Health Sciences Certification

GMP Audit Report

Facility Name: Uintah Basin Manufacturing LLC DBA Uintah Basin Herbals

Address: 1392 East 1300 South, Vernal, Utah, United States

Facility # C0558577

Audit Type : NSF/ANSI 455-2 - 2018 Good Manufacturing Practices for Dietary Supplements

Audit# – Visit#: 3138792 - 2570925

Audit Date: 04-JAN-2022 to 06-JAN-2022

Summary of GMP Audit Results			
Critical*	**Major***	**Minor***	**Grade**
0	**0**	**0**	**A**

* NCs represents Nonconformances

NSF/ANSI 455-2 - 2018 Good Manufacturing Practices for Dietary Supplements

Company/Contact Information		Audit Information	
Facility# - Name	C0558577 - Uintah Basin Manufacturing LLC DBA Uintah Basin Herbals	**Audit# - Visit#**	3138792 - 2570925
		Audit Type	455-2GMP
		Template Version	1.5
Address	1392 East 1300 South, Vernal, Utah, United States, 84078	**Audit Category**	CERTIFICATION
		Audit Year	2022
Facility Contact	Mrs. Amber Sabin	**Period**	
Phone	435-823-0442		
Fax			
Email	amber@uintahbasinherbals.com	**Auditor**	Steven Ault
Audit Contact	Mrs. Amber Sabin	**Audit Start Time**	04-JAN-2022 09:00:00 AM
Corporate # - Name	C0558576 **-** Uintah Basin Manufacturing LLC DBA Uintah Basin Herbals	**Audit End Time**	06-JAN-2022 04:00:00 PM
Corporate Contact	Mrs. Amber Sabin		

This report summarizes the NSF/ANSI 455-2 - 2018 Good Manufacturing Practices for Dietary Supplements audit of C0558577 - Uintah Basin Manufacturing LLC DBA Uintah Basin Herbals.

The purpose of this audit is to evaluate the facility's compliance with the NSF/ANSI 455-2 - 2018 Good Manufacturing Practices for Dietary Supplements program requirements. The audit focuses on the following areas: administration and regulatory, quality management, CAPA, complaints, supplier qualification, product safety, facilities, production and process controls, laboratory controls, warehouse and distribution. The audit represents a finite sample of processes and records and may not have captured every instance of potential nonconformance.

Draft findings from the audit were presented during the closing meeting. Any nonconformances cited are detailed in this report. Corrective action for these must be submitted through NSF Connect and approved within 10 business days of receipt of the corrective action notification. If you have any questions regarding the report, please feel free to contact your Account Manager Seema Mallya at 1-734-214-6130.

Audit Result

Audit Report	Critical	Major	Minor
07-JAN-2022 CERTIFICATION	**0**	**0**	**0**

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Audit Nonconformance Summary			
SECTION	**Critical**	**Major**	**Minor**
Facility Information	0	0	0
NSF 455 Certification Program Requirements	0	0	0
Audit Administration	0	0	0
Context of the organization	0	0	0
Leadership	0	0	0
Planning	0	0	0
Support	0	0	0
Operation	0	0	0
Performance evaluation	0	0	0
Improvement	0	0	0
TOTAL	**0**	**0**	**0**

Certification Requirements Summary		
Certification Requirements	**Acceptable**	**Not Acceptable**
	1	0

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Facility Information	
Policy Reference	**Question/Notes**
1	Facility Type & Description **Single** Contract Manufacturing or Co-Manufacturing Manufacturing, Warehouse & Distribution On-Site
2	Product Technologies (Key Manufacturing Stages) **Multiple** Distribution (Receiving & Shipping) Observed during plant tour. Finished product ready to ship: Item F-714, Lot 21F7141103-101; Item F-724, Lot 21F7241013-100; Item F-603, Lot 21F6031007-100 Liquid Formulation Extraction process: turmeric root, Lot 22105-200; astragalus root, Lot 220105-201; organic herbal blend, Lot 22F5230105-101 Manufacturing Mixing Weigh out and blending: Item F-733, Lot 22F4000104-100 Primary Packaging Bottling: Item F-733, Lot 22F7330103-101 Labeling: Item F720, Lot 21F7201118-100 Warehouse Observed during plant tour. Raw material, WIP, and finished product storage.
3	Product Category (Product Type) **-** Ingestible Liquid Ingestible Oil
4	Exclusions: (5.3.4 - Exclusion of products or processes from the scope of the certification audit shall be permitted. The exclusion of products is acceptable only where (1) the excluded products can be clearly differentiated from the products in scope, and (2) those products are produced in a physically segregated area of the site.) **Not applicable** **There are no exclusions.**
5	Site is operational for the defined scope during the audit (5.4.3 - The site shall ensure that the operations for each product technology and product category will be operational for the intended scope of certification). **Acceptable**

NSF 455 Certification Program Requirements	
Policy Reference	**Question/Notes**
PP - 12	Audit Type: **On-site** NSF 455 Certification Program
GP - 14	Prompt and thorough access shall be granted to the auditor during the NSF audit. **Acceptable**
GP - 25	Documents requested during the NSF audit shall be provided in a timely manner. **Acceptable**
GP - 28	The NSF 455 Certification Mark shall not be used on materials, ingredients, components, or finished products. **Acceptable**

Audit Administration	
Policy Reference	**Question/Notes**
1	People at the opening Meeting (Recorded the Full Name & Positions of those attending using the format Name: Role separated by commas) **Amber Sabin: CEO, Taleah Garisau: QC/QA Director, Justin Downing: Executive Assistant/Sales**

