

Audit Template Report

GMP Registration Annual Audit

Audit Template Summary			
Template ID	6341	Effective Date	01-Nov-2012
Audit Type - Version	GMPA - 1.6	Expiration Date	
Template Type	AUDITFORM	Max Possible Score	0
Score Formula	NONE	Score Formula Type	NONE
Score Applicable Flag	N	Additional Score Calc	
Additional Grading		Section Name Editable	N
Grade Rule	DEFAULT (The very basic audit grade rule, including only PASS grade.)		
Facility Report	GMPA Site Audit Report		
Final Report	GMPA Complete Audit Report		
Form Instruction			
Audit Report Footer			

Section 0. Visit Summary (0)

1) Opening meeting attendees: Name and Title: (Max Score: 0)
Answer:

2) Employees who assisted during the audit: (Max Score: 0)
Answer:

3) Closing meeting attendees: Name and Title: (Max Score: 0)
Answer:

Section 1. 21 CFR 111: Subpart B: Personnel (0)

1) 111.10a: Procedures have been established that define work requirements for personnel to prevent microbial contamination from illness. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

2) 111.10b1,2,3: Hygienic practices have been 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. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

3) 111.10b4: Procedures for removal of jewelry and other items or appropriate coverings. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

4) 111.10b5,6,8,9: Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

5) 111.10b7: Appropriate change rooms are available if needed and there is adequate storage of personal effects. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

6) 111.12c: Personnel must be qualified and have adequate training, experience and/or education necessary to perform job functions. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

7) 111.12b: Quality responsibilities are distinct and separate from operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

8) 111.13a: Procedures have been established to define the requirements for personnel who will supervise activities. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

9) 111.13b: Personnel who are designated as supervisors are qualified and have written requirements. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

10) 111.14a,b: Procedures have been established and records are maintained documenting compliance to these procedures. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

11) 111.12a: Job descriptions are available for all personnel and personnel have received GMP and appropriate training for their assigned functions. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 2. 21 CFR 111: Subpart C: Physical Plant and Grounds (0)

12) 111.15a1,2,3: Grounds have been properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

13) 111.15a4: Waste treatment and disposal is adequate and does not provide a source of potential contamination. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

14) 111.15b1,2: Production Facility is maintained in a clean and sanitary condition and in a proper state of repair. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

15) 111.15a5: Entrances to the facilities are properly controlled and maintained to prevent contamination. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

16) 111.15c1: Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and adequate under the conditions of use; and are free from microorganisms of public health significance. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

17) 111.15c3: Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been 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. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

18) 111.15d1,2: Procedures have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

19) 111.15d3: Pest control procedures have been established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

20) 111.15e: The water supply is safe and sanitary and under suitable temperature and pressure. Water that may contact a product contact surface or is in fact a component must meet U.S. Federal, State and Local requirements for drinking water. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

21) 111.15e,f3: Water sources do 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. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

22) 111.15f: Plumbing is of adequate size and design for intended usage. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

23) 111.15g: Sewage and waste disposal is properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

24) 111.15f4: Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.). (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

25) 111.15f5: Backflow and cross-connection prevention is in place. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

26) 111.15h: Bathrooms are provided and are of adequate number and location. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

27) 111.15h: Bathrooms and hand washing facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

28) 111.15i: Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing by personnel. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

29) 111.15j: Solid waste and trash are disposed of appropriately and not allowed to accumulate. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

