

**School of Studies in  
Pharmaceutical Sciences,  
Jiwaji University**

**B. Pharmacy**

**Pharmaceutics**

**Dr. Suman Jain**

## **Course Objectives:**

This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

## **Student Learning Outcomes:**

- 1) Describe history of profession of pharmacy
- 2) Explain basic dosage forms and solve pharmaceutical calculations
- 3) Interpret professional way of handling prescriptions
- 4) Design various conventional dosage forms

## **Module-I (10 hrs)**

- ❖ **Historical Background and Development of Profession of Pharmacy**
- ❖ **Dosage Forms**
- ❖ **Prescription**
- ❖ **Posology**

# Pharmacopoeia

- Derived from Greek word '**Pharmakon**' means **drug** and '**Poiea**' means **to make**.
- It is a legal and official book issued by recognized authorities usually appointed by Government of each country.
- It comprises list of pharmaceutical substances, **formulae** along with their **description and standards**.

## List of Pharmacopeias

Argentine

Belgian

British

Egyptian

French

Hungarian

Italian

Yugoslavian

Netherlands

Portuguese

Russian

Turkish

Austrian

Brazilian

Chinese

European

German

Indian

Japanese

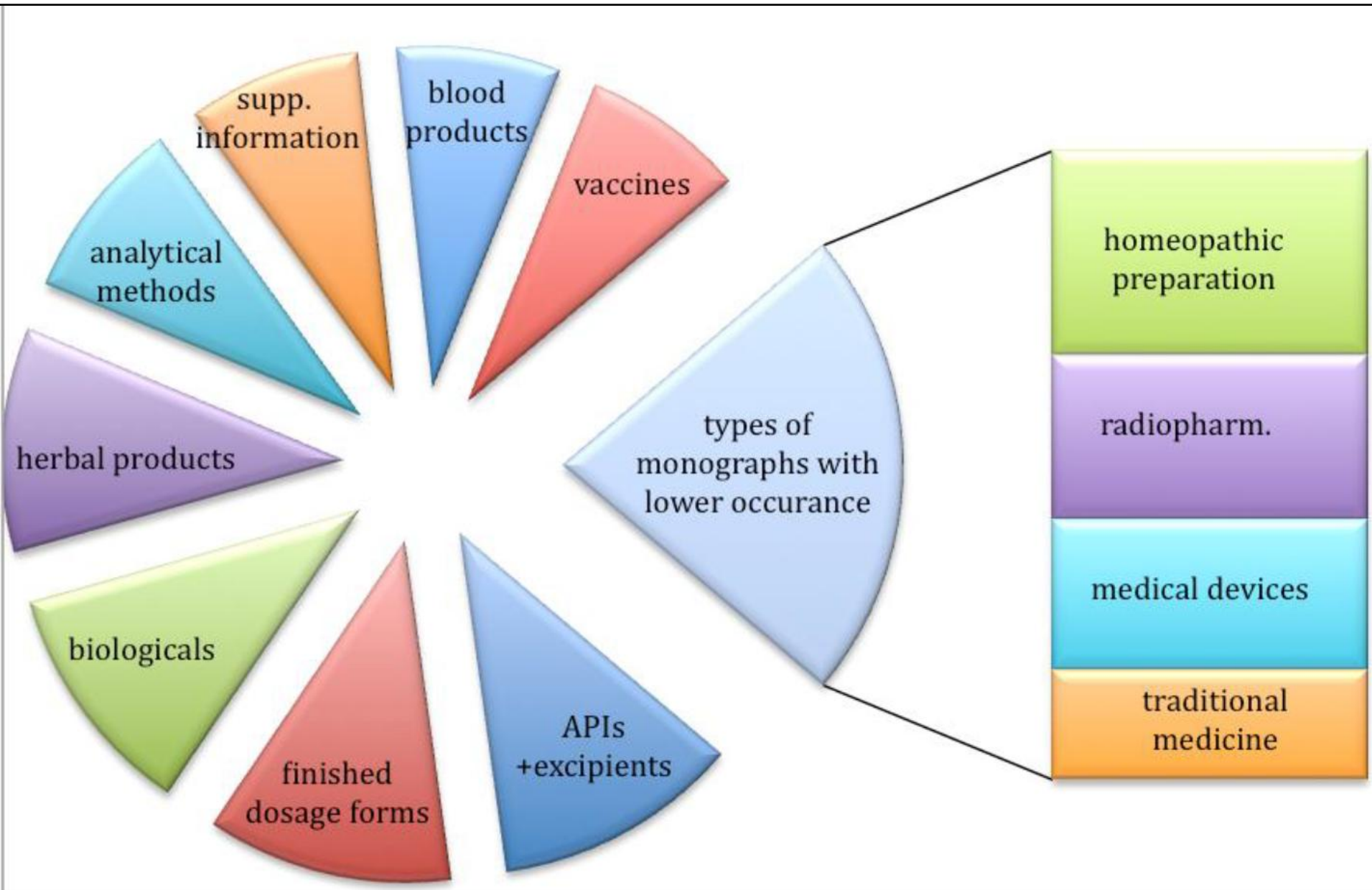
Mexican

Polish

Rumanian

Spanish

United states



## **Classification**

The drug compendia (collection of information) are classified as:

- (i) Official compendia
- (ii) Non-official compendia

### **A) Official Compendia**

- These are the compilations of drugs and other related substances which are recognized as legal standards of **purity, quality and strength** by government agency of respective countries of their origin.
- Ex., Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), British Pharmaceutical Codex (BPC), United States Pharmacopoeia (USP), National Formulary (NF), The State Pharmacopoeia of USSR, Pharmacopoeias of other countries

## **B) Non-official Compendia**

- The book other than official drug compendia which are used as **secondary reference** sources for drugs and other related substances are known as non-official drug compendia.
- e.g. Merck Index, Extra Pharmacopoeia (Martindale), United States Dispensatory etc.



# Indian Pharmacopoeia

- First official IP was appeared in **1868** which was edited by Edward John Waring
- In pre-independence days, **BP** was used in India
- The colonial addendum of BP 1898 was published in 1900 appeared as **Government of India edition** in 1901