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2	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details. **Facility is located at 1392 East 1300 South, Vernal, UT 84078 USA.** **There is a single building totaling 20,000 sq. ft. that houses all operations: offices, manufacturing, warehousing, receiving, and distribution. Facility began operations in April 2020.There are currently 26 full time and 5 temporary employees. There is a single shift: M-Th - 5am - 3:30pm.**
3	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **Amber Sabin, Taleah Garisau, Justin Downing**
4	Auditor Recommendation. **Recommendation not provided.** **Audit grade decision is made after technical review is complete.**

Context of the organization		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.1.1	Quality responsibilities shall be distinct and separate from operations. [21C FR 111.12(b)] **Reviewed current organizational chart dated 12-6-21. Quality is separate from operations.**	**Compliant**
4.1.2	Quality control (QC) operations shall be identified and implemented. [21 CFR 111.65] **P-024 Rev 3 Quality Assurance / Quality Control Operations**	**Compliant**
4.1.3	US FDA facility and Bioterrorism registrations and process filings shall be current and maintained. (physical address, scope, expiration dates, etc.) **FDA Facility registration number xxxxx6328, expiration 12-31-22.**	**Compliant**

Leadership		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.2.1	Procedures shall be established for the responsibilities of the QC operations. [21 CFR 111.103 and 21 CFR 111.105] **P-024 Rev 3 Quality Assurance / Quality Control Operations**	**Compliant**
4.2.2	Management shall conduct biennial reviews to assess the suitability and effectiveness of the quality system. **P-024 Rev 3 Quality Assurance / Quality Control Operations** **Procedure establishes the Responsibilities for Senior Management reviews.**	**Compliant**
4.2.3	QC responsibilities for laboratory test methods and examinations used to test each specification requirement shall be defined, shall be appropriate for their intended use and shall be followed. Test methods and examinations shall be used according to established criteria. [21 CFR 111.320]	**Compliant**
4.2.4	QC operations and authority shall be established for master manufacturing record and batch production record. [21 CFR 111.123(a1),(a2),(a3)] **P-026 Rev 2 Master Manufacturing Records**	**Compliant**
4.2.5	QC operations and responsibilities shall include the authority to reject any component or product if any specification is not met. [21 CFR 111.113(a)]	**Compliant**
4.2.6	Sanitation supervisors shall be assigned and shall be qualified. [21 CFR 111.15(k)] **QC/QA Director is acting Sanitation Supervisor.**	**Compliant**
4.2.7	Competent supervisory personnel shall be responsible for ensuring transportation operations are conducted in compliance with 21CFR 1.908. [21 CFR 1.908]	**Compliant**
4.2.8	Procedures shall be established that define work requirements for personnel to prevent microbial contamination due to a health condition. [21 CFR 111.10(a)] **P-601 Rev 2 Personal Hygiene**	**Compliant**
4.2.9	Hygienic practices shall be established to include appropriate garments, personal hygiene, hand washing, and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled or contaminated. [21 CFR 111.10(b1),(b2),(b3)] **P-001 Rev 3 Personal Practices**	**Compliant**

4.2.10	Procedures shall be in place for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on the use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures shall be established to prevent contamination from all potential sources. [21 CFR 111.10(b5),(b6),(b8),(b9)] **P-001 Rev 3 Personal Practices**	**Compliant**
4.2.11	Procedures shall be in place for the control of jewelry and other personal care items. [21 CFR 111.10(b4)] **P-001 Rev 3 Personal Practices**	**Compliant**
4.2.12	Visitor (regulator, contractor, customer, non-site employee, etc.) policy and procedures shall be established. **P-062 Rev 2 Plant Visitor**	**Compliant**

Planning		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.3.1	A hazard analysis shall be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of dietary supplement to determine whether there are hazards requiring specifications and process controls. [21 CFR 111.70 & 21 CFR 117.130] **P-605 Rev 3 HARPC Program** **HACCP Decision Tree Flow Chart Rev 1, 4-20-20** **HACCP Process Flow Char Rev 1, 8-20-20** **Hazard Analysis Critical Control Point Rev 1, 4-20-20** **HACCP Hazard Analysis Worksheet Rev 1, 4-20-20**	**Compliant**
4.3.2	A risk-based supplier qualification program is established and implemented for all ingredients. The program includes a supplier/ingredient risk evaluation, appropriate qualification activities as determined by the risk evaluation, and assurance that only approved suppliers are used. [21 CFR 117.405 & 21 CFR 117.410] **P-039 Rev 3 Supplier Qualification Program**	**Compliant**
4.3.3	Manufacturing processes shall be designed to produce a product that consistently meets specifications. [21 CFR 111.355]	**Compliant**
4.3.4	Production and processes shall be designed to ensure the quality of the product and the QC unit has approved the control systems. [21 CFR 111.60]	**Compliant**
4.3.5	Specifications shall be established for components, in-process materials, labels, packaging components, and finished product. The basis is adequately documented for how meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the dietary supplement specifications will be met. [21 CFR 111.70] **P-019 Rev 2 Specifications**	**Compliant**
4.3.6	A crisis management plan is developed to manage significant disruptive events, including, but not limited to, natural disasters and catastrophic events that may impact the ability of the manufacturer to deliver a safe product. **UBH Safety Plan and Crisis Management Plan Rev 2, dated 11-23-21**	**Compliant**