- 30) 111.15j2,3: Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 31) 111.15j4: Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 32) 111.15k: Sanitation supervisors have been assigned and are qualified. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 33) 111.16: Procedures have been established for cleaning of the plant. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 34) 111.20a: All facilities are of adequate size, construction, and design for their intended use. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 35) 111.20b: There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 36) 111.20c: There are adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 37) 111.20c1: Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, dietary supplements, packaging, and labels that will be used. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 38) 111.20c2: Areas have been provided for quarantine and release of materials to be used in the manufacture, packaging, or labeling of dietary supplements. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 39) 111.20c3: Areas have been provided to separate the manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 40) 111.20c4,5,6,7: Separate or defined areas exist for laboratory analysis and holding of laboratory supplies and samples, cleaning of contact surfaces, packaging and labeling, and holding of components or dietary supplements. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 41) 111.20d1i: Walls, floors, ceilings can be adequately cleaned and kept in good repair. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 42) 111.20d1ii: Fixtures, ducts, piping, etc. are kept clean, do not drip or leak or provide a source of condensation that could contaminate components, products, or contact surfaces. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 43) 111.20d1iii: Adequate ventilation and airflow is provided in all areas of the facility. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 44) 111.20d1iv: Temperature and humidity control equipment is of adequate design for its intended function and is functioning properly. (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 45) 111.20d1v,d2: Working areas 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 must be located and operated in a manner that minimizes the potential for contamination with particulates and microorganisms. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 46) 111.20e: Adequate lighting is provided in all production and examination areas where equipment is cleaned and examined, etc. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 47) 111.20f: Lighting that is suspended or located above areas where materials or equipment are exposed must be safety-type or the facility must be constructed in a manner that will protect against contamination with glass, etc. (Max Score: 0, Question Importance level: 3)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)
- 48) 111.20g: In areas where open vessels are used, there is adequate protection against contamination, (e.g. use of protective coverings, physical location, use of skimming equipment). (Max Score: 0, Question Importance level: 2)
 Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

49) 111.20h: Production areas do not provide a haven for pests, pest infestation, filth, etc. (adequate screening and other measures are used). (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

50) 111.23a,b: Records have been maintained for plant cleaning and pest control, and in accordance with Subpart P. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

51) 111.23c: Records have been maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15(e)(2). (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 3. 21 CFR 111: Subpart D: Equipment and Utensils (0)

52) 111.25a,b: Procedures have been established for calibration of all instruments, controls, automated, mechanical, and electronic equipment, etc. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

53) 111.25c: Procedures have been established for the cleaning and sanitization of all utensils and equipment. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

54) 111.25c: Procedures and programs have been established for maintaining equipment. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

55) 111.27a1: All equipment and utensils are corrosion resistant, made of nontoxic materials, and of suitable design, construction, and workmanship for their intended use. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

56) 111.27a2: Equipment and utensils are of appropriate design and construction 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. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

57) 111.27a3iv: Equipment and utensils are designed and constructed to withstand the environment in which they are used and do not degrade upon exposure to components, process materials, cleaning agents, etc. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

58) 111.27a3v: Equipment and utensils protect components and dietary supplements from contamination from any source. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

59) 111.27a4: Equipment and utensils are constructed as seamless, or if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

60) 111.27a3i,ii,iii: Equipment is installed and maintained to facilitate cleaning. Equipment and utensil surfaces are corrosion-resistant, made of non-toxic materials and are inspected at routine intervals for signs of wear, damage, etc. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

61) 111.27a5: Equipment such as freezers, refrigerators, etc. that are used to hold components or dietary supplements must be functioning properly and adequately designed. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

62) 111.27a6,b,c: Instruments and controls that are used in all areas must be accurate and precise (calibrated as required), maintained, and adequate in number. Instruments and controls must be calibrated before first use (and then after at the frequency specified by the manufacturer or at routine intervals) and must be repaired when they are not able to be adjusted to agree with a reference standard. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

63) 111.27a7: Process gases that are used and contact dietary supplements, components, and contact surfaces must be controlled so as not to cause contamination (e.g. filters). (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

64) 111.27d: All equipment, instruments, utensils, contact surfaces etc. must be maintained, cleaned and sanitized as necessary. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

65) 111.27d1: Equipment, utensils, etc. must be disassembled as necessary to assure maintenance, cleaning, and sanitization. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

66) 111.27d2: Low moisture processing: Equipment, utensils, and contact surfaces are dry and sanitized. If wet-cleaned, drying and sanitization is performed. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