- In 1946 Government of India issued one list known as ‘**The Indian Pharmacopoeial list**’
- Committee under chairmanship of Sir **R. N. Chopra** along with other 9 members prepared ‘The Indian Pharmacopoeial list’

- It was prepared by Department of Health, Govt. of India, Delhi in 1946.
- In 1948 Government of India appointed an **IP committee** for preparing ‘Pharmacopeia of India’
- Tenure of this committee was 05 years.
- Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published **first edition of IP in 1955**
- **First edition of IP** is written in **English** & official titles of monographs given in **Latin**.
- It covers **986** monographs.

- **Supplement** to this edition was published in 1960.
- **2<sup>nd</sup> edition** of IP was published in **1966** under the chairmanship of Dr. B. Mukherjee
- **274** monographs from IP 55 & their supplement were deleted.
- **93** new monographs were added.
- Official titles of monographs given in English
- Dose were expressed in **Metric system**
- For Tablets and Injections “**USUAL STRENGTH**” have been given.
- **Formulations** of the drugs were given immediately after the monograph of drugs.

- Supplement to this edition was published in **1975**.
- **126** new monographs have been included & **250** monographs amended.
- Cholera vaccine has been deleted.
- **3<sup>rd</sup> edition** of IP was published in **1985** with **02 volumes** & **09** appendices.
- **261** new monographs have been added.
- **450** monographs were deleted.

- **Addendum I:** Published in 1989, **46** new monographs added and **126** amended.
- **Addendum II:** Published in **1991** were **62** new monographs added and **110** amended.
- **4<sup>th</sup> edition** of IP was published in **1996** under the chairmanship of Dr. Nityanand.
- It covered **1149** monographs and **123** appendices.
- It includes **294** new monographs & **110** monographs have been deleted.

- **Addendum I:** Effective from 31<sup>st</sup> December **2000**, 42 new monographs have been added.
- **Addendum II:** Effective from 30<sup>th</sup> June **2003**, 19 new monographs have been added.
- The **veterinary** supplement of IP **1996** contains 208 monographs & 04 appendices.
- **5<sup>th</sup> edition** of IP was published in **2007** & addendum to this edition was published in 2008.
- IP 2007 is presented in **03 Volumes**.
- **Volume 1:** contains general notices & general chapters.