Support		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.4.1	A master site plan or facility diagram/floor plan shall be on file reflecting the current layout of the building. **Reviewed current facility diagram which show both pedestrian and forklift traffic flows.**	**Compliant**
4.4.2	All facilities shall be of adequate size, construction, and design for their intended use. [21 CFR 111.20(a)]	**Compliant**
4.4.3	Working areas shall have adequate access and space, aisles are clear, etc. to allow for persons to perform their duties and protect against contamination or mix-ups. Use of fans and other air-blowing equipment shall be located and operated in a manner that minimizes the potential for contamination with particulates and microorganisms. [21 CFR 111.20(d1v), 21 CFR111.20(d2)]	**Compliant**
4.4.4	Grounds shall be properly maintained through the removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc. [21 CFR 111.15(a1),(a2),(a3)] **Exterior grounds were observed to be properly maintained.**	**Compliant**
4.4.5	Entrances to the facilities shall be properly controlled and maintained to prevent contamination. [21 CFR 111.15(a5)] **All exterior entrances were observed to be properly controlled and sealed.**	**Compliant**

4.4.6	In areas where open vessels are used, there shall be adequate protection against contamination including the use of protective coverings, physical location, use of skimming equipment. [21 CFR 111.20(g)]	**Compliant**
4.4.7	Production areas shall not provide harborage for pests, pest infestation, filth, etc. (e.g., adequate screening and other measures are used). [21 CFR 111.20(h)]	**Compliant**
4.4.8	Production area walls, floors, ceilings shall be adequately cleaned and shall be kept in good repair. [21 CFR 111.20(d1i)]	**Compliant**
4.4.9	Fixtures, ducts, piping, etc., are kept clean, shall not drip or leak or provide a source of condensation that could contaminate components, products, or product contact surfaces. [21 CFR111.20(d1ii)]	**Compliant**
4.4.10	Plumbing shall be of adequate size and design for the intended usage. [21 CFR 111.15(f)]	**Compliant**
4.4.11	Floor drainage shall be adequate providing immediate and continuous drainage, with no pooling and equipped with proper drain covers, etc. [21 CFR 111.15(f4)]	**Compliant**
4.4.12	For any automated, mechanical, or electronic equipment the manufacturer shall have established appropriate controls to ensure that equipment functions in accordance with its intended use, including power backup for critical systems. [21 CFR 111.30(e)]	**Compliant**
4.4.13	Toilet and hand washing facilities shall be provided, shall be of adequate number and location, shall be kept clean, and shall not be a potential source of contamination to components, products, contact surfaces, etc. [21 CFR 111.15(h)] **P-011 Rev 2 Hand Washing Facilities**	**Compliant**
4.4.14	Hand washing facilities shall be constructed and located in appropriate areas to ensure proper hand washing of personnel. [21 CFR 111.15(i)]	**Compliant**
4.4.15	Appropriate changing rooms shall be available and have adequate storage of personal effects. [21 CFR 111.10(b7)]	**Compliant**
4.4.16	Waste treatment and disposal shall be adequate and does not provide a source of potential contamination. [21 CFR 111.15(a4)]	**Compliant**
4.4.17	Solid waste and trash shall be disposed of appropriately, not allowed to accumulate, and does not provide a potential source of contamination to components, products, contact surfaces, etc. [21 CFR 111.15(j)]	**Compliant**
4.4.18	Hazardous waste shall be properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. [21 CFR 111.15(j4)] **Facility does not generate any hazardous waste.**	**Not Applicable**
4.4.19	Sewage and waste disposal shall be properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc. [21 CFR 111.15(g)]	**Compliant**
4.4.20	Procedures and programs shall be established for maintaining equipment including for calibration of all instruments, controls, automated, mechanical, laboratory, and electronic equipment, etc. [21 CFR 111.25] **P-061 Rev 2 Calibration Program** **P-017 Rev 4 Equipment Calibrations**	**Compliant**
4.4.21	Instruments and controls that are important to product quality and safety shall be accurate and precise, adequately maintained, and adequate in number. [21 CFR 111.27(a6)]	**Compliant**
4.4.22	Complete records shall be made and kept of any calibration of instruments and controls that are important to product quality and safety. [21 CFR 111.35(b3)] **Reviewed current calibration records for scales, temperature monitors, and Blichman extractor temperature monitors.**	**Compliant**
4.4.23	QC operations reviews and approves all processes and/or procedures for calibrating equipment, instruments, and controls; including the periodic review of calibration records, etc. [21 CFR 111.117]	**Compliant**
4.4.24	Procedures shall be established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. [21 CFR 111.15(d1),(d2)]	**Compliant**
4.4.25	Pest control procedures shall be established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc. [21 CFR 111.15(d3)] **P-007 Rev 2 Pest Control**	**Compliant**
4.4.26	Records shall be maintained for plant cleaning and pest control in accordance with Subpart P - Records and Recordkeeping. [21 CFR 111.23(a),(b)]	**Compliant**
4.4.27	Adequate ventilation and airflow shall be provided in all areas of the facility. [21 CFR 111.20(d1iii)]	**Compliant**
4.4.28	Adequate lighting shall be provided in all production areas, examination areas, where equipment is cleaned, examined, etc.	**Compliant**
4.4.29	Lighting that shall be suspended or located above areas where materials or equipment are exposed shall use safety-type bulbs or the facility shall be constructed in a manner that will protect against contamination with glass, etc. [21 CFR 111.20(f)]	**Compliant**
4.4.30	Temperature and humidity control equipment shall be of adequate design for its intended function and is functioning properly. [21 CFR 111.20(d1iv)] **P-015 Rev 3 Equipment and Utensils** **Temperatures are monitored and documented 3 times daily during operations for Processing, Bottling, Labeling& Packaging, and Warehouse Areas. Reviewed logs for 12-20-21, 12-21-21, and 1-3-22. The form is also used to document ATP testing results for cleaning/sanitizing verification.**	**Compliant**