67) 111.27d3: Wet Processing: Contact surfaces are cleaned and sanitized before use and after any interruptions. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

68) 111.27d4: Surfaces that do not come into direct contact with components or dietary supplements are cleaned. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

69) 111.27d5: Disposable items (single-service) are stored in appropriate containers; handled, used, dispensed, and disposed of in a manner that protects against contamination. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

70) 111.27d6: Cleaning and sanitizing agents are adequate and safe for their intended use. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

71) 111.27d7: Portable equipment and utensils are properly stored after cleaning and sanitization. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

72) 111.30a,b,c: Automated, mechanical, or electronic equipment must be functioning properly and be adequately designed. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

73) 111.30d,e: Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

74) 111.35a,b1iii: Procedures for maintenance, cleaning, sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation are maintained. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

75) 111.35b2: Equipment logbooks have been maintained for each equipment and includes the date of use, and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is in the batch record). (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

76) 111.35b3,b4: Records are available of calibrations, inspections, and checks of any automated, mechanical, or electronic equipment. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

77) 111.35b5i,ii: Backup electronic files have been 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 are an exact and complete record and are secure from alterations, erasures, or loss and damage. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

78) 111.35b6: Documentation of controls used that ensure that equipment functions in accordance with its intended use. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 4. 21 CFR 111: Subpart E: Production and Process Control System (0)

79) 111.55: Production and process control systems have been implemented for each production process and/or product. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

80) 111.60: Production and processes have been designed to ensure the quality of the product and the Quality Control Unit has approved the control systems. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

81) 111.65: Quality Control operations have been identified and implemented. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

82) 111.70, 111.70c2: Specifications have been 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. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

83) 111.73: A system has been established to determine if all specifications that are established have been met. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

84) 111.75a1: Dietary ingredients are sampled, tested, and confirmed (released) prior to use in production. Conduct at least one appropriate test or examination to verify the identity of dietary ingredient (unless company has submitted a petition for an ID test exemption that has been approved by the FDA). (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

85) 111.75a2i: Other raw materials or components (i.e., those that are not dietary ingredients) are sampled, tested (or confirmed), and released prior to use in production. Conduct appropriate tests or examinations (or rely on the COA from the qualified supplier). (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

86) 111.75a2iia,b,c,d,e: Supplier Qualification Procedures are established and include initial qualification, periodic examination (re qualification), and procedures for disqualification. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

87) 111.75b.c,c3,d: Proper testing procedures or programs have been established to determine if in process and finished product specifications for purity, composition, strength of the dietary supplement have been met. The basis for performing reduced testing is adequately documented and it justifies how the testing procedures or program selected will help ensure that the full - specifications for the dietary supplement will be met. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

88) 111.75e: For products that are received for packaging and labeling, visual examinations are performed and documentation is available to determine whether the product meets established specifications. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

89) 111.75f: Packaging and labeling materials are visually examined, at a minimum, and are reviewed against the supplier's invoice to determine conformance with specifications. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

90) 111.75g: Packaging and labeling of the finished packaged and labeled dietary supplement are visually examined, at a minimum, to determine that the correct packaging and labeling has been used. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

91) 111.75h: Scientifically valid methods are used and include at least one of the following, a gross organoleptic analysis, macroscopic analysis, microscopic analysis, chemical analysis, or another scientifically valid method. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

92) 111.77: Procedures and controls have been established for investigation and handling of materials that do not meet specification requirements. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

93) 111.80: Procedures have been established for the collection of representative samples. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

94) 111.83: Procedures have been established for the collection of reserve samples for each lot of finished material. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

95) 111.87: The Quality Control Unit conducts all material reviews and makes disposition decisions. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

96) 111.90: Procedures have been established for the handling of unexpected events. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

97) 111.90a,b: Reprocessing controls have been established and meet all requirements and have been approved by the Quality Control Unit. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