- **Volume 2 & 3:** Contains general monographs on drug substances, dosage forms & Pharmaceutical aids.
- **6<sup>th</sup> edition** of IP is published in **2010** by the Indian Pharmacopoeia Commission (IPC), Ghaziabad
- This edition would be effective from 1<sup>st</sup> September, 2010.
- The Indian Pharmacopoeia 2010 is presented in **03 volumes**.

- **Volume I:** contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters.
- **Volume II:** contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (**A to M**).
- **Volume III:** contains Monographs on drug substances, dosage forms and pharmaceutical aids (**N to Z**).



- Monographs on vaccines and immunosera for human use, herbs and herbal products, blood and blood-related products, biotechnology products and veterinary products.
- Products of biotechnology, **indigenous herbs and herbal products**, veterinary vaccines and additional antiretroviral drugs and formulations, fixed-dose combinations.
- Standards for new drugs and drugs used under national health programmes are added

- Monographs of **excipients**, anticancer drugs, herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of vaccines and immunosera are also upgraded in view of development of latest technology in the field.
- A new chapter on **liposomal** products and a monograph of liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
- A chapter on **NMR** is incorporated in Appendices.
- The chapter on **microbial contamination** is also updated to a great extent to harmonize with prevailing international requirements.

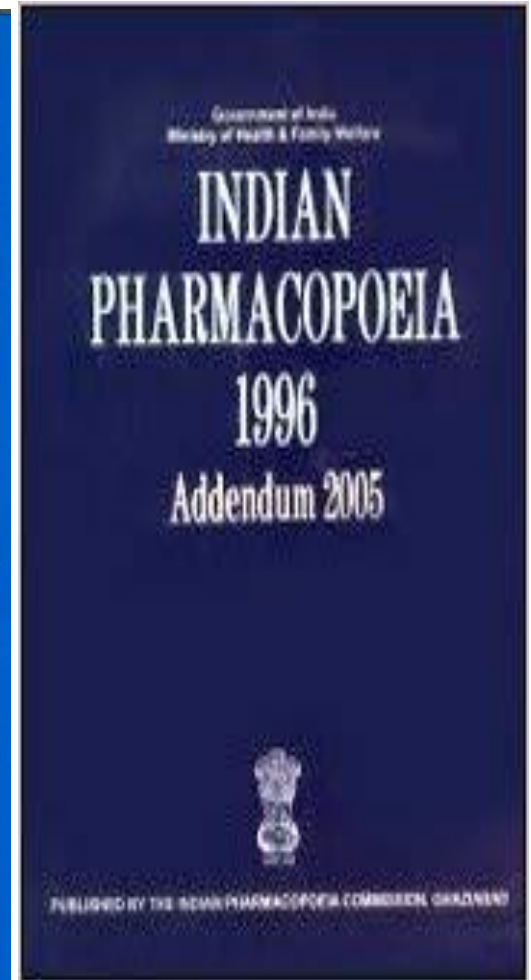
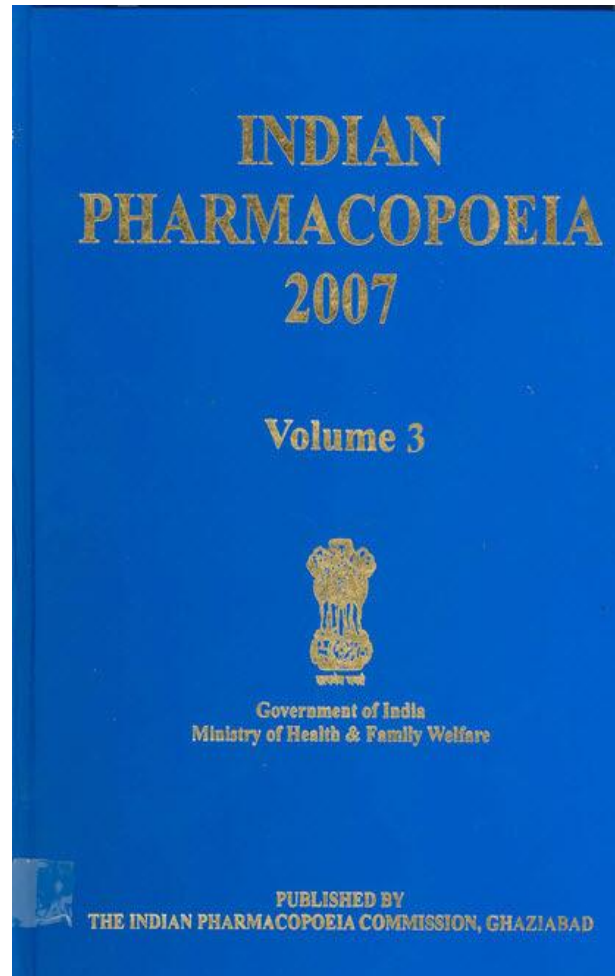
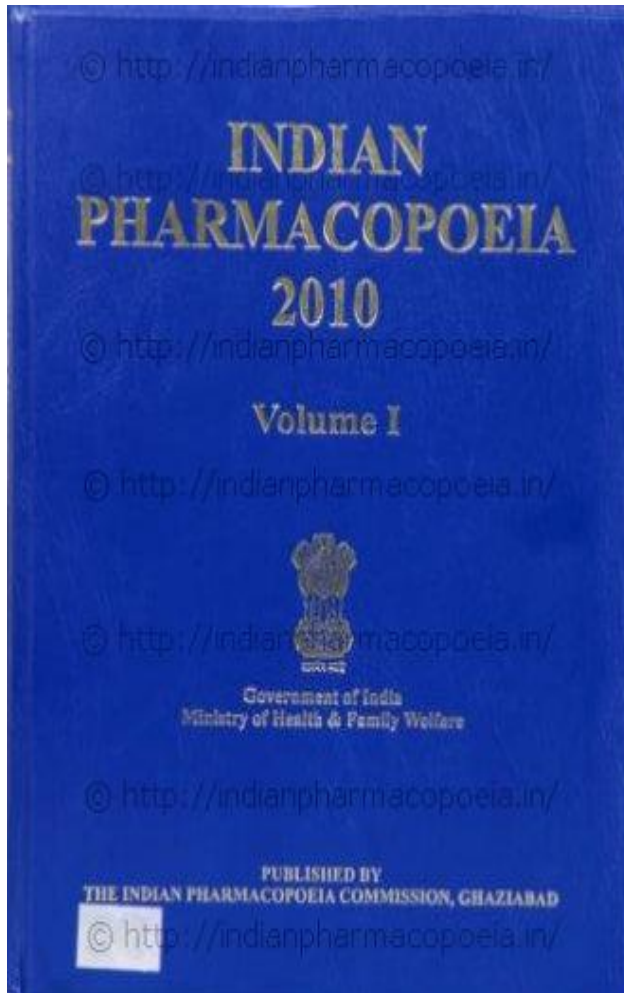
## 7<sup>th</sup> Edition of IP (2014)

