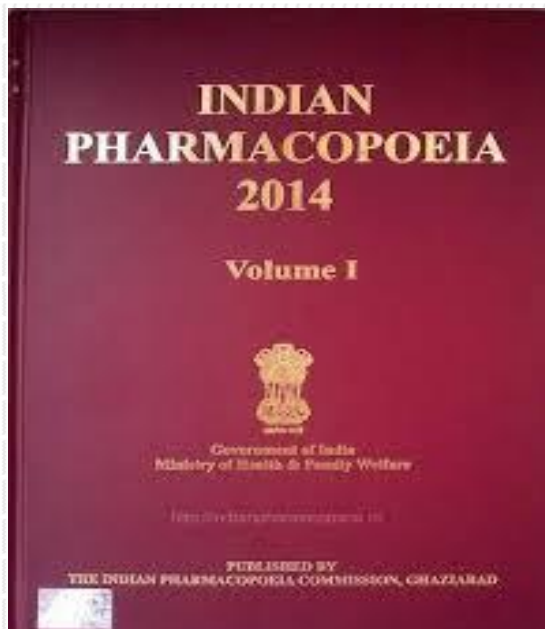


INTRODUCTION TO PHARMACOPOEIA

Pharmaceutics I Unit 2nd



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:**
 - a) Argentine b) Austrian c) Belgian d) Brazilian e) **British**
 - f) Chinese g) Egyptian h) **European** i) French j) German
 - k) Hungarian l) **Indian** m) **International** n) Italian o) Japanese
 - p) Yugoslavian q) Mexican r) Netherlands s) Nordic t) Polish
 - u) Portuguese v) Rumanian w) Russian x) Spanish y) Turkish
 - z) **United state**.

INDIAN PHARMACOPOEIA

- First official Pharmacopeia of India appeared in **1868** which was edited by **Edward John Waring**.
- In preindependence days, British Pharmacopeia 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 Pharmacopeial list“
- Committee under chairmanship of **Sir R. N. Chopra** alongwith other nine members prepared „The Indian Pharmacopeial list“
- It was prepared by Dept. of Health, Govt. of India, Delhi in **1946**.
- In **1948** Government of India appointed an Indian Pharmacopeia committee for preparing „Pharmacopeia of India“
- Tenure of this committee was five years.
- Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published first edition of IP in **1955**.

INDIAN PHARMACOPOEIA

- It is written in **English** & official titles of monographs given in **Latin**.
- It covers **986** monographs.
- Supplement to this edition was published in **1960**.
- Second edition of **IP** was published in **1966** under the chairmanship of **Dr. B. Mukkerji**.
- 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.
- **274** monographs from IP 55 & their supplement were deleted.
- **93** new monographs were added.
- Supplement to this edition was published in **1975**.
- **126** new monographs have been included & **250** monographs have been amended.
- **Cholera vaccine** has been deleted.

INDIAN PHARMACOPOEIA

- Third edition of **IP** was published in **1985** with two volumes & nine appendices.
- **261** new monographs have been added.
- **450** monographs were deleted.
- Addendum I to IP was published in **1989** were **46** new monographs added and **126** amended.
- Addendum II was published in **1991** were **62** new monographs added and **110** amended.
- Fourth edition of **IP** was published in **1996** under the chairmanship of **Dr. Nityanand**.
- It has been made effective from **1st December 1996**.
- It covered **1149** monographs and **123** appendices.
- It includes **294** new monographs & **110** monographs have been deleted.
- Addendum I has been made effective from **31st December 2000** were **42** new monographs have been added.
- Addendum II has been made effective from **30th June 2003** were **19** new monographs have been added.
- The veterinary supplement to **IP 1996** contains **208** monographs & **four** appendices.

INDIAN PHARMACOPOEIA

- Fifth edition of **IP** was published in **2007** & addendum to this edition was published in **2008**.
- **IP 2007** is presented in **Three Volumes**.
- Volume **One** contains general notices & general chapters.
- Volume **Two & Three** contains general monographs on drug substances , dosage forms & Pharmaceutical aids.

INDIAN PHARMACOPOEIA 2010

- **6th edition** of **IP** is published in **2010**.
- The **6th edition** of the Indian Pharmacopoeia 2010 is published by the **Indian Pharmacopoeia Commission (IPC) Ghaziabad** in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.
- It supersedes the **2007** edition but any monograph of the earlier edition that does not figure in this edition.
- This edition would be effective from **1st September, 2010**.
- The Indian Pharmacopoeia **2010** is presented in **three 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**).

