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URL

<http://www.usp.org/>

Subject

Pharmacopoeias – United States;
 Medicine—United States—Standards.
 Medicine -- United States -- Formulae, receipts, prescriptions.

Accessibility

On subscription base

Language

English, Chinese, Spanish, Portugal (Multilingual)

Publisher

The United States Pharmacopeial Convention

Brief History

The United States Pharmacopeia (USP) is a pharmacopeia for the United States published annually by the United States Pharmacopoeial Convention, a nonprofit organization that owns the trademark and copyright. The USP was founded in 1820.

Scope and Coverage

The USP is published in a combined volume with the National Formulary (a formulary) as the **USP-NF**. If a drug ingredient or drug product has an applicable USP quality standard (in the form of a USP-NF monograph), it must conform in

order to use the designation "USP" or "NF." Drugs subject to USP standards include both human drugs (prescription, over-the-counter, or otherwise), as well as animal drugs. USP-NF standards also have a role in U.S. federal law; a drug or drug ingredient with a name recognized in USP-NF is deemed adulterated if it does not satisfy compendial standards for strength, quality or purity. USP also sets standards for dietary supplements, and food ingredients (as part of the Food Chemicals Codex). USP has no role in enforcing its standards; enforcement is the responsibility of FDA and other government authorities in the U.S. and elsewhere.

Kind of Information

USP establishes written (documentary) and physical (reference) standards for medicines, food ingredients, dietary supplement products, and ingredients. These standards are used by regulatory agencies and manufacturers to help to ensure that these products are of the appropriate identity, as well as strength, quality, purity, and consistency. Prescription and over-the-counter medicines available in the United States must, by federal law, meet USP-NF public standards, where such standards exist. Many other countries use the USP-NF instead of issuing their own pharmacopeia, or to supplement their government pharmacopeia. USP's standards for food ingredients can be found in its *Food Chemicals Codex* (FCC). The FCC is a compendium of standards used internationally for the quality and purity of food ingredients like preservatives, flavorings, colorings and nutrients. While the FCC is recognized in law in countries like Australia, Canada and New Zealand, it currently does not have statutory recognition in the United States, although FCC standards are incorporated by reference in over 200 FDA food regulations. USP obtained the FCC from the Institute of Medicine in 2006. The IOM had published the first five editions of the FCC. USP also conducts verification programs for dietary supplement products and ingredients. These are testing and audit programs. Products that meet the requirements of the program can display the USP Verified Dietary Supplement Mark on their labels. This is different from seeing the letters "USP" alone on a dietary supplement label, which means that the manufacturer is claiming to adhere to USP standards. USP does not test such products as it does with USP Verified products.

Special Features

- USP conducts meetings and courses to bring together the world's leading scientific, regulatory, and healthcare experts to share knowledge and provide insight for the effective development and application of standards that help protect the global supply of medicines, dietary supplements, and foods. Users can browse and register for courses and webinars available around the world.
- USP conducts **User Forums** for free seminars on how to use USP resources, hot topics, and how to get involved with USP and also conducts Workshops on a variety of scientific, regulatory, and public health topics. Open to all interested parties.
- It has a Center for Pharmaceutical Advancement and Training Courses.
- The USP has another products like Food Fraud Database 2.0, Reference Standards, USP–NF, USP–NF Spanish Edition, USP-NF Archive, Dietary Supplements Compendium 2015, USP Dictionary, USP Compounding Compendium, Food Chemicals Codex,

Remarks

The United States Pharmacopeia is a compendium of drug information. Since 1992, USP has worked cooperatively with the United States Agency for International Development (USAID) to help developing countries address critical issues related to poor quality medicines. USP works internationally, largely through agreements with other pharmacopeias, as well as regulatory bodies, manufacturer associations and others. In recent years, USP signed a series of Memoranda of Understanding (MOU) with groups including the Chinese Pharmacopoeia Commission, nine countries belonging to the Association of Southeast Asian Nations (ASEAN), and the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (Roszdravnadzor). USP also operates an international office in Switzerland, and offices and laboratories in Brazil, India and China. In November 2014, a delegation from Global LifeSci Development Corporation, as part of Montgomery County's business visit to India visited US Pharmacopeial Convention at IKP Knowledge Park at Hyderabad in India.

Comparable Tools

- International Pharmacopoeia
(<http://apps.who.int/phint/en/p/about/>)
- European Pharmacopoeia
(<https://www.edqm.eu/>)
- Indian Pharmacopoeia Commission
(<http://ipc.nic.in/>)
- Chinese Pharmacopoeia
(<http://wp.chp.org.cn/en/index.html>)
- British Pharmacopoeia
(<https://www.pharmacopoeia.com/>)

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