- 313 New monographs on drug substances, dosage forms & pharmaceutical aids (A to Z)
- 43 New drugs substances monographs
- 10 Antibiotic monographs
- 31 Herbal monographs
- 05 Vaccines & immunosera for human use
- 06 Insulin products, 07 biotechnology products etc. along with the 19 new general chapters
- **19 New radiopharmaceutical** monographs & 1 general chapter is first time being included in this edition

## 8<sup>th</sup> Edition of IP (2018)

- 04 Volumes
- 170 Chemical Monographs
- 15 herbal monograph
- 10 monograph on **blood and related products**
- 06 monographs on biotechnology derived products
- 02 monographs on vaccine and immune sera
- 03 monographs of radiopharmaceuticals
- 14 monographs of veterinary nonbiologicals

# Indian Pharmacopoeia



# British Pharmacopoeia

- First edition of BP was published in **1864** & consist of two sections
- **Part I:** Materia Medica
- **Part II:** Preparation & compounds
- **Second** edition of BP was published in 1867
- **Third** edition of BP was published in 1885
- **Fourth** edition of BP was published in 1898
- **Fifth** edition of BP was published in 1914
- **Eighth** edition of BP was published in 1953: Titles of drugs & preparations were in **English** instead of Latin and metric system.

- It has been published annually.
- In **BP 2007** monographs has been introduced for material specifically used in preparation of **Traditional Chinese Medicines**.
- Term ‘Prolonged release’ has been replaced the term ‘**Slow**’ and the term ‘Gastro-resistant’ has been replaced with ‘**Enteric coated**’ in number of monographs.
- **BP 2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.
- It has been made effective from 1<sup>st</sup> January 2008.
- BP 2007-2009 were given in **06 Volumes** i.e. Vol. I to Vol. VI.

- **Volume I & II:** Contains medicinal substances.
- **Volume III:** Contains formulated preparations, blood related products, immunological products, **radiopharmaceutical** preparations, surgical materials & **homoeopathic preparations**.
- **Volume IV:** Contains supplementary chapters, IR spectra etc.
- **Volume V:** Contains veterinary products
- **Volume VI:** Contains CD ROM version.



## **BP 2010**

- The Stationery Office, on behalf of BP Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA), has recently published the BP, 2010.
- BP is the official collection of standards for UK medicinal products and pharmaceutical substances.
- Published annually, the BP contains monographs for pharmaceutical substances, formulated preparations and other articles used in the practice of medicine.
- The standards in the BP 2010 are legally effective in the UK from 1 January 2010.

- BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864.
- It is used in almost 100 countries worldwide and remains an essential reference for any individual or organization working within pharmaceutical research and development, manufacturing and testing across the globe.
- BP 2010 has **40 monographs** for formulated preparations, including **veterinary** medicines and additional standards for widely used unlicensed formulations.

- All **European Pharmacopoeia** 6th edition material upto and including Supplement 6.5 is integrated into the text of the BP 2010.
- BP supports regulatory work in the fields of **herbal and complementary medicines** by providing additional new and revised monographs for herbal medicinal products and for homeopathic stocks and mother tinctures.
- Print edition of BP 2010 comprises **4 volumes** of BP 2010 and a single volume of BP (Veterinary) 2010.

# BP 2013

The BP 2013 package includes:

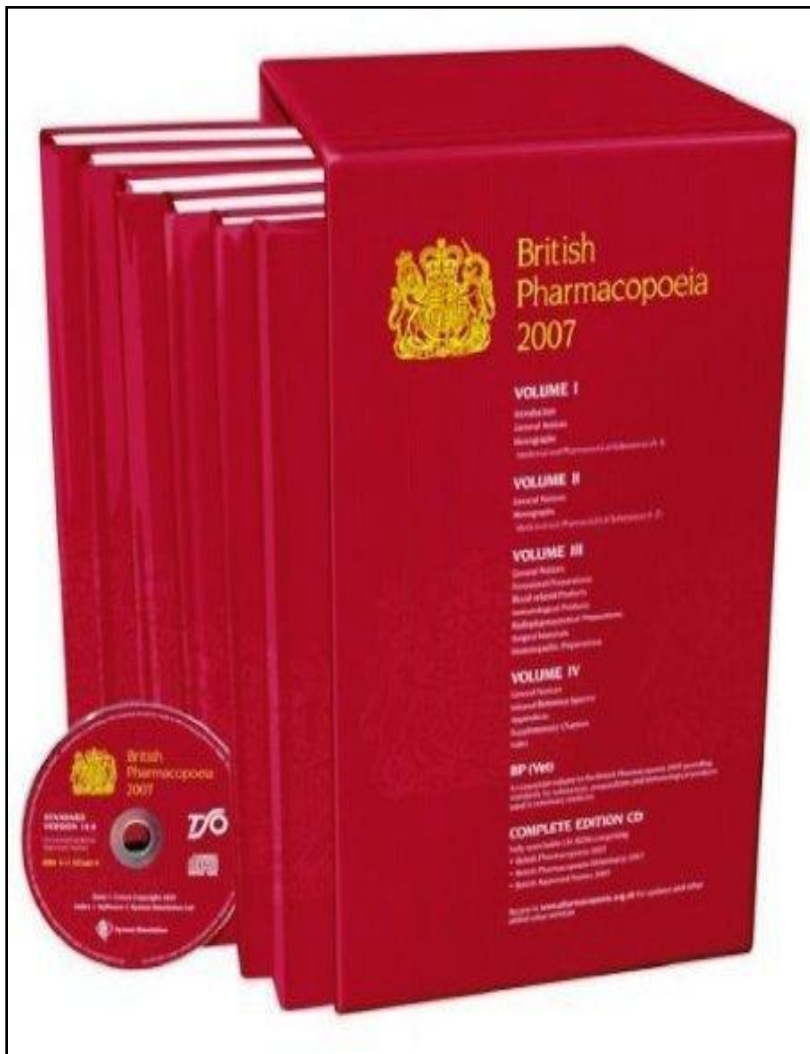

- **06 volume** printed edition including the BP (Veterinary) 2013
- **41 new** BP monographs
- **40 new** European Pharmacopoeia monographs
- **619** amended monographs
- **6 new** and 1 amended Infrared Reference Spectra

## BP 2014

- The 2014 edition includes almost **3500** monographs which are legally enforced by the Human Medicines Regulations 2012.
- The BP 2014 package comprises **5 volumes** of BP 2014 and a single volume of BP (Veterinary) 2014, along with a fully searchable **CD-ROM** and online access to provide you with flexible resources.
- Legally effective from 1 January 2014
- **40 new**, 272 amended and 4 new BP (Vet) monographs
- **03** new Supplementary Chapters
- **01** new BP (Vet) Supplementary Chapter

# BP 2018

- 35 new monographs
- 185 amended BP monographs
- 04 new monographs for **unlicensed formulations**
- 04 new monographs for **herbal medicines**
- 06 new monographs for **veterinary medicines**

# British Pharmacopoeia 2010

Setting the standard for compliance across the globe  
Publishing August 2009

# United State Pharmacopoeia (USP)

- 1<sup>st</sup> edition of USP was published on 15<sup>th</sup> Dec. 1820 in both **Latin & English**
- From 1820 to 1942 it was published at 10 years intervals
- From 1942 to 2000 it was published at 05 years intervals
- From **2002** it was published annually
- First National Formulary of the united state appeared in 1888
- USP21-NF16 have **08** supplements
- First appeared in January 1985 & last in November 1988



- USP22-NF17, 1990 is the 3<sup>rd</sup> revision that consolidates USP & NF into a single volume
- **Electronic version** of USP-NF on floppy disks was introduced in 1992
- USP23-NF18, was published in Mumbai at the end of 1994
- USP23 has 10 supplements.
- 1<sup>st</sup> supplement was published in January 1995 & Last in May 1999.
- 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 03 volume set.
- Volume I contains general chapters, while Volume II, III contains monographs.
- 1<sup>st</sup> supplement to USP30-NF25, appeared from August 2007 & 2<sup>nd</sup> supplement from November 2007 which was official from May 2008.
- From 2006, Spanish edition of USP is also being published.

## **United States Pharmacopoeia 30 – National Formulary 25:**

- New heavier paper stock
- Complete table of **contents and index** in each volume
- Special 'Using the New USP-NF Print' tutorial CD
- Convenient slipcase for easy access and storage (English edition only).

## **States Pharmacopoeia 31 - National Formulary 26:**

- It is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF).
- Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP.
- Excipients monographs are included in the NF

## **States Pharmacopoeia 32 - National Formulary 27:**

- 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
- Creates in-house standards for operating procedures and specifications
- Expedites new product development and approvals

## **States Pharmacopoeia 33 - National Formulary 28:**

- 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
- Establishes in-house standard operating procedures and specifications
- Facilitates new product development and approval.

## **United States Pharmacopoeia 34 - National Formulary 29:**

- Published in **2011**
- USP 34-NF 29 features 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.