INDIAN PHARMACOPOEIA 2010

- **Volume III** contains Monographs on drug substances, dosage forms and pharmaceutical aids **(N to Z)**.
- Followed by Monographs on Vaccines and Immunoserum for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products.
- The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a day are omitted from this edition.

INDIAN PHARMACOPOEIA 2010

- The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of Vaccines and Immunoserum 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 harmonise with prevailing international requirements.

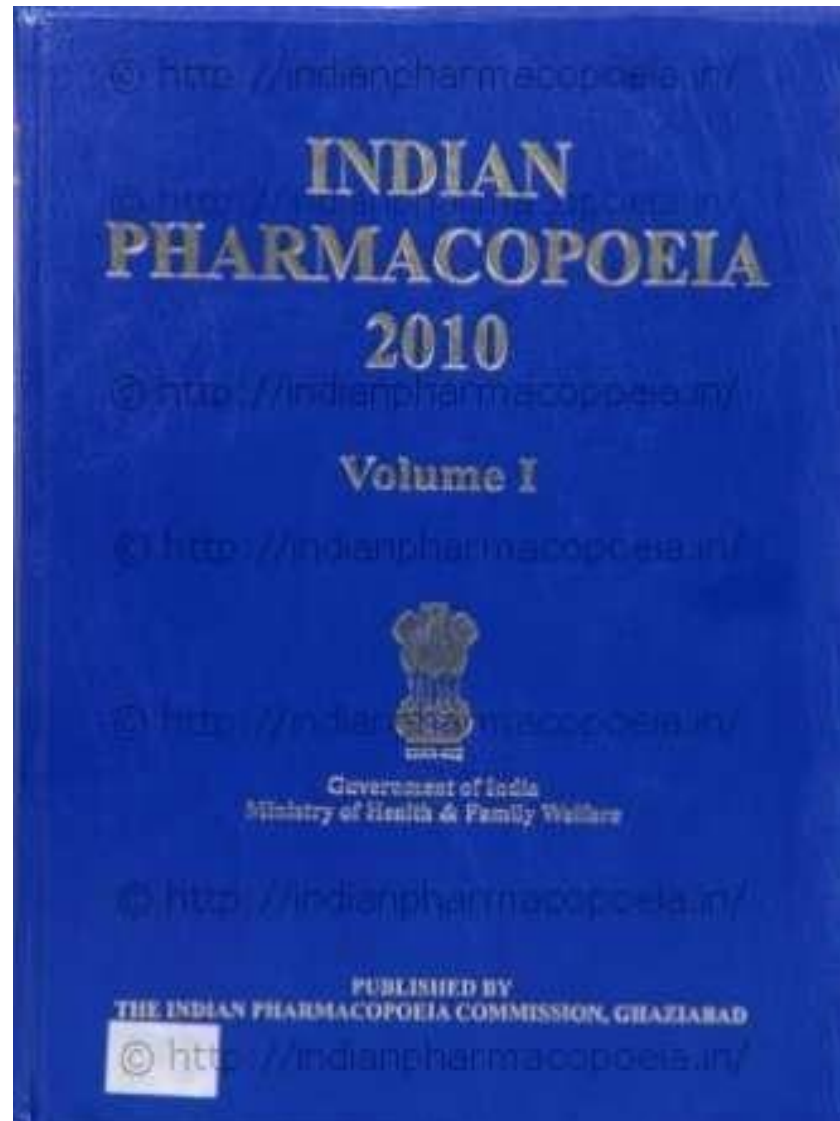
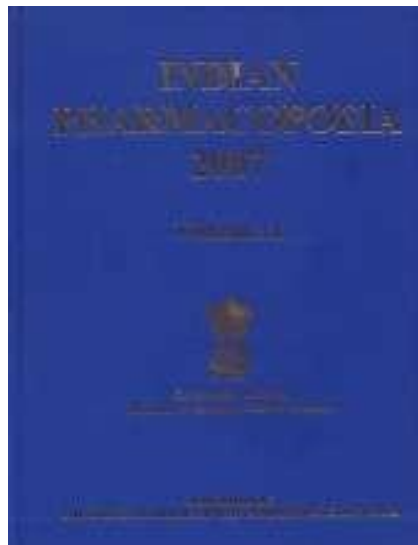
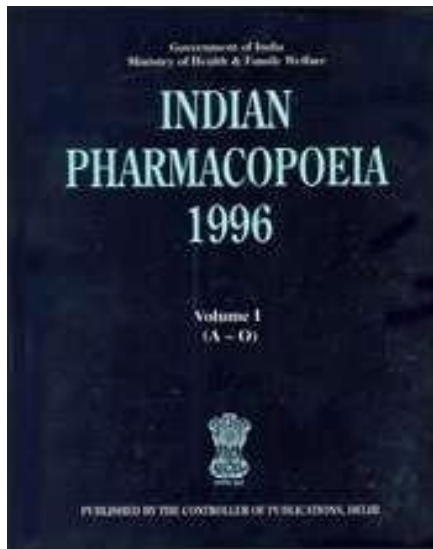
Seventh Edition of Indian Pharmacopoeia

