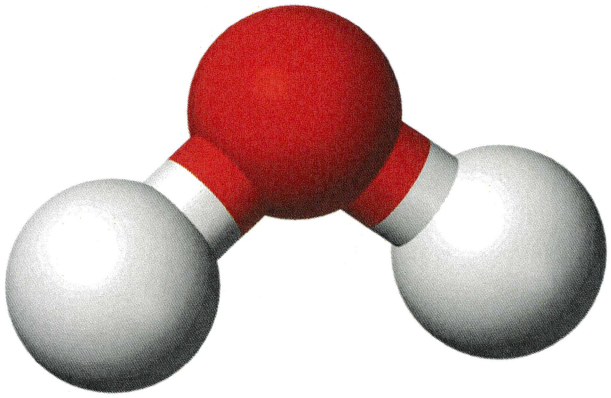
BIOSPECTRA
Premium Pharmaceutical Ingredients

WATER FOR INJECTION (WFI)



BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date:	Cassie Baun 5/3/24

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1. WATER FOR INJECTION (WFI), BIO EXCIPIENT GRADE:

1.1. General Product Information:

1.1.1. Product Name:
1.1.1.1. Water for Injection (WFI)
1.1.2. Product Code:
1.1.2.1. Current Code: WAFI-3150
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 Water for Injection manufactured by and at the BioSpectra, Bangor, PA facility.
1.1.4. Molecular Formula:
1.1.4.1. H_2O
1.1.5. Molecular Weight:
1.1.5.1. 18.02 g/mol

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

1.2.1. General Information:
1.2.1.1. BioSpectra manufactures Water for Injection in its Bangor, PA facility. Water for Injection is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
1.2.2. Manufacturing:
1.2.2.1. The manufacturing of Water for Injection is performed at BioSpectra's Bangor, PA facility utilizing dedicated equipment.
1.2.3. Packaging:
1.2.3.1. The packaging of Water for Injection 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 Water for Injection 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 Water for Injection is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. This Grade of Water for Injection 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# 7732-18-5
1.3.2. Origin:
1.3.2.1. Water for Injection is generated by BioSpectra's Zone L USP/EP Purified Water for Injection System.
1.3.3. Synonyms:
1.3.3.1. AQUA; water, distilled, conductivity or of similar purity
1.3.4. Morphological Form:
1.3.4.1. Clear colorless liquid
1.3.5. Manufacturing Process:

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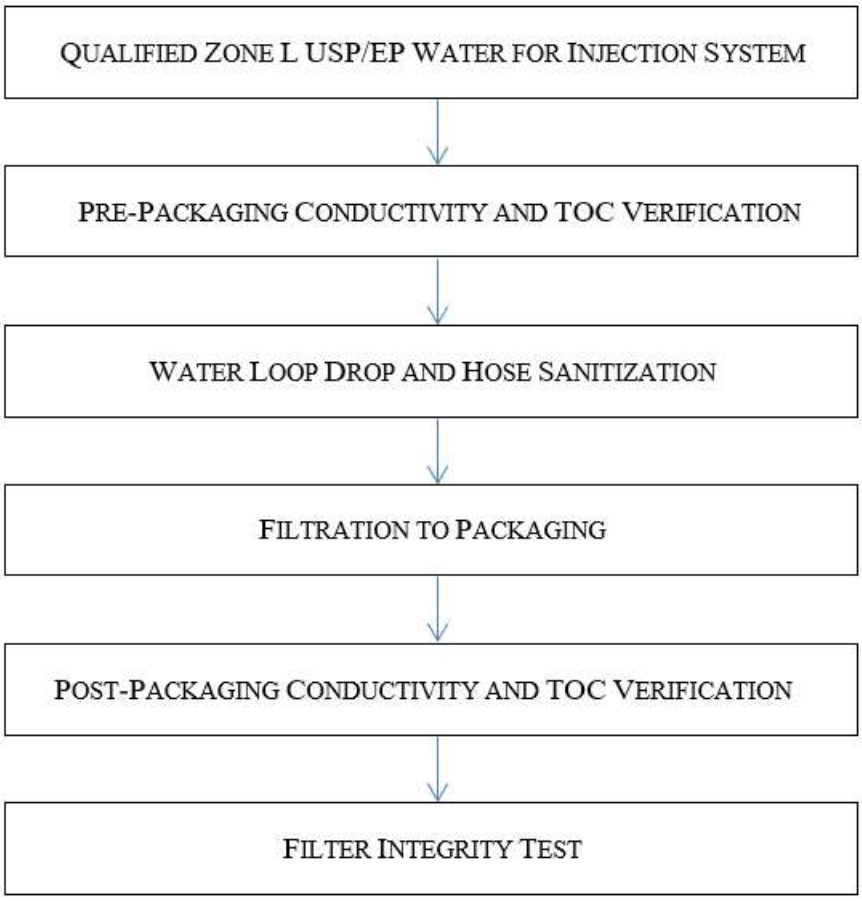
1.3.5.1. The BioSpectra Excipient Manufacturing Process for Water for Injection is available in the Water for Injection Process Flow Diagram DCN: BSI-DGM-0197 v.1.0 and is performed by the following:

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. USP, EP, JP

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 Water for Injection Safety Data Sheet for the REACH Number, if applicable, or contact your Commercial Team Representative for further information.

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1.4.4. BSE/TSE Statement:

1.4.4.1. Water for Injection, Bio Excipient Grade manufactured by BioSpectra starts from potable water and is processed through BioSpectra's Pretreatment System, RO/CEDI Loop, WFI Storage and Distribution System. BioSpectra does not use any materials of animal or human origin in the BioSpectra manufacturing process of Water for Injection, Bio Excipient Grade. BioSpectra does not analyze for BSE/TSE.

