PHARMACEUTICAL ANALYSIS

SEMESTER I

Mrs. D. V. Jain

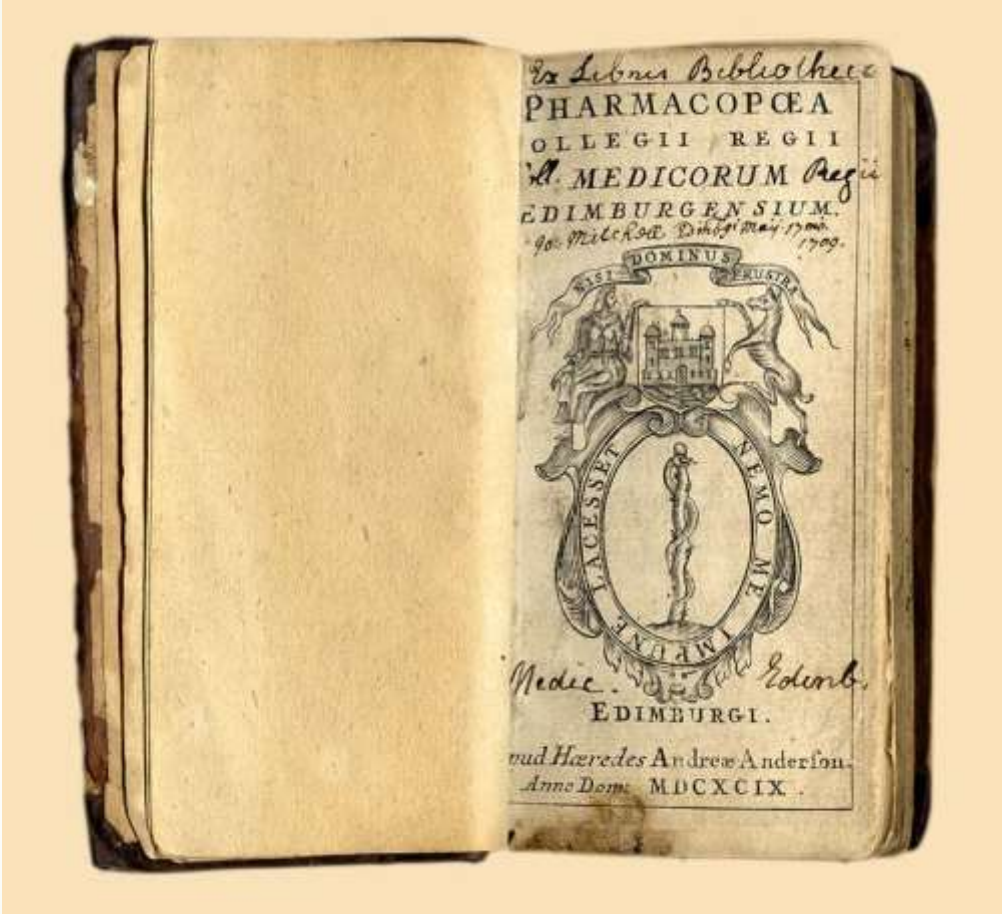
(M.Pharm, Pharmaceutical chemistry)

Asst. Professor - Department of Pharmaceutical Chemistry

K.K.Wagh College of Pharmacy, Nashik

Contents:

- Pharmacopoeia
- Impurity



INTRODUCTION TO PHARMACOPOEIA

- The word is derived from Greek words **‘pharmakon’** means **a drug** and **‘poiein’** means **to make.**
- It is a book containing directions for the identification of samples and the preparation of compound medicines.
- It is a legal and official book published by the authority of a Government or a medical or pharmaceutical society.
- It is a legislation of a nation which sets standards and mandatory quality indices for drugs, the raw materials used to prepare them and the various pharmaceutical preparations.
- In 1820, the first United State Pharmacopoeia (U.S.P.) was released. In 1864, the first British Pharmacopoeia (B.P.) was published with inclusion of monographs on benzoic acid, Gallic acid, tartaric acid, tannic acid, camphor, lactose, sucrose and seven alkaloids along with their salts.

1. Indian Pharmacopoeia

- First official Pharmacopeia of India appeared in **1868** which was edited by **Edward John Waring**.
- In pre-independence days, British Pharmacopeia was used in India.
- In **1946** Government of India issued one list known as "**The Indian Pharmacopeial list**"
- Committee under chairmanship of **Sir R. N. Chopra** along with 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**.

a) Indian Pharmacopoeia 1955

- It is written in English & official titles of monographs given in Latin.
- It covers 986 monographs.
- Dose were expressed in Metric system and English.
- Weight and measurements in metric system.
- List of preparations given at the end. Abbreviated titles used.

b) Indian Pharmacopoeia 1966

- **Second edition** of **IP** was published in **1966** under the chairmanship of **Dr. B Mukherjee**.
- Official titles of monographs given in English.
- 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.

c) Indian Pharmacopoeia 1985

- **Third edition** of **IP** was published in **1985** with two volumes & nine appendices.
- **261** new monographs have been added and **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.
- Dissolution had been introduced New analytical techniques(flame, electrophoresis, flourimetry) gas liquid chromatography, microbial limit test were introduced.

d) Indian Pharmacopoeia 1996

- **Fourth edition** of **IP** was published in **1996** under the chairmanship of **Dr. Nityanand**.
- It has been made effective from 1st December1996.
- 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 December2000 were **42** new monographs have been added.
- **Addendum II** has been made effective from 30th June 2003were **19** new monographs have been added.
- **The veterinary supplement** to IP 1996 contains **208** monographs & four appendices.

e) Indian Pharmacopoeia 2007

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

f) Indian Pharmacopoeia 2010

- The **Sixth edition** of the IP 2010 is published by the Indian Pharmacopoeia Commission (IPC) Ghaziabad in accordance with a plan and completed through the untiring efforts of its members. **IP 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). **Volume III** contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z). Followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood- related products, Biotechnology products and Veterinary products.
- Microbial contamination chapter updated NMR chapter incorporated in appendices. Chapter on liposomal products also added.

