



USP-NF

Background

In the United States and many countries, medicines must undergo rigorous quality testing before they are made available to patients. Manufacturers submit analytical testing data to regulatory authorities to demonstrate compliance with regulatory requirements, including product [identity, purity, potency, and performance](#).

Standardized analytical testing procedures and acceptance criteria give manufacturers and regulatory authorities consistent, independently verified ways to confirm medicine quality and protect consumers.

Opportunity to strengthen quality

Commonly accepted guidelines, such as those in the [USP-NF](#), help regulators, manufacturers, and other stakeholders advance the supply of quality medicines. They also support greater efficiency in the drug development and approval process, helping to prevent quality concerns from resulting in medicine shortages, and clarifying the proper distribution, storage, use and disposal of medicines.

USP solutions

- The *USP-NF* combines the *United States Pharmacopeia (USP)* and the *National Formulary (NF)*. It is an online platform in which over 100,000 subscribers access over 5,000 USP public quality standards for chemical and biologic medicines, active pharmaceutical ingredients (APIs), dietary ingredients and dietary supplements, and excipients, as well as standards for various analytical testing methods, medicine storage and distribution, compounded medicines, prescription labeling and many other aspects of medical products development, manufacture and use.
- *USP-NF* includes two types of documentary standards (monographs and General Chapters), General Notices, reagents and reference tables, and other resources. It is also one of the ways to access Pharmacopeial Forum where stakeholders comment on proposed new and updated standards.
- USP public quality standards are recognized in federal law for drugs marketed in the United States. They are also recognized by law in over 50 countries and used in more than 150 countries.

Why it's important

USP–NF standards provide a benchmark for evaluating the quality of medicines. They give manufacturers and other stakeholders independently validated analytical procedures and acceptance criteria that can help reduce risk and improve regulatory predictability. The online platform provides easy access to official, up-to-date standards they can use to develop and manufacture quality drug ingredients and finished products that meet regulatory requirements.

Web resources

- <https://www.usp.org/about/public-policy/overview-of-monographs>
- <https://www.usp.org/about/legal-recognition/standard-categories>
- <https://www.uspnf.com/purchase-usp-nf>