UNITED STATE PHRMACOPOEIA

- The U.S. Pharmacopeia Convention (USP) is a private, non-profit body of 300 delegates representing state and national associations and colleges of medicine, nursing, and pharmacy; industry; and agencies of the federal government. Incorporated in 1900, the purposes of USP are to set standards for health care products in the U.S. and to collect and disseminate product use and information to providers and consumers.
- Every five years, USP publishes revised standards for drugs in *The United States Pharmacopeia* and *The National Formulary*. These standards are recognized as official by the federal government and are enforceable by the FDA. The standards include specifications pertaining to drug strength, quality, purity, packaging, and labelling
- Difference between pharmacopoeia and Formulary →
- U.S.P. is recognized as the official compendium for drugs in the U.S. according to the Federal Food Drug & Cosmetic Act.
- U.S.P sets the standards for drug identity, strength and purity.
- FDA enforces the standards set by USP.
- The U.S.P. is published in a combined volume with the national formulary as the U.S.P-NF
- U.S.P. sets standards for both human drugs and animal drugs
- U.S.P. also sets standards for the dietary supplements and food ingredients.

Pharmacopoeia	Formulary
It is an official Publication	It is an unofficial Publication
Published by legal authorities	Published by Drug administration authority
Brand names aren't included	Brand names are included
Can be followed by physicians of whole over the world	Can't be followed by physicians of whole over the world
Published less frequently (5 yearly or more)	Published more frequently (yearly or two yearly)

USP History

- USP was established by Dr. Lyman Spalding with 10 physician in Jan 1820
- **USP published *United States Pharmacopeia (U.S.P)* since 1820.**
- Federal Food & Drugs Act recognized the USP & NF in 1906 and enforced by FDA in 1938.
- First National formulary of the United States appeared in 1888.
- **In 1975, USP acquired the *National Formulary (NF),* which contains excipients standards**
- **USP acquired the *Food Chemicals Codex* (*FCC) in 2006.***
- **Provides quality standards (*U.S.P, NF, FCC*)**
- **Expert volunteers (Expert Committees) are scientific decision-makers**
- Objective Of USP
    i) Compendial standard setting and revision
    ii) To set standards for Drug Substance & Drug Product on Strength, purity, quality packing, labelling etc.

Edition of U.S.P

1st Edition

- Published in 1820
- It contain 217 drugs

2nd Edition

- Published in 1905
- But it was titled VIII as it was the 8th revision

❖ USP and NF got unified on 5th July 1974 and thereafter a single volume is published for both

- **USP22-NF17** –
    - In 1990- 22nd edition of USP combined with 17th edition of NF published
    - Electronic version of USP-NF on floppy disk was introduced in 1992
- **USP23-NF18** was published in Mumbai as an Asian edition at the end of 1994
- **USP23** has ten supplements.
- **USP24-NF19** appeared from first January 2000.

- **USP30-NF25** appeared from May 2007.
  - It contains scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.
  - It contains 4,100 monographs and 200 general chapters.
  - It has been printed in three volume set.
  - Volume I contains general chapters & Volume II & III contains monographs.
  - First supplement to USP30-NF25 appeared from August 2007 & second supplement from November 2007 which will be considered official from May 2008.
  - From 2006, Spanish edition of USP is also being published.
- **USP31-NF26**
- **USP32-NF27**
  - More than 4,200 monographs
  - Includes over 200 general chapters, covering general tests and assays
  - Displays helpful guides and charts that make it easy to find focus-specific information
  - Includes information on emerging areas of science and medicine
  - Helps ensure compliance with official standards
  - Enables validation of test results against proven benchmarks
  - Expedites new product development and approvals
- **USP33-NF28**
  - More than 4,400 monographs
  - Over 200 general chapters covering general tests and assays
  - A new, easy-to-read format and monograph layout
  - Helpful guides and charts that make it easy to find focus-specific information
  - Ensures compliance with official standards
  - Facilitates new product development and approval.
- **USP34-NF29**
  - Contain more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics.
  - USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.
- **USP35 - NF30**
  - The 'United States Pharmacopeia 35 - National Formulary 30' (USP-NF) is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from 1 May, 2012 to 30 April, 2013.
- **USP39-NF34, 2016**
  - Contain more than 4900 monographs
  - More than 300 general chapters
  - Focus specific charts and a combined index to find the information needed
- **USP43-NF38, 2020**
  - The *USP* 43–*NF* 38 is the last edition that will be available in print or on a USB flash drive. Future supplements and editions – including the First and Second Supplements to *USP* 43–*NF* 38 – will **not** be printed or on flash drives.
  - Starting with the First Supplement to *USP* 43–*NF* 38 that will be published on February 1, 2020, print and USB flash drive formats will not be available. Only the online format will contain all current *USP–NF* content.