NSF International Standard for Dietary Supplements —
Dietary supplements

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8 Good Manufacturing Practices

The manufacture and handling of dietary supplements and dietary supplement ingredients shall meet all applicable regulatory requirements set forth by 21 CFR § 111, with the following additional requirements, which are already stated in Section 8 of the standard.

~~Written procedures shall be established and followed for the maintenance of Good Manufacturing Practices.~~

8.1 Written recall procedures

Procedures shall be established and followed that define the recall of a product(s) should it become necessary.

Written procedures shall be established and followed.

~~**8.1 Personnel**~~

~~**8.1.1 Disease control**~~

~~All personnel having illnesses or medical conditions such as open lesions or infected wounds, that could be a possible source of microbial contamination shall be removed from the manufacturing process so as to prevent adulteration of the product during manufacture and storage. Personnel shall be instructed to report such health conditions to their supervisors.~~

~~Written procedures shall be established and followed for these procedures.~~

~~**8.1.2 Cleanliness**~~

~~All personnel having direct contact with raw materials, in process materials, exposed products, and packaging components, as well as those individuals utilizing processing equipment and utensils, shall conform to a level of basic hygiene and personal cleanliness while on duty to protect the product against adulteration. These methods may include but are not limited to:~~

- ~~wearing outer garments that protect against the adulteration of products and equipment;~~
- ~~maintaining personal cleanliness;~~
- ~~washing hands thoroughly before starting work and at any other time when the hands may have become soiled or contaminated;~~
- ~~removing all unsecured jewelry and hand jewelry and covering hand jewelry that cannot be removed;~~
- ~~using gloves that are maintained in an intact, clean, and sanitary condition;~~

– wearing hair nets, caps, beard covers, arm covers, or other effective hair restraints;

– storing clothing and other personal effects outside of processing areas;

– preventing personal care products from entering product; and

– avoiding the consumption of food, drink, and medication, as well as the use of chewing gum and tobacco products, in the processing areas.

Written procedures shall be established and followed.

8.1.3 Education and training

All personnel shall have written job descriptions and shall possess education, training, and/or experience to perform their assigned functions. All personnel shall receive GMP education and training to perform their assigned functions.

Written records of education and training shall be retained and routinely updated in order to document education and training progress.

Written procedures shall be established and followed.

8.1.4 Supervision

The responsibility for assuring compliance by all personnel with these requirements shall be assigned to qualified personnel with the proper education, training, and/or experience.

Written procedures shall be established and followed.

8.2 Plant and grounds

8.2.1 Grounds

The grounds of a manufacturing plant shall be kept in a condition that protects against adulteration of product. Methods shall include but are not limited to:

– storing equipment properly and removing litter, waste, and vegetation that could attract or harbor pests within the immediate vicinity of buildings;

– maintaining roads, yards, parking lots, and drainage areas to prevent product adulteration and pest infestation; and

– disposing of all waste and rubbish so as to prevent adulteration of the dietary product during manufacture and storage and to ensure a clean, safe work environment.

Written procedures shall be established and followed.

8.2.2 Plant construction and design

Plant buildings and structures shall be of a size, construction, and design to facilitate maintenance, cleaning, and sanitary operation and to prevent mix-ups between different raw materials and finished products. The plant buildings and structures shall:

– provide sufficient space for placement of equipment and storage and segregation of materials;

~~— provide effective design or operating practices that reduce the potential for mix-ups or adulteration of in-process or finished products;~~

~~— perform maintenance functions including cleaning, sanitation, waste treatment and disposal, and elimination and prevention of pest infestations;~~

~~— provide adequate lighting in manufacturing areas;~~

~~— provide safety-type light bulbs, fixtures, and skylights to protect against possible adulteration by glass breakage;~~

~~— provide ventilation, air filtration, heating, and/or cooling to control microorganisms, dust, humidity, and temperature in order to prevent adulteration of product, and to provide a safe, clean work environment; and~~

~~— provide adequate screening or other protection against pests.~~

~~Written procedures shall be established and followed.~~

~~8.3 Sanitation of buildings and facilities~~

~~8.3.1 General maintenance~~

~~All buildings, structures, fixtures, and equipment shall be constructed in such a manner that floors, walls, ceilings, work surfaces, and equipment can be cleaned and sanitized. All buildings and fixtures shall be maintained in a sanitary condition and shall be kept in good repair.~~