- The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.

Seventh Edition of Indian Pharmacopoeia

- A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 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.
- This edition of Indian Pharmacopoeia-2014 is now under printing and will be available to stakeholders probably in Sept.2013, before three months of its effective date, i.e. 1st Jan. 2014.

INDIAN PHARMACOPOEIA



BRITISH PHARMACOPOEIA

- First edition of **BP** was published in **1864**.
- It consist of two sections
- Part I:- **Materia Medica** & Part II:- **Preparation & compounds**.
- Second edition of **BP** was published in **1867**.
- Fourth edition of **BP** was published in **1898**.
- Fifth edition of **BP** was published in **1914**.
- Eighth edition of **BP** was published in **1953**.
- In this edition 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.

BRITISH PHARMACOPOEIA

- BP **2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.
- It has been made effective from **1st January 2008**.
- **BP 2007 -2009** were given in Six Volumes i.e. **Volume I to Volume 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.
- **Volume VI** contains CD ROM version.
- Current edition of **BP 2010** is in process.

THE BRITISH PHARMACOPOEIA 2010

TSO (The Stationery Office), on behalf of the British Pharmacopoeia Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA), has recently published the British Pharmacopoeia (BP) 2010.

The British Pharmacopoeia (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.

The BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864. Today, it is used in almost 100 countries worldwide and remains an essential reference for any individual or organisation working within pharmaceutical research and development, manufacturing and testing across the globe.

New to the BP 2010 are 40 monographs for formulated preparations, including veterinary medicines and additional standards for widely used unlicensed formulations. All European Pharmacopoeia 6th edition material up to and including Supplement 6.5 is integrated into the text of the BP 2010. In addition to the expanding number of monographs for licensed formulated products, the BP supports the 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.

The print edition of the BP 2010 comprises four volumes of the BP 2010 and a single volume of the BP (Veterinary) 2010.

THE BRITISH PHARMACOPOEIA (BP) 2013

The BP 2013 package includes:

Six volume printed edition including the BP (Veterinary) 2013

New for 2013:

41 new BP monographs

40 new European Pharmacopoeia monographs

619 amended monographs

6 new and 1 amended Infrared Reference Spectra

THE BRITISH PHARMACOPOEIA 2014

The only official source of British pharmaceutical standards

Produced by the British Pharmacopoeia Commission Secretariat of the Medicines and Healthcare Products Regulatory Agency, and updated annually, the British Pharmacopoeia (BP) is the official, authoritative collection of standards for UK medicinal substances for human and veterinary use.

The 2014 edition includes almost 3500 monographs which are legally enforced by the Human Medicines Regulations 2012.

Global standards

Now used in over 100 countries, the BP remains an essential reference for all individuals and organisations working within pharmaceutical research and development, manufacture and testing around the globe.

Flexible access options

The BP 2014 package comprises five volumes of the British Pharmacopoeia 2014 and a single volume of the British Pharmacopoeia (Veterinary) 2014, along with a fully searchable CD-ROM and online access to provide you with flexible resources.

