NSF/ANSI 173 Dietary Supplements Product Certification Standard

November 8, 2022

NSF INTERNATIONAL
789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA

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NSF/ANSI 173
ONLY ANSI-ACCREDITED DS PRODUCT STANDARD

Public, accredited Standards ensure dynamic documents with requirements that are:

- Current —standards are revised annually at a minimum
- Transparent —standards are public documents available to everyone
- Balanced —standards are created and maintained with balanced representation of stakeholders

ANSI PROCESS

- ANSI Standards are developed by stakeholders who are directly impacted.
  - Joint Committee is convened with a balanced representation of public health/regulatory, industry and user members
  - Joint Committee oversees standard creation and revisions
    - Ensures that standards address public health, safety, and environmental issues
    - Votes to approve standards and revisions
    - Responds to requests for interpretation of standards

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ANSI PROCESS

JOINT COMMITTEE – DIETARY SUPPLEMENTS
DRAFT Agenda
Tuesday, November 1, 2022
8:00 am – 12:00 pm PT
The Beacon Center 4505 W Hacienda Ave g2, Las Vegas, NV 89118
Microsoft Teams Click here to join the meeting

Draft Agenda

	Item	Speaker
8:00	Welcome	R. Brooker / B. Zamora
	Roll Call	R. Brooker
	Antitrust Statement	R. Brooker
	Review of Agenda	B. Zamora
	Review of Draft Meeting Summary: October 26, 2021	B. Zamora
	Membership	R. Brooker / B. Zamora
	Withdrawn	
8:10	DS-2021-5 Collagen Peptides 173i100	R. Brooker

ANSI PROCESS

8:12	**Recent Ballots**	
	DS-2021-6 Mercury 173i101	R. Brooker
	DS-2022-1 Clean up 173i102	R. Brooker
	DS-2022-1 And/or 173i103	R. Brooker
	DS-2016-8 Probiotic Viability 173i66	R. Brooker
	DS-2021-4 Section 7.3.7 *E. coli* 173i99	R. Brooker
	Old Issues	
8:20	DS-2021-1 Remove Section 5.3.7 Other product claims 173i96	B. Reinbold
8:50	DS-2022-3 Adulterants 173i104	J. Travis
9:20	DS-2022-4 Fish Oil Section 5.3.6.1 173i105	H. Rice

NSF/ANSI 173 CONTENTS

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GENERAL

Purpose

This Standard provides test methods and evaluation criteria for dietary supplement products

Scope

Defines inclusion and exclusions

Formulation submission

The manufacturer shall submit the complete formulation information

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NORMATIVE REFERENCES

A list of the referenced documents cited in the document in such a way as to make them indispensable for the application of the document.

Examples:

21 CFR Chapter 9, Federal Food, Drug and Cosmetic Act (FFDCA)

21 CFR § 101.9, Nutrition Labeling of Food

21 CFR § 101.36, Nutrition Labeling of Dietary Supplements

21 CFR Chapter 21, Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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DEFINITIONS

Terms used in this Standard that have special technical meaning are defined here

3.12 dietary supplement:[12] A product (other than tobacco) that:

— is intended to supplement the diet and bears or contains 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;

— is intended for ingestion in pill, capsule, tablet, powder, or liquid form;

— is not represented for use as a conventional food or as the sole item of a meal or diet;

— is labeled as a "dietary supplement" or has the word "dietary" deleted and replaced by the name of the dietary ingredient(s) in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins);

— does include an article that is approved as a new drug under Section 505, certified as an antibiotic under Section 507, or licensed as a biologic under Section 351, of the Public Health Service Act (42 USC § 262), and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary (US Department of Health and Human Services, FDAP) has issued a regulation, after notice, and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under Section 402(f); and

— does not include an article that is approved as a new drug under Section 505, certified as an antibiotic under Section 507, or licensed as a biologic under Section 351 of the Public Health Service

LABELING AND LITERATURE REQUIREMENTS

Product labels shall declare the identity of dietary ingredient(s) and/or marker constituent(s) included in the product. Labels of products other than proprietary blends shall declare the quantity of each dietary ingredient and/or marker constituent, which shall be labeled by common name according to the Merck Index or in accordance with the appropriate regulatory agency guidance when available. Labels of products containing botanicals shall include the part of the plant from which the ingredients are derived. Common names of botanicals shall be in accordance with Herbs of Commerce or the International Code of Botanical Nomenclature. The amount of active or desired ingredient shall be listed in addition to the total amount of the ingredient. Product literature may include this information.