~~Written procedures shall be established and followed.~~

~~8.3.2 Cleaning and sanitizing agents~~

~~Cleaning and sanitizing agents, pesticide chemicals, and fungicides shall be safe and effective for their intended use. NSF-registered proprietary substances and non-food compounds are acceptable when used for their intended purpose.~~

~~Cleaning and sanitizing agents, pesticide chemicals, and fungicides shall be identified, used, 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.~~

~~Written procedures shall be established and followed.~~

~~8.3.3 Pest control~~

~~Effective means shall be taken to exclude pests from the entire plant. The use of insecticides or rodenticides is permitted only with precautions and restrictions that protect against adulteration of raw materials, products, equipment, or packaging materials.~~

~~No evidence of pests shall be present on product or packaging or in the vicinity of the plant.~~

~~Pest control inspections shall be performed routinely.~~

~~Written procedures shall be established and followed.~~

~~**8.3.4 Water supply**~~

~~Potable water, as a minimum quality water, at designated temperature and pressure where appropriate, shall be provided in all areas where required for processing and cleaning or for employee sanitary facilities. Water shall meet or exceed the standards prescribed in the USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality.~~

~~Written procedures shall be established and followed.~~

~~**8.3.5 Plumbing**~~

~~Plumbing shall be of a size and design and installed and maintained to:~~

- ~~carry sufficient quantities of water to required locations throughout the plant;~~
- ~~convey sewage and liquid waste from the plant properly;~~
- ~~avoid adulteration of product and contamination of water supplies or equipment;~~
- ~~provide floor drainage in areas where floors are subject to flooding; and~~
- ~~prevent contamination of fresh water with discharge wastewater or sewage.~~

~~Written procedures shall be established and followed.~~

~~**8.3.6 Sewage disposal**~~

~~Sewage shall be disposed into a properly maintained and approved sewage system that complies with local regulatory requirements.~~

~~Written procedures shall be established and followed.~~

~~**8.3.7 Toilet facilities**~~

~~Each plant shall provide its employees with readily accessible toilet facilities. Each plant shall maintain toilet facilities in a sanitary condition, properly stocked, and in good repair at all times. Each plant shall provide self-closing doors that do not open into areas where materials and/or product are exposed to airborne contamination.~~

~~Written procedures shall be established and followed.~~

~~**8.3.8 Hand-washing facilities**~~

~~Hand-washing facilities shall be convenient and furnished with tempered running water and shall include:~~

- ~~hand-washing facilities at each location where employees are required to wash their hands;~~
- ~~effective hand-cleaning and sanitizing preparations;~~
- ~~air dryers or sanitary towel services;~~
- ~~devices or fixtures that protect against the recontamination of clean, sanitized hands; and~~
- ~~signs directing employees to wash hands before they start work, after each absence from their work station, and when their hands have become soiled or contaminated.~~

~~Written procedures shall be established and followed.~~

~~**8.3.9 Rubbish disposal**~~

~~Refuse receptacles and rubbish disposal practices that protect against adulteration or the harborage of pests shall be provided.~~

~~Written procedures shall be established and followed.~~

~~**8.3.10 Supervision**~~

~~The overall sanitation of the plant shall be under the supervision of one or more designated individuals with qualifications based on education, experience, and/or training.~~

~~Written procedures shall be established and followed.~~

~~**8.4 Equipment and utensils**~~

~~**8.4.1 Design and construction**~~

~~Equipment shall be constructed, installed, and maintained so as to facilitate the cleaning and disinfection of the equipment and the surrounding areas. Equipment shall be used for its intended purpose.~~

~~Equipment and utensils having direct contact with product shall be constructed of inert, non-toxic materials and designed to withstand the environment to which they are subjected during the manufacturing process and during cleaning and disinfection.~~

~~Seams on utensils and processing equipment shall be smoothly bonded or maintained to minimize the accumulation of residues and the opportunity for growth of microorganisms.~~

~~All plant equipment and utensils shall be designed, constructed, and maintained to preclude the adulteration of raw materials, packaging materials, in-process materials, and finished product with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.~~

~~Cleaners, disinfectants, sanitizers, lubricants, and/or coolants used on utensils and processing equipment shall be suitable for use in food processing.~~

~~All equipment with critical parameters (such as time, temperature, pressure, speed controls, etc.) that require monitoring shall have suitable measuring devices.~~

~~Each freezer and cold storage compartment shall be fitted with a temperature-measuring device, automatic control, or alarm system.~~

~~Compressed air and other gases that come into contact with a product or ingredient or are used to clean equipment or utensils shall be treated in such a way that the materials with which they come in contact are not adulterated.~~

