2000 Powell Street
Suite 600, Emeryville, CA 94608
Phone: 510-452-8000

Good Manufacturing Practices Audit

Company Information		Audit Information	
Facility Name:	Bioactive Services LLC-NJ	**Audit Type:**	Initial
Address:	470 East Sydney Drive, Sparks, NV	**Audit Method:**	On-Site
		Auditor:	Dave Marciniak
		Auditor Email:	dimarciniak@netscape.net
Contact:	Arkalgud Balakrishna	**Audit Date(s)**	
Title:	SQFP	**Start Date:**	9/11/2024
Phone:	908-361-5684	**End Date:**	9/11/2024
Email:	Kris@bioactiveresources.com	**SCS Contact**	
		Technical:	FoodSafety@scsglobalservices.com

Scoring Explanation for Each Section and Overall:

Minor Non-Conformance:	1% Deduction
Major Non-Conformance	5% Deduction
Critical Non-Conformance	50% Deduction

Overall Audit Scoring Definitions	
Audit Rating	**Score**
Excellent	95 - 100%
Good	86 - 94%
Fair	70 - 85%
Audit Failure	< 70%

Audit Result	
Excellent	99.0%

Audit Attendance				
Name	**Job Title**	**Opening Meeting**	**Facility Walk**	**Closing Meeting**
Arkalgud Balakrishna	SQFP	x	x	x
Dave Marciniak	Lead Auditor	x	x	x

Audit Scope	
Scope:	Dietary Supplements
Exclusions:	None

Facility Information

Year Built:	2017
Months of Operation:	January-December
# of Employees:	14
Facility Size (sq. ft.):	11,000

Changes Since Previous Audit (If Applicable):
This was the first GMP audit conducted at this location.

Hours of Operation by Shift: (Ex. 0800am to 0430pm)		
	1st	6:00-2:30
	2nd	3:00-11:00
	3rd	
	4th	

# of HACCP Plans:	1

Brief Description of the Production Process:	**Include # of lines, CCPs, and any relevant information**

This was the initial GMP audit for Bioactive services located in a light suburban setting in Sparks, Neveda. The main processing building encompesses aproximately 18,000 sq ft. An additional 11,000 sq ft warehouse is available nearby. The facility operates five days per week with 56 employees. One HACCP plan covers blending, product sterilization and packaging.

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Non-Conformance Summary Sheet & Corrective Action Plan

Company Information		Audit Information		Premilinary Audit Results	
Facility Name:	Bioactive Services LLC-NJ	**Audit Type:**	Initial	**Minor NCs**	**1**
		Audit Method:	On-Site		
Address:	470 East Sydney Drive, Sparks, Nevada 89437			**Major NCs**	**0**
		Auditor:	Dave Marciniak		
		Auditor Email:	dimarciniak@netscape.net	**Critical NCs**	**0**
			Audit Date(s)		
Contact:	Arkalgud Balakrishna	**Start Date:**	9/11/124		
Title:	SQFP	**End Date:**	9/11/2024		
Phone:	908-361-5684		**SCS Contact**		
Email:	Kris@bioactiveresources.com	**Email:**	FoodSafety@scsglobalservices.com		

MINOR Non-Conformance: A Corrective Action Plan (CAP), including Root Cause and Preventative Action, is required to be submitted and approved by the auditor within **30 calendar** days from the end of the audit.

MAJOR Non-Conformance: A Corrective Action Plan (CAP), including Root Cause and Preventative Action, is required to be submitted and approved by the auditor within **30 calendar** days from the end of the audit.

CRITICAL Non-Conformance: The audit is deemed a failure. No certificate will be granted. Corrective action requirements outlined under the **Failed** rating are required before a re-audit can occur. **Certificates will not be issued until the CAP has been submitted, reviewed, and accepted.**

Note: CAP response is not required to be submitted for score of 96% or above unless required by customer.

	9/11/24		9/11/24
FACILITY SIGNATURE	**DATE**	**AUDITOR SIGNATURE**	**DATE**

Section Number	Audit Question	Rating	Evidence	Corrective Action Plan (Include Date To Be Completed)	Root Cause Analysis & Preventative Action	Responsible Person (Name & Title)	Auditor Approval	Auditor Approval Date

2.6.1	Critical Limits: i. For each identified CCP/PC, the food safety team shall identify and document critical food safety limits that separate acceptable product from unacceptable product; ii. Critical limits shall be measurable. Variable or attribute measures are acceptable; iii. There shall be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified process authority; iv. Critical limits shall be validated and re-validated annually.	Minor	SOP -04-05-01 for the operation of the metal detector includes requirements for calibration with 1.0 mm Fe and non-Fe as well as 1.5 mm SS standards. Operation was verified during the audit, however, the HACCP plan dated June, 2024 documents calibration with 1.2 mm Fe and non-Fe as well as 1.6 mm SS standards.					

Section Name	Section Number	Audit Question	Rating	Evidence
1.0 Management Commitment & Responsibility				
1.1 Management Policy	1.1.1	A documented Food Safety Policy shall be in place that: i. Defines the site's commitment to manufacturing safe food; ii. Defines the methods used to meet applicable statutory, regulatory, and customer requirements; iii. Defines the methods used to continually improve the Food Safety System.	Compliant	The food safety policy is included in the policy manual. The statement is also posted in the common areas of the facility. The policy includes requirements for continuous improvement.
	1.1.2	The Food Safety Policy shall be: i. Signed by the person with overall responsibility for the site; ii. Effectively communicated to all staff; iii. Displayed in a prominent location.	Compliant	The food safety policy is signed by the CEO. The policy was dated 3/1/24. The statement is posted in the common areas of the facility.
1.2 Management Responsibility & Authority	1.2.1	There shall be an up to date organizational chart outlining the structure of the site.	Compliant	The organization chart included in the policy manual was current.
	1.2.2	The organization shall appoint a Food Safety Leader or team to develop, implement, verify, validate, and maintain the organization's food safety management system. The food safety lead and/or team shall: i. Be a full-time employee of the organization; ii. Be trained in HACCP or other applicable regulatory food safety plan development (i.e. Preventive Controls);	Compliant	The SQFP has attended a certified HACCP course. Certificates dated 10/12/12 was available for the SQFP. The SQFP is a full time employee of the facility.
	1.2.3	Management shall establish procedures to improve the effectiveness of the food safety management system to demonstrate continual improvement.	Compliant	Senior site management has processes in place to demonstrate continuous improvement and to ensure the integrity of the food safety systems when there are organizational or personnel changes.
	1.2.4	All persons shall have responsibility and authority to report food safety problems to senior management.	Compliant	Employees have responsibility and authority to report food safety problems to senior management. Responsibility is included in the policy manual.
1.3 Management Review	1.3.1	Senior management shall document and implement a management review policy that defines the responsibility and methods used to review the entire Food Safety Management System on an annual basis.	Compliant	Management reviews are completed annually. The management review meeting from July and August, 2024 were documented.
	1.3.2	The management review agenda shall include at a minimum: i. Update on previous management review action plans and timelines for completion ii. Failures of the Food Safety Management System and/or HACCP Plans iii. Results on Internal and External Audits iv. Customer Complaint Trending Analysis v. Non-conforming product results vi. Any site crisis management situations or recalls that have occurred vii. Continuous improvement to the Food Safety Management System viii. Changes to customer and/or regulatory requirements that could affect the Food Safety Management System.	Compliant	The SQF System is reviewed annually by the site's senior management team per SOP-01-01 dated 5/1/22 . The review includes changes to the food safety management system documentation (policies, procedures, specifications, and food safety plans); food safety culture performance; food safety objectives and performance; corrective and preventive actions and trends related to internal audits, external audits, customer complaints, verification and validation activities; hazard and risk management system; and follow up actions from previous management review.