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LABELING AND LITERATURE REQUIREMENTS

Caffeine

Supplements containing 5 mg to 25 mg of naturally occurring caffeine must declare the presence of caffeine on the label.

Supplements containing 25 mg or greater of naturally occurring caffeine must declare the total amount of caffeine per serving on the label

In addition, if the product contains caffeine at greater than 100 mg per serving, warnings are required

- do not use if sensitive to caffeine
- not recommended for use by children under 18 years of age
- not recommended for use by pregnant or nursing women

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LABELING AND LITERATURE REQUIREMENTS

Probiotics

identification of the bacteria including genus, species, and strain based on widely accepted nomenclature

Extended release

If the supplement is manufactured using an extended release technology not intended to follow the USP criteria, then intended release characteristics must be disclosed on the product label

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PRODUCT REQUIREMENTS

Identity

Ingredient —the identity of the dietary ingredient shall be verified

Finished Product —The finished product identity claims shall be reviewed to determine if select claims shall be verified in accordance with Section 6.1 or 8

Quantity

Ingredient —COA claims for dietary ingredients shall be reviewed to determine a set of verification tests to confirm quantity

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PRODUCT REQUIREMENTS

Quantity

Finished Product

Finished product claims shall be reviewed to determine a set of verification tests to confirm quantity of dietary ingredients, marker constituents and nutritional declarations as declared on the label in accordance with Sections 6.2 and 8

The product tested shall contain at least 100% (minus the measure of uncertainty of the analytical method) of the quantity of each Class I dietary ingredient or marker constituent

The product tested shall contain at least 80% (minus the measure of uncertainty of the analytical method) of the quantity of each Class II dietary ingredient or marker constituent

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PRODUCT REQUIREMENTS

Contaminants

Metals

Ingredients

Finished Products

- inorganic arsenic content shall not exceed 0.01 mg per daily dose (mg/d)
- cadmium content shall not exceed 0.0041 mg/d
- chromium (VI) content shall not exceed 0.02 mg/d
- lead content shall not exceed 0.01 mg/d
- mercury content shall not exceed 0.002 mg/d

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PRODUCT REQUIREMENTS

- Pesticides
- Microbiological contaminants
  - Dietary ingredients and finished products
    - Aflatoxins shall be less than 20 ppb
    - Liquid products with ≤50% alcohol shall not contain Pseudomonas aeruginosa
    - Liquid products with an alcohol content ≥ 50% are exempt from microbial testing.
    - Products containing probiotic bacteria are exempt from total aerobic microbial count and their limits

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NSF/ANSI 173 DIETARY SUPPLEMENT STANDARD

PRODUCT REQUIREMENTS

Table 5.3
Acceptable limits for microbiological contaminants in finished products[1]

Finished products		Aerobic	Yeast / mold	Enterobacteriaceae
Category 1	finished products containing only vitamin and minerals	1×10^3 CFU/g	1×10^2 CFU/g	1×10^2 CFU/g
Category 2	finished products containing botanical ingredient – extract / other dietary supplement ingredient	1×10^4 CFU/g	1×10^3 CFU/g	1×10^2 CFU/g
Category 3	finished products containing botanical ingredients – nonextract	1×10^7 CFU/g	1×10^5 CFU/g	1×10^4 CFU/g

[1] The category designation shall be based on ingredients present at 1% or more by weight in the formula as provided in the full product formulation. For a product containing ingredients from more than one category, the finished product category will be assigned based on the ingredient with the highest category number.

Table 5.4
Acceptable limits for pathogenic microbiological contaminants in finished products[1]

Finished products		*Salmonella* spp.	*E. coli*[2]	*S. aureus*
Category 1	finished products containing only vitamin and minerals	ND[3]	ND[3]	ND[3]
Category 2	finished products containing botanical ingredient – extract / other dietary supplement ingredient	ND[3]	ND[3]	ND[3]
Category 3	finished products containing botanical ingredients – nonextract	ND[3]	1×10^2 CFU/g	ND[3]

[1] The category designation shall be based on ingredients present at 1% or more by weight in the formula as provided in the full product formulation. For a product containing ingredients from more than one category, the finished product category will be assigned based on the ingredient with the highest category number.

Examples:

a) A product containing only Vitamin C and zinc shall be in Category 1.
b) A product containing Vitamin C, zinc, and green tea extract shall be in Category 2.
c) A product containing Vitamin C, zinc, and Echinacea shall be in Category 3.

[2] Upon the presence of *E. coli*, Section 7.3.7 is to be followed to determine whether the colonies are enterovirulent. There is a zero tolerance for the presence of enterovirulent *E. coli*.