~~Instruments and controls shall be accurate and maintained.~~

~~Written procedures shall be established and followed.~~

~~**8.4.2 Sanitation of equipment and utensils**~~

~~All utensils and equipment shall be cleaned as frequently as necessary to ensure quality and integrity of the product using safe cleaning and sanitizing agents, then stored in a manner that protects against recontamination.~~

~~A written record of major equipment cleaning and use shall be maintained in individual equipment logs that show the date, product, and lot number of each batch processed and the cleaning or maintenance performed. The person(s) performing the cleaning and/or maintenance shall record in the log that the work was performed. Entries in the log shall be in chronological order. Manufacturers shall provide rationale for the selection of cleaning and sanitizing methods.~~

~~Written procedures shall be established and followed.~~

~~8.5 Quality assurance/control and laboratory operations~~

~~8.5.1 Quality assurance/control operations~~

~~Quality control operations shall be employed to ensure that products conform to standards of purity, quality, and composition and that packaging materials are safe for their intended purposes.~~

~~Written procedures shall be established and followed.~~

~~8.5.2 Quality assurance/control unit~~

~~There shall be a quality assurance/control unit that has the responsibility and final authority to:~~

- ~~approve or reject all procedures, specifications, controls, test methods, and results that impact the purity, quality, and composition of an ingredient or product;~~
- ~~approve or reject all raw materials, packaging materials, labeling, and finished products, including contract-manufactured products, based on conformance to established specifications;~~
- ~~review completed production records and determine whether the product is approved for distribution. This evaluation shall be documented and maintained as part of the batch record;~~
- ~~establish procedures for changing or revising all documentation (such as protocols, methods, recordkeeping, formulas, etc.);~~
- ~~review and approve all changes to documentation (such as protocols, methods, recordkeeping, formulas, etc.);~~
- ~~ensure that the most current revision of all documentation (such as protocols, methods, recordkeeping, formulas, etc.) is in use at all times;~~
- ~~implement corrective action when documented procedures are not followed; and~~
- ~~approve or reject deviations committed in the manufacturing of a product.~~

~~GMP internal audits shall be performed by the quality control unit periodically with documented corrective action kept on file.~~

~~The responsibilities and procedures applicable to the quality control unit shall be established in writing and followed.~~

~~Written procedures shall be established and followed.~~

~~8.5.3 In-house and/or contract laboratories~~

~~In-house and/or contract laboratories shall be available for performance of the quality assurance/control tasks and responsibilities.~~

~~Written procedures shall be established and followed.~~

~~8.5.4 Test methods~~

~~All test methods used for ingredient and product testing shall be reliable and shall yield appropriately reproducible and accurate results.~~

~~Written procedures shall be established and followed.~~

~~8.5.5 Laboratory records~~

~~Records of laboratory data derived from all specified tests shall be maintained.~~

~~Written procedures shall be established and followed.~~

~~8.5.6 Shelf life~~

~~All products shall bear an expiration date or a statement of product shelf life as appropriate or dictated by governing regulatory authorities. These dates shall be supported by data and/or rationale to reasonably ensure that the product meets the manufacturer's established specifications throughout the product shelf life.~~

~~Accelerated stability studies or data from similar product formulations may be used for an initial determination of shelf life. Product shelf life may be confirmed and extended on the basis of real-time studies on product stored under labeled storage conditions.~~

~~Manufacturer's established specifications may include organoleptic or other qualitative or quantitative testing.~~

~~Written procedures shall be established and followed.~~

~~8.6 Production and process controls~~

~~8.6.1 Master production and control records~~

~~A master production and control record (including, for example, manufacturing formula, raw materials specifications, component specifications, and/or finished product specifications) shall be prepared for the manufacture of each product and shall be reviewed and approved by the quality control unit.~~

~~Master production and control records shall include:~~

- ~~a complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s) and other specifications;~~
- ~~the amount of each raw material used;~~

  ~~NOTE – Each batch shall be formulated to provide no less than 100% of each claimed dietary ingredient throughout the shelf life of the product.~~

- ~~the name, and weight or measure, of each dietary ingredient per unit or portion or per unit of weight or measure of the product;~~
- ~~a statement of the total weight or measure of any dietary supplement unit;~~
- ~~a statement of the theoretical weight or measure of the manufactured product and the acceptable range beyond which an investigation is required;~~

- a description of the product container(s), closures(s), and product label(s), including positive identification of all labeling used; and

- manufacturing and process control instructions.

Written procedures shall be established and followed.

