



USP documentary standards

Background

Pharmaceutical manufacturers and regulatory authorities check product quality across the entire supply chain from raw materials through manufacturing and distribution until the product reaches consumers. USP public documentary standards (also known as pharmacopeial or compendial standards) articulate agreed-upon testing methods and acceptance criteria used in quality assurance and quality control protocols provide benchmarks to evaluate medicine [identity, purity, strength and performance](#). They provide transparency on quality expectations for medicines. These public quality standards can be utilized by any stakeholder to help assess the quality of medical products.

Opportunity to strengthen quality

Manufacturers and regulatory agencies rely on clearly defined quality expectations for medicines and their ingredients, and methods to validate that they meet these expectations. USP documentary standards establish these expectations and the processes for authenticating them.

USP solutions

USP public documentary standards give manufacturers and regulatory authorities consistent, independently set analytical procedures and acceptance criteria to confirm medicine quality.

- *United States Pharmacopeia-National Formulary (USP–NF)* is an online platform for accessing over 5,000 currently official and pending USP documentary standards for medicines. *USP–NF* includes two main types of documentary standards: monographs and General Chapters.
- USP monographs are product-specific documentary standards that articulate quality attributes, tests, and acceptance criteria for chemical and biologic medicines, active pharmaceutical ingredients (APIs), and excipients. USP monographs are legally required quality standards for drugs marketed in the United States. They are also recognized by law in over 50 countries and used in more than 150 countries.
- USP General Chapters provide frequently cited procedures that can apply to multiple monographs. Compliance with General Chapters numbered below 1,000 is required when referenced in another General Chapter below 1,000, in monographs or in General Notices. General Chapters numbered 1,000 through 1,999 are informational.

Why it's important

USP public quality standards play an important role in the global medicines supply chain. They support the consistent development, manufacture, distribution, and administration of safe and effective medicines, helping governments and manufacturers increase the availability of safe, quality medicines. USP documentary standards provide manufacturers with precise quality specifications, making the approval process for generic medicines more efficient. Documentary standards also enable manufacturers and regulators to determine the identity of a drug, control for harmful levels of impurities, and ensure the correct potency of the drug and its ability to be properly absorbed in the body. This helps patients to trust that medicines with the same name identified in a USP documentary standard will be consistent in quality no matter who manufactures them.

Web resources

- Monographs
 - <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>
- General Chapters
 - <https://www.usp.org/frequently-asked-questions/identifying-official-text>
 - <https://online.uspnf.com/uspnf>
 - https://online.uspnf.com/uspnf/document/1_GUID-E09DC39F-1D28-4D90-8D76-0ED109FFB640_7_en-US?source=TOC