[3] ND = Not detected. Not detected requires that no colonies shall be present in 10 g of sample when tested under the conditions of the USP Method cited in Section 7.3. The detection level for this testing is 10 CFU/g for the period of time tested.

PRODUCT REQUIREMENTS

Botanical constituents

- Aristolochic acid
- Pyrrolizidine alkaloids
- Ephedrine alkaloids
- Known adulterants

Industrial contaminants

- PCBs, PCDDs, PCDFs and dioxin-like PCBs in fish oil
- Diethylene glycol in glycerin
- Residual solvents

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PRODUCT REQUIREMENTS

Disintegration

- Standard
- Delayed release
- Extended release

Caffeine

- Less than 200 mg per serving and less than 800 mg per daily dose

Protein

- Products with protein greater than 5% daily value (DV), shall exclude quantifiable nonprotein nitrogen-containing substances

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PRODUCT REQUIREMENTS

Hemp and/or hemp derived ingredients

- THC content shall not exceed the limit established by the country of sale
- THC concentration must account for the potential conversion of THCA into THC

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Test methods used by testing laboratories for identification and quantification

Identification test methods

Morphological, Microscopic and Chemical

Scientifically valid and fit for purpose approaches include comparison to authentic reference materials (see ISO/TR 79:2015),17 official compendia, or other appropriate references, including botanical or pharmacognosy literature

Sensory

These methods are highly dependent on individual training, experience, and sensory sensitivity. The qualifications of each individual using sensory evaluations shall be documented.

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TEST METHODS USED BY TESTING LABORATORIES FOR IDENTIFICATION AND QUANTIFICATION

Quality assurance for identification test methods

Identification test methods shall be performed using certified reference standards or materials when available.

Ideally, a reagent blank (negative control), a reference standard (positive control) and the sample are to be prepared and compared by the analysis technique.

If no reference standard is available, and published literature provides photos or drawings of macroscopic or microscopic characteristics or fingerprint descriptions, use of this information to support the identity confirmation is allowable

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TEST METHODS USED BY TESTING LABORATORIES FOR IDENTIFICATION AND QUANTIFICATION

Quantification test methods

The quantity of marker constituents shall be evaluated in accordance with the most appropriate method, where such exists. Sources for methods should include but are not limited to AOAC International, AHP, USP, and other method sources.

The quantity of vitamins and minerals shall be evaluated in accordance with the methods listed in the AOAC International, USP, or other method sources.

The most appropriate available method should be selected to confirm quantity claims for the product under evaluation. Sources for methods should include AOAC International, AHP, USP, and other method sources. The selected method is to be scientifically valid and suitable for the purpose of analysis of the specific sample type being tested.

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TEST METHODS USED BY TESTING LABORATORIES FOR IDENTIFICATION AND QUANTIFICATION

- Quality assurance for quantitative test methods
  - Calibration
    - Multilevel calibration curves
    - Single-level calibration curves
  - Blanks
  - Repeatability / accuracy
    - All matrices for which the laboratory has not previously performed repeatability studies shall be prepared and analyzed in triplicate.

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TEST METHODS USED BY TESTING LABORATORIES FOR IDENTIFICATION AND QUANTIFICATION

Quality assurance for quantitative test methods

- Accuracy
  - Analysis of a CRM or in-house control material (traceable to a CRM if possible) may be used if the available CRM matrices or in-house controls represent a good match to the sample matrix.
  - Two additional preparations shall be spiked with the reference standard(s) and analyzed to assess recovery.
- Continuing calibration verification (CCV)

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TEST METHODS USED BY TESTING LABORATORIES FOR DETECTION OF CONTAMINANTS

Test methods for metals

Pesticides

- Multiresidue methods
- Methods for pesticides in Panax ginseng and Panax quinquefolius

Test methods for microbiological contaminants

- USP <2021> and <2022>

Aflatoxins

Test methods for chemical contaminants

- The most appropriate method should be selected to confirm claims for the product under evaluation.

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TEST METHODS USED BY TESTING LABORATORIES FOR DETECTION OF CONTAMINANTS

Test methods for PCBs, dioxins and dioxin-like PCBs in fish oil

Test method for residual solvents

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GOOD MANUFACTURING PRACTICES (GMP)

The manufacture and handling of dietary supplements and dietary supplement ingredients shall meet all applicable regulatory requirements set forth by 21 CFR § 111, with the following additional requirements

- Written recall procedures
- Compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Compliance with the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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GOOD MANUFACTURING PRACTICES (GMP)

Requirement for testing of diethylene glycol (DEG) in glycerin ingredients

Requirement for oils —Rancidity

Solvents —food or pharmaceutical grade

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