Section Name	Section Number	Audit Question	Rating	Evidence
	1.3.3	Documented minutes of the management review meetings must include: i. Attendance of the meeting ii. Discussion topics and status of agenda items iii. Follow-up actions, assignments, and agreed timelines for completion	Compliant	The most recent management review included a listing of attendees, agenda topics and follow up assignments and timelines.
1.4 Legislation and Regulatory Requirements	1.4.1	The organization shall document and implement methods and responsibilities to ensure the organization remains updated and compliant with requirements of all relevant current legislation; this includes the requirement to be registered with all relevant regulatory authorities and where appropriate, authorized to undertake food manufacturing activities.	Compliant	The facility is registered with the FDA under the Bioterrorism Act. The facility is inspected by the State of Nevada. The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice has been documented in the policy manual.
	1.4.2	The facility shall maintain a file of regulatory actions, visits, reports, or other notifications received from any regulatory agency. Written responses with appropriate corrective actions shall be maintained.	Compliant	Regulatory files are maintained by the SQFP. A regulatory visit SOP is included in the policy manual.
2.0 Food Safety Plan				
2.1 Preliminary Steps	2.1.1	The facility shall have a documented Food Safety Plan that is compliant to the local regulatory requirements (i.e. Preventive Control Plan, Codex HACCP, etc.) AUTO-FAIL: THERE IS NO EVIDENCE AVAILABLE TO SUGGEST THE FACILITY HAS AN IMPLEMENTED FOOD SAFETY PLAN OR HACCP PROGRAM.	Compliant	Food Safety Plans have been developed, implemented and maintained by the supplier. The HACCP plans are filed in the HACCP book and maintained by the SQFP.
	2.1.2	A food safety team shall be assembled with individuals having the appropriate product and process specific knowledge and expertise necessary for the development of an effective food safety plan.	Compliant	A food safety team is established and included in the HACCP manual.
	2.1.3	The food safety team shall: i. Have a team leader with formal HACCP/HARPC training with certificate available; ii. Be involved with the development, final approval, and subsequent reviews of the plan; iii. Be representative of major functions within the organization that have an impact of food safety.	Compliant	The SQFP has attended a certified HACCP course. Certificates dated 10/12/12 was available for the SQFP.
	2.1.4	Where external resources are used for the development and maintenance of the food safety system, applicable training records shall be maintained.	N/A	The HACCP plan is maintained internally.

Section Name	Section Number	Audit Question	Rating	Evidence
2.2 Product Characteristics	2.2.1	Develop a description of the product(s): i. Product names in the scope of the Food Safety Plan; ii. Composition; iii. Biological, Chemical, and Physical characteristics relevant to food safety; iv. Shelf life and required storage conditions; v. Intended Use; vi. Packaging and labeling requirements; vii. Method(s) of distribution and delivery.	Compliant	All characteristics are defined in the product specifications and in the HACCP plan.
2.3 Process Flow Diagrams	2.3.1	The HACCP Team shall construct a clear and easy to understand process flow diagram for each HACCP plan. The same flow diagram may be used for a number of products that are manufactured using similar processing steps.	Compliant	HACCP flow diagrams were dated 5/1/22 and included all required operations.
	2.3.2	The Process Flow Diagram shall include Critical Control Points (CCPs) and/or Preventive Controls (PCs), be current, and be verified. The process flow diagram shall: i. Outline each step in the process that is directly under the control of the establishment; ii. Where raw materials, ingredients, processing aids, packaging materials, utilities, and intermediate products enter the flow; iii. Where rework and waste handling occur.	Compliant	HACCP flow diagrams were included all required operations.
	2.3.3	Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation.	Compliant	HACCP flow diagrams were included in the HACCP plan and outlined all required operations.
2.4 Hazard Analysis	2.4.1	Identification – The food safety team shall prepare a list of all hazards (chemical, physical, and biological, radiological, or other) that may be reasonably expected to occur at each step, from raw material receipt, processing, manufacturing, storage, and distribution. Evaluation shall include all ingredients, equipment, processing steps, and packaging materials.	Compliant	The Critical Control Points have been identified as temperature control and metal detection. This is based on the hazard analysis including physical, chemical and microbiological hazards for each process step, ingredient and packaging.
	2.4.2	Assessment – The food safety team shall conduct an assessment of identified hazards to determine which need to be prevented, eliminated, or reduced to acceptable levels.	Compliant	The Critical Control Points have been identified as temperature control and metal detection. This is based on the hazard analysis including physical, chemical and microbiological hazards for each process step, ingredient and packaging.
	2.4.3	The assessment shall include: i. The likelihood of hazard occurrence; ii. The severity of their adverse health effects; iii. The qualitative and/or quantitative evaluation of the presence of hazards to determine significance.	Compliant	Hazard analysis met the requirements of 2.4.3.

Section Name	Section Number	Audit Question	Rating	Evidence
2.5 Determination of Control Measures	2.5.1	The food safety team shall determine and document the control measures that must be applied to prevent, eliminate or reduce all significant hazards to an acceptable level.	Compliant	The Critical Control Point is monitored and documented according to the plan. Any deviations from established control limits are documented and investigated.
2.6 Critical Control Points (CCPs) and/or Preventive Controls (PCs)	2.6.1	Critical Limits: i. For each identified CCP/PC, the food safety team shall identify and document critical food safety limits that separate acceptable product from unacceptable product; ii. Critical limits shall be measurable. Variable or attribute measures are acceptable; iii. There shall be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified process authority; iv. Critical limits shall be validated and re-validated annually.	Minor	SOP -04-05-01 for the operation of the metal detector includes requirements for calibration with 1.0 mm Fe and non-Fe as well as 1.5 mm SS standards. Operation was verified during the audit, however, the HACCP plan dated June, 2024 documents calibration with 1.2 mm Fe and non-Fe as well as 1.6 mm SS standards.
	2.6.2	Monitoring: i. All CCPs/PCs shall have a documented and fully implemented procedure that describes how the CCP/PC is to be monitored, who is responsible for performing it, how often it is completed, and where the activity is to be documented. The type and frequency of monitoring shall be sufficient to guarantee the CCP/PC is in control. ii. Documentation of the measured attribute shall be clearly identified in HACCP records. iii. Records associated with the monitoring of each CCP/PC shall include the date, time, result of measurement, shall be signed by the person responsible for the monitoring. Where records are in electronic form, there shall be evidence that records have been checked and verified.	Compliant	The two CCPs identified are metal detection with magnets and metal detectors and time and temperature The critical limits documented in the CCP master plan are, retaining all ferrous and non-ferrous metal fragments by the magnet and for metal detectors it is 1.0 mm for Fe, NonFe and 1.5 mm for SS. Magnets are checked every two hours. If metal fragments are found on the magnet the products are held until the investigation is completed. Metal detectors are challenged every 2 hrs. (+/-30 min) by quality technicians and/or production supervisors. Records from May, 2024 production were reviewed.
	2.6.3	Corrective Actions: i. Specific corrective actions to deal with deviations from established critical limits shall be in place for each CCP/PC. ii. Corrective actions shall include instructions of necessary actions to take to secure and manage affected product, including who needs to be informed in the event that a critical limit is exceeded. iii. Corrective actions shall ensure that the CCP/PC has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation. iv. There shall be documented product disposition procedures in the event that of a CCP/PC deviation. AUTO-FAIL: FAILURE TO TAKE CORRECTIVE ACTION FOR A CRITICAL LIMIT DEVIATION.	Compliant	Corrective action protocols are documented in the policy manual.