1.4.5. Allergens Statement:

1.4.5.1. Water for Injection, Bio Excipient Grade manufactured by BioSpectra starts from potable water and is processed through BioSpectra's Pretreatment System, RO/CEDI Loop, WFI Storage and Distribution System. BioSpectra does not use any Allergens in the BioSpectra manufacturing process of Water for Injection, Bio Excipient Grade. BioSpectra does not analyze Water for Injection, Bio Excipient Grade for Allergens.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. Water for Injection, Bio Excipient Grade manufactured by BioSpectra starts from potable water and is processed through BioSpectra's Pretreatment System, RO/CEDI Loop, WFI Storage and Distribution System. BioSpectra does not use any Genetically Modified Organisms in the BioSpectra manufacturing process of Water for Injection, Bio Excipient Grade. BioSpectra does not analyze for GMO.

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 Water for Injection manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. BioSpectra does not analyze Water for Injection, Bio Excipient Grade for residual solvents.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. Water for Injection, Bio Excipient Grade manufactured by BioSpectra is manufactured without the use of metal catalysts and metal reagents.

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that all wooden pallets, if applicable, used in the packaging and shipping of Water for Injection manufactured at BioSpectra are ISPM 15 compliant.

1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Water for Injection, Bio Excipient Grade 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.

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1.4.11. Melamine Statement:

1.4.11.1. Water for Injection, Bio Excipient Grade manufactured by BioSpectra starts from potable water and is processed through BioSpectra's Pretreatment System, RO/CEDI Loop, WFI Storage and Distribution System. BioSpectra does not use melamine in the BioSpectra manufacturing process of Water for Injection, Bio Excipient Grade. BioSpectra does not analyze Water for Injection, Bio Excipient Grade for melamine.

1.5. Miscellaneous Product Information:

1.5.1. Description of Batch:

1.5.1.1. The Water for Injection process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan.

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: WAFI-0124-00001

1.5.2.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where WAFI represents Water for Injection. 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 Water for Injection batch of 2024 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.

1.5.2.2.2. QS7: WAFI-L08-0524-0001

1.5.2.2.2.1. The first four digits are alpha digits which indicate the material, where WAFI represents Water for Injection. 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 05 represents May. 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 Water for Injection 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 Water for Injection, 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. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.

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

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

BioSpectra Quality Management System Regulatory Packet

Signature/Date: Cassie Baun 10/23/23

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

1.1.2. Customer Audit Policy:

1.1.2.1. BioSpectra allows for customer audits as required by the customer and as appropriate for the scope of materials purchased. Access to the raw material supply chain is also available. Each customer audit provides a general overview of processing information and facility operations.

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.

1.1.3.1.2. BioSpectra opened the Stroudsburg, PA facility 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.

1.1.3.1.3. BioSpectra purchased the Bangor, PA facility 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.

1.1.3.1.4. In April of 2021 BioSpectra opened the Wind Gap Corporate Center which houses office and warehousing space. The warehouse consists of multiple push-back racking systems with a total of 252 rack positions and additional pallet positions designated on the warehouse floor. This facility is the Corporate Center with office locations for Commercial, IT, Human Development, and Finance. Additionally, this facility is the training center and Security Headquarters. The Corporate Center also includes warehousing space for storage of raw materials, components, manufacturing equipment (in storage), and facilities supplies in accordance with cGMP guidelines. There are no products currently manufactured at this site.

1.1.3.1.5. In 2023, BioSpectra opened the Supply Chain Center in Stroudsburg PA, which houses office 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 Way 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 the BioSpectra Bangor Site Quality Overview DCN: BSI-SOP-0218.

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

1.1.3.2.3. The BioSpectra Jacobsburg Road facility is 25,000 square feet. Detailed site information is available in the BioSpectra Wind Gap Site Quality Overview DCN: BSI-SOP-0425.

1.1.3.2.4. The BioSpectra 3rd Street Supply Chain Center is approximately 52,000 square feet.

1.1.3.3. Site Activities Conducted

1.1.3.3.1. The activities conducted at BioSpectra include the following:

1.1.3.3.1.1. Chemical Manufacturing
1.1.3.3.1.2. Multi-Compendial Testing
1.1.3.3.1.3. Enzyme Analysis (If Applicable)
1.1.3.3.1.4. Blending
1.1.3.3.1.5. Wet Chemistry Analysis
1.1.3.3.1.6. Spectroscopy: UV/VIS, IR
1.1.3.3.1.7. Karl Fischer Titrations
1.1.3.3.1.8. Melting Point Determination
1.1.3.3.1.9. Residue on Ignition
1.1.3.3.1.10. Titrations

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. ISO Registration and ISO Certification:

1.2.1.1. BioSpectra Facilities are not registered with ISO.

1.2.2. General GMP Statement:

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

1.2.2.2. 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.

1.2.3. Other certifications or external audit programs:

1.2.3.1. 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. Senior Management Review is conducted quarterly 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 Senior Management 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 Procedures. 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 Senior Management reviews, which review at a minimum CAPAs, Customer Complaints, Discrepancy Investigations, Lab Investigations, Internal Audits, External Audits, and Batch Failures.

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 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. Periodic cleaning of a process is performed, verified, and documented in accordance with the Batch Record. The samples must meet designated rinse 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 List.

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 Senior Management quarterly.

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

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

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 deviation 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 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 Senior Management annually.

1.3.6.5. Improvement

1.3.6.5.1. OOS and Deviation Investigations, Internal and External Audit Reports, and Customer Complaints are reviewed during the Annual Product Reviews and or the Senior Management 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 the 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 it is 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 an Emergency Action Plan 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