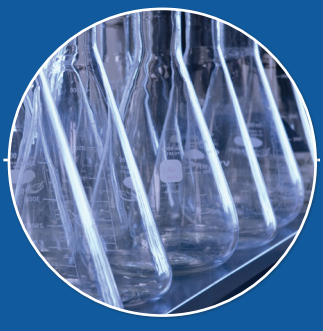
NSF International Standard /
American National Standard

NSF/ANSI 173 - 2016

Dietary Supplements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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

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Foreword[2]

The purpose of NSF/ANSI 173 is to serve as an evaluation tool for analyzing dietary supplements. Certification to this Standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This Standard provides test methods and evaluation criteria to allow for the determination that a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this Standard as they become available.

NSF/ANSI 173 was developed with participation from the dietary supplements industry, public health regulators, and distributors of dietary supplements. Participation and technical guidance was provided by representatives of the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association.

This edition of the Standard (NSF/ANSI 173-2016) includes the following revisions, which allow NSF International increased flexibility in selecting finished product claims for analysis based on the number of finished product claims and ingredients present on the product label.

Issue 49

This ballot revised language in 5.3.1.1 to provide transparency to manufacturers (i.e. purchasers of raw materials) and consistency between raw material evaluations and finished product evaluations.

Issue 50

This ballot added new language that required a prescribed protein method for measuring and subtracting non-protein nitrogen sources as well as free amino acids from the protein result.

Issue 51

This ballot added language specifying maximum caffeine levels per serving.

Issue 54

This ballot is added new language that exempted probiotic products from the required Total Aerobic Microbial Count and Total Combined Yeast Mold Count due to the nature of the product.

Issue 57

This ballot revised the way that NSF/ANSI 173 addresses the oil rancidity requirement by removing the oil rancidity requirement from testing verification section (NSF/ANSI 173, Section 5-7) and shifting it to the Good Manufacturing Practices Section 8.

Issue 58

This ballot created a more current list of pesticides for NSF/ANSI 173.

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Issue 60

This ballot updated NSF/ANSI 173 to replace the term “raw material” with either “component”, “components, including dietary ingredients”, or “dietary ingredient” as appropriate.

NSF offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact the General Manager of Dietary Supplements, P.O. Box 130140, Ann Arbor, Michigan 48113–0140 or at 734-769-8010.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a Continuous Maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on Dietary Supplements at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

NSF International Standard
for Dietary Supplements —

Dietary supplements

1 General

1.1 Purpose

This Standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified, that the product contains the quantity of dietary ingredients and marker constituents declared on the product label, and that the product does not contain unacceptable quantities of contaminants.

This Standard provides criteria for determining that Good Manufacturing Practices were followed in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that contain one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document. Conventional foods are excluded from the scope of this Standard.

Manufacturers shall exercise due diligence to ensure compliance with all applicable regulatory requirements, but compliance with this Standard in itself does not imply that all regulatory requirements have been met.

1.3 Formulation submission

The manufacturer shall submit, at a minimum, the following information for each product:

— complete formulation information, which includes the following:

  — the composition of the formulation (in percent or parts by weight for each ingredient in the formulation including excipients);

    NOTE – Ranges shall be considered acceptable.

  — the reaction process, if applicable;

  — the component ID number (if applicable), chemical/material name, trade name and supplier(s) for each chemical present in the formulation;

  — a list of known or suspected impurities associated with the finished product; and