98) 111.95: Records are maintained specifications, supplier qualification and testing to ensure product meets purity, strength and composition. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 5. 21 CFR 111: Subpart F: Production and Process Control System: Requirements for Quality Control (0)

99) 111.103: Procedures have been established for the responsibilities of the Quality Control operations. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

100) 111.105: Quality Control Personnel have established roles and responsibilities. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

101) 111.110: Quality Control Laboratory Operations have been established. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

102) 111.113a: Quality Control Operations responsibilities include the authority to reject any component or product if any specification is not met. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

103) 111.113b: Quality Control Personnel may authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

104) 111.113c: The Quality Control person responsible for making the material review and disposition decision has documented the review and disposition decision at the time of performance. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

105) 111.117: Quality Control Operations review and approves all processes and/or procedures for calibrating equipment, instruments, and controls; including the periodical review of calibration records, etc. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

106) 111.120: Quality Control Operations must review and approve components, labels and packaging materials for intended use. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

107) 111.123a1-a3: Quality Control Operations and authority have been established for master manufacturing record and the batch production record. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

108) 111.123a4-a8: Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

109) 111.123b: Quality Control has not approved and released product in any form that does not meet the specifications unless Quality Control approved deviations have been documented. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

110) 111.127: Quality Control Operations have been established for packaging and labeling. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

111) 111.130: Quality Control Operations have been established to handle returned dietary supplements. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

112) 111.135: Quality Control Operations ensures that product complaints, deviations, and unplanned occurrences are handled properly. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

113) 111.140, GMP-PP-7: Quality Control Operations prepares and maintains all records required by subpart F. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 6. 21 CFR 111: Subpart G: Production and Process Control System: Requirements for Components, Packaging, and Labels. (0)

114) 111.153: Receiving, sampling, testing, release procedures have been established to fulfill this Subpart. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

115) 111.155: Quality Control requirements have been established for components. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

116) 111.160: Quality Control requirements have been established for packaging materials and labels. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

117) 111.165: Quality Control requirements have been established for products that are received for packaging and labeling as a dietary supplement and bulk finished product. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

118) 111.170: Rejected components, packaging, labeling, and products are appropriately quarantined and dispositioned. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

119) 111.180: Records have been established and are being maintained to meet the requirements of Subpart G. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 7. 21 CFR 111: Subpart H: Production and Process Control System: Requirements for the Master Manufacturing Record (0)

120) 111.205a: Master Manufacturing Records have been prepared for each unique formulation and batch size of the dietary supplement. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

121) 111.205b1,2: The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

122) 111.210: Master Manufacturing Records contain all of the required elements. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 8. 21 CFR 111: Subpart I: Production and Process Control System: Requirements for the Batch Production Record (0)

123) 111.255a,d: Batch Production Records are available per Subpart P for each batch of dietary supplement that has been manufactured. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

124) 111.255b,c: The Batch Production Record contains complete information relating to the production and control of each batch. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

125) 111.260: The Batch Record follows the master record and each step is performed appropriately. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 9. 21 CFR 111: Subpart J: Production and Process Control System: Requirements for Laboratory Operations (0)

126) 111.303: Procedures have been established for laboratory operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

127) 111.310: Laboratory facilities used are adequate for testing of components, in-process materials, and dietary supplements. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

128) 111.315a: Laboratory controls have been established and have been approved by Quality Control, including criteria for establishing specifications. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

129) 111.315b,c,d,e: Parameters have been set for laboratory controls for sampling plans, criteria for examination and testing methods, and standard reference materials. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

130) 111.320: Quality Control responsibilities for laboratory test methods and examinations used to test each specification requirement have been defined, are appropriate for their intended use, and are being followed. Test methods and examinations are used according to established criteria. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

131) 111.325, GMP-PP-7: Quality Control Operations have maintained appropriate records as required. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

132) Preamble 21CFR 111 Final Rule: For all products that bear expiration date or a statement of product shelf life, the shelf life must be supported. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 10. 21 CFR 111: Subpart K: Production and Process Control System: Requirements for Manufacturing Operations (0)