Section Name	Section Number	Audit Question	Rating	Evidence
2.7 Verification and Validation	2.7.1	There shall be written verification activities that confirm that the plan is being implemented as intended.	Compliant	A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity for 2024 has been prepared and available for verification.
	2.7.2	Verification activities shall include where appropriate: i. Review of the HACCP system and Plan and its records. ii. Review of deviations and product dispositions. iii. Confirmation that CCPs/PCs are properly monitored and kept under control. iv. Management sign-off that no deviations took place or that all deviations resulted in the prescribed corrective action.	Compliant	Records verified included batch production records, CCP records, supplier qualification program and the recall program. A random review of the daily pre-op inspection records from July, 2024 confirmed verification activities are carried out as per the documented frequencies. The methods, responsibility and criteria for verifying the effectiveness of monitoring pre-requisite programs critical control points and other food safety controls identified are documented and implemented in the Verification Schedule. A random review of the verification records (pest control, cleaning, preventive maintenance and calibration records) from July, 2024 confirmed verification activities are carried out as per the documented frequencies.
	2.7.3	Validation of the food safety plan shall be available through documentation or supporting data that confirms: i. The Plan is scientifically and technically sound. ii. All hazards have been identified. iii. CCPs/PCs are effective and valid and that if the food safety plan is properly implemented, these hazards will be effectively controlled.	Compliant	The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and validating critical food safety and quality limits to ensure they achieve their intended purpose are documented in the SOP-02-20 dated 6/9/22 and included in the policy manual. The validation methods ensure that critical limits and control measures effectively provide the level of control required for HACCP and the various pre-requisite programs.
	2.7.4	The HACCP plan shall be reviewed and validated by the HACCP team at minimum annually, or as needed based on changes to raw materials/processes/product change, and/or corrective and preventive actions. At the time of the HACCP plan review, the HACCP team shall also include a review of the training needs and competency of its members, to ensure that the expertise of the team remains current. This validation of the plan and review of the team shall be documented.	Compliant	The validation methods ensure that critical limits and control measures effectively provide the level of control required for HACCP and the various pre-requisite programs. The SOP for validation activities includes CCPs. Critical food safety and quality limits are re-validated at least annually in accordance with the HACCP Plan.
3.0 Food Safety Management System				
3.1 Document & Record Control	3.1.1	The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.	Compliant	The methods and responsibility for maintaining document control and ensuring staff have access to current documents are included in SOP-02-01 dated 4/5/22. The SQF Practitioner is responsible for the program and for maintaining and making revisions to documents.
	3.1.2	Documents shall be safely stored and readily accessible.	Compliant	Documents were safely stored and readily accessible by the Compliance Manager.
	3.1.3	The facility shall have procedures for the retention and storage of records relevant to the control of the process or evaluation of food safety.	Compliant	The Control of Quality Records (SOP-02-01, dated 4/5/22) outlines the procedures for managing quality records. In general, records are retained for a period of three years. The procedure also outlines the location, retention period, disposition and responsibility for each type of records.

Section Name	Section Number	Audit Question	Rating	Evidence
	3.1.4	All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.	Compliant	Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage and have documented retention times. Records are retained by the SQFP.
	3.1.5	Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations. AUTO-FAIL: EVIDENCE OF INTENTIONAL RECORD FALSIFICATION.	Compliant	Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage and have documented retention times. Records are retained by the SQFP.
3.2 Emergency Preparedness / Crisis Management	3.2.1	An emergency preparedness plan, based on the understanding of known potential food safety risks (i.e. natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply) shall be define the methods and responsibilities for handling emergency situations.	Compliant	Senior management outlining has prepared a business continuity procedure based on the understanding of known food safety threats to a business and responsibility the organization will implement to cope with a business crisis that may impact on the ability of the supplier to deliver safe food. The plan is documented in SOP-01-03 dated 6/25/24.
	3.2.2	The emergency preparedness plan shall be reviewed, tested and verified at least annually.	Compliant	The business continuity plan is reviewed, tested and verified at least annually. Requirements for annual testing are included in the plant protocols.
3.3 Customer Complaint Management	3.3.1	There shall be a written procedure for handling and documenting customer and/or consumer complaints that addresses responsibilities, response time, root cause investigation and, where appropriate, corrective action.	Compliant	The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities is documented in the policy manual in SOP -01-02 dated 3/31/22.
	3.3.2	Complaint data shall be analyzed for significant trends. Where there has been a significant increase in a complaint or a serious complaint, root cause analysis shall be used to implement ongoing improvements to product safety.	Compliant	The SQFP is responsible for addressing all complaints and deciding on corrective actions. A complaint log is maintained. The complaints are conveyed to senior management for review. The SQF Practitioner is responsible for documenting and creating the complaint trend log.
	3.3.3	Records of complaints received, and actions taken shall be made available.	Compliant	Records were maintained by the SQFP.
3.4 Specifications	3.4.1	There shall be documented finished product specifications that define acceptable product attributes.	Compliant	Specifications for all raw and packaging materials, including, ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety have been documented and kept current.
	3.4.2	Standards for raw materials, work in process and finished products shall be documented.	Compliant	Specifications for all raw and packaging materials, including, ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety have been documented and kept current.
	3.4.3	Standards shall properly identify the products or materials and criteria for evaluation.	Compliant	All raw and packaging materials and ingredients comply with the relevant legislation. This is assured through specifications, COA, letters of guarantee and certifications. A few raw materials are required to conform to 21 CFR 111 since the facility also produces dietary supplements.

Section Name	Section Number	Audit Question	Rating	Evidence
	3.4.4	The facility shall have a procedure and documentation to ensure specification changes or additions properly implemented for all products.	Compliant	Protocols for specification changes are documented in the policy manual.
3.5 Approved Supplier Program	3.5.1	There shall be a documented approved supplier program that defines the responsibility, methods, and criteria for approving the suppliers of raw materials, packaging, and contracted services that may impact food safety.	Compliant	Procedures for approval and monitoring of suppliers are documented in SOP-03-01 dated 4/13/22 and included in the policy manual. Per the procedure, all materials and components used in manufacturing are to be from approved suppliers. The approved supplier list for contract service suppliers was dated 7/12/24.
	3.5.2	Suppliers that shall be considered as part of this program include, but are not limited to, ingredient/raw material suppliers, packaging material suppliers, and chemical suppliers.	Compliant	All materials are covered by the approved supplier protocols.
	3.5.3	The program shall contain specific criteria on how suppliers are evaluated. Approval and disqualification criteria shall be included.	Compliant	The purchasing department is responsible for evaluating and approving suppliers. The company uses 'new supplier survey form' for this purpose.
	3.5.4	An Approved Supplier List is available to associates that are receiving goods. The list is verified against the items on every inbound load prior to acceptance of the goods.	Compliant	A register of approved suppliers is maintained and includes contact information for all approved vendors.
3.6 Food Defense & Biosecurity	3.6.1	The methods, responsibility and criteria for preventing food adulteration caused by a deliberate acts or terrorist-like incidents shall be documented and implemented.	Compliant	The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident are documented in the Facility Security - Food Defense plan included in SOP-02-10 dated 6/24/24.
	3.6.2	The food defense plan shall include: i. Clearly defined roles and responsibilities; ii. Security assessment of off -site storage; iii. Protection of air, gas and water supplies; iv. Protection of process control systems; v. Protection of environmental control systems; vi. Protection of sensitive data systems and the data (e.g., formulations, specifications, business information); vii. Identification and management of unusual occurrences.	Compliant	The plant protocols meet the criteria established in 3.6.2.
	3.6.3	The food defense plan shall be reviewed and challenged at least annually.	Compliant	Requirements for an annual challenge to the food defense plan are documented in SOP-02-10.
	3.6.4	All associates are trained on the Food Defense Program annually at a minimum. Associates are encouraged to report any signs of tampering or suspicious activity.	Compliant	Food defense training was completed in the annual refresher training program.
3.7 Food Fraud	3.7.1	The facility shall implement a food fraud vulnerability assessment that includes all raw materials, packaging, and site related fraudulent activities.	Compliant	The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident are documented in the Facility Security - Food Defense plan.
	3.7.2	Based on the vulnerability assessment, mitigation strategies should be implemented to reduce risks to an acceptable level.	Compliant	A food fraud vulnerability assessment and mitigation program was documented in the Food defense SOP dated 6/24/24.
	3.7.3	The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.	Compliant	The Practitioner with the team reviews the food defense plan annually.