New for 2014

Legally effective from 1 January 2014

40 new BP monographs

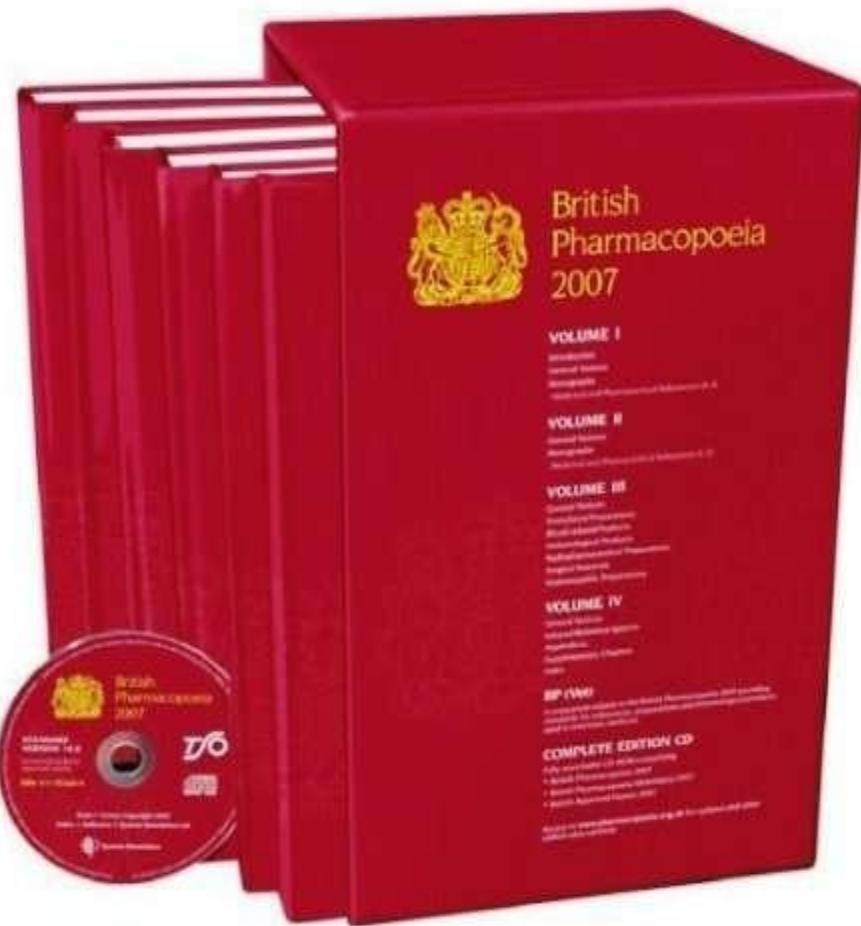
272 amended monographs

Three new Supplementary Chapters

Four new BP (Vet) monographs

One new BP (Vet) Supplementary Chapter

BRITISH PHARMACOPOEIA



BRITISH PHARMACOPOEIA



**British
Pharmacopoeia
2010**

Setting the standard for compliance across the globe
Publishing August 2009

UNITED STATE PHARMACOPOEIA

- **First edition** of United state Pharmacopeia was published on 15th **December 1820** in both *Latin & English*.
- From 1820 to 1942 it was published at **Ten years** intervals.
- From 1942 to 2000 it was published at **Five years** intervals.
- From 2002 it was published **annually**.
- First *National Formulary* of the united state appeared in **1888**.
- **USP21-NF16** have eight supplements.
- First appeared in **January 1985** & last in **November 1988**.
- **USP22-NF17, 1990** is the third 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 as an Asian edition at the end of **1994**.

UNITED STATE PHARMACOPOEIA

- *USP23* has ten supplements.
- First 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 **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.
- Current edition of **USP 2014** is in process.

- **UNITED STATES PHARMACOPOEIA 30 – NATIONAL FORMULARY 25**

Highlights include:

- 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).
- **UNITED STATES PHARMACOPOEIA 31 - NATIONAL FORMULARY 26**
- The USP-NF 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. Excipient monographs are included in the NF.

• **UNITED STATES PHARMACOPOEIA 32 - NATIONAL FORMULARY 27**

The USP 32-NF 27 Contains :

- 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.

- **UNITED STATES PHARMACOPOEIA 33 - NATIONAL FORMULARY 28:**

- **The USP 33-NF 28 Contains:**

- 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 PHARMACOPEIA 34 - NATIONAL FORMULARY 29:**

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.

