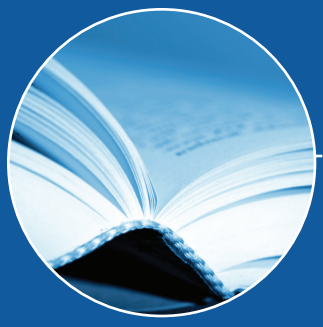
NSF International Standard /
American National Standard

NSF/ANSI 173 - 2010

Dietary Supplements



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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

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NSF International

American National Standards Institute

Designated as an ANSI Standard
November 22, 2010

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 August 2006
Revised July 2007
Revised April 2008
Revised September 2008
Revised April 2009
Revised November 2010

Published by

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

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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 (NSF/ANSI 173-2010) includes the following revisions:

Issue 31 - Diethylene glycol (DEG)
Sections 5.3.6.2 Contaminants in Glycerin and 7.5.2 Test methods for Glycerin have been added to the Standard.

Issue 33 - Section 7
Testing methodologies have been updated in Section 7.3 Test methods for microbiological contaminants.

Issue 34 – Dioxins
Acceptance levels for dioxins and dioxin-like PCBs have been updated in Section 5.3.6 Industrial Contaminants.

Issue 35 - Enteric Coated Tablets
Disintegration testing for delayed release/enteric coated capsules and tablets has been updated in Section 5.4 Disintegration.

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. Comments should be sent to Chair, Dietary Supplements, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140,USA.

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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 also 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 man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. This Standard does not include products represented for use as conventional foods.

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.

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 raw material 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