Section Name	Section Number	Audit Question	Rating	Evidence
3.8 Hold & Release	3.8.1	Documented procedures shall be in place outlining the identification, storage, handling and as required, disposal of non-conforming product, raw material, ingredients, WIP, or packaging detected during receipt, storage, processing, handling, or delivery.	Compliant	The management of non-conforming product and equipment is described in SOP-02-05 dated 4/7/22 and included in the policy manual. The scope covers non-process and process related and non-conforming equipment error.
	3.8.2	Non-conforming product must be segregated and/or controlled from inadvertent dispatch.	Compliant	A hold tag program has been implemented to identify non-conforming product.
	3.8.3	A hold log or register must be in place	Compliant	The hold log and supporting documentation are maintained by the SQFP.
	3.8.4	Records of investigation, corrective action, disposition, and disposal (if required) of all holds must be documented and maintained.	Compliant	Records were verified to be maintained by the SQFP
	3.8.5	The facility must document and implement a hold and release procedure that includes: i. Responsible person(s) for releasing product ii. Methods used to release product iii. Requirements to release product	Compliant	All finished goods are on a positive release program.
	3.8.6	Records shall be maintained for all product releases.	Compliant	Records are maintained by the SQFP.
3.9 Internal Audit	3.9.1	There shall be routine facility inspections (can be completed by a cross functional team or by a designated individual at the facility) performed monthly to assure management that GMP policies have been: i. Effectively implemented; ii. Facilities and equipment are maintained to meet sanitary and operational needs.	Compliant	The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System including facility and equipment inspections, pre-requisite programs, food safety plans and legislative controls are documented in SOP-02-08 dated 4/7/22 and included in the policy manual.
	3.9.2	Inspections shall be documented to show non-conformances identified and corrective actions taken.	Compliant	Inspections are documented. Corrective actions taken.
4.0 Resources				
4.1 Resources	4.1.1	Training shall be provided to new hires (operating and management personnel) for the topics below, at a minimum: i. Personal hygiene and GMPs ii. Based safe food handling iii. HACCP Overview iv. Food Defense v. Allergens vi. Pest Control	Compliant	The company provides training on hygiene, food safety, food defense and pre-requisite programs to new employees as well as annual refresher training to current employees.