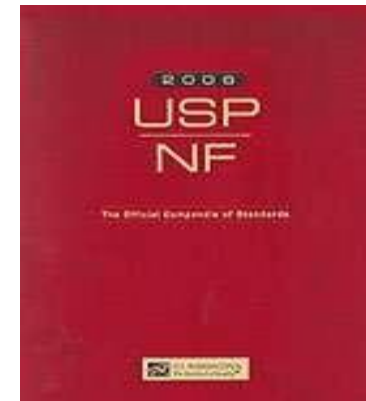
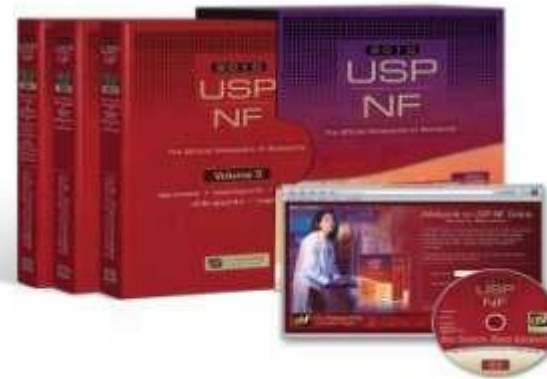
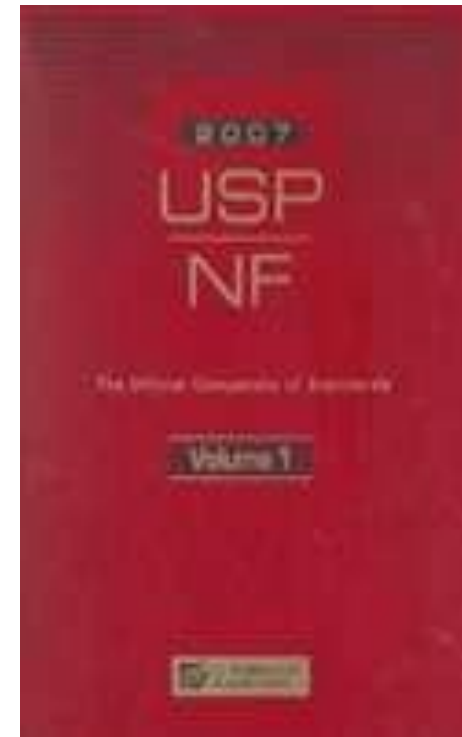
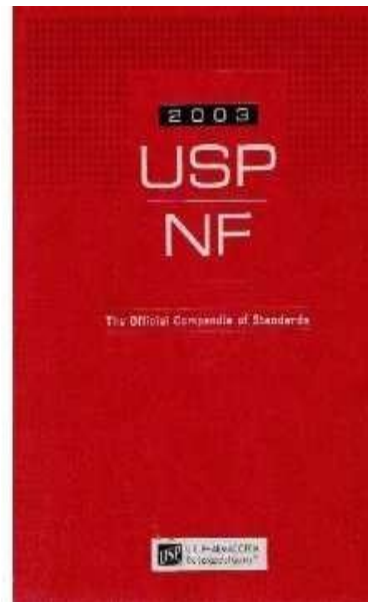
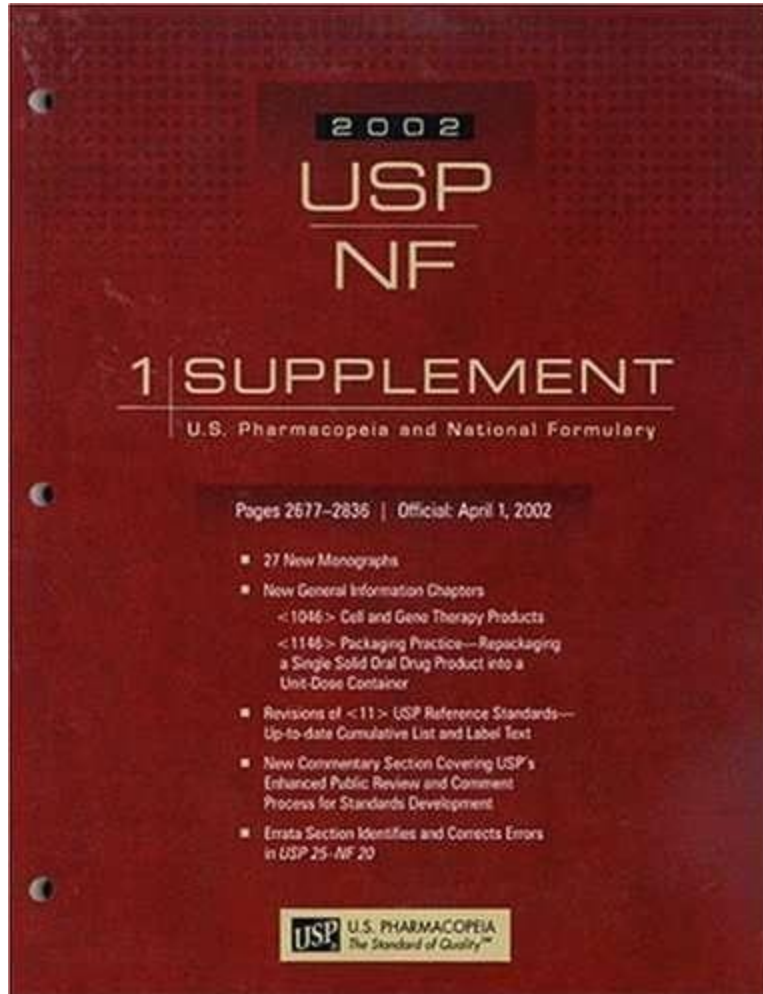
- **UNITED STATES PHARMACOPEIA 35 - NATIONAL FORMULARY 30:**