4.4.31	Controls shall be in place to verify the backgrounds of new, contracted, seasonal and temporary employees prior to hiring. **Background checks are performed prior to hiring.**	**Compliant**
4.4.32	Personnel shall be qualified and have adequate training, experience and/or education necessary to perform job functions. [21 CFR 111.12(c) & 21 CFR 117.4] **P-003 Rev 2 Employee Training** **Reviewed training records for Operations Manager, QC/QC Director, Warehouse Supervisor, and Warehouse Hourly. Also reviewed records of attendance for custom cGMP, FSVP, Environmental Monitoring, and Labeling trainings performed August and October 2021.**	**Compliant**
4.4.33	Procedures shall be established to determine the requirements and qualifications (such as education, training, or experience) for personnel who will supervise activities. [21 CFR 111.13(a), (b) & 21 CFR 117.4]	**Compliant**
4.4.34	Records shall be maintained documenting compliance to established procedures that ensure that supervisors are appropriately qualified by education, training, or experience. [21 CFR 111.14(a), (b) & 21 CFR 117.4]	**Compliant**
4.4.35	Job descriptions shall be available for all personnel and personnel have received food safety, GMP, and appropriate training for their assigned functions. [21 CFR 111.12(a) & 21 CFR 117.4] **Reviewed job descriptions for Warehouse Supervisor, Warehouse Hourly, QA/QC Director, and Operations Director.**	**Compliant**
4.4.36	A document control program shall be established and followed outlining the initiation, formatting, review, approval, distribution (to include personnel training requirements), document storage, change control, retention, and disposal of documents and records. [21 CFR 111.105] **P-063 Rev 2 Document Management**	**Compliant**
4.4.37	Good documentation practices shall be established and followed concerning paper and electronic documents and records. [21 CFR 111.105] **GDP requirements are established and part of GMP training.**	**Compliant**
4.4.38	QC operations shall prepare and maintain all records required by Subpart F - Production and Process Control System: Requirements for Quality Control. [21 CFR 111.140]	**Compliant**
4.4.39	Records shall be maintained of specifications, supplier qualification, and testing to ensure product meets purity, strength and composition. [21 CFR 111.95]	**Compliant**
4.4.40	Receiving records shall be made and kept for components, packaging, and labels, and for products received for packaging and labeling. [21 CFR 111.180]	**Compliant**
4.4.41	Procedures shall be established that describe the requirements for record retention under Subpart P - Records and Recordkeeping. [21 CFR 111.605] **P-037 Rev 2 Records Retention and Disposition**	**Compliant**
4.4.42	Records required by 21 CFR 111 shall be maintained for at least one year after the shelf life date or at least two years beyond the date of distribution of the last batch associated with those records. [21 CFR 111.605(a)]	**Compliant**
4.4.43	All records shall be maintained as original record, as true copies or as electronic records. [21 CFR 111.605(b)]	**Compliant**
4.4.44	QC operations shall maintain appropriate records as required. [21 CFR 111.325]	**Compliant**
4.4.45	Electronic GMP inventory records that are created, modified, maintained, archived, retrieved, or distributed by a computer system, shall be 21CFR11 compliant. [21 CFR 11]	**Compliant**
4.4.46	Backup electronic files shall be maintained of the following; current software programs, outdated software programs that may be necessary to retrieve past records, and data that was entered. Backup files shall be an exact and complete record and are secure from alterations, erasures, or loss and damage. [21 CFR 111.35(b5i), (b5ii)]	**Compliant**

Operation		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.5.1	Areas shall be clearly defined with adequate space to allow for effective receiving, inspection, holding and staging, component and finished good quarantine, finished goods, dietary supplements, packaging, and labeling. [21 CFR 111.20(b),(c1),(c2),(c3)] **P-603 Rev 2 Receiving Material** **P-020 Rev 2 Sampling, Testing, Releasing and Approving for Use Raw Material Components and Dietary Supplements**	**Compliant**
4.5.2	There shall be adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials. [21 CFR 111.20(c)] **P-602 Rev 2 Preventing Cross-Contamination During Storage and Preparation**	**Compliant**

