ABOUT USP
USP–NF
Understanding USP-NF
General Notices
Development Process
Publication and Comment Schedule
Pharmacopeial Harmonization
Anti-Counterfeiting Measures
Contact
Get Involved
Compendial Notices
Revisions and Commentary
Compendial Tools
Pharmacopeial Forum
FOOD CHEMICALS CODEX
PENDING & NON-US MONOGRAPHS
REFERENCE STANDARDS
USP VERIFIED
EDUCATION
USP IN DEVELOPING COUNTRIES
MEETINGS
SHOP ALL PRODUCTS

Information For:
Manufacturers
Regulators
Healthcare Providers
Consumers
Members/ Volunteers

Search USP Careers
Attend a USP Event

Home › USP–NF › Understanding USP-NF

Email Page Printable Version

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Understanding USP–NF

What is the USP–NF?

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

Monographs and General Chapters

The USP–NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and 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.

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.

Tests and procedures referred to in multiple monographs are described in detail in the USP–NF general chapters.
View a sample USP–NF monograph (118KB).

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

Official recognition

The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as the 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. The USP–NF is also widely used by manufacturers wishing to market therapeutic products worldwide. Meeting USP–NF standards is accepted globally as assurance of high quality.

Standards established through a public process

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

Warning: USP–NF on Unauthorized Web Sites

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If you are aware of an unauthorized Web site that claims to include the USP–NF, please report the Web site's address to webmaster@usp.org.

What's New

Call for Candidates: USP Expert Panel on Glycoconjugate Vaccine Product Class Chapter (05/17/11)
USP Expert Panel on Impurities in Drug Products (05/06/11)
Ten New Revision Bulletins (04/29/11)
Five Notices of Stage 6 Harmonization (04/29/11)
April Errata (04/29/11)
PF 37(3), May-June 2011 (04/29/11)
Revisions, Deferrals, Cancellations (04/29/11)
Expert Committee Work Plans (04/29/11)
Monograph Modernization list updated (04/29/11)
Interim Revision Announcement: <85> Bacterial Endotoxins Test (02/25/11)
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