



U.S. Pharmacopeia
The Standard of QualitySM

USP Standards Development

The United States Pharmacopeial (USP) Convention establishes state-of-the-art documentary and reference standards to ensure the quality and consistency of medicines, dietary supplements, and food ingredients. The existence of public, science-based standards for these substances is essential to maintaining and improving public health. Developed through a unique process of public involvement, standards setting is USP's core activity.

USP provides documentary standards in monograph form for more than 4,000 prescription and over-the-counter drugs, dietary supplements, medical devices, and other health care products—disseminated through the *United States Pharmacopeia* and *National Formulary* (*USP–NF*). USP also establishes documentary standards for more than 1,000 food ingredients—published in the *Food Chemicals Codex* (*FCC*). USP Reference Standards are physical materials (chemical and biological) used by the pharmaceutical and food industries to test conformity to *USP–NF* and *FCC* monograph standards.

USP–NF

This publication contains two separate official compendia—the *United States Pharmacopeia* (*USP*) and the *National Formulary* (*NF*). *USP* was established in 1820 and contains legally recognized standards of identity, strength, quality, purity, packaging, and labeling for active ingredients and therapeutic products, including nutritionals and dietary supplements. The *NF*, established in 1888 by the American Pharmaceutical Association, includes standards for excipients, botanicals, and other similar products. USP purchased the *NF* in 1975, combining the two publications to create the *USP–NF*.

The U.S. Federal Food, Drug, and Cosmetic Act of 1938 recognizes *USP–NF* standards as enforceable by the Food and Drug Administration (FDA). All prescription and over-the-counter medications sold in the United States must—by law—meet the standards in the *USP–NF*. In addition, these standards are recognized worldwide—used in more than 130 countries around the globe.

FCC

This compendium provides standards for the identity, quality, and purity of ingredients contained in processed foods—including colorings, flavorings, nutrients, preservatives, and processing aids. USP acquired the *FCC* in 2005 from the Institute of Medicine, which had published the compendium since 1966. In 2008, USP released the Sixth Edition of the *FCC*, the first version published under its direction.

The *FCC* is an internationally recognized compendium. Adherence to its standards carries regulatory weight in many countries, sometimes as a legal requirement for manufacturing or importing, or for demonstration of self-regulation.

USP–NF and FCC Revision Processes

The revision processes for USP compendia are continuous. Revisions, along with proposals for new standards, can be suggested by any health care practitioner, scientist, consumer, or organization, and are considered and reviewed by the Expert Committees of USP's Council of Experts. If the revision is approved, it will be published, depending on the date, either in the next year's *USP–NF* or in one of its two semi-annual *Supplements* for medicines, or in the next biennial edition of the *FCC* or its annual *Supplement* for food ingredients.

The Council of Experts is USP's elected scientific standards-setting body. It includes 40 Standards Expert Committees that develop and revise compendial approaches for standardization of therapeutic drugs and biologics, blood and blood products, vaccines, and

Headquarters

12601 Twinbrook Parkway
Rockville, Maryland 20852
+1-301-881-0666

Europe/Middle East/Africa

Münchensteinerstrasse 41
CH-4052 Basel, Switzerland
+41 (0)61 316 30 10

USP–India Private Limited

ICICI Knowledge Park
Genome Valley
Labs 7-10, Phase III
Turkapally, Shameerpet
Ranga Reddy District
Hyderabad 500 078, A.P., India
+91-40-2348-0088

USP–China

Building 11
Lane 67 Libing Road
Zhongjiang Hi-Tech Park
Shanghai, 201203, China
+86-21-51370600

USP–Brazil

WTorre Technology Park
Avenida Ceci 1600, Barueri
São Paulo/SP - Brasil
+55 11 3245-6400



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other articles, and 17 Information Expert Committees that consider every aspect of clinical medicine as they relate to USP initiatives, including development of the Medicare Part D Model Guidelines. These committees focus on disease by organ system, as well as on cross-cutting topics such as special populations (the elderly and children), infectious diseases, critical care medicine, and general topics, such as therapeutic decision support and healthcare informatics.

Reference Standards

USP Reference Standards are vials of highly characterized (tested) chemical substances, used worldwide to conduct the tests that ensure each substance meets the standards listed in the *USP-NF* or *FCC*. USP has more than 2,100 official reference standards for pharmaceuticals and food ingredients, one of the largest collections in the world.

Reference Standards Development Process

When USP identifies the need for a new reference standard (based on monographs in USP compendia that require its use), it requests the bulk material from the manufacturer. USP subjects candidate materials it receives from manufacturers to rigorous analysis and review. USP tests the materials in its own laboratories and then requests collaborative testing by the FDA and independent laboratories. USP compares and analyzes the results of this collaborative testing and prepares a report for its independent volunteer Reference Standards Expert Committee, which determines whether the candidate material is suitable to be established as an official USP Reference Standard. USP's meticulous packaging, stringent quality control checks, and Continued Suitability for Use testing enhance the quality and integrity of official USP Reference Standards.

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