4.5.3	The use of wood and non-wood pallets is controlled to prevent possible contamination of exposed raw materials and products. **P-063 Rev 2 Wood Pallets**	**Compliant**
4.5.4	Areas shall be separate for laboratory analysis and supplies. [21 CFR 111.20(c4),(c5),(c6),(c7)] **There is not on-site laboratory.**	**Not Applicable**
4.5.5	Equipment shall be of appropriate design and construction (corrosion-resistant, made of non-toxic materials, seamless (if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants)) so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. Equipment shall be installed and maintained to facilitate cleaning and are inspected at routine intervals for signs of wear, damage, etc. [21 CFR 111.27(a3i),(a3ii),(a3iii)]	**Compliant**
4.5.6	Utensil surfaces shall be corrosion-resistant, made of nontoxic materials, maintained to facilitate cleaning, and are inspected at routine intervals for signs of wear, damage, etc. [21 CFR 111.27(a3i),(a3ii),(a3iii)]	**Compliant**
4.5.7	Equipment logbooks shall be maintained for each equipment and include the date of use, and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is in the batch record). [21 CFR 111.35(b2)]	**Compliant**
4.5.8	Automated, mechanical, laboratory or electronic equipment shall be suitable for intended use, functioning properly, and be adequately designed. [21 CFR 111.30(a),(b),(c),(d),(e)]	**Compliant**
4.5.9	Documentation shall be maintained of the controls used that ensure that equipment functions in accordance with its intended use. [21 CFR 111.35(b6)]	**Compliant**
4.5.10	Disposable items (single-service) shall be stored in appropriate containers; handled, used, dispensed, and disposed of in a manner that protects against contamination. [21 CFR 111.27(d5)]	**Compliant**
4.5.11	All equipment including freezers, refrigerators, etc., that are used to hold components or dietary supplements shall be adequately designed and functioning properly. [21 CFR 111.27(a5)]	**Compliant**
4.5.12	Process gases that are used and contact dietary supplements, components, and contact surfaces shall be controlled so as not to cause contamination (e.g., filters). [21 CFR 111.27(a7)] **Compressed air is tested semi-annually at point-of-use as part of Environmental Monitoring Program.**	**Compliant**
4.5.13	The production facility shall be maintained in a clean and sanitary condition and in a proper state of repair. [21 CFR 111.15(b1), (b2)] **Production areas were observed to be maintained in clean and sanitary condition and in proper state of repair.**	**Compliant**
4.5.14	Procedures shall be established for cleaning of the plant. [21 CFR 111.16] **P-052 Rev 2 Sanitation Process Standards** **P-005 Rev 3 Facilities Sanitation**	**Compliant**
4.5.15	All equipment, instruments, utensils, contact surfaces, etc., shall be maintained, cleaned and sanitized (to include disassembly as required by procedure) as necessary. [21 CFR 111.27(d)] **P-016 Rev 2 Equipment and Utensils Cleaning and Sanitization** **P-606 Rev 2 Sanitation Effectiveness**	**Compliant**
4.5.16	Procedures for maintenance, cleaning, and sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation shall be maintained. [21 CFR 111.35(a),(b1iii) & 21 CFR 111.25(c)] **P-018 Rev 2 Equipment Maintenance** **P-005 Rev 3 Facilities Sanitation** **Reviewed Processing Room daily Cleaning Log dated 12-21-21.**	**Compliant**
4.5.17	Cleaning and sanitizing compounds shall be established for cleaning the facility. These agents shall be safe and adequate under the conditions of use; and shall be free of organisms that are of public health significance. [21 CFR 111.15(c1), 21 CFR 111.27(d6), & 21 CFR 117.35(b1)] **P-006 Rev 2 Cleaning and Sanitizing Agents** **Reviewed Approved Chemical List dated 11-3-21.**	**Compliant**
4.5.18	Cleaning and sanitizing agents, lubricants, pesticides, chemicals, and fungicides shall be identified, used, and held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials. [21 CFR 111.15(c3)] **All chemicals were observed to be properly labeled and stored.**	**Compliant**
4.5.19	Low moisture processing: Equipment, utensils, and contact surfaces shall be dry and sanitized. If wet-cleaned, drying and sanitization shall be performed. [21 CFR 111.27(d2)]	**Compliant**
4.5.20	Wet processing: Contact surfaces shall be cleaned and sanitized before use and after any interruptions. [21 CFR 111.27(d3)]	**Compliant**
4.5.21	Procedures shall be established for cleaning and sanitizing all filling and packaging equipment and utensils. [21 CFR 111.415(a)] **P-016 Rev 2 Equipment and Utensils Cleaning and Sanitization**	**Compliant**
4.5.22	Surfaces that do not come into direct contact with components or dietary supplements shall be cleaned. [21 CFR 111.27(d4)]	**Compliant**

4.5.23	Portable equipment and utensils shall be properly stored after cleaning and sanitization. [21 CFR 111.27(d7)]	**Compliant**
4.5.24	Supplier qualification procedures shall be established and include initial qualification, periodic examination (requalification), and procedures for disqualification. [21 CFR 111.75(a2iiA),(b),(c),(d),(e)] **P-039 Rev 3 Supplier Qualification Program** **Vendor qualification is documented on Supplier Verification Form. Reviewed Supplier Verification Forms for bulk herbs, glycerin, and janitorial services providers.**	**Compliant**
4.5.25	Direct importers of components, bulk dosage forms, or finished dietary supplements shall be established and implemented a foreign supplier verification program (FSVP). [21 CFR 1.511] **Facility does not directly import any components, bulk dosage forms, or finished dietary supplements.**	**Not Applicable**
4.5.26	Receiving, sampling, testing, release procedures shall be established to fulfill Subpart G - Production and Process Control System: Requirements for Components, Packaging, and Label. [21 CFR 111.153] **P-603 Rev 2 Receiving Material** **P-057 Rev 3 Materials Testing** **P-020 Rev 2 Sampling, Testing, Releasing and Approving for Use Raw Material Components and Dietary Supplements**	**Compliant**
4.5.27	QC operations shall review and approve components, labels and packaging materials for intended use. [21 CFR 111.120] **P-025 Rev 2 Requirements for Raw Material Components, Packaging Components, Labels and Products Received for Packaging or Labeling as Dietary Supplements**	**Compliant**
4.5.28	A planned deviation process shall be established to expedite the approval of raw materials, packaging materials, and other component suppliers as necessary on an emergency basis. **P-023 Rev 2 Treatments, In-Process Adjustments and Reprocessing.**	**Compliant**
4.5.29	The water supply and delivery system shall be safe and sanitary. Water that may contact a product contact surface or is, in fact, a component shall meet U.S. federal, state and local requirements for drinking water. [21 CFR 111.15(e), (f3) & 21 CFR 117.37(a)] **P-008 Rev 2 Water Supply** **Purified water is used as a component. Water is tested weekly.**	**Compliant**
4.5.30	Water sources shall not act as a potential source of contamination of the dietary supplement, either due to water purity or due to the configuration and construction of the water delivery system.	**Compliant**
4.5.31	Backflow and cross-connection prevention shall be in place. [21 CFR 111.15(f5)] **Reviewed Cross Connection Control Hazard Assessment Inspection Report from local area water provider dated November 12-1-21. Reviewed Cross Connection Control Survey for internal backflow assemblies in manufacturing dated 7-29-20.**	**Compliant**
4.5.32	Records shall be maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15(e2). [21 CFR 111.23(c)] **Reviewed water testing results for cleaning water, purified water, and glycerin water.**	**Compliant**
4.5.33	QC requirements shall be established for packaging materials and labels. [21 CFR 111.160]	**Compliant**
4.5.34	Packaging and labeling materials shall be visually examined, at a minimum, and shall be reviewed against the supplier's invoice, guarantee, or certification to determine conformance with specifications. [21 CFR 111.75(f) & 21 CFR 111.155]	**Compliant**
4.5.35	QC requirements shall be established for products that are received for packaging and labeling as a dietary supplement and bulk finished product. [21 CFR 111.165]	**Compliant**
4.5.36	For products that are received for packaging and labeling, visual examinations shall be performed, and documentation is available to determine whether the product meets established specifications. [21 CFR 111.75(e)]	**Compliant**
4.5.37	Written procedures shall be in place for retesting materials to extend shelf life. **P-057 Rev 3 Material Testing**	**Compliant**
4.5.38	Weighing operations shall be done in a controlled area so as to not cause contamination. **P-055 Rev 2 Formula Blending**	**Compliant**
4.5.39	Master manufacturing records shall be prepared for each unique formulation and batch size of the dietary supplement. [21 CFR 111.205(a)] **P-026 Rev 2 Master Manufacturing Records**	**Compliant**
4.5.40	The master record shall identify specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. [21 CFR 111.205(b1),(b2)]	**Compliant**
4.5.41	Master manufacturing records shall contain all the required elements as defined in 21 CFR111.210. [21 CFR 111.210]	**Compliant**
4.5.42	For each manufactured batch of dietary supplement, the batch production record shall accurately follow the master manufacturing record with all steps being performed, and it shall contain complete information related to the production and control of the batch. Batch production records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21 CFR 111.255] **P-027 Rev 2 Batch Production Records**	**Compliant**