g) Indian Pharmacopoeia 2014

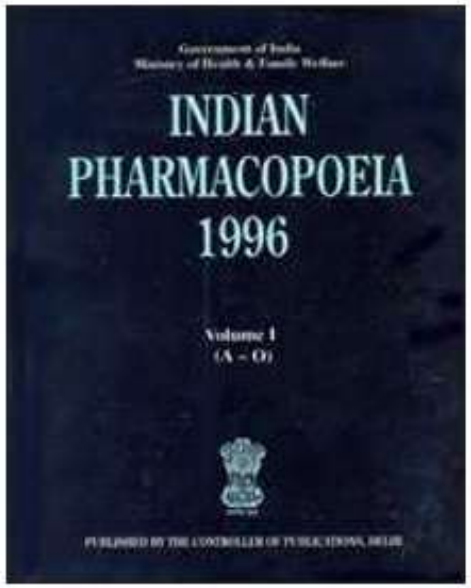
- **Seventh edition** of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes.
- The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.

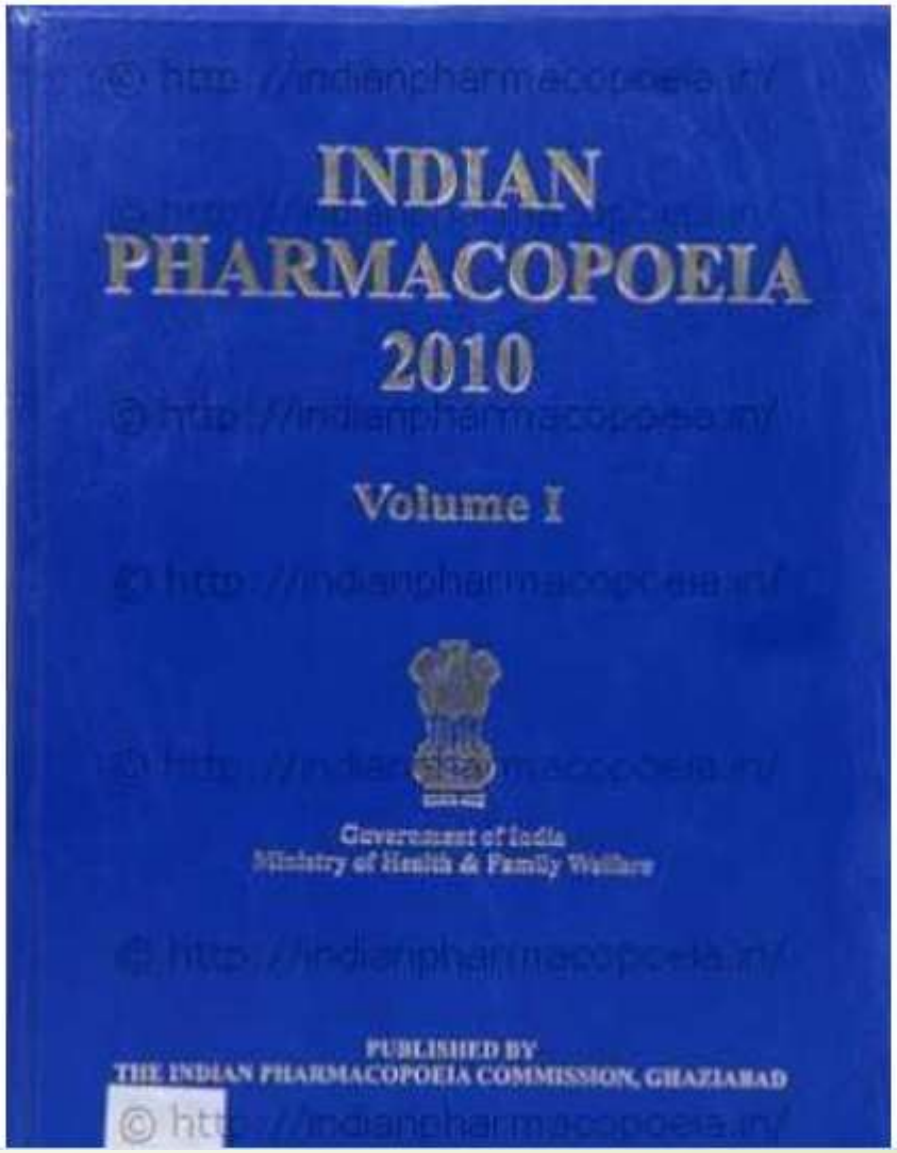
- The **IP 2014** incorporates **2548** monographs of drugs out of which **577** are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.
- A list of **577** New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing **313** New Monographs 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.

