pharmaceutical Ingredients (API). The Quality Manual will reference all associated documentation within BioSpectra's Quality System for further evidence of compliance to the regulations, standards and guidelines.

1.2.2. ISO Registration and ISO Certification:

1.2.2.1. BioSpectra Facilities are not registered with ISO.

1.2.3. General GMP Statement:

1.2.3.1. BioSpectra's quality system is designed to state and define the compliance standard to which all BioSpectra operations are held. The BioSpectra Quality System was derived from the interpretations of ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients and the Joint IPEC-PQG Good Manufacturing Practice Guide for Pharmaceutical Excipients. All personnel are GMP trained on a scheduled frequency which ensures their awareness and understanding of cGMP guidelines. The facility is inspected on a scheduled frequency to verify continuous compliance in accordance with BioSpectra's Quality System. Specific manufacturing processes conducted at

BioSpectra's facilities are validated in accordance with BioSpectra's approved Manufacturing Process Validation Master Plan. All products available from BioSpectra are available with distinct Key Compliance Attributes.

1.2.3.2. BioSpectra manufactures and processes Chemical Reagents, Life Science Intermediates, Excipients, and Active Pharmaceutical Ingredients. The manufacturing of BioSpectra products includes a validation of the processes, qualification of the utilities and equipment, and identifying compliance attributes according to the regulatory needs of the product or process. BioSpectra also performs various other processing or handling of products. This includes blending, particle manipulation, custom solutions, or packaging.

1.2.4. Other certifications or external audit programs:

1.2.4.1. BioSpectra has been audited by third party auditors in support of supply chain management. Further information is available through BioSpectra's Compliance Department.

1.3. **ICH-Q7 GMP-Compliance Details:**

1.3.1. BioSpectra manufactures Bio FUISA, Bio Active, and Bio Excipient Grade products in accordance with ICH Q7 Guidance Documents. BioSpectra manufactures Bio Pharma Grade products in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide.

1.3.2. Quality Management Systems:

1.3.2.1. General Requirements

1.3.2.1.1. BioSpectra has created and implemented the Quality System, which provides the necessary requirements for all aspects in the manufacture, testing, and release of all BioSpectra products.

1.3.2.1.2. Leadership Review is conducted twice per year to review all investigations, internal and external audits, as well as corrective actions and preventative actions among other quality and commercial related topics in accordance with the Leadership Review Procedure.

1.3.2.1.3. BioSpectra's quality policies ensure that all operations conducted at BioSpectra are performed in accordance with ICH Q7 Guidance Documents.

1.3.2.1.4. All responsibilities of the Quality Unit are clearly defined.

1.3.2.1.5. BioSpectra products are manufactured in accordance with BioSpectra's Manufacturing Process Validation Master Plan. All utilities, equipment and processes are qualified for use in the processing of the applicable product grade.

1.3.2.2. Documentation Requirements

1.3.2.2.1. Documentation rules and standards are defined by BioSpectra's Document Creation Revision, Review and Approval Process, as well as the Record Storage, Retention and Control Procedure. Documentation entry requirements and rules are defined in the Documentation Entry and Error Correction Procedure, and the Data Integrity Procedure.

1.3.2.3. Change Control

1.3.2.3.1. BioSpectra's Change Control system is defined by the Change Control SOP. Any changes are detailed in the Change Control Program and must be approved at minimum by Quality, Management, and any applicable departments. Customer notification of any changes are provided in the mutually agreed upon time frame as required.

1.3.3. Management Responsibility:

1.3.3.1. Management of BioSpectra reviews operations on a daily basis.

1.3.3.2. Management reviews and assesses the adequacy and efficiency of the Quality System. This is conducted through Leadership reviews, which review at a minimum CAPAs, Customer Complaints, Discrepancy Investigations, Lab Investigations, Internal Audits, and External Audits.

1.3.3.3. Management provides necessary objectives for appropriate planning of operations, for continuous development and growth.

1.3.4. Resource Management:

1.3.4.1. Provision of Resources

1.3.4.1.1. Management develops and assigns the necessary resources to ensure all operations at BioSpectra are performed efficiently.