133) 111.353: Procedures, including sanitation, operation and control have been established for manufacturing operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

134) 111.355: Manufacturing processes have been designed to produce a product that consistently meets specifications. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

135) 111.360: Manufacturing Operations are conducted using adequate sanitation principles. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

136) 111.365a-g: Precautions have been taken to prevent contamination, such as microbial, filth, chemical, foreign material, etc., throughout the manufacturing process. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

137) 111.365h,i: Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

138) 111.365j,k: Manufacturing operations have included 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. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

139) 111.370: Rejected Dietary Supplements are removed from Manufacturing Operations and placed in quarantine until disposition is determined. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

140) 111.375: Records have been established and are being maintained to meet the requirements of Subpart K. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 11. 21 CFR 111: Subpart L: Production and Process Control System: Requirements for Packaging and Labeling Operations (0)

141) 111.403: Procedures have been established for all packaging and labeling operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

142) 111.410a: The condition of packaging meets the specifications required to ensure the quality of the dietary supplements being packaged. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

143) 111.410b: Packaging and labels are controlled for issuance and are reconciled after use. Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

144) 111.410c: Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

145) 111.410d: Records are maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

146) 111.415: A Master Manufacturing Record has instructions for filling, assembling, packaging, labeling, and other related operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

147) 111.415a: Procedures have been established for cleaning and sanitizing all filling and packaging equipment and utensils. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

148) 111.415d: Physical separation is implemented to prevent mix-ups with other components and dietary supplements. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

149) 111.415b,c: Filling and packaging operations are appropriately protected from contamination sources (i.e., airborne) by using sanitary handling procedures. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

150) 111.415e: Procedures have been established to identify unlabeled materials that will be held for future labeling operations to prevent mix-ups. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

151) 111.415f: Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

152) 111.415g: Procedures have been established to sample a representative number of units to assure compliance with specifications. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

153) 111.415h: Disposal procedures have been established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

154) 111.420a: All repackaging or relabeling operations have first been approved by the Quality Control Unit. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

155) 111.420b: Representative samples of each batch of repackaged or relabeled dietary supplement have been examined to determine if they conform to specifications. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

156) 111.420c: Quality Control Unit has dispositioned each batch of repackaged or relabeled dietary supplement prior to release for distribution. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

157) 111.425: An appropriate quarantine system has been established for holding any rejected packaged and labeled dietary supplement. Procedures have been established and records are kept for the quarantine system. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

158) 111.425: Areas for storing rejected packaged and labeled dietary supplements have been demonstrated to meet the necessary requirements. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

159) 111.430: Records have been established and are being maintained to meet the requirements of Subpart L. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 12. 21 CFR 111: Subpart M: Holding and Distributing (0)

160) 111.455: Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

161) 111.460: In-process materials are held under appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

162) 111.465: Reserve samples are held under appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

163) 111.470: Distribution of product must occur under conditions that will protect against contamination and deterioration. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

164) 111.475b1: Procedures have been established for the holding and distribution operations. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

165) 111.475b2: Product distribution records have been retained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 13. 21 CFR 111: Subpart N: Return of Dietary Supplements (0)

166) 111.503: Procedures have been established for the handling of returned dietary supplements. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

167) 111.510: Returned supplements have been appropriately quarantined until dispositioned by the Quality Control Unit. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

168) 111.515: Any returned dietary supplement must be either destroyed or disposed of unless the Quality Control Unit has determined that the material can be salvaged or reprocessed. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

169) 111.520: Any salvaged material has been so designated by the Quality Control Unit. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

170) 111.525: Any reprocessed material has met its original specification and the Quality Control Unit has appropriately dispositioned the material (release or reject). (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

171) 111.530: If the reason for a return implicates other batches, an investigation has been performed to determine if those batches comply with specifications. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