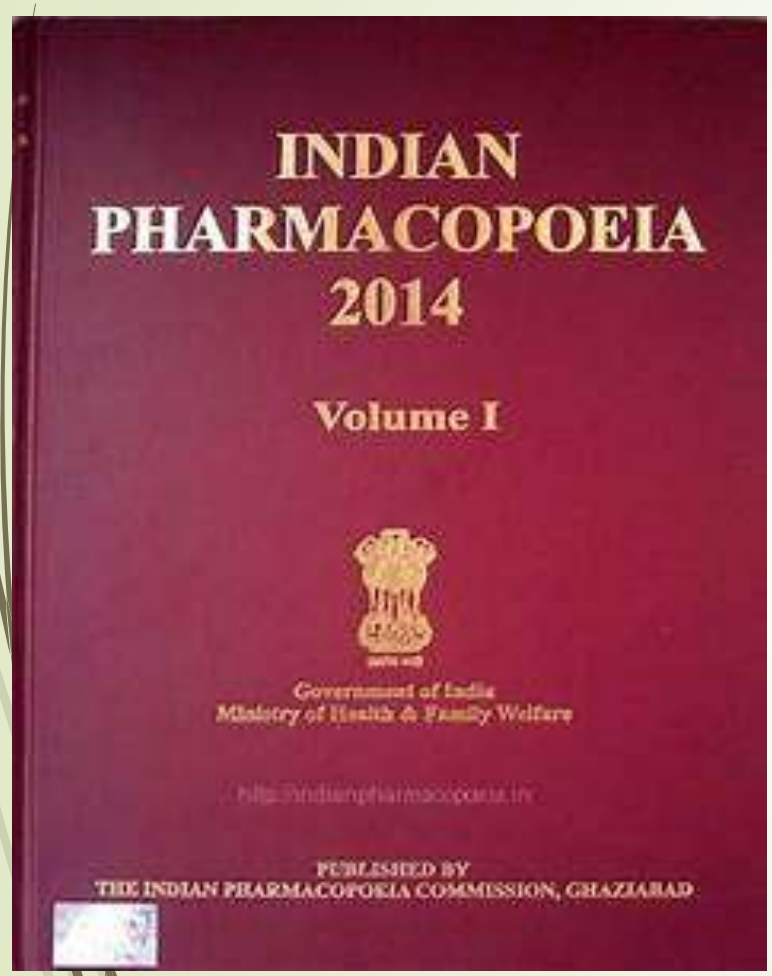
h) Indian Pharmacopoeia 2018

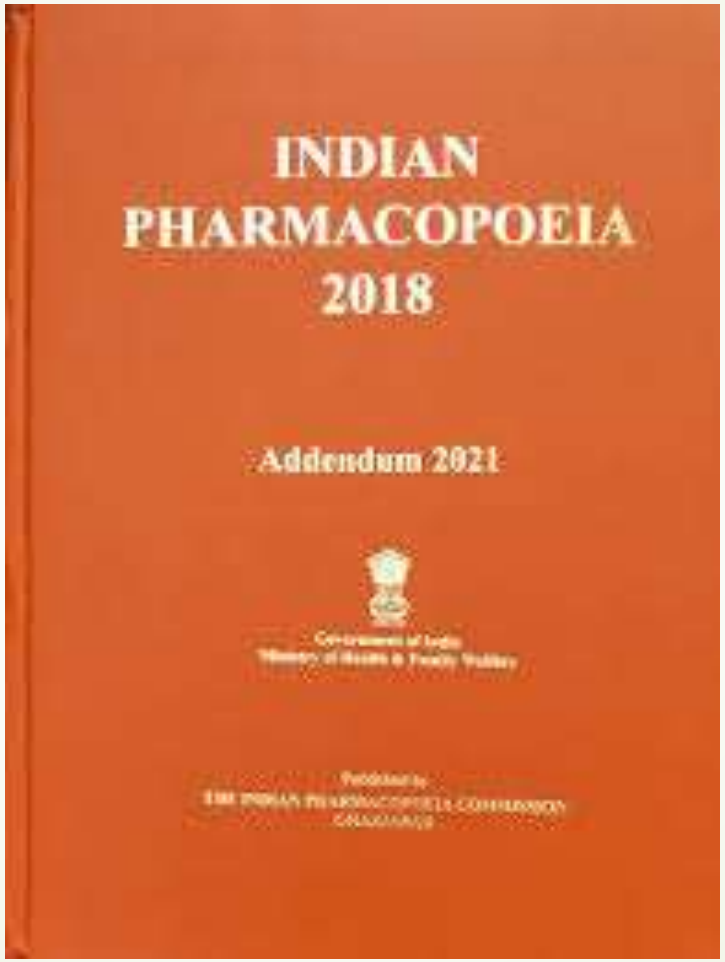
- It is effective from 7th February 2018
- Presented in 4 hard volumes.
- New 217 monographs included.
- General chemical test, TLC, IR, UV, HPLC has be given.
- Pyrogen test replaced by bacterial endotoxin test (BET) in parenteral preparations.
- Index is incorporated in all volumes.
- Chapters on volumetric glasswares conductivity dissolution test disintegration test, dimensions of hard gelatin capsule were revised.
- 53 new fixed dose combinations included, out of which 25 FDC are not available in any pharmacopoeia.
- General chapters on maintenance, identification preservation and disposal of microorganism have been included.

