



*NSF International Standard /
American National Standard*

NSF/ANSI 173 - 2017

Dietary Supplements



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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

Standard Developer

NSF International

Designated as an ANSI Standard

July 11, 2017

American National Standards Institute

Prepared by
The NSF Joint Committee on Dietary Supplements

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
January 2003

Revised July 2005 Revised 2018
Revised August 2006
Revised July 2007
Revised April 2008
Revised September 2008
Revised April 2009
Revised November 2010
Revised September 2011
Revised August 2012
Revised February 2014
Revised April 2016

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation "NSF/ANSI 173 – 2017."

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Foreword²

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 173-2017) 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 61

Adds the ability to use simulated gastric fluid as a disintegration test method for uncoated, film-coated, plain-coated, and hard and soft gelatin capsules (section 5.4.1).

Issue 63

Adds labeling requirements and disclosures for caffeine under (section 4.1).

Issue 64

Adds labeling requirements for probiotic products or ingredients: CFUs, storage directions, and strain identification (section 4.2).

Issues 69 & 74

Revises maximum allowable levels (MAL) for pesticides as contaminants in Dietary Supplements in Annex D.

Issue 71

Updates AOAC, *Official Methods of Analysis*, Normative References to the most current edition (section 2)

Issue 72

Updates the units from CFU/g to MPN/g or MPN/mL in Table 8.1 and Table 8.3 (section 8).

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

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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