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NSF International Standard for Dietary Supplements — Dietary supplements

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8 Good Manufacturing Practices

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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.

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 incoming raw material in accordance with the receiving manufacturer's specifications. Specifications shall include identity, and as applicable to the material, for purity, quality, strength, and composition.

Written procedures shall be established and followed to verify the identity of each lot of raw material. These procedures may include quality policies regarding vendor qualification which support reduced testing.

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.

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