Section Name	Section Number	Audit Question	Rating	Evidence
	4.1.2	There shall be specific training for identified critical food safety activities. This shall include: i. CCP/PC monitoring, corrective action, and verification responsibilities prior to the individual being assigned sole responsibility for such activities. ii. Sanitation employees (including new sanitation employees, applicable operators, temporary sanitation employees, and contract sanitation employees). Training shall include master Sanitation Schedule, Standard Sanitation Operating Procedures (SSOPs), food handling sanitation, and sanitation chemical safety.	Compliant	The site has implemented a training program documented in the policy manual. The SOP covers the necessary competencies for plant personnel. This program requires training to be conducted in implementing HACCP, CCP Monitoring, Personal Hygiene, GMPs, Sampling and Test Methods, Environmental Monitoring, Allergen Management, and other tasks identified as critical to meeting the effective implementation of the SQF code.
	4.1.3	The facility has defined the competencies required for personnel charged with program responsibilities. These competencies are documented in job descriptions and in contract documents for contracted resources.	Compliant	Job descriptions are monitored in the policy manual.
	4.1.4	Training shall be provided in the language and presentation format that can be easily and clearly understood by the trainee.	Compliant	Training is completed in English. Interpreters are available if required.
	4.1.5	Refresher training on the topics identified in 4.1.1 shall be provided to all employees and documented at minimum annually, or when changes in the facilities are such that refresher training is required.	Compliant	Requirements for orientation training as well as annual refresher training are documented. Refresher GMP training was completed in several sessions documented on 7/12/24.
	4.1.6	Employee training records shall be maintained.	Compliant	Records are maintained by the SQFP.
5.0 Control of Operations				
5.1 Calibration & Equipment Performance	5.1.1	The facility must develop and implement a documented calibration plan. The plan must include: i. Responsibility of plan; ii. Identification of all equipment that require calibration. At a minimum, must include equipment used in the measurement and monitoring of product; iii. Frequency of calibration; iv. Calibration of critical equipment must be to certified and traceable standards, adjusted as necessary, and safeguarded where applicable from unintended adjustments (including handling, maintenance, and storage); v. Procedure for handling out of calibration equipment and potential impact on products that have been produced since last acceptable calibration activity.	Compliant	Instrumentation used in the process includes scales, metal detectors, magnets and thermometers. Scales are to be calibrated annually, and metal detectors and thermometers calibrated annually. Metal detectors were calibrated on 4/30/24. Magnets are tested twice annually. Testing was last completed in January and July, 2024.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.1.2	Records must be available, including: i. Calibration results ii. Calibration date iii. Who performed the calibration. iv. Calibration certificate, against a certified standard, where applicable.	Compliant	he Calibration procedure describes instrumentation calibration methods, standards, schedule, records and responsibilities. The procedure covers handling of equipment that is not suitable for use in production.
5.2 Foreign Material Control	5.2.1	The facility must have a documented and implemented program to prevent, detect, and control foreign material in products produced.	Compliant	Detection and control of foreign matter is described in SOP-04-05 dated 5/6/2.
	5.2.2	A procedure for the control or glass, brittle or hard plastic, ceramic or other similar materials must be in place when the use of these items cannot be avoided. Procedures must be documented and include: i. A documented list detailing location, number, type and condition of such materials is audited at a frequency based on risk (minimum annually); ii. Instructions for handling the cleaning, replacement and disposal of glass, brittle/hard plastic, or ceramics to minimize the risk of breakage.	Compliant	Glass and brittle plastics are monitored quarterly. The most recent inspection was completed on 7/8/24. The responsibilities and procedures for the foreign object control program are included in the documented procedure.
	5.2.3	Actions required in the case of broken glass, brittle or hard plastic and/or ceramic located near the product processing/packaging areas shall include at a minimum: i. Quarantining products and production areas potentially affected; ii. Cleaning of the production area and/or equipment; iii. Proper handling and disposal of all waste and cleaning tools to prevent cross contamination (e.g., segregation of waste, disposal of cleaning tools); iv. Documented inspection of the production area and equipment with documented approval to continue production; v. Documentation of corrective action and root cause analysis to prevent reoccurrence.	Compliant	Protocols are documented in the policy manual.
	5.2.4	Magnets (if utilized) must be used to protect product and equipment. They must not introduce dust or collected metal back into product stream during inspection process. Magnets must: i. Be of an appropriate design for the process to reduce the risk of ferrous metal; ii. Plate magnets must include steps to trap metal. iii. Must be monitored for pull strength to ensure minimal magnet degradation at least every two years. iv. Be positioned to enable easy inspection and must be inspected on a documented frequency.	Compliant	Control methods utilized and described include magnets and metal detection in the blending/mixing and packing processes.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.2.5	Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.	Compliant	The critical limits documented in the CCP master plan are, retaining all ferrous and non-ferrous metal fragments by the magnet and for metal detectors it is 1.0 mm for Fe, NonFe and 1.5 mm for SS. Magnets are checked at the end of each production run or at the end of each shift.
	5.2.6	Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.	Compliant	If metal fragments are found on the magnet both the operations manager and the SQFP are communicated, the products are held until the investigation is completed. Metal detectors are challenged every 2 hrs. Records from August, 2024 were reviewed.
	5.2.7	Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.	Compliant	Wood pallets are regularly monitored. All pallets observed by the auditor were found to be clean and in good repair.
	5.2.8	Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained.	Compliant	Knives used in production are monitored daily.
	5.2.9	When foreign material is removed by a protective device and investigation must be conducted to identify the source or cause of all unexpected materials. Records must be maintained.	Compliant	Protocols are documented in the policy manual. Records are maintained by the SQFP.
	5.2.10	Loose objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.	Compliant	Loose objects were not observed.
5.3 Product Rework	5.3.1	The responsibility and methods outlining how the product is reworked (recycled or recouped) shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel ii. Reworked product is clearly identified and traceable iii. Each batch of reworked product is inspected or analyzed as required before release iv. Inspections and analyses shall conform to the requirements for verification. v. Release of reworked product shall conform to product release requirements.	Compliant	Rework protocols are included in the policy manual.
	5.3.2	Records of all reworking operations shall be maintained.	N/A	Products are not reworked at this location.
5.4 Sampling & Testing	5.4.1	Based on risk, a raw materials testing protocol shall be in place that defines: i. Materials that require testing; ii. Methods and frequency of testing iii. Responsibility of testing iv. Acceptable limits v. Corrective actions for out of tolerance results Records of testing shall be maintained.	Compliant	The documentation providing sampling and testing protocols is included in SOP-03-03 dated 4/15/22. The document describes the process for sampling, inspecting and analyzing raw materials, work in progress and finished product.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.4.2	Based on risk, a finished product testing protocol shall be in place that defines: i. Products that require testing; ii. Methods and frequency of testing iii. Responsibility of testing iv. Acceptable limits v. Corrective actions for out of tolerance results Records of testing shall be maintained.	Compliant	Raw material and finished product testing records from the production of nutritional supplements processed in May, 2024 were reviewed. The sampling and testing protocols outline what needs to be checked by whom and at what frequency. Proficiency testing protocols have been implemented. Internal laboratory results are compared to external laboratory testing the verify proficiency. Outside laboratories are certified to ISO 17025.
5.5 Allergens	5.5.1	An allergen control policy shall be documented and implemented that includes a list of allergens in the facility per regulatory requirements and controls, including identification, used to prevent allergen cross-contamination. AUTO-FAIL: EVIDENCE OF CROSS-CONTACT BETWEEN NON-ALLERGENIC MATERIAL AND ALLERGENIC MATERIAL THAT WOULD RESULT IN A THREAT TO HEALTH AND A CLASS I OR CLASS II RECALL.	Compliant	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product is documented in the Allergen Control Program outlined in SOP-04-03 Rev 1 included in the policy manual.
	5.5.2	The facility must segregate raw materials/ingredients that contain allergens from those that are allergen free during storage. In facilities where full segregation is not possible, the facility must store like-above like only or where materials with the lowest number of allergens present to be stored on top. This requires common allergens to be present in all materials.	Compliant	Allergens are allowed to be stored over non-allergens if they are to be blended into the same product.
	5.5.3	The facility shall have an Allergen Validation Procedure, based on risk, in place that requires testing against all allergens of concern utilizing a scientifically justified method. The validation must be completed at least annually with records maintained.	Compliant	Allergen validation results for tree nuts were completed using allergen specific test kits.
	5.5.4	The facility has a documented Allergen Changeover Procedure that includes: i. A documented allergen clean-up that includes full sanitation of the area with a pre-op inspection completed by QA. ii. A documented check to ensure that all raw materials, finished product labels and packaging from the previous run has been removed from the processing area prior to start-up of the next production run. iii. A changeover matrix is in place that shows when an allergen changeover is required.	Compliant	The documented allergen changeover requirements are documented in the policy manual.
	5.5.5	Reworking of product that contain allergenic material must be conducted in a manner that does not contribute to the contamination of other products.	N/A	Products are not reworked at this location.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.5.6	The facility shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. AUTO-FAIL: OBJECTIVE EVIDENCE OF MISLABELED PRODUCT THAT CONTAIN ALLERGENS AND ARE NOT DECLARED ON THE LABEL.	Compliant	Label approval records are maintained by the SQFP. Label reconciliation records are documented in the production reports.
5.6 Unloading, Loading, and Transport Program	5.6.1	The facility shall have an implemented Trailer Inspection Program for incoming raw materials that includes inspections for: i. Pest activity ii. Evidence of Tampering iii. Trailer damage iv. Strong odors v. Excessive dirt/filth vi. Product temperatures (if applicable) vii. Trailer Set Temperature (if applicable) viii. Trailer Actual Temperature (if applicable) ix. Seal verification (except LTLs) Records of inspections shall be maintained.	Compliant	Methods for the transportation of products are documented (Transport and Delivery) in SOP-08-03 and SOP-08-02. Procedures and documentation were observed to be compliant with the requirements of the SQF code. Vehicles used to transport product are properly maintained. Loading practices are designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity. Loading check-off list including inspection results for cleaning, rodent, and seal number.
	5.6.2	If refrigerated or frozen raw materials are received, the product temperatures must be documented at the beginning, middle, and end of unloading.	N/A	There is no refrigerated transport.
	5.6.3	Materials shall be inspected, tested, or covered by COA to verify conformity with specified requirements prior to acceptance or use. The method of verification shall be documented.	Compliant	COAs and testing results were available for all raw materials received.
	5.6.4	If bulk loads are received: i. A wash ticket or confirmation of previous load must be documented to ensure there is no risk of product contamination ii. Bulk ports are locked at all times when not in use. A facility designee shall unlock the port for the truck driver iii. Bulk hosing is inspected prior to unloading. If found to be unclean, or if not used like product during the previous delivery, the product is not received.	N/A	Bulk loads are not received.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.6.5	The facility shall have an implemented Trailer Inspection Program for outgoing materials/products that includes inspections for: i. Pest activity ii. Evidence of Tampering iii. Trailer damage iv. Strong odors v. Excessive dirt/filth vi. Product temperatures (if applicable) vii. Trailer Set Temperature (if applicable) viii. Trailer Actual Temperature (if applicable) ix. Seal verification (except LTLs) Records of inspections shall be maintained.	Compliant	Trailer inspection records were available.
	5.6.5	Vehicles shall be pre-cooled prior to loading and shipping of finished product.	Compliant	There is no refrigerated transport.
5.7 Traceability & Recall	5.7.1	The facility shall have a recall program that includes the following: i. Definition of how the facility defines a "lot" ii. Recall Team with names and contact information iii. Recall team members roles and responsibilities iv. An outlined recall process, including the investigation, analysis, corrective action, preventive action, and product disposition v. Contact list for all customers, applicable certification bodies, and regulatory agencies. The responsibility for contacting these entities must be clearly defined.	Compliant	The facility has prepared a recall policy outlining protocols for required activities and responsibilities. The SOP is documented in the policy manual. The procedure includes the requirement to perform an annual regular trace exercise. Mock recall records are maintained by the SQFP. The mock recall reports dated 6/24/24 accounted for 100% recovery and was completed in under 2 hours. In addition, during the course of the audit a vertical trace exercise was completed on nutritional items packed on 5/24/24.
	5.7.2	The facility shall conduct at least one mock recall/traceability exercise per year that must include: i. Finished Product ii. Raw material iii. Food contact packaging	Compliant	The procedure includes the requirement to perform an annual regular trace exercise. Mock recall records are maintained by the SQFP. The mock recall reports dated 6/24/24 accounted for 100% recovery and was completed in under 2 hours. In addition, during the course of the audit a vertical trace exercise was completed on nutritional items packed on 5/24/24.
	5.7.3	Mock recall/traceability exercises shall demonstrate a 95-100% accounting of product within 4 hours, taking into account normal loss, waste, or shrinkage.	Compliant	Mock recall records are maintained by the SQFP. The mock recall reports dated 6/24/24 accounted for 100% recovery and was completed in under 2 hours. In addition, during the course of the audit a vertical trace exercise was completed on nutritional items packed on 5/24/24.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.7.4	Records of the mock recall/traceability exercises must be maintained and include: i. Total quantity of product made ii. Finished product shipped and destination, iii. Finished product on hand, iv. Finished product otherwise categorized (e.g., damaged, lost, samples), v. Finished product unaccounted for, vi. A calculated percent recovery, vii. Start and end times for the exercise.	Compliant	The mock recall reports dated 6/24/24 accounted for 100% recovery and was completed in under 2 hours. In addition, during the course of the audit a vertical trace exercise was completed on nutritional items packed on 5/24/24.
	5.7.5	If a mock recall/traceability exercise was completed and outside of set timeframe or % of accounted product, a documented corrective action must be completed.	Compliant	Protocols are documented in the policy manual. Records are maintained by the SQFP.
	5.7.6	Materials used in the process shall be traceable including: i. Ingredients ii. Rework iii. Carryover and Work in process iv. Food contact packaging materials AUTO-FAIL: THE LACK OF ANY SYSTEM TO TRACE INGREDIENTS AND/OR FINISHED PRODUCT AS PER REGULATORY REQUIREMENTS.	Compliant	All materials were observed to be traceable.
	5.7.7	Bulk ingredients, when used, shall maintain the same ability to be traced as other ingredients. If absolute traceability is not possible because of commingling, validated procedures shall be documented to ensure that full traceability of bulk ingredients is possible.	N/A	Bulk ingredients are not used.
5.8 Inventory Stock Rotation	5.8.1	A written procedure for ensuring effective stock rotation principles are applied shall implemented and maintained.	Compliant	The stock rotation protocols are documented in the policy manual. FIFI has been implemented.
	5.8.2	If “first in, first out” (FIFO) is not required for specific products, this shall be documented.	Compliant	he facility employs FIFO or customer requirements for stock rotation.

