USP-NF

The United States Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopeial standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements.

USP-NF Updates

- Two Notices of Intent to Revise (posted 17–Nov–2017)
- Two General Announcements (posted 17–Nov–2017)
- One Publication Correction (posted 17–Nov–2017)
- Four New or Revised Revision Bulletins (posted 17–Nov–2017)
- One New Interim Revision Announcement (posted 17–Nov–2017)
- USP 41-NF 36 Commentary- updated November 13, 2017 (posted 17–Nov–2017)
- Cumulative List Updated (posted 17–Nov?2017)

USP–NF Components

USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF.

Monographs

A monograph includes the name of the ingredient or preparation; the definition; packaging, storage, and labeling requirements; and the specification. The specification consists of a series of tests, procedures for the tests, and acceptance criteria. These tests and procedures require the use of official USP Reference Standards. Medicinal ingredients and products will have the stipulated strength, quality, and purity if they conform to the requirements of the monograph and relevant general chapters.

- View a sample USP–NF monograph.

General Chapters

Tests and procedures referred to in multiple monographs are described in detail in the USP–NF general chapters.

General Notices

The General Notices provide definitions for terms used in the monographs, as well as information that is necessary to interpret the monograph requirements.

Official Recognition

The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP–NF to avoid possible charges of adulteration and misbranding. Learn more.

Standards Established through a Public Process

USP creates and continuously revises USP–NF standards through a unique public–private collaborative process, which involves pharmaceutical scientists in industry, academia, and government as well as other interested parties from anywhere in the world.

Warning Notice about USP–NF on Unauthorized Websites