172) 111.535a: Procedures have been established for salvage and reprocessing operations according to Subpart P. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

173) 111.535b1,2,3: Documentation has been maintained for material reviews and dispositions, all testing results, any reevaluations by the Quality Control Unit for reprocessed materials. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

174) 111.535b4: All Quality Control Unit evaluations and decisions have been documented. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

175) 111.535: Records for returned dietary supplements have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 14. 21 CFR 111: Subpart O: Product Complaints (0)

176) 111.553: Procedures have been established describing how product complaints will be received, investigated, and documented. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

177) 111.560a: All product complaints have been 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. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

178) 111.560b: The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

179) 111.560c: The investigation for a product complaint was appropriately extended to other batches, products, processes, etc. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

180) 111.570a: Records for each product complaint and investigation have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

181) 111.570bii: Product complaint information has included adequate information. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 15. 21 CFR 111: Subpart P: Records and Record Keeping (0)

182) 111.605: Procedures have been established that describe the requirements for record retention under Subpart P. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

183) 111.605a: Records will be maintained for 1 year after the shelf life date or 2 years beyond the date of distribution of the last batch associated with those records. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

184) 111.605b: All records are maintained as original record, as true copies or as electronic records. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 16. 21 CFR 11: Electronic Records; Electronic Signatures (0)

185) 21 CFR 11: Are electronic GMP records being created? (Max Score: 0)

Answer: 1. Yes (0) Electronic records must comply with the requirements in 21 CFR 11.
2. No (0)

186) 21 CFR 11: Are electronic signatures being used on GMP records? (Max Score: 0)

Answer: 1. Yes (0) Electronic signatures must comply with the requirements in 21 CFR 11.
2. No (0)

Section 17. NSF Policies – GMP - Facility Registration Audits (0)

187) GMP-GP-3: Prompt and thorough access is granted to the auditor during the NSF audit. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0)
2. Not Acceptable* (0)
3. Not Applicable (0)
4. Not Observed (0)

188) GMP-GP-4: Documents requested during the NSF audit are provided in timely a manner. (Max Score: 0, Question Importance level: 3)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

189) GMP-PP-9: The NSF GMP Registered Facility Mark is not used on materials, ingredients, components, or finished products. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

190) NSF GMP 8.1: Procedures have been established to define the recall of a product. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

191) NSF GMP 8.2: Manufacturers of dietary supplements shall submit application to US FDA for registration, receive a registration number, and provide the registration number upon request. (Max Score: 0, Question Importance level: 2)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

192) NSF GMP 8.3: Procedures shall be established and followed for reporting serious adverse events to the US FDA in accordance with the dietary supplement and non-prescription drug consumer protection act. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

Section 18. NSF Policies - Product Certification Audits (0)

193) PC-PP-2: The NSF Certification Mark is only on the package or container used to store or display the Certified Product at the point of sale, except as specifically exempted by NSF policy. The NSF GMP Registered Facility Mark is not used on materials, ingredients, components, or finished certified products. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

194) PC-PP-11: The Company has submitted and maintains the complete signed Authorized Registered Formulation (ARF) for NSF Certified Product manufactured at this site. The ingredients used to manufacture the Certified Product were obtained from suppliers that are listed on the ARF and the ingredient ID numbers and descriptions match the ARF. The quantity of the ingredients used in the Certified Product matches the quantity specified on the ARF. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

195) PC-PP-20, PC-PP-21: The Company has approved specifications for NSF Certified Products and associated raw materials. All required release testing was performed on Certified Products and on the raw materials used to manufacture the certified batches. The certified batches were released by QA. (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)

196) NSF/ANSI-173-4.0: Product labels shall declare the identity of dietary ingredient(s) and/or marker constituent(s) included in the product. (i.e., the Product Label should match the ARF). (Max Score: 0, Question Importance level: 1)

Answer: 1. Acceptable (0) 2. Not Acceptable* (0) 3. Not Applicable (0) 4. Not Observed (0)