1.3.4.2. Human Resources and Learning Development

1.3.4.2.1. Each employee engaged in the manufacturing, processing, packing, testing, or holding of a BioSpectra product has the education, training, and experience, or any combination thereof, to enable that person to perform his or her assigned functions. BioSpectra provides training to all employees in the particular operations specific to that employee's job description, BioSpectra's Safety Program and cGMPs. Qualified individuals perform cGMP training on a continual basis and with sufficient frequency to ensure that each BioSpectra employee remains familiar with cGMPs. BioSpectra is a non-union facility.

1.3.4.3. Infrastructure (Facilities and Equipment)

1.3.4.3.1. Facility utilities and equipment are qualified to perform as intended and are maintained in accordance with BioSpectra's Preventative Maintenance Program.

1.3.4.4. Work Environment

1.3.4.4.1. In order to protect the product, the operator, and visitors, BioSpectra requires hairnets, beard nets (where applicable), uniforms, safety glasses or goggles, disposable laboratory coats and/or sleeves (where applicable), and safety shoes to be worn in all manufacturing areas. (Visitors may be exempt from the requirement of safety shoes). Production area cleaning is performed and documented at the conclusion of each batch. Cleaning of a process is performed, verified, and documented in accordance with the Batch Record and Cleaning Worksheet Procedure, as applicable. The samples must meet designated rinse and/or swab requirements to ensure that all equipment used in the manufacture of BioSpectra products remains free of contamination and to ensure production of the purest Finished Good is available.

1.3.5. Product Realization:

1.3.5.1. Design and Development

1.3.5.1.1. All processes at BioSpectra are developed, qualified, and validated for intended use. Multi-use equipment is cleaned in accordance with BioSpectra's approved Process Cleaning Program.

1.3.5.2. Purchasing

1.3.5.2.1. BioSpectra purchases all controlled items for validated processes from BioSpectra's Supplier, Manufacturer, and Service Provider Lists in accordance with the Materials Handling procedure.

1.3.5.3. Production and Service Provision

1.3.5.3.1. The manufacturing of BioSpectra products includes a validation of the processes, qualification of the utilities and equipment, and identifying compliance attributes according to the regulatory needs of the product or process.

1.3.5.4. Control of Measuring and Monitoring Devices

1.3.5.4.1. BioSpectra has an extensive Calibration and Preventative Maintenance Program for the equipment and measuring devices utilized in manufacturing as well as the Quality Control Laboratory. All QC test methods are validated or verified according to ICH, USP <1225> and USP <1226> guidelines.

1.3.6. Measurement, Analysis and Improvement:

1.3.6.1. General

1.3.6.1.1. BioSpectra provides complete testing of products in each phase of manufacturing from raw materials to finished goods. The Stability Testing Program and Impurity Profiles are also maintained for each product. The QC Laboratory has Multi-Compendial testing capabilities and uses state-of-the-art calibrated equipment to ensure accurate testing.

1.3.6.1.2. All testing is reviewed by QC and reviewed by QA during Certificate of Analysis issuance. All batch records are reviewed by Quality Assurance before release and shipment of product.

1.3.6.2. Monitoring and Measurements

1.3.6.2.1. BioSpectra handles all customer complaints in accordance with BioSpectra's Written and Verbal Complaints procedure. Customer Complaints are evaluated for each product annually as a part of the Annual Product Review and reported to Leadership during Leadership Review at minimum.

1.3.6.2.2. Critical Process Parameters, Critical Quality Attributes, OOS, and Process Deviations at minimum are evaluated during the Annual Product Reviews.

1.3.6.2.3. BioSpectra conducts Internal Audits in accordance with the Internal Audit Procedure. Internal Auditors may not audit areas of their own work.

1.3.6.2.4. Analytical Methods used for analysis are validated or verified in accordance with USP <1225> and <1226> and other ICH Guidance Documents.

1.3.6.2.5. All data for testing is recorded directly into permanently bound, sequentially numbered laboratory notebooks, analytical procedures, or data cards using permanent ink. All sample identification information is recorded on sample labels, as well as in the laboratory notebooks or data cards.

1.3.6.2.6. All electronic printouts of raw data are retained by BioSpectra for a minimum of six years.

1.3.6.2.7. Each analysis performed is signed and dated by the Analyst performing the analysis.

1.3.6.2.8. There are detailed Laboratory procedures regarding the execution of analytical methods and the preparation of solutions.

