



U.S. Pharmacopeia
The Standard of QualitySM

What is a Phar-ma-co-pe-ia?

In simple terms, the word *phar-ma-co-pe-ia* is a compound, created from two Greek words: *pharmakon* (medicine or charm) and *poiein* (to make).

Defined as “a book containing a compilation of pharmaceutical products with their formulas and methods of preparation,” the word pharmacopeia has a rich, historic meaning with roots tracing back to 15th century Florence, Italy¹. At that time, a physician named Lodovico dal Pozzo Tossichanelli did a smart, yet simple thing—he produced a “little book of drug formulas” in response to a request from the local guild of pharmacists seeking information about quality standards in drug therapy. Little did he know that he would be setting standards for the future of worldwide public health.

Centuries later across the Atlantic, America’s founding forefathers revived Tossichanelli’s idea and further defined the term “pharmacopeia.” It was used indiscriminately to label a variety of “drug books” regardless of whether they represented legal or authoritative standards.

In 1820, the *United States Pharmacopeia (USP)* was published containing formulae for the preparation of 217 drugs considered to be the “most fully established and best understood” at the time. In 1888, the American Pharmaceutical Association created the *National Formulary (NF)*, which included formulations and unofficial preparations for widely sold products.

Yet it wasn’t until the passage of the Federal Food and Drugs Act in 1906 that standards in the *USP* were recognized as official standards for the United States. The Federal Food, Drug, and Cosmetic Act of 1938 further solidified *USP*’s role in U.S. law, designating *USP*, as well as *NF* and Homeopathic Pharmacopeia standards, as enforceable by the U.S. Food and Drug Administration (FDA). Finally in 1975, USP purchased the *NF*, combining the two publications under one cover to create the *United States Pharmacopeia–National Formulary*.

The Modern Pharmacopeia

In modern times, the multi-billion dollar pharmaceutical industry produces thousands of drugs annually, although not much has changed with regard to the initial intent for a pharmacopeia.

The *USP–NF* contains more than 4,000 monographs for prescription and over-the-counter products, dietary supplements, medical devices, and other health care products. In its present form, somewhat different than Tossichanelli’s original black book, the *USP–NF* is published annually and is available as a CD-ROM and online as well as in hardcover. USP also produces an Asian edition and a Spanish edition of the *USP–NF*.

Other Pharmacopeias

In addition to USP, there are three other large pharmacopeias in the world, which include the European Pharmacopeia (EP) (www.phEur.org), the British Pharmacopeia (BP) (www.pharmacopeia.org), and the Japanese Pharmacopeia (JP) (<http://jpdn.nihs.go.jp/jp14e/index.html>), all of which share the goal of publishing and producing standards for pharmaceuticals.

While its global counterparts are part of the ministries of health in their countries, USP has remained a practitioner-based, nongovernmental standards-setting organization. All

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pharmacopeias, however, seek to advance public health by ensuring the quality and consistency of medicines and promoting the safe and proper use of medications.

USP Today

As they have been for nearly two hundred years, USP standards continue to be established today by volunteer scientific experts, through an open and transparent process that includes public involvement. USP's science-based standards are used and accepted worldwide.

In addition to developing standards for medicines and dietary supplements, USP sets standards for food ingredients in processed foods via the *Food Chemicals Codex (FCC)*. USP also participates in various activities beyond standards setting related to the application and use of standards—with the primary goal of improving global public health. These include patient safety initiatives such as medication error reporting programs; verification programs that assure the quality and purity of dietary supplements and pharmaceutical and dietary supplement ingredients; pharmacopeial education programs that offer instruction on how to meet official USP standards, among other related topics; and global assistance initiatives that work to improve drug quality and appropriate use of drugs in developing countries.

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1 Source: *The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000*

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