Section Name	Section Number	Audit Question	Rating	Evidence
5.9 RTE / High Risk Foods ***DEFINITION: Food or food product with known attributes for microbiological growth, physical or chemical contamination, or which may allow for the survival of pathogenic microbial flora or other contaminants which, if not controlled, may contribute to illness of the consumer. It may also apply to a food that is deemed high risk by a customer, declared high risk by the relevant food regulation or has caused a major foodborne illness outbreak.***	5.9.1	Airborne contaminants shall be minimized: i. Ready to eat processing and high risk area shall be positive air. Sufficient filtered air shall be brought into high risk/high care processing areas where potentially hazardous foods are exposed post lethality to provide a net positive pressure differential in the exposed product area(s) relative to surrounding areas. Positive pressure shall be demonstrable at all openings between higher risk and lower risk areas. ii. The creation of aerosols that could potentially disperse harmful organisms into the processing environment shall be strictly controlled when exposed product is present in the processing area and after sanitation has been completed and the area and equipment awaits the start of production.	N/A	This is not a high risk operation. Aerosols are adequately controlled.
	5.9.2	Protective clothing shall be utilized to reduce the risk of cross-contamination: i. Employees shall don distinctively colored clothing immediately prior to entry into the high risk/high care area. The clothing designated for these areas shall be protected from contamination. Disposable garments shall be changed prior to entering any high risk/high care area.	N/A	This is not a high risk facility. Smocks and disposable gloves are worn in product areas.
	5.9.3	The facility shall have a documented and implemented environmental monitoring program that includes the following: i. Identify the test microorganism(s) ii. Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites shall be adequate to determine whether preventive controls are effective. iii. Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples shall be adequate to determine whether controls are effective iv. Identify the (tests) conducted, including analytical method(s) used v. Include the laboratory conducting the testing (if applicable) vi. Corrective actions for out of tolerance results viii. Pathogen analyses shall not be performed at a plant laboratory unless there is an effective program to secure pathogen organisms from misuse. The pathogen testing laboratory shall comply with relevant regulatory requirements as well as the Good Laboratory (GLP) requirements. Laboratory Procedures and Documentation shall meet recognized standards. Labs certified to ISO 17025 shall be acceptable. Records of environmental monitoring must be maintained.	Compliant	The plant protocols are documented in SOP-04-02 dated 5/5/22. Sampling locations are randomly selected by processing zones. Samples are tested for Listeria sp., Salmonella and E.coli. Corrective action protocols are documented in the plant SOP. The twice monthly test results for the period July-August, 2024 were reviewed.

