USP Standards: Monographs (Written Standards)

What is a monograph?

A monograph is a written document, or standard, that describes an item (e.g., a finished drug, a drug ingredient, or food chemical). A monograph published in any USP compendium (in a book, CD-ROM, or on line) provides: the name of a substance; its definition; package, storage, and labeling requirements; and information on tests needed to ensure the substance is of the appropriate strength, quality, and purity.

Why are monographs important?

Monographs give scientists, governments, manufacturers, and others a public standard by which to judge an article's quality. Without a monograph, the uniformity, consistency, and quality of ingredients and products cannot be assured. The existence of a public standard for substances consumed in the global marketplace is a key element of the safety nets that help maintain and improve public health.

What is a public standard?

Public standards are developed in an open and collaborative process, seeking informed input from independent experts with a wide variety of backgrounds – healthcare, regulatory, industry, academia, and others. This is different from private standards, which may be developed by a manufacturer and not made available for outside assessment and commentary. While private standards are frequently the starting point for USP standards (see below) and are generally of high quality, the transparency of USP's open process provides a high level of public assurance that the standard had been developed using a broadly representative body of science.

What are monographs used for?

Primarily, monographs are used to help control the quality of pharmaceutical, dietary supplement, and food ingredient products. Governmental agencies (such as the FDA) use USP monographs to test for compliance to the standard, and they guide testing for identity, strength, and purity by the manufacturer.

What is USP's role in developing monographs?

USP has a critical role in developing monographs as public standards. USP creates the official public monographs for prescription and over-the-counter medications in the United States in conjunction with the pharmaceutical industry and others. Monographs for these products are published in the *United States Pharmacopeia and National Formulary* (*USP–NF*). The current *USP–NF* comprises more than 4,500 monographs and are named in the U.S. Federal Food, Drug, and Cosmetic Act as the official compendia of the nation. *USP–NF* standards are also used in more than 130 countries.

USP also creates monographs for food ingredients in processed foods (including colorings, flavorings, nutrients, preservatives, and processing aids), working in coordination with the food industry and other stakeholders. These standards are published in the *Food Chemicals Codex* (*FCC*)—the current edition of which includes more than 1,000 monographs. In addition, USP publishes the *Dietary Supplements Compendium* (*DSC*), comprising monographs that help ensure the quality of dietary supplements and their ingredients.

How are monographs developed?

USP–NF monographs: The development process frequently begins with manufacturers, who submit a draft monograph to USP. This draft monograph is the starting point for the official public standard. USP scientific staff take this draft monograph, review the data and conduct laboratory tests, and then prepare a proposed monograph—which is sent to a group of expert scientific volunteers (USP's Council of Experts [CoE] and its Expert Committees) for their scientific opinion of the relative merits of the proposal. If approved by the CoE, the proposed monograph is published in the *Pharmacopeial Forum* (*PF*). *PF* is a peer-reviewed journal that provides interested parties, such as pharmaceutical and dietary supplement manufacturers, government agencies and others, the opportunity to review and comment as the CoE develops and/or revises *USP–NF* standards—and is the working vehicle of the CoE. Public comments are received and reviewed by the appropriate USP Expert Committee. Once the comments are accepted and incorporated, the new monograph is published in the *USP–NF*. It then becomes an official monograph, and its requirements must be adhered to in order to market that product within the United States or other country that recognizes the *USP–NF* as its official compendia.

FCC monographs: A process similar to that described above for *USP–NF* is followed for *FCC*, except that proposed *FCC* monographs are published in the *FCC Forum*, an online vehicle that accepts public comment on proposed additions to *FCC* or revisions to any of its standards. These comments are reviewed by the CoE's Food Ingredients Expert Committee. If accepted, the new monograph is then published in the *FCC*.