

What Is a Phar·ma·co·pe·ia?

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, Italy.¹ 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, early Americans 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, a group of physicians concerned for the quality and consistency of medicines published the first *United States Pharmacopeia (USP)*, which contained formulas 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 quality 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 official compendia enforceable under the adulteration and misbranding provisions. Finally in 1975, USP purchased the *NF*, combining the two publications under one cover to create the *United States Pharmacopeia–National Formulary (USP–NF)*.

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 4,500 monographs for prescription and over-the-counter products, dietary supplements, medical devices, and other healthcare 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, online, and in hardcover. USP also produces a Spanish edition of the *USP–NF*, and is working on versions in other languages as well.

In 2006, USP acquired the *Food Chemicals Codex (FCC)*, a similar book of quality standards for food ingredients (such as flavorings, colorings, stabilizers, etc.). While *FCC* is not recognized in U.S. law in the same way as the *USP–NF*, over 200 *FCC* standards are specified in FDA regulations, and many food manufacturers rely on it to help them ensure the quality of the ingredients they purchase and the products they sell. USP also publishes the *Dietary Supplements Compendium (DSC)*, comprising formulas and methodologies that help ensure the quality of the ingredients and supplements that millions of Americans take every day.

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

Other Pharmacopeias

In addition to USP, there are three other large pharmacopeias in the world, the European Pharmacopoeia (EP) (www.phEur.org), the British Pharmacopoeia (BP) (www.pharmacopoeia.co.uk), and the Japanese Pharmacopoeia (JP) (<http://jpdn.nihs.go.jp/jp14e/>), all of which share the goal of publishing and producing quality standards for pharmaceuticals. Other countries have smaller national pharmacopeias, and USP works collaboratively with many of them as well as with their larger counterparts.

While its global counterparts are part of the ministries of health in their countries or federations, USP has remained a practitioner-based, nongovernmental standards-setting organization. All pharmacopeias, however, seek to advance public health by helping to ensure the quality and consistency of medicines and promoting the safe and proper use of medications.

USP Today

As they have been for nearly 200 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 relied on worldwide.

In addition to developing standards for medicines, food ingredients, and dietary supplements, 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; verification programs that help ensure 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.