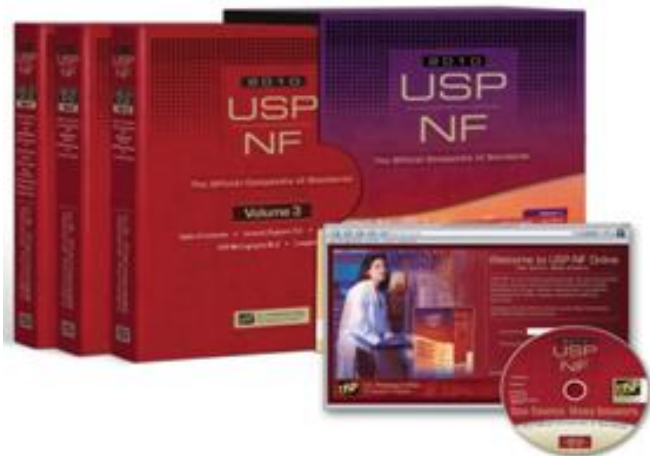
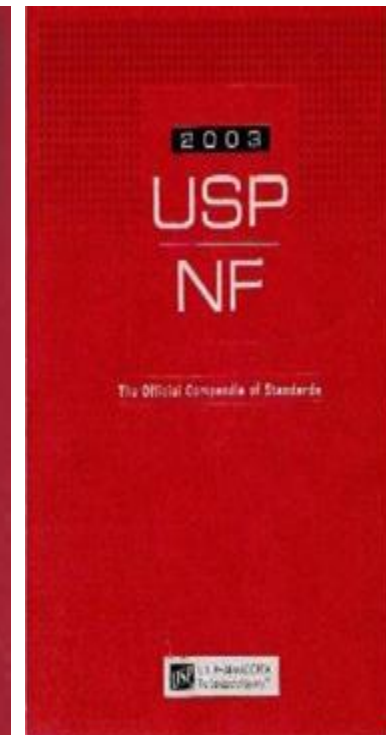
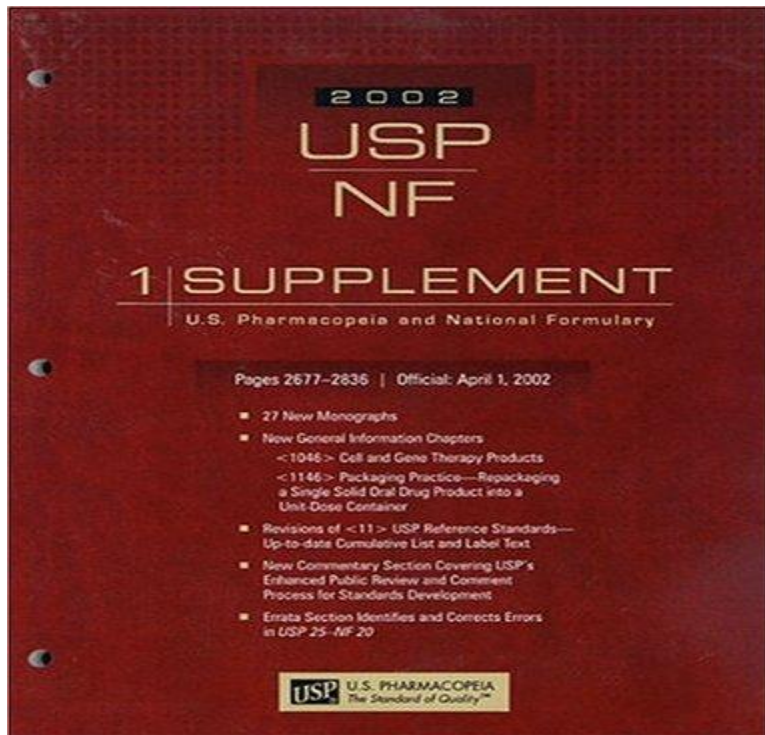
## **States Pharmacopoeia 35 - National Formulary 30:**

- 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.



## **States Pharmacopoeia 41 - National Formulary 36:**

- Published in 2018
- 4900 monographs
- 350 chapters
- Sections of solutions, reagents, indicators
- Section on **hazardous drug** handling



# European Pharmacopeia

- EP commission started working since **1964** to prepare EP
- 1st edition: published 1967
- 2nd edition: published 1980
- 3rd edition: published 1997
- 4th edition: published 2001, valid from 1 January 2002
- 5th edition: published 15 June 2004, valid from 1 January 2005
- 6th edition: published 16 July 2007, valid from 1 January 2008
- 7th edition: published June 2010, valid from 1 January 2011
- 8th edition: published June 2013, valid from 1 January 2014

**EUROPEAN  
PHARMACOPŌEIA**

**6.0**  
volume 1

**01/2008**



**EUROPEAN  
PHARMACOPŌEIA**

**6.5**  
supplement

**07/2009**