8.6.2 Batch production and control records

Batch production and control records shall be prepared and followed for each batch of product. These records shall include complete information relating to the production and control of each batch. The records shall be an accurate reproduction of the appropriate master production and control record and shall include documentation that each significant step in the manufacturing process was accomplished, including:

- dates;

- identity of individual major equipment and lines used;

- specific identification, including lot number, of each raw material or in-process material used;

- weight or measure of each raw material used in the course of processing;

- if performed, in-process testing results;

- quality control results;

- details and results of packaging and labeling area inspections;

- a statement of the actual yield at the conclusion of each critical process step of the manufacture and a statement of the percentage of theoretical yield, as appropriate;

- label control records, including specimens, copies, or records of all labels used;

- a description of product containers and closures used;

- special notes of any investigations or deviations from the described process; and

- identification of the persons performing and directly supervising described process.

Any deviations from written and approved specifications, standards, and test methods shall be recorded on the batch record and justified.

Written procedures shall be established and followed.

8.6.3 Handling and storage of raw materials, in-process materials, and rework

Raw materials, in-process materials, and rework shall be inspected and segregated or otherwise handled as necessary to verify that they are clean and suitable for processing. They shall be stored and transported under conditions that protect against adulteration and minimize deterioration.

Containers of raw materials shall be inspected upon receipt to ensure that their condition has not contributed to the adulteration or deterioration of the contents.

~~Raw agricultural materials that contain soil or other extraneous material shall be washed or cleaned, as necessary.~~

~~Raw materials, in-process materials, and rework shall be held in bulk or in containers and under conditions of temperature and humidity that prevent the materials from becoming adulterated or contaminated.~~

~~Written procedures shall be established and followed for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials.~~

~~Written procedures shall be established and followed for the receiving, processing, storage, and final delivery of product requiring temperature control.~~

~~Effective and documented measures shall be taken to minimize the potential risk of major food allergen cross-contamination in the receipt, storage, production, and shipping of ingredients and finished goods. Each lot of raw material shall be identified with a distinctive lot number and shall be controlled according to its status (e. g., quarantined, approved, or rejected).~~

~~Each lot of raw material, in-process material, and rework that is liable to adulteration with filth, insect infestation, or other visually evident extraneous materials shall be examined against established specifications.~~

~~Each lot of raw material, in-process material, and rework that is liable to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.~~

~~Raw materials and other ingredients susceptible to adulteration with aflatoxin or other natural toxins shall comply with current USFDA regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into a finished dietary ingredient or dietary supplement.~~

~~At a minimum, a representative sampling/testing program shall be in place to evaluate the presence of microbial contamination, aflatoxin or other natural toxins, and all other established specifications.~~

~~Written procedures shall be established and followed to verify the identity of each lot of raw material.~~

~~Approved raw materials shall be rotated so that the oldest approved stock is used first.~~

~~Raw materials shall be retested or reexamined after a specified time in storage or after exposure to conditions that are likely to have an adverse effect on the purity, quality, or composition of the raw material.~~

~~Rejected raw materials shall be identified and controlled under a system that prevents their use in manufacturing or processing operations, and they shall be stored in separate storage facilities.~~

~~Written procedures shall be established and followed.~~

~~8.6.4 Manufacturing operations~~

~~All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of dietary products shall be conducted in accordance with sanitation principles in a manner that provides protection against adulteration from chemical, microbiological, and other extraneous sources.~~

~~Written procedures shall be established and followed for all inspection, manufacturing, packaging, and storage operations.~~

~~Effective measures shall be taken to segregate raw materials, packaging materials, in-process materials, rework, and finished products.~~

~~All containers, processing lines, and major equipment used during the production of a batch shall be identified at all times to indicate their contents.~~

~~Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in the product.~~

~~Effective measures shall be taken for the identification, storage, and disposal of rejected and/or adulterated products.~~
~~Written procedures shall be established and followed that describe tests to be conducted to ensure the purity, compositions, and quality of the finished product.~~

~~Written procedures shall be established and followed prescribing the method for reprocessing batches that do not conform to finished goods standards or specifications.~~

~~Written procedures shall be established and followed.~~

~~8.6.5 Packaging and labeling operations~~

~~Filling, assembling, packaging, and other operations shall be performed in such a way that products are protected against adulteration.~~

~~Written procedures shall be established and followed for the receipt, storage, and examination of packaging materials.~~

~~Labels for each different product type, strength, or quantity of contents shall be stored separately and controlled in a manner consistent with Good Manufacturing Practices.~~