1.3.6.2.9. USP Primary Reference Standards may be used when available.

1.3.6.2.10. Finished Good Testing is performed on every lot of finished product manufactured prior to release. Testing is reviewed by Quality Control or a qualified designee and reviewed by Quality Assurance prior to the release of material.

1.3.6.2.11. OOS results are documented and investigated. All re-tests and re-samples must be justified prior to execution.

1.3.6.2.12. All Raw Material and Finished Good Samples are retained for five years, with an appropriate amount of sample available for testing the retain.

1.3.6.2.13. Impurity and Degradation Profiles are completed on the product during validation and during each subsequent validation.

1.3.6.2.14. Stability of materials is determined in Accordance with ICH Q1A.

1.3.6.3. Control of Nonconforming Product

1.3.6.3.1. Materials that do not conform to specifications are isolated in quarantine and an OOS investigation as well as a discrepancy investigation, as applicable, are performed to determine the root cause of the nonconformance. Material is completely tested prior to shipment and shipments are not released by Quality Assurance until all investigations are concluded with a final disposition statement of the product.

1.3.6.3.2. Material may be reprocessed in accordance with the Material Reprocessing or Reworking Procedure. Routine reprocessing may occur if a reprocess batch is included in the validation in accordance with the Manufacturing Process Validation Master Plan.

1.3.6.3.3. Additional reworking may be conducted after a risk analysis is completed and Temporary Operating Instructions and/or discrepancy investigation are issued. TOI must be approved by QA and management, as well as QC and Production, when applicable. Any material that is reworked must be placed into the BioSpectra Stability Program.

1.3.6.3.4. Materials that are returned to BioSpectra are evaluated by Quality for any risk to the production process and if the material is deemed acceptable it is tested and used as raw material.

1.3.6.4. Analysis of Data

1.3.6.4.1. All Critical Quality Attributes and measurable Critical Process Parameters are evaluated statistically during the Annual Product Review. Results and trends of the Annual Product Review are reported to Leadership annually.

1.3.6.5. Improvement

1.3.6.5.1. OOS and Discrepancy Investigations, Internal and External Audit Reports, and Customer Complaints are reviewed during the Annual Product Reviews and/or the Leadership Reviews. CAPAs are presented at the conclusion of the investigation reports and the audit responses.

2. SITE AND SUPPLY CHAIN SECURITY OVERVIEW:

2.1. Supply Chain Security:

2.1.1. Evaluation of Carriers

2.1.1.1. All non-BioSpectra-owned carriers utilized by BioSpectra are approved through mutual agreement with customers or as requested by the customer.

2.1.2. Tamper Evident Packaging

2.1.2.1. BioSpectra packaging may be sealed using an approved sequentially numbered and traced BioSpectra seal. The seals provide evidence of tampering.

2.1.2.2. Seals may be issued by Production or Quality personnel and traceability of each seal may be evident with a seal accountability form as well as the sequential numbering.

2.1.2.3. Tamper Evidence may be apparent using the BioSpectra sequentially numbered seals.

2.1.3. Environmental Controls, if applicable, are in the product specific regulatory packet.

2.1.4. Qualification of distributors is performed as necessary based on customer requests and expectations.

2.1.5. Repacking and relabeling activities are not applicable once shipped from a BioSpectra facility unless specifically in an agreement or contract with BioSpectra's customers.

2.2. **Safety and Environmental Information:**

2.2.1. BioSpectra's Health and Safety Program is comprised of a number of controlled policies aimed at protecting employees, the surrounding community, the environment, and the customers BioSpectra serves. These policies have been developed using regulatory guidelines and industry regulations.

2.2.2. BioSpectra is not currently registered to ISO 14001, OHSAS 18001, or Responsible Care.

2.2.3. BioSpectra has created Emergency Action Plans to provide all BioSpectra employees with the appropriate procedure to safely and effectively respond to or safely evacuate from an emergency situation at either BioSpectra facility. This plan provides information for the appropriate response to be used in the event of a fire, medical, chemical spill/release, security threat, or weather-related emergency.

3. CONTACT INFORMATION:

3.1. https://www.biospectra.us/about-us/commercial-marketing-team