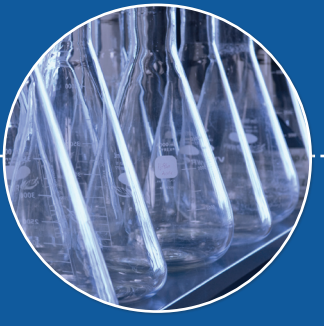
NSF International Standard /
American National Standard

NSF/ANSI 173 - 2019

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

Dietary Supplements

Standard Developer
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Contents

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 contains the following revisions:

Issue 81

This revision expands the content of NSF 173 with respect to its references to known toxic constituents and known adulterants and to add recognition of certain botanical species that are prohibited from use in dietary supplements. Changes were made to Section 5.3.4 and Annex N-1 (formerly Annex A).

Issue 84

This revision updates the definition of “dietary supplement” (Section 3.8)

This revision also includes an editorial update to the names of the Annexes within. The Annexes are being changed from alpha characters to numeric, preceded by a ‘Normative’ or ‘Informative’. The table below shows the previous name of the Annex with the corresponding new name of the Annex:

Annexes	
Previously known as:	**Now known as:**
Annex A	Normative Annex 1 (N-1)
Annex B	Informative Annex 1 (I-1)
Annex C	Informative Annex 2 (I-2)
Annex D	Normative Annex 2 (N-2)

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, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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NSF/ANSI 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 (GMP) 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