4.5.43	The batch record shall follow the master record and each step shall be performed appropriately. [21 CFR 111.260] **Reviewed batch records for:** **1) Item F-714, Lot 21F7141103-101** **2) Item F-724, Lot 21 F7241110-100** **3) Item F-603, Lot 21 F6031007-100**	**Compliant**
4.5.44	Manufacturing operations shall be conducted using adequate sanitation principles. [21 CFR 111.360] **P-016 Rev 2 Equipment and Utensils Cleaning and Sanitization**	**Compliant**
4.5.45	Throughout the manufacturing process precautions shall be taken to prevent contamination, such as microbial, filth, chemical, foreign material, etc. [21 CFR 111.365(a),(b),(c),(d),(e),(f),(g)] **P-602 Rev 2 Preventing Cross-Contamination During Storage and Preparation**	**Compliant**
4.5.46	A food allergen control program shall be in place. [21CFR117.80] **P-605 Rev 2 Allergens Control Management** **Facility does not currently source or store any allergenic materials.**	**Compliant**
4.5.47	Manufacturing operations shall include controls in manufacturing steps to prevent contamination, including metal detection. [21 CFR 111.365(h),(i)] **P-058 Rev 3 Glass and Brittle Plastic** **P-070 Rev 1 Heavy Metal Detection**	**Compliant**
4.5.48	Manufacturing operations shall include the identification of all process lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number, and when necessary, the phase of manufacturing. [21 CFR 111.365(j),(k)]	**Compliant**
4.5.49	Production and process control systems shall be implemented for each production process and/or product. [21 CFR 111.55] **P-053 Rev 2 Extraction Process** **P-055 Rev 2 Formula Blending** **P-056 Rev 2 Bottling**	**Compliant**
4.5.50	Records shall be established and shall be maintained to meet the requirements of Subpart K – Production and Process Control System: Requirements for Manufacturing Operations. [21 CFR 111.375]	**Compliant**
4.5.51	A master manufacturing record shall include instructions for filling, assembling, packaging, labeling, and other related operations. [21 CFR 111.415]	**Compliant**
4.5.52	Procedures shall be established for all packaging and labeling operations. [21 CFR 111.403] **P-009 Rev 2 Packaging and Labeling**	**Compliant**
4.5.53	QC operations shall be established for packaging and labeling. [21 CFR 111.127] **P-056 Rev 2 Bottling**	**Compliant**
4.5.54	Packaging and labeling of the finished packaged and labeled dietary supplement shall be visually examined, at a minimum, to determine that the correct packaging and labeling has been used. [21 CFR 111.75(g)]	**Compliant**
4.5.55	The condition of the packaging shall meet the specifications required to ensure the quality of the dietary supplements being packaged. [21 CFR 111.410(a)]	**Compliant**
4.5.56	Packaging and labels shall be controlled for issuance and are reconciled after use. [21 CFR 111.410(b)] **P-041 Rev 3 Label Management**	**Compliant**
4.5.57	Records shall be maintained to allowa complete history and control of the packaged and labeled dietary supplement through distribution. [21 CFR 111.410(d)]	**Compliant**
4.5.58	Separation shall be implemented to prevent mix-ups with other components and dietary supplements. [21 CFR 111.415(d)]	**Compliant**
4.5.59	Filling and packaging operations shall be appropriately protected from contamination sources (e.g., airborne) by using sanitary procedures. [21 CFR 111.415(b),(c)]	**Compliant**
4.5.60	Procedures shall be established to identify unlabeled materials that will be held for future labeling operations to prevent mix-ups. [21 CFR 111.415(e)]	**Compliant**
4.5.61	Procedures shall be established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement. [21 CFR 111.415(f)]	**Compliant**
4.5.62	Disposal procedures shall be established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used. [21 CFR 111.415(h)]	**Compliant**
4.5.63	Records shall be established and are being maintained to meet the requirements of Subpart L – Product and Process Control System: Requirements for Packaging and Labeling Operations. [21 CFR 111.430]	**Compliant**
4.5.64	QC personnel shall authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency. [21 CFR 111.113(b)] **P-023 Rev 2 Treatments, In-Process Adjustments and Reprocessing**	**Compliant**
4.5.65	Reprocessing controls shall be established and meet all requirements and have been approved by the QC unit. [21 CFR 111.90(a),(b)]	**Compliant**
4.5.66	All repackaging or relabeling operations shall be first approved by the QC unit. [21 CFR 111.420(a)]	**Compliant**
4.5.67	QC unit shall disposition each batch of repackaged or relabeled dietary supplement prior to release for distribution. [21 CFR 111.420(c)]	**Compliant**