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.**

UNITED STATE PHARMACOPOEIA



U.S. Pharmacopeia
The Standard of QualitySM



EUROPEAN PHARMACOPEIA

- European pharmacopeia commission started working since 1964 to prepare EP

Editions

- 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

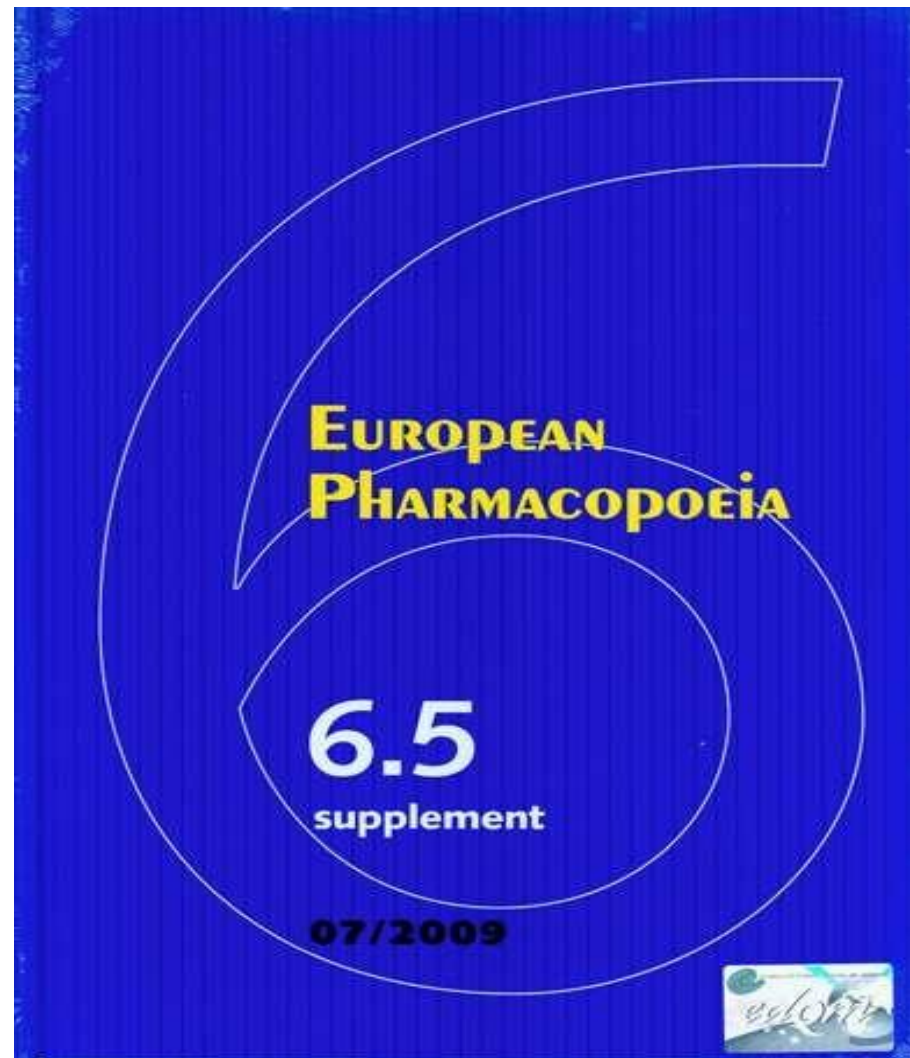
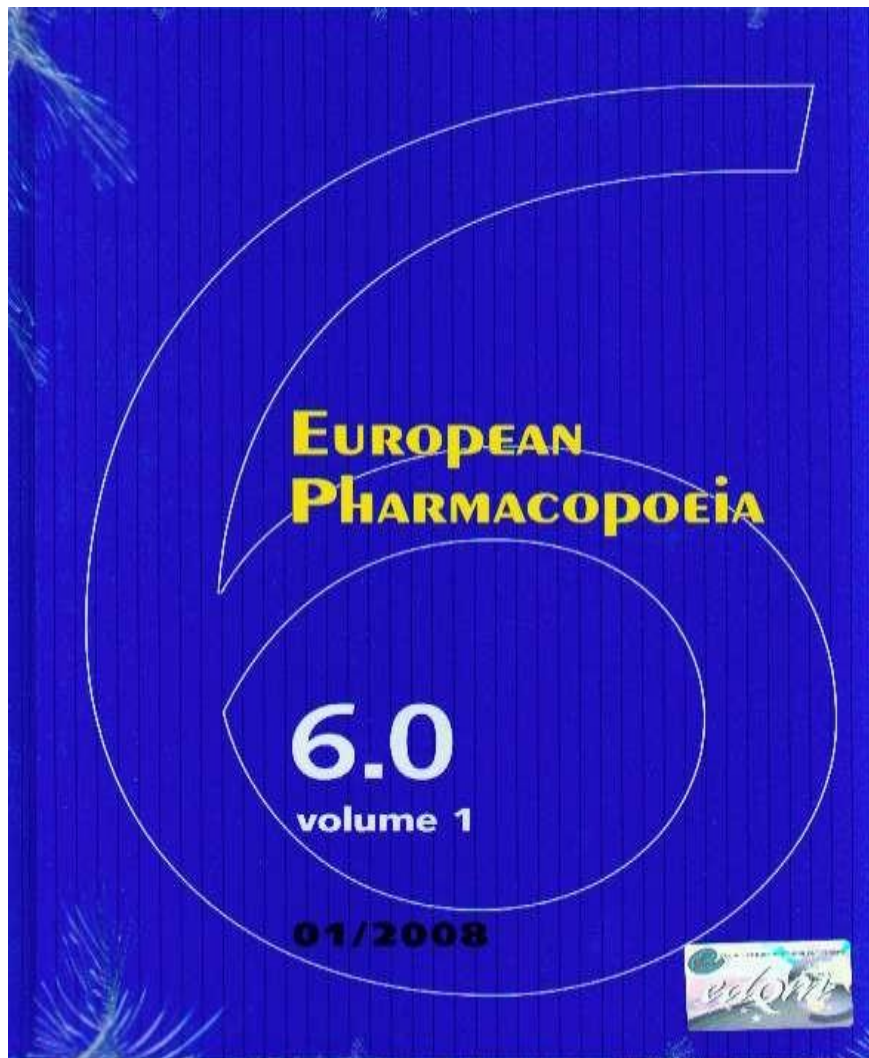
Since its 5th edition, the pharmacopoeia is published in 2 volumes. Volume 1 contains general chapters and monographs (e.g. on dosage forms, methods of analysis, reagents), volume 2 contains all substance monographs. During runtime of current edition several supplements are published. Electronic versions are also available (CD-ROM, USB stick and online version).

EUROPEAN PHARMACOPOEIA 8TH EDITION

PUBLISHED ON JUNE 2013

- The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production.
- It covers active substances, excipients and preparations of chemical, animal, human or herbal origin, homoeopathic preparations and homoeopathic stocks, antibiotics, as well as dosage forms and containers. It also includes texts on biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations. The European Pharmacopoeia and its requirements are legally binding in the member states of the European Pharmacopoeia Convention and the European Union.

EUROPEAN PHARMACOPEIA



EUROPEAN PHARMACOPEIA



THANK

YOU