Section Name	Section Number	Audit Question	Rating	Evidence
	5.9.4	The facility shall have a documented and implemented finished product testing program that includes the following: i. Be scientifically valid; ii. Identify the test microorganism(s) or other analyte(s); iii. Specify the procedures for identifying samples, including their relationship to specific lots of product; iv. Include the procedures for sampling, including the number of samples and the sampling frequency; v. Identify the test(s) conducted, including the analytical method(s) used; vi. Identify the laboratory conducting the testing; and vii. Include corrective action procedures. Records of finished product testing must be maintained.	Compliant	The documentation providing sampling and testing protocols is included in SOP-03-03 dated 4/15/22. The document describes the process for sampling, inspecting and analyzing raw materials, work in progress and finished product. Raw material and finished product testing records from the production of nutritional supplements processed on 5/24/24 were reviewed. The sampling and testing protocols outline what needs to be checked by whom and at what frequency. Proficiency testing protocols have been implemented. Internal laboratory results are compared to external laboratory testing the verify proficiency. Outside laboratories are certified to ISO 17025.
6.0 Control of Facility				
6.1 Site Construction & Layout	6.1.1	Walls shall be finished and maintained to prevent the accumulation of dirt, minimize condensation and mold growth, and facilitate cleaning.	Compliant	Walls were clean and well maintained..
	6.1.2	Floors shall be suitably hard-wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious, be maintained in good repair and facilitate cleaning.	Compliant	Floors were adequately maintained.
	6.1.3	Where elevated walkways are adjacent to or pass over production lines, they shall be: i. designed to prevent contamination of products and production lines ii. easy to clean iii. correctly maintained.	Compliant	Walkways were adequately designed and maintained.
	6.1.4	Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination.	Compliant	Ceilings were adequately maintained.
	6.1.5	Doors (both internal and external) shall be maintained in good condition. At a minimum: i. external doors and dock levelers shall be close fitting or adequately proofed ii. external doors to open product areas shall not be opened during production periods except in emergencies iii. where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress.	Compliant	doors were adequately maintained.
	6.1.6	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.	Compliant	Lighting was adequate.
	6.1.7	Light bulbs and fixtures in areas where food products and packaging material are exposed are shielded or protected against breakage.	Compliant	Lights were protected.
	6.1.8	Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust.	Compliant	Ventilation was adequate.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.1.9	Drains shall be designed, constructed, and located so that the risk of contamination of materials or products is avoided. Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over processing lines.	Compliant	Drains were well maintained and free running.
6.2 Plant Utilities	6.2.1	The facility shall have a documented and implemented plant utilities program that includes the monitoring of Compressed Air, Water, Steam, Ice, or other gas systems such as Nitrogen or CO2.	Compliant	Utilities are adequately monitored.
	6.2.2	WATER USED IN PROCESSING, HANDWASHING, CLEANING, STEAM GENERATING, AND ICE CREATION MUST BE POTABLE AND MEET LOCAL REGULATORY REQUIREMENTS AT A MINIMUM. FAILURE TO MEET REGULATORY OR CUSTOMER SPECIFIC REQUIREMENTS RESULTS IN AUTO-FAIL.	Compliant	Potable water is supplied to the facility by a municipal water system. It is used for equipment, facility cleaning, and employee hygiene. Process water for sterilization is RO treated. Water is tested monthly for potability. Results from July, 2024 testing were reviewed.
	6.2.3	Facility's that are on public water/sewer shall send water in for testing at an ISO 17025 certified laboratory annually at a minimum to test the water supply for potability. Samples should be collected at point of use (i.e. hand wash station, hose drops, on-site ice maker, etc.). Testing should include microorganisms at a minimum.	Compliant	Potable water is supplied to the facility by a municipal water system. It is used for equipment, facility cleaning, and employee hygiene. Process water for sterilization is RO treated. Water is tested monthly for potability. Results from July, 2024 testing were reviewed.
	6.2.4	Facility's that are on well water shall send water in for testing at an ISO 17025 certified laboratory quarterly at a minimum to test the water supply for potability. Samples should be collected at point of use (i.e. hand wash station, hose drops, etc.). Testing should include heavy metals, microorganisms and chemicals at a minimum.	N/A	The facility does not operate wells.
	6.2.5	An adequate supply of water for processing and sanitation. The water supply must also be able to reach a temperature adequate for cleaning.	Compliant	Water supply was adequate.
	6.2.6	Steam used for product manufacture and that touches product contact surfaces, including food contact packaging materials, shall be potable. Documentation shall be made available that indicates all boiler water additives are approved for use with food.	Compliant	RO water is used for steam generation. RO water is tested.
	6.2.7	Water treatment program shall be documented along with training or qualification of personnel involved in the process. i. All chemicals used shall have food grade approval and be documented ii. Treatment records shall include testing results, amounts used, and when used. iii. Water treatment shall be verified by 3rd party vendors.	Compliant	RO water is monitored.
	6.2.8	Purchased ice (manufactured ice brought into the facility from an outside vendor) shall have annual certificates of potability or documented satisfactory microbiological testing results.	N/A	Ice is not used.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.2.9	Backflow prevention devices, gap breaks and check valves shall be verified by a certified 3rd party annually at a minimum. Records of the verification shall be available upon request for review.	Compliant	Backflow prevention devices are installed and were tested on 11/2/23
	6.2.10	Fans shall be on sanitation schedules and compressed air lubricants shall be food grade.	Compliant	Fans were well maintained. Lubricants were food grade.
	6.2.11	Compressed air that is in direct contact with the product shall be filtered at point of use.	Compliant	Compressed air for cleaning is tested at least annually.
	6.2.12	A Letter of Guarantee must be on file for all gases used in the facility that contact product or packaging materials (i.e. Nitrogen or CO2)	N/A	Gases are not used.
6.3 Equipment & Utensils	6.3.1	Utensils, tools, and containers shall be properly identified for their intended use by labels and/or color coding.	Compliant	Utensils were color coded.
	6.3.2	Utensils, tools, and containers used to handle edible material shall not be used to handle inedible material and are clearly identified and maintained.	Compliant	Utensils were adequately identified.
	6.3.3	All utensils, tools, and containers must be constructed of appropriate materials.	Compliant	utensils were constructed of food grade materials.
	6.3.4	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.	Compliant	Equipment was adequately maintained.
	6.3.5	Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable. AUTO-FAIL: OBSERVATION OF EQUIPMENT THAT IS CONTAMINATING PRODUCT THAT WOULD RESULT IN A CLASS I OR CLASS II RECALL.	Compliant	Equipment was stainless steel.
	6.3.6	Forklifts or other equipment used to move raw materials, finished products, and packaging throughout the facility must be clean and maintained in good condition.	Compliant	Forklifts did not present a food safety hazard.
6.4 Maintenance Program	6.4.1	The facility shall have a documented and implemented preventative maintenance program that covers all equipment and facilities.	Compliant	The PM program is documented manually.
	6.4.2	Nonfood grade materials or otherwise inappropriate materials including, but not restricted to, wire, tape, string, plastic or cardboard shall not be used for temporary repair in processing areas.	Compliant	Temporary repairs were not observed. Plant protocols are documented in the policy manual.
	6.4.3	There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe processing.	Compliant	Cleaning protocols are documented in the SSOPs
	6.4.4	Records of all maintenance activity shall be maintained.	Compliant	Maintenance records are maintained in the maintenance log book.