4.5.68	Dietary supplements, components, in-process materials, labeling, and packaging shall be held under the appropriate conditions of temperature, humidity, and light. Storage conditions shall not lead to a mix-up, contamination, or deterioration. [21 CFR 111.455 & 21 CFR 111.460]	**Compliant**
4.5.69	Distribution of product shall occur under conditions that will protect against contamination and deterioration. [21 CFR 111.470] **P-602 Rev 2 Preventing Cross-Contamination During Storage and Preparation**	**Compliant**
4.5.70	Procedures shall be established for the holding and distribution operations. [21 CFR 111.475(b1)]	**Compliant**
4.5.71	Vehicles and transportation equipment shall be designed and constructed of such material and workmanship to prevent dietary supplements transported therein from becoming unsafe, e.g., adulterated during transportation operations. [21 CFR 1.906] **Facility does not have any internal vehicles or transportation equipment used to transport dietary supplements or ingredients.**	**Not Applicable**
4.5.72	Written procedures shall be in place for transportation operations and shall be conducted to prevent dietary supplements from becoming unsafe during transportation operations. [21 CFR 1.908] **Trailer inspections are performed for incoming and outgoing shipments. Reviewed Carrier Inspection Log for 11-17-21 to 12-7-21.**	**Compliant**
4.5.73	Product distribution records shall be retained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21 CFR 111.475(b2)]	**Compliant**
4.5.74	An appropriate quarantine system shall be established and shall be demonstrated to meet the necessary requirements per procedures. Rejected dietary supplements, components, packaging, labeling, and products shall be removed from manufacturing operations and placed in quarantine until disposition is determined. Records shall be kept for the quarantine system. [21 CFR 111.170, 21 CFR 111.370, & 21 CFR 111.425]	**Compliant**
4.5.75	Procedures shall be established for the handling of returned dietary supplements that include appropriately quarantining the returned product until dispositioned by the QC unit. Procedures shall be established for salvage and reprocessing operations according to Subpart P – Records and Recordkeeping. [21 CFR 111.503, 21 CFR 111.510, & 21 CFR111.535(a)] **P-035 Rev 1 Returned Dietary Supplements**	**Compliant**
4.5.76	QC operations shall be established to handle returned dietary supplements. Any returned dietary supplement shall be either destroyed or disposed of unless the QC unit has determined that the material can be salvaged or reprocessed. Any salvaged material shall be approved by the QC unit following a material review and disposition. [21 CFR 111.130, 21 CFR 111.515, & 21 CFR 111.520]	**Compliant**
4.5.77	Any reprocessed material shall meet its original specification and the QC unit appropriately dispositions the material (release or reject). [21 CFR 111.525]	**Compliant**
4.5.78	If the reason for a return implicates other batches, an investigation shall be performed to determine if those batches comply with specifications. [21 CFR 111.530]	**Compliant**
4.5.79	Documentation shall be maintained for material reviews and dispositions, all testing results, any reevaluations by the QC unit for reprocessed materials. [21 CFR 111.535(b1),(b2),(b3),(b4)]	**Compliant**
4.5.80	Records for returned dietary supplements shall be maintained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21 CFR 111.535]	**Compliant**

Performance evaluation		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.6.1	Procedures shall be established for the collection of representative samples. [21 CFR 111.80] **P-020 Rev 2 Sampling, Testing, Releasing and Approving for Use Raw Material Components and Dietary Supplements**	**Compliant**
4.6.2	Samples shall be collected in a controlled area so as to not cause contamination.	**Compliant**
4.6.3	Packaging and labeling materials shall be examined before usage to determine that they conform to the master manufacturing record. [21 CFR 111.410(c)]	**Compliant**
4.6.4	Procedures shall be established to sample a representative number of units to assure compliance with specifications. [21 CFR 111.415(g)]	**Compliant**
4.6.5	Procedures shall be established for the collection of reserve samples for each lot of finished material. [21 CFR 111.83]	**Compliant**
4.6.6	Reserve samples shall be held under appropriate conditions (e.g., temperature, humidity, and light) and shall not lead to a mix-up, contamination, or deterioration. [21 CFR 111.465] **Retention samples are stored in a temperature monitored contolled-access room.**	**Compliant**

