



AMERICAN INSTITUTE OF THE HISTORY OF PHARMACY

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This slide presentation was compiled and produced by Robert McCarthy, Ph.D., Professor and Dean *Emeritus* at the University of Connecticut School of Pharmacy for his class “The History of American Pharmacy.” Prof. McCarthy created this version of the slide talk for his class in the Spring of 2016.

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EVOLUTION OF THE PHARMACOPOEIA

PHRX 4001W-002

The History of American
Pharmacy

Spring 2016

An American Pharmacopeia

- 1808: The Massachusetts Pharmacopoeia is published providing a state guide to drug standards.
 - The Massachusetts Pharmacopoeia was used by apothecaries to properly fill prescriptions from physicians since it defined the identity of drugs and preparations.
- 1820: The U.S. Pharmacopeial Convention founded in Washington, DC; although all state medical societies were invited to send delegates, only 11 states attended; only about 200 drugs were included in the first *USP* since they were the only ones deemed “most fully established and best understood.”

United States Pharmacopoeia (USP)

- 1830: The first revision of the *USP* published; revisions continue at an interval of every 10 years.
- 1848: Congress passes legislation making the *USP* an official compendium.
- 1888: First *National Formulary (NF)* published by the American Pharmaceutical (now Pharmacists) Association.
- 1900: USP Convention and Board of Trustees created.
- 1906: *USP* and *NF* standards for strength, quality, and purity recognized as official.



Mt. Vernon, Va. May 4, 1900. U.S.P.

United States Pharmacopoeia (USP)

- 1938: *USP* and *NF* standards for strength, quality, purity, packaging, and labeling recognized as official and enforced by FDA; "New Drug" concept established; FDA approves drugs for safety before marketing.
- 1942: *USP* revision cycle changed to every 5 years.
- 1971: *USP* moves headquarters to Rockville, MD.
- 1975: *USP* acquires *NF* from APhA.
- 1977: *USP* and *NF* scope redefined: *USP* specifies standards for drug substances and dosage forms; *NF* specifies standards for excipients.
- 1980: *USP* and *NF* published under same cover; *USP* Dispensing Information (*USP* DI) published.
- 1993: Federal Omnibus Budget Reconciliation Acts (OBRA '90 and '93) name *USP* DI as source of information that state Medicaid agencies can use for drug utilization review, patient counseling, and medically accepted off-label uses of medicines.

United States Pharmacopoeia (USP)

- 1994: USP signs an agreement with the American Medical Association to combine the information in *AMA's Drug Evaluations* database with the *USP DI* database to develop a single product that contains drug and therapeutic information.
- 2002: *USP-NF* published annually.
- 2000s: USP develops offices/laboratories around the world and collaborates with the pharmacopoeias of other nations in developing drug standards.



Source: USP Web Site

National Formulary

- 1883: NY Pharmacist Samuel Bendiner and NY hospital pharmacist Charles Rice led an effort to modernize the *US Pharmacopoeia*; Bendiner inspired the creation of the *New York and Brooklyn Formulary (NYBF)*; Rice negotiated an agreement to share the information in the *NYBF* to develop a national formulary, which it was hoped would be used by physicians in prescribing rather than recommending the use of proprietary medicines.
- 1886: APhA published a preliminary draft of the *National Formulary of Unofficial Preparations*, asking for feedback from the pharmacy profession.
- 1888: The *National Formulary (NF)* is published for the first time by APhA.
- 1906: The second revision of the *NF* coincides with the passage of the Food & Drug Act, which named the *NF* as one of the official standards for pharmaceuticals, much to the surprise of APhA.

THE REFERENCE ONLY

NATIONAL FORMULARY

OF

UNOFFICIAL PREPARATIONS.

FIRST ISSUE.

BY AUTHORITY OF THE
AMERICAN PHARMACEUTICAL ASSOCIATION.



PUBLISHED BY THE AMERICAN PHARMACEUTICAL ASSOCIATION.

1888.

National Formulary (NF)

- The first three editions of the *NF* provided practicing pharmacists with formulas for small scale compounding, allowing for competition with ready-made preparations.
- 1916: *National Formulary IV* set “definite standards.”
- 1935: The *NF* established a drug standards lab at the University of Illinois College of Pharmacy.
- 1938: APhA established the Drug Standards Laboratory in Washington, DC.; during the 1960s, this lab was revitalized through financial support from USP (which was using this lab’s services) and the AMA.
- In 1960, there were discussion of merging the *NF* and *USP*; by 1966, formal discussion of a merger was underway.
- 1975: USP purchased both the *NF* and Drug Standards Laboratory from APhA.
- 1998: USP licensed *USP DI* to The Thomson Company; *USP DI* is published by their Micromedex subsidiary.



USP Today

- “USP is a unique organization whose activities are directed by three governing bodies composed of more than 900 volunteers and whose day-to-day operations are managed by an executive team and staff of more than 800 employees.”
- **“Governance:** USP is governed by the Convention membership, the Board of Trustees, and the Council of Experts and its Expert Committees. These decision-making bodies guide USP’s activities in the best interest of quality public health.”
- **“Executive Team:** USP’s executive team helps manage all USP operations at its five international locations in support of the governing bodies’ standards-setting activities. USP staff provide support for volunteer and member activities, scientific testing, quality assurance, standards acquisition, verification services, training in developing regions, education programs, customer service, harmonization, and outreach and communications efforts.”

Source: USP Web Site.

USP Today

USP's Compendial Activities

The *United States Pharmacopeia* and the *National Formulary* (USP–NF)



Food Chemicals Codex

USP Dietary Supplements Compendium

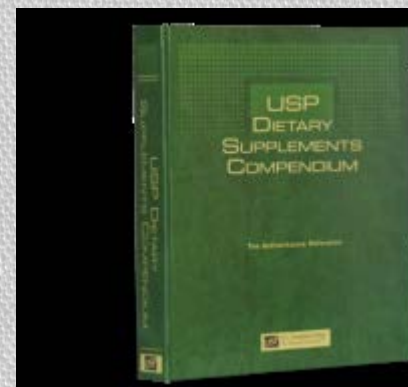
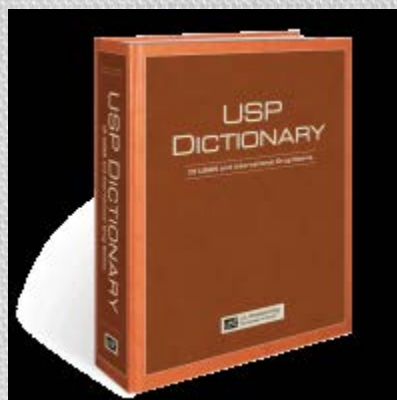
USP Medicines Compendium (MC)



Reference Standards

Other Resources

- Pharmacopeial Forum
- FCC Forum
- USP Dictionary
- Chromatographic Columns



USP Today

- *United States Pharmacopeia 38 - National Formulary 33*
 - Published November 1, 2014; official May 1, 2015
- *Supplement 1 to the United States Pharmacopeia 38 - National Formulary 33*
 - Published February 1, 2015; official August 1, 2015
- *Supplement 2 to the United States Pharmacopeia 38 - National Formulary 33*
 - Published June 1, 2015; official December 1, 2015