~~Obsolete labels, labeling, and other packaging materials shall be destroyed and such destruction documented in writing.~~

~~Written procedures shall be established and followed to ensure that the correct labels, labeling, and packaging materials are issued and used.~~

~~Each package shall be identified with a lot number that permits determination of the history of the manufacture and control of the batch.~~

~~Packaging shall be examined to provide assurance that the containers and packages in the lot have the correct labels and lot numbers.~~

~~Written procedures shall be established and followed.~~

~~8.7 Warehousing, distribution, and post-distribution processes~~

~~8.7.1 Storage and distribution~~

~~Storage and transportation of finished product shall be conducted under conditions that protect the product against physical, chemical, and microbial adulteration, as well as deterioration of the product and container.~~

~~Distribution records shall be maintained and retained for at least one year beyond the expiration date or shelf life.~~

~~Written procedures shall be established and followed.~~

~~**8.7.2 Written recall procedures**~~

~~Procedures shall be established and followed that define the recall of product(s) should it become necessary.~~

~~Written procedures shall be established and followed.~~

~~**8.7.3 Complaint files**~~

~~Written procedures shall be established and followed for the handling of all written and oral product complaints. Such procedures shall provide for review by the quality control unit and determination of the need for an investigation.~~

~~A written record of each complaint shall be maintained for at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record shall include, where known, the name and description of the product, lot number, source and nature of the complaint, and response, if any. When an investigation is conducted, the written record shall include the findings of the investigation and follow up action taken.~~

~~**8.7.4 Returned products**~~

~~Returned products shall be identified as such and held. Unless examination, testing, or other investigations prove that the product meets standards of purity, composition, and quality, it shall be controlled to prevent redistribution.~~

~~A returned product may be reprocessed provided that the subsequent product meets appropriate quality and safety specifications.~~

~~Records pertaining to returned products that are reprocessed and/or redistributed shall be maintained and shall include the name and description of the product, lot number, reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned product.~~

~~Records shall be maintained for at least one year after the expiration or shelf life date of the batch of product.~~

~~Written procedures shall be established and followed.~~

~~**8.7.5 Product salvaging**~~

~~Products that have been subjected to improper storage conditions including, but not limited to, hazardous chemicals, extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged, nor returned to the marketplace.~~

~~Written procedures shall be established and followed.~~

~~**8.7.6 Defect action level**~~

~~Some dietary ingredients and dietary supplements, even when produced under GMP, contain natural or unavoidable defects that at low levels are not hazardous to health. The USFDA and other applicable regulatory agencies have established maximum levels for these defects in foods produced under GMP and uses these levels in deciding whether to recommend regulatory action.~~

~~Defect action levels shall also be established for dietary products whenever it is necessary and feasible to do so. The manufacturer of a dietary product shall utilize quality control operations that reduce natural or unavoidable defects to the lowest level that is currently feasible.~~

~~The mixing of a dietary ingredient or dietary supplement containing defects beyond any established defect action level with another lot of dietary ingredient or dietary supplement shall not be permitted and renders the final lot adulterated, regardless of the defect level of the final product.~~

~~Written procedures shall be established and followed.~~

~~8.7.7 Reserve samples~~

~~A reserve sample of each raw material and each batch of a product, at least twice the quantity necessary to perform all the required tests, shall be retained, packaged, and stored under conditions consistent with the product labeling until at least one year after the expiration date.~~

~~Written procedures shall be established and followed.~~

~~8.8 Files for substantiation of health claims and statements of nutritional support~~

~~A file shall be maintained that includes information for substantiating health claims and statements of nutritional support.~~

~~Written procedures shall be established and followed.~~

8.~~9~~2 Compliance with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Manufacturers of Dietary Supplements shall submit application to USFDA for registration, receive a Registration Number, and provide the Registration Number upon request.

~~8.10 Record retention~~

~~Written procedures shall be established and followed for recordkeeping.~~

~~Records of regulatory inspections shall be kept on file with documented corrective action.~~

~~Records of testing, production, control, distribution, and documentation required for Good Manufacturing Practices shall be retained for at least one year after the expiration or shelf life date of the batch.~~

~~Raw materials records shall be maintained for at least one year after the expiration or shelf life date of the last batch of product incorporating the raw material.~~

~~All records relating to the manufacture of a product (e. g., records of maintenance, cleaning, and calibration of equipment) shall be maintained for at least one year after the expiration or shelf life date of the last batch of product produced.~~

8.3 Compliance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act

Written procedures shall be established and followed for reporting serious adverse events to the USFDA in accordance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act.

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