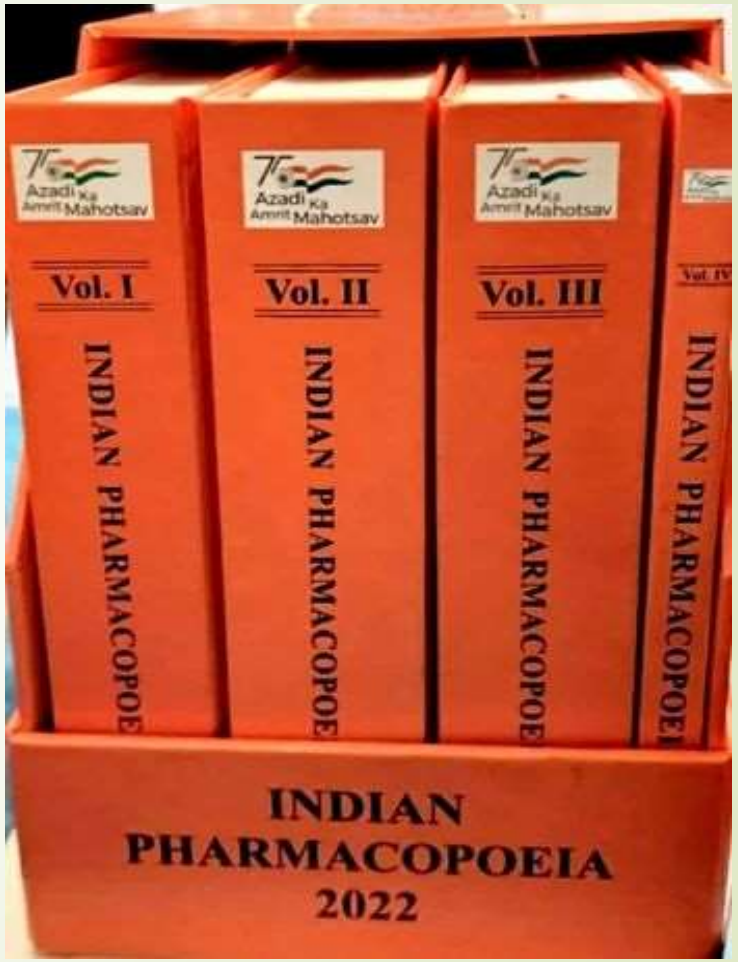
Indian Pharmacopoeia






INDIAN
PHARMACOPOEIA
2014
Volume I
Government of India
Ministry of Health & Family Welfare
PUBLISHED BY
THE INDIAN PHARMACOPOEIA COMMISSION, GHAZIABAD


INDIAN
PHARMACOPOEIA
2018
Addendum 2021


Azadi Ka Amrit Mahotsav
Vol. I
Vol. II
Vol. III
INDIAN PHARMACOPOEIA
INDIAN
PHARMACOPOEIA
2022

Features of various editions of Indian Pharmacopoeia

Sr. No. of Edition	Year of publication	Name of Chairman	Year of addendum released	Features of edition
First	1955	Dr. B. N. Ghosh	1960	Contains both western and traditional system drugs commonly used in India.
Second	1966	Dr. B. Mukherjee	1975	Contains both western and traditional system drugs commonly used in India.
Third	1985	Dr. Nityanand	1989 (1st) 1991 (2nd)	In this Pharmacopoeia, inclusion of traditional system of drugs was limited. However, most of the new drugs manufactured and/or marketed were included while only those herbal drugs which had definite quality control standards had got place in it.
Fourth	1996	Dr. Nityanand	2000 (1st) 2002 (2nd) 2005 (3rd)	It focuses on those drugs and formulations that cover the National Health Care Programmes and the National essential medicines. It contained monographs on antiretroviral, anticancer, anti-tubercular and herbal drugs. It further emphasised on biological monographs such as vaccines, immunosera for human use, blood products, biotechnological and veterinary (biological and non-biological) preparations

Fifth	2007	Mr. Prasanna Hota and Mr. Naresh Dayal	2008	It is presented in 3 volumes : • Volume I contains general notices and general chapters. • Volumes II and III contain general monograph and drug substances, dosage forms and pharmaceutical aid.
Sixth	2010	Mr. P. K. Pradhan	2012	It comprises of three volumes, each having different features. Volume I comprises of notices, preface, about Indian Pharmacopoeia Commission, acknowledgements, introduction, general chapters and reference data. Volume II contains general notices, dosage forms (general monographs), drug substances, dosage forms and pharmaceutical aids (A to M). Volume III includes general notices, drug substances, dosage forms and pharmaceutical aids (N to Z), vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products, veterinary products and index.

Seventh	2014	Mr. Keshav Desiraj (until February 2014) and Mr. Lov Verma (February 2014 onwards)	2015	It is presented in four volumes, and includes products of biotechnology, indigenous herbs, herbal products, veterinary vaccines and additional antiretroviral drugs, as well as, formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added, while the drugs and their formulations, not used currently are deleted from this edition. The IP 2014 incorporates 2548 monographs of drugs, among these 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotic monographs, insulin products and herbal products etc. 19 New Radiopharmaceutical Monographs and 1 general chapter is being included in this edition for the first time.

2. 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**.
- **Third and Fourth edition** of BP was published in **1885 and** 1898.
- **Fifth edition** of BP was published in **1914**.

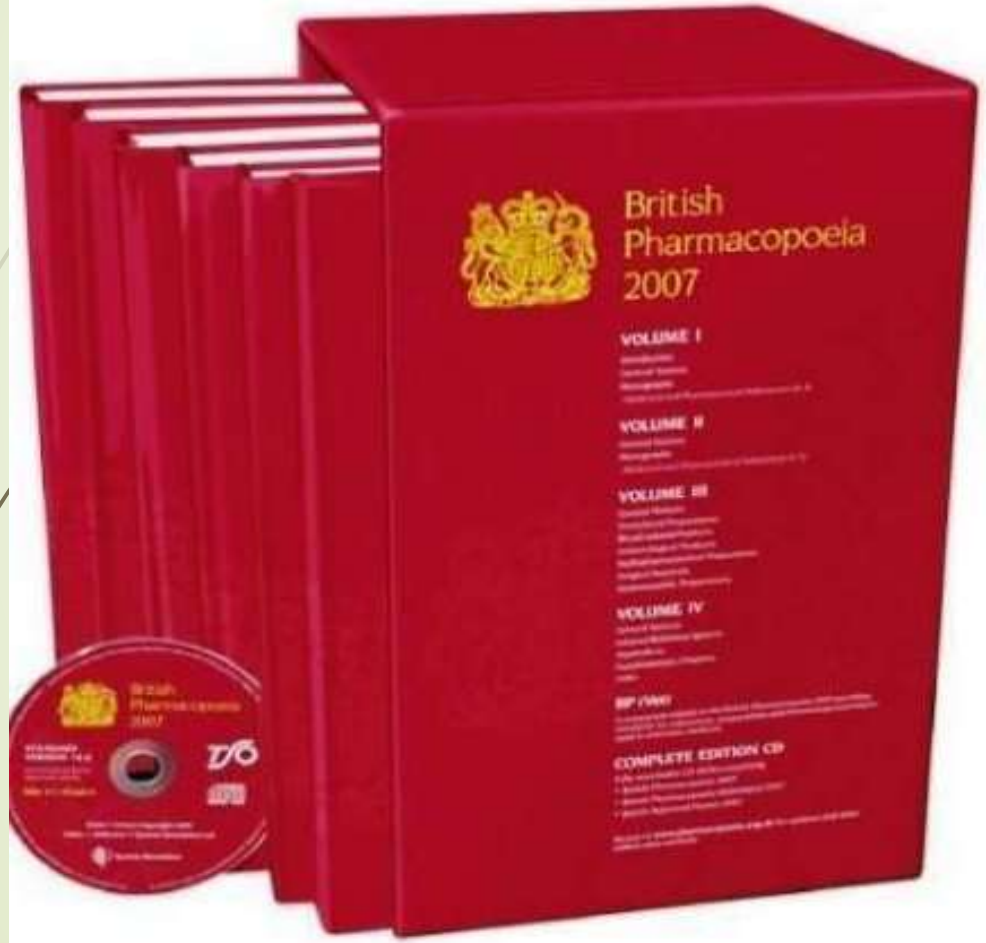
- **Eighth edition** of BP was published in **1953**.
- In this edition titles of drugs & preparations were in English instead of Latin and metric system.
- It has been published annually.
- In **BP 2007** monographs has been introduced for material specifically used in preparation of Traditional Chinese 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.
- **BP 2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.