4.6.7	A system shall be established to determine if all specifications that are established have been met. [21 CFR 111.73] **P-057 Rev 3 Material Testing** **Finished product specifications are established, and the dietary supplement products are tested to verify identity, strength, purity and composition.**	**Compliant**
4.6.8	Dietary ingredients shall be sampled, tested, and released prior to use in production. Conduct at least one appropriate test or examination to verify the identity of the dietary ingredient (unless the company has submitted a petition for an ID test exemption that has approved by the FDA). [21 CFR 111.75(a1)] **P-057 Rev 3 Material Testing** **P-020 Rev 2 Sampling, Testing, Releasing and Approving for Use Raw Material Components and Dietary Supplements**	**Compliant**
4.6.9	Other raw materials or components (i.e., those that are not dietary ingredients) shall be sampled, tested (or confirmed), and released prior to use in production. Conduct appropriate tests or examinations (or rely on Certificate of Analysis (COA) from the qualified supplier). [21 CFR 111.75(a2i)] **P-057 Rev 3 Material Testing**	**Compliant**
4.6.10	Proper testing procedures or programs shall be established to determine if in-process and finished product specifications for purity, composition, and strength of the dietary supplement have been met. The basis for performing reduced-testing shall be adequately documented and it justifies how the testing procedures or program selected will help ensure that the full-specification for the dietary supplement will be met. [2 1CFR 111.75(b), (c),(d)]	**Compliant**
4.6.11	QC operations shall determine if process and product specifications have been met. The product shall not be released if it does not meet the specifications, unless QC approved deviations have been documented. [21 CFR 111.123(a),(b)]	**Compliant**
4.6.12	The QC person shall be responsible for making the material review and disposition decision shall document the review and disposition decision at the time of performance. [21 CFR 111.113(c)]	**Compliant**
4.6.13	Representative samples of each batch of repackaged or relabeled dietary supplement shall be examined to determine if they conform to specifications. [21 CFR 111.420(b)]	**Compliant**
4.6.14	QC laboratory operations and procedures shall be established. [21 CFR 111.110 & 21 CFR 111.303]	**Compliant**
4.6.15	Scientifically valid methods shall be used and include at least one of the following: [21 CFR 111.75(h)] - gross organoleptic analysis; - macroscopic analysis; - microscopic analysis; - chemical analysis; or - another scientifically valid method.	**Compliant**
4.6.16	Laboratory facilities used shall be adequate for testing of components, in-process materials, and dietary supplements. [21 CFR 111.310] **There is no on-site laboratory. All testing is performed by approved contract laboratories.**	**Compliant**
4.6.17	Laboratory controls shall be established and have been approved by QC, including criteria for establishing specifications. [21 CFR 111.315(a)] **P-019 Rev 2 Specifications**	**Compliant**
4.6.18	Parameters shall be set for laboratory controls for sampling plans, criteria for examination and testing methods, and standard reference materials. [21 CFR 111.315(b),(c),(d),(e)] **P-057 Rev 3 Materials Testing**	**Compliant**
4.6.19	QC operations shall ensure product complaints and deviations/unplanned occurrences are handled properly. [21 CFR 111.135]	**Compliant**
4.6.20	Procedures shall be established describing how product complaints will be received, investigated, and documented and that the product complaint information includes adequate information. [21 CFR 111.553 & 21 CFR 111.570(b2ii)] **P-036 Rev 2 Complaints** **P-067 Rev 3 Complaint Management** **Reviewed Consumer Complaint Form dated 12-15-21**	**Compliant**
4.6.21	All product complaints shall be reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality. [21 CFR 111.560(a)]	**Compliant**
4.6.22	The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, shall be approved by the QC unit. [21 CFR 111.560(b)]	**Compliant**
4.6.23	The investigation for a product complaint shall be appropriately extended to other batches, products, processes, etc. [21 CFR 111.560(c)]	**Compliant**
4.6.24	Records for each product complaint and investigation shall be maintained. Records shall be maintained for at least one year after the shelf life date, if shelf life dating is being used, or at least two years beyond the date of distribution of the last batch associated with those records. [21 CFR 111.570(a)]	**Compliant**

4.6.25	Procedures shall be established to define the recall of a product. The written recall plan shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps as appropriate to the facility. [21 CFR 117.139]	**Compliant**
4.6.26	Procedures shall be established to define traceability and mock recall exercises at a minimum of once a year to include trace forward and trace backward. **P-042 Rev 0 International Product Recall Procedure** **On site trace exercise was performed on second day of audit. Raw material glycerin, Lot 2009243-210414, was traced forward through distribution. All raw material, intermediate blends, and finished products were 100% reconciled.**	**Compliant**
4.6.27	For all products that bear expiration date or a statement of product shelf life, the shelf life shall be supported. [Preamble to 21 CF R111 final rule] **Reviewed shelf life data for products F-724 and F-729.**	**Compliant**
4.6.28	An internal audit program shall be established and is conducted. QC personnel shall have established roles and responsibilities. [21 CFR 111.105] NOTE - There is no specific CFR Reference regarding internal audits as it is embedded within 21 CFR 111.105 **P-068 Rev 2 Internal Audit Program**	**Compliant**

Improvement		
NSF/ANSI 455-2 GMP	**Question/Notes**	
4.7.1	Procedures and controls shall be established for investigation and handling of materials or processing that do not meet specification requirements. [21 CFR 111.77]	**Compliant**
4.7.2	QC personnel shall conduct a material review and make disposition decisions to approve treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification is not met. [21 CFR 111.90] **P-023 Rev 2 Treatments, In-Process Adjustments and Reprocessing**	**Compliant**
4.7.3	Procedures shall be established for a corrective and preventative action (CAPA) program for handling all nonconformances identified within the scope of this Standard. **P-064 Rev 3 Corrective and Preventive Action**	**Compliant**

* Represents nonconformances.