Section Name	Section Number	Audit Question	Rating	Evidence
6.5 Cleaning, Sanitation, & Housekeeping	6.5.1	A Master Sanitation Schedule shall be in place and kept up to date for all non-daily routine cleaning. The Master Sanitation Schedule shall include all areas of the facility.	Compliant	A master sanitation schedule is prepared and adequately documented.
	6.5.2	Documented cleaning procedures shall be implemented and include the following: i. Name of equipment being cleaned ii. Chemicals used for cleaning and sanitizing iii. Chemical concentration requirements iv. Equipment disassembly and reassembly instructions v. Detailed cleaning instructions	Compliant	SSOPs are prepared by the chemical service provider.
	6.5.3	Only chemicals approved for use in a food processing facility shall be used in the cleaning and sanitizing of equipment.	Compliant	Cleaning materials were acceptable. All materials contained SDS information.
	6.5.4	Chemical titrations shall be documented weekly at a minimum. If titrations are out of spec, corrective/ preventive actions are documented to address any potential product contamination that may have occurred due to the chemical concentration level.	Compliant	Chemical titrations are documented and included in the titration log book.
	6.5.5	The facility has a documented system in place to verify sanitation effectiveness. Acceptable forms of sanitation effectiveness include, but are not limited to, the use of ATP and/or APC/TPC.	Compliant	ATP testing is completed.
	6.5.6	The facility shall have a documented Pre-Operational Inspection program in place.	Compliant	Pre=op inspections are completed daily.
	6.5.7	Trained personnel shall document an inspection of the equipment to verify it is visibly clean prior to releasing the equipment to production.	Compliant	Equipment is inspected by QA.
	6.5.8	General Requirements: i. Wash down hose nozzles must be kept off the floor ii. Product and packaging materials must be protected during sanitation activities iii. Floors must be kept free of standing water and ice	Compliant	Hoses were on racks. There was no standing water.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.5.9	Chemical Storage: i. Chemicals are stored in a locked area, segregated from the storage of ingredients/raw materials, finished goods, and packaging materials. ii. The chemical storage area has restricted access. iii. The SDS' and labels are available for all chemicals stored in the chemical storage area.	Compliant	Chemical storage was adequate.
	6.5.10	All Sanitation containers shall be labeled with the chemical label from the manufacturer. Unlabeled containers shall not be allowed in the facility.	Compliant	Sanitation chemical containers were labelled.
6.6 Pest Control Program	6.6.1	The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin. AUTO-FAIL: OBSERVATION OF PESTS, PEST EXCRETA OR INFESTATION IN OR ON INGREDIENTS, PACKAGING, WORK IN PROCESS, OR FINISHED GOODS.	Compliant	The pest control program is documented in the PCM
	6.6.2	The pest and vermin management program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program. ii. Identify the target pests for each pesticide application. iii. Outline the methods used to prevent and/or eliminate pest problems. iv. Outline the frequency with which pest status is to be checked. v. Include on a site map the identification, location, number and type of bait stations set. vi. List the chemicals used. vii. Measure the effectiveness of the program to verify the elimination of applicable pests.	Compliant	The documented Integrated Pest Control procedure describes facility pest control program requirements, the methods of control and the use of chemicals on site for pest control in and around the facility. The program also includes the general requirements for use of a PCO with frequency, documentation, and training requirements listed.
	6.6.3	Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison shall not be used inside ingredient or animal food storage areas or processing areas.	Compliant	Electric insect control devices are maintained by the PCP.
	6.6.4	Records of pest control applications shall be maintained.	Compliant	Records are included in the PCM.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.6.5	Pesticides and other toxic chemicals: i. Be clearly labeled, stored, handled and applied by properly trained personnel. ii. Used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved. iii. ensure unused pest control chemicals and empty containers are disposed in compliance with regulatory requirements.	N/A	Pesticides are not stored on-site
	6.6.6	Pest control contractors shall be licensed and approved by the local relevant authority. If a pest control contractor is not used, company personnel shall be licensed and approved by local relevant authority.	Compliant	Licenses were included in the PCM.
	6.6.7	Pest control contractors, or properly licensed personnel, shall: i. Use only trained and qualified operators who comply with regulatory requirements ii. Use only approved chemicals iii. Provide a pest control management plan which will include a site map indicating the location of bait stations and traps iv. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments v. Provide a written report of their findings and the inspections and treatments applied.	Compliant	PCP is licensed and written reports issued.
6.7 Personnel & Amenities	6.7.1	Employees and contractors who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean, and in good condition. i. Snaps shall be used in lieu of buttons on all clothing and smocks exposed to the processing environment ii. No pockets above the waist are in any company issued uniforms. If pockets are above the waist, nothing can be stored in them.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.2	Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints unless a risk assessment indicates otherwise.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.3	Clothing must be stored in a manner that does not contribute to the risk of contamination (i.e. hung up, removed before entering restroom and break rooms, etc.).	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.4	False fingernails/fingernail polish/false eyelashes, etc. are not allowed in any processing area.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.5	No jewelry shall be allowed in the production area (receiving, processing, through shipping). Exceptions can be made for plain wedding bands, medic alert jewelry, and religious jewelry.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.7.6	Handwashing is required: i. Before starting work ii. Following each break iii. After using the restroom iv. After touching unsanitary surface v. After coughing, sneezing, or touching body parts vi. Anytime hands/gloves become soiled or contaminated Hand sanitizer and glove changes are not an acceptable substitute for handwashing.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.7	Handwashing Facilities: i. Shall be located at all entry ways intro the main processing area at a minimum ii. Shall have hot water available within 20 seconds iii. Shall have soap and single use paper towels available iv. Shall have instructions posted at all hand wash stations in language's understood by all employees	Compliant	Handwash stations were adequately maintained.
	6.7.8	Restrooms: i. Not open directly into the processing area. Restrooms that are located in the processing area have a vestibule separating the entrance to the restroom from the processing area. ii. Be maintained in a clean and sanitary manner. iii. Have hot water, soap and single-use paper towels available at all times. iv. All toilets are functioning properly. No toilet clogs are observed during on-site assessments. v. Associates shall not wear smocks/lab coats in the restrooms. The facility shall provide a designated place to hang these items for restroom breaks	Compliant	Restroom areas were adequate.
	6.7.9	Locker Rooms: i. Locker Rooms are maintained in a clean and sanitary manner. ii. Associates do not leave personal belongings on benches, on the tops of the lockers, or in any area that is not designed to store personal belongings. iii. Food shall not be allowed to be stored in lockers.	Compliant	Locker rooms were adequately maintained.
	6.7.10	Break Rooms / Cafeterias: i. Break rooms and Cafeterias are maintained in a clean and sanitary manner. ii. Areas around and behind microwaves, vending machines, coolers and storage shelves are kept clean to prevent pests. iii. Trash is not observed to be on tables or the floor.	Compliant	Break rooms were adequately maintained.
	6.7.11	A Blood Borne Pathogen Policy shall be in place to address any events that result in exposure to human blood.	Compliant	A blood borne pathogen policy is included in the policy manual.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.7.12	Associates with open sores, boils, and/or infected wounds are prohibited from working in any area where there is a possibility that food, ingredients, packaging material, and/or product contact surfaces could become contaminated.	Compliant	Personnel practices were acceptable. Protocols are included in the policy manual. Annual remaining is provided.
	6.7.13	Contractors and visitors, including drivers, shall be made aware of all procedures for access to premises and the requirements of the areas they are visiting, with special reference to hazards and potential product contamination. Contractors working in product processing or storage areas shall be the responsibility of a nominated person.	Compliant	A visitor and contactor policy is documented in the policy manual.
6.8 Storage Areas	6.8.1	Raw material, ingredient, packaging, and finished product storage areas shall remain clean, orderly, and free from spilled, damaged, or exposed products.	Compliant	Storage areas were clean and well maintained.
	6.8.2	Product shall be stored off the floor or on pallets An effective perimeter (18") shall be maintained between walls and ceilings	Compliant	Product is stored on pallets.
	6.8.3	Controlled Temperature Storage: i. Refrigerated, frozen, and other controlled temperature storage rooms shall be monitored at minimum daily, or through continuous recording and alarming devices, to ensure that appropriate temperatures are maintained for their contents (typically less than or equal to 40°F/4°C for refrigerated and equal to or less than 0°F/-18°C for frozen). ii. Temperature logs shall be maintained.	N/A	There is no refrigerated storage.
6.9 Waste Handling & Disposal	6.9.1	Internal and external waste collection containers and rooms housing waste facilities shall be managed to minimize risk. These shall be: i. clearly identified ii. designed for ease of use and effective cleaning iii. well maintained to allow cleaning and, where required, disinfection iv. emptied at appropriate frequencies. External waste containers shall be covered or doors kept closed as appropriate.	Compliant	Waste management was acceptable.

Section Name	Section Number	Audit Question	Rating	Evidence
	6.9.2	Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.	N/A	Inedible waste is not held for animal feed.
6.10 Outside Grounds	6.10.1	The external areas shall be maintained in good order. Where grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of contamination of the product.	Compliant	Outside grounds were adequately maintained.
	6.10.2	The building fabric shall be maintained to minimize potential for product contamination (e.g. elimination of bird-roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants).	Compliant	The building exterior was adequately maintained.