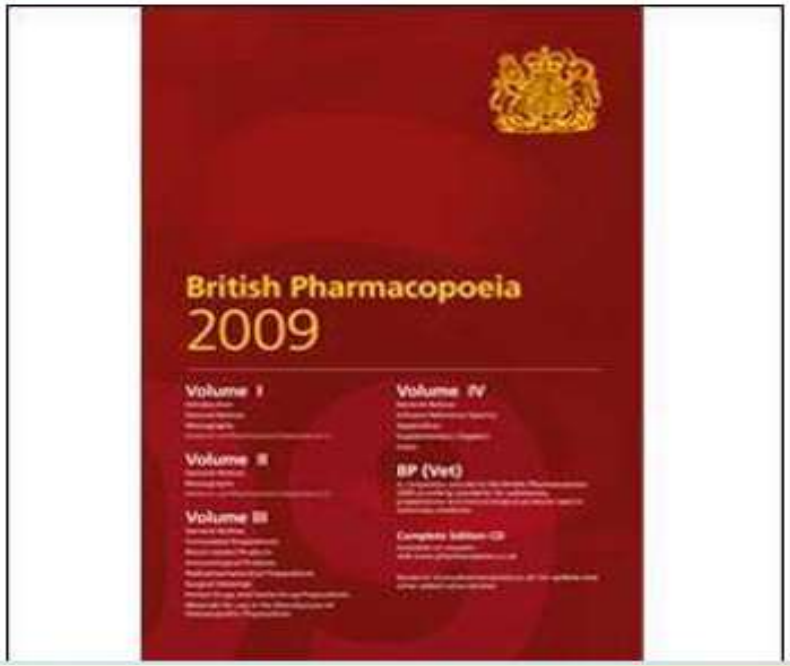
- It has been made effective from 1st January2008.
- **BP 2007 -2009** were given in **Six Volumes** i.e. Volume I to Volume VI. Volume I & II contains medicinal substances.
- **Volume III** contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.
- **Volume IV** contains supplementary chapters, IR spectra etc.
- **Volume V** contains veterinary.
- **Volume VI** contains CD ROM version.

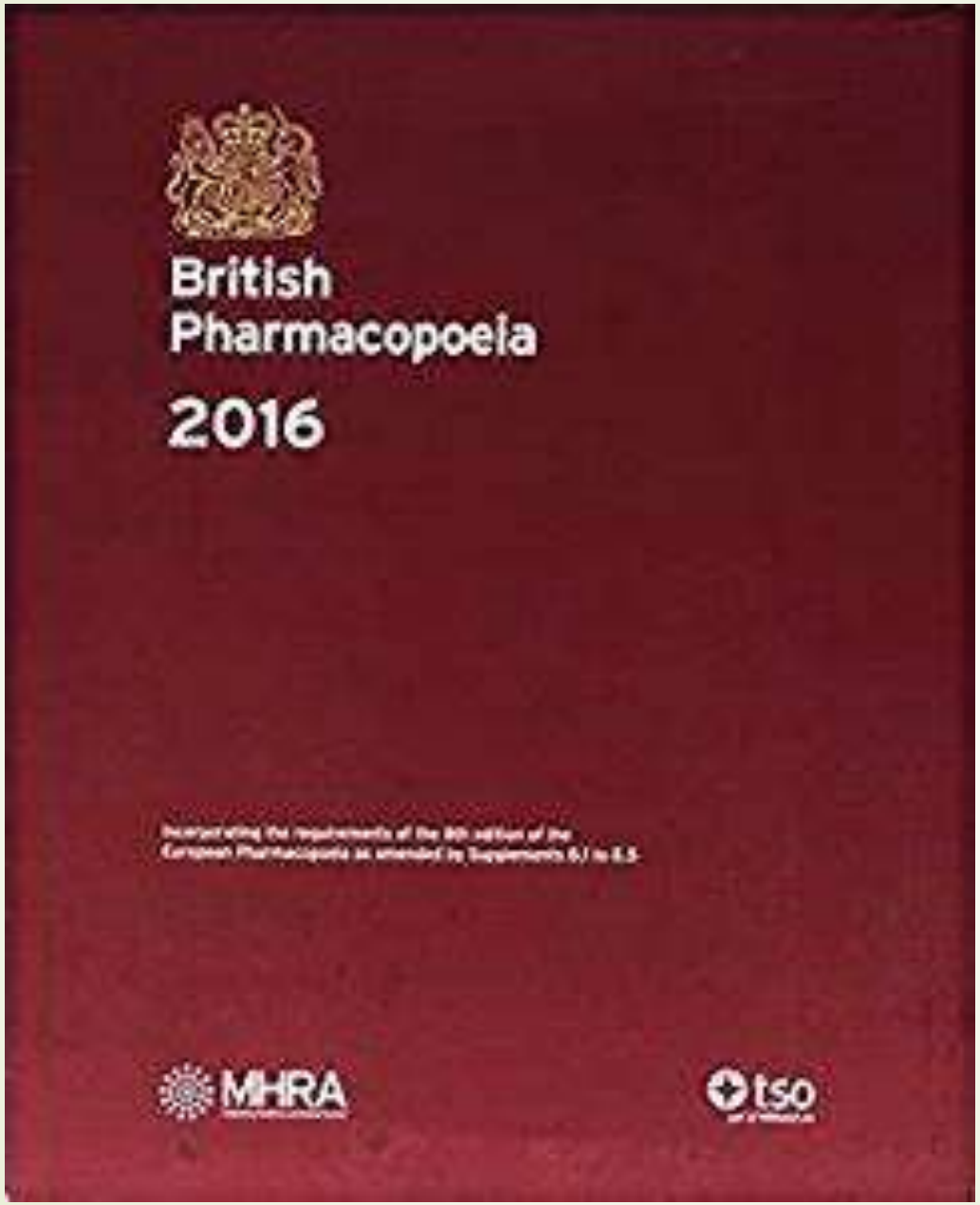
Highlights Of British Pharmacopoeia 2014:

- Legally effective from 1st January 2014
- 40 new BP monographs are included.
- 272 amended monographs.
- Three new supplementary chapters are included.
- Four new BP(vet) monographs are included.
- One new BP (vet) supplementary chapter is included.

BRITISH Pharmacopoeia






British
Pharmacopoeia
2016
MHRA
tso

3. UNITED STATE PHARMACOPOEIA (USP)

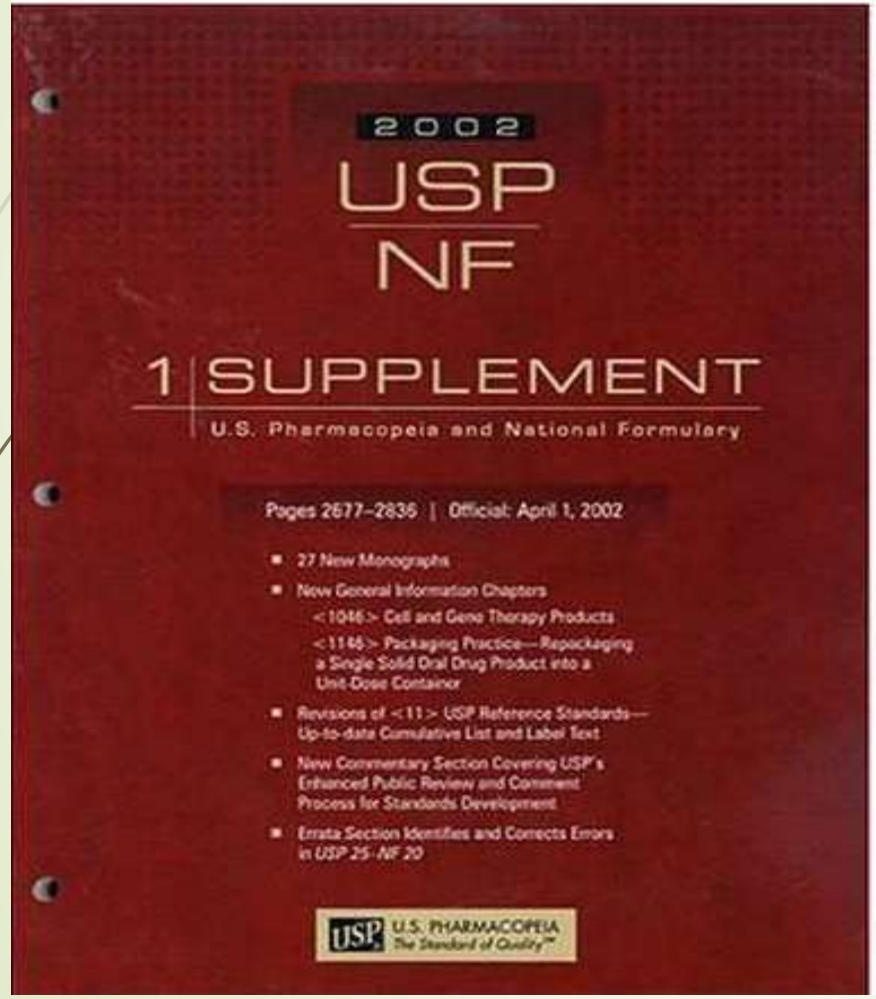
- **First edition** of United state Pharmacopeia was published on**15th December 1820** in both Latin &English.
- From **1820** to **1942** it was published at Ten years intervals.
- From **1942** to **2000** it was published at Five years intervals.
- From **2002** it was published annually.

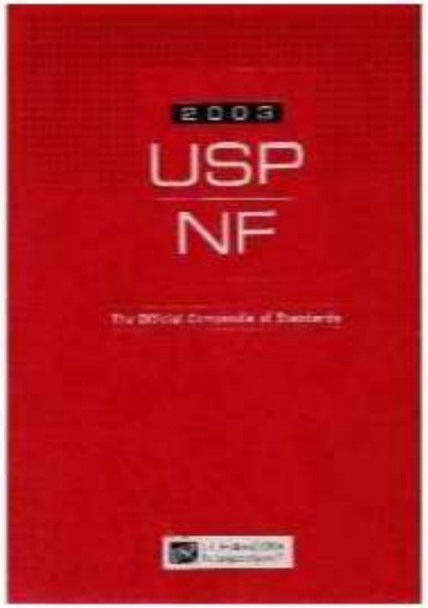
- First National Formulary of the united state appeared in**1888**.
- After **1975** both USP and NF are published as **USP-NF**.
- **USP 21-NF16** have eight supplements.
- First appeared in January 1985 & last in November1988.
- **USP 22-NF17**, 1990 is the third revision that consolidates USP& NF into a single volume.
- **Electronic version** of **USP-NF** on floppy disks was introduced in **1992**.
- **USP 23-NF18**, was published in Mumbai as an Asian edition at the end of **1994**.

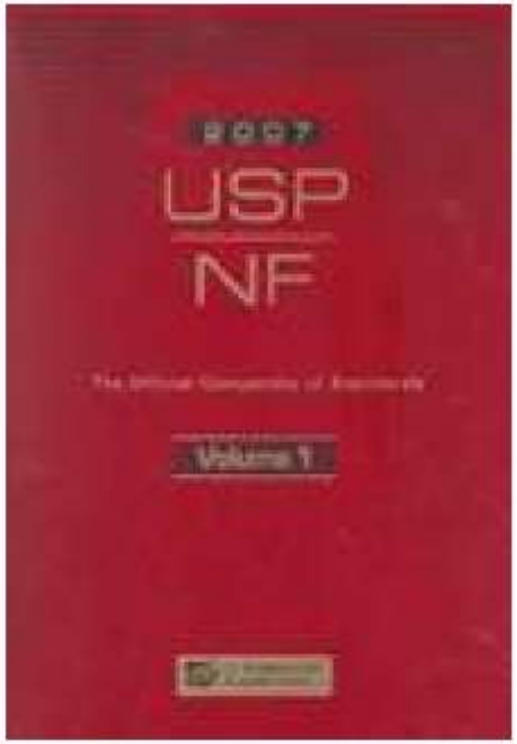
- **USP 34-NF 29,** offers harmonized material, more than **4,500** monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics and more than **230** General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.
- **USP 36-NF 31,** is a latest edition, published on November 1,2012 in English, and became official from 1 May**2013**. It contains more than 4,600 monographs, more than 260 general chapters providing guidance for assays, tests, and procedures.

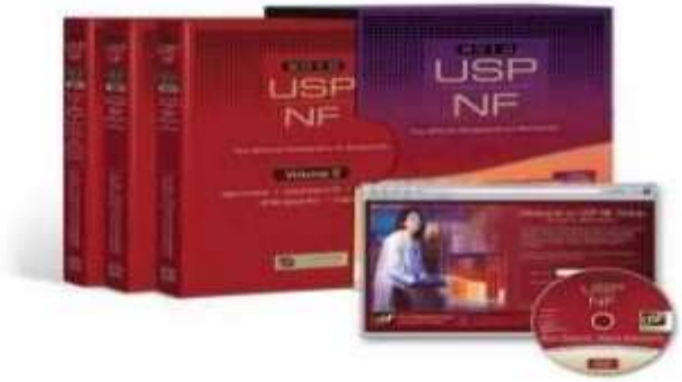
UNITED STATE Pharmacopoeia

U.S. Pharmacopeia
The Standard of Quality™









EUROPEAN PHARMACOPEIA (EP)

- European pharmacopeia commission started working since 1964 to prepare EP.
- Adopted by Germany, France, Italy, Netherlands, Switzerland and Belgium.

BRITISH PHARMACOPOEIAL CODEX (BPC)

- Introduced in 1903 by Britain.
- First edition in 1907.
- And subsequent by 1911,1923,1934,1949,1954,1963,1968.
- Comprises of general monograph also provide medicaments that are not provided in BP and BNF.

PHARMACOPOEIAL DESCRIPTION

- 3 main sections-

a) General notices

b) Monographs

c) Appendices

- It contains useful informations of pharmaceutical progress since last edition
- It summarizes various changes including additions or deletions in the present edition compared to last edition.

OFFICIAL MONOGRAPH

- Monograph means written study of a drugs and formulations which give description, assay, assay limits and other details necessary for maintaining standards
- Derived from Greek words mono- single , grapho = to write.
- A monograph in I.P. includes-

1. Title: official name of compound in English, subtitles also given as synonyms, e.g. calcium carbonate- precipitated chalk.

2. Chemical formula: graphic and molecular formulae are given.

3. Atomic and molecular weight: are shown at the top right hand corner of the monograph, e.g. magnesium chloride- mole.wt.-202.30

4. Definition: official definition of substance, preparation and other article are also given.

5. Category: expresses the pharmacological or therapeutic or pharmaceutical application of the compound.

6. Dose: provides the quantity guidance to the prescriber or the physician to achieve the desired therapeutic effects in adults. The dose can be altered as and when required, e.g. dose of calcium carbonate is 1-5 gm.

7. Usual strength: indicates strength marketed for information of the pharmacist and the medical practitioner.

8. Description: indicates a physical description such as amorphous nature or crystalline, odour, colour and taste.

9. Solubility: as per IP , different degrees of solubility are-

Descriptive terms	Relative quantity of olvent for 1 part of solute
Very soluble	Less than 1 part
Freely soluble	1 to 10 parts
Soluble	10 to 30 parts
Sparingly soluble	30 to 100 parts
Slightly soluble	100 to 1000 parts
Very slightly soluble	1000 to 10000 parts
Practically insoluble	More than 10000

10. Test Methods: indicated by test method numbers ib brackets immediately after the heading of the test or at the end of the text.

11. Identification: involves specific chemical tests for identifying the substance.

Some identification tests include: Infrared absorption spectroscopy, Ultraviolet visible spectroscopy, Melting point or Boiling point, simple chemical tests.

12. Tests and assay: official methods prescribed for the minimum sample available.

13. Limits: tests are designed to identify and control small quantities of impurities present in a substance.

14. Assay: gives the method which determine the percentage content of a particular chemical in the given test sample.

15. Storage: useful in preserving the activity of the chemical, e.g. well closed container, light resistant container, single dose container.I.P. also prescribes conditions for storage, e.g. at room temperature i.e. temp of working area, cool and dry place, etc.

16. Storage containers:

a) well closed containers means substance is stable protected from dust, dirt, insects, etc.

b) Tightly closed container: substances is protected from atmospheric oxygen, moisture,CO2.

c) Light resistant container: substances is protected from light and stored in amber or dark colored containers.

d) Single dose containers.

17. Labelling: it is governed by D & C Rule, 1945.

18. Appendices: it contains general information, e.g. the I.P. 1985 have the following appendix:

Appendix No.	Contents
Appendix No. 1	Apparatus for test & assay, e.g. Volumetric flask
Appendix No. 2	Biological tests & assays
Appendix No. 3	Chemical tests & assays
Appendix No. 4	Microbiological tests & assays
Appendix No. 5	Physical tests & determinations, e.g. pH, M.P., etc.
Appendix No. 6	General information

NEW INCLUSION/ EXCLUSION OF MONOGRAPH

- Storage & labeling included.
- Structural formulae included.
- Titles have been changed, e.g. Hyoscine HBr for Scopolamine HBr.
- IR & UV tests are provided as alternative tests.
- HPLC introduced in addendum II of 1985.
- Qualitative tests have been replaced by quantitative tests for determination of particular matter.
- Bicarbonate deleted due to instability.
- Design & Statistical analysis of biological assay is revised.
- Veterinary monographs on vaccines added.
- Numbers of monographs have been updated, e.g. acyclovir, alprazolam, captopril, mannitol, thiotepa, albendazole, etc.

IMPURITY

1. Impurities in pharmaceuticals are unwanted chemicals that remain with the API, developed during formulation which influence the efficacy and safety of pharmaceuticals products. The ICH has formulated a workable guideline regarding the control of impurities.

Types Impurities:

IMPURITIES

Organic

a) By-product impurities
b) Degradation products
c) Intermediate product
d) Reagents, Ligands, catalysts
e) Enantiomeric impurities

Inorganic

a) Reagents, catalysts
b) Heavy metals
c) Other materials e.g. charcoal, filter aids

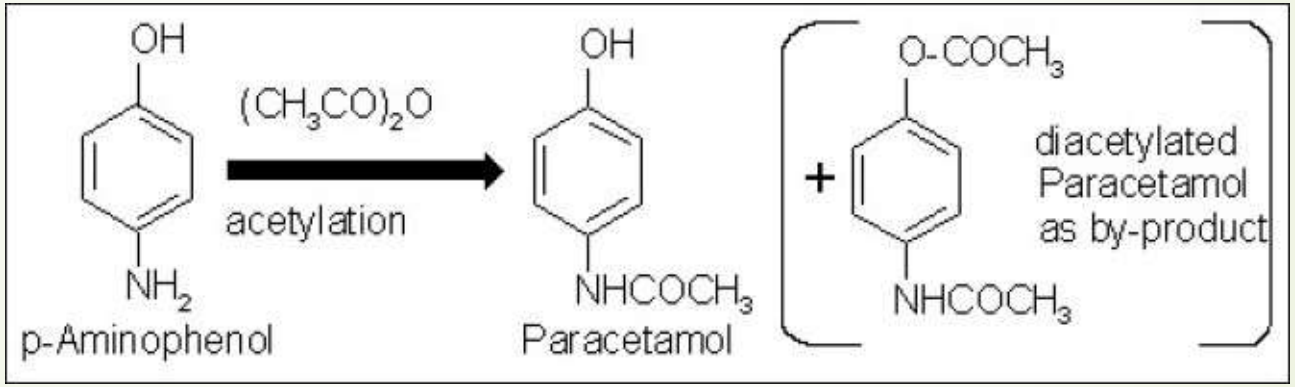
Residual solvents

a) Class I - benzene, ccl4 because of their carcinogenic and toxicity
b) Class II- methylene chloride, methanol, pyridine, acetonitrile
c) Class III- acetic acid

1. Organic Impurities:

may arise during the manufacturing process, storage of the drug substance, during the synthesis, purification.

a) By-product Impurities: 100% yield of single end product during synthesis is very rare, there is always a chance of some by-product with desired end product, e.g. in the synthesis of paracetamol, diacetylated paracetamol may be formed as a by-product.



b) Degradation products: impurities can also be formed by degradation products resulting from storage or formulation to different dosage forms.

e.g. the degradation of penicillins and cephalosporins, where the presence of a β-lactum ring and an amino group in the side chain leads to degradation.

c) Intermediate Product: sometimes in the reaction these intermediates do not get converted into end product and remains as such as an impurity with the end product.

e.g. potassium iodide is prepared by the reaction of potassium hydroxide and iodine.

$$6KOH + 3I_2 \longrightarrow 5KI + KIO_3 + 3H_2O$$

potassium hydroxide — Iodine — potassium iodide — potassium iodate — water

Potassium iodate formed as intermediate, may remain as an impurity, if not properly converted to potassium iodide.

d) Reagents, ligands and catalysts: these are the chemicals used to carry out various reactions, impurities are less commonly found in APIs. In some cases they may produce a problem as impurities.

e) Enantiomeric impurities: stereoisomers are related products similar to the drug substance, with toxicological side effects or altered physicochemical properties, e.g. levofloxacin (S-ofloxacin), levalbuterol (R-albuterol),etc.

2. Inorganic impurities:

It may derive from the manufacturing processes used for bulk drugs. These impurities are normally known and identified.

a) Reagents, ligands and catalysts: these impurities are rare, in some cases they may produce a problem as impurities, e.g. when calcium chloride is roasted with sodium carbonate, precipitates of calcium carbonate are formed.

b) Heavy metals: main sources of heavy metals are the water used in the processes, where acidification or acid hydrolysis takes place. These impurities can be avoided by using demineralized water.

c) Other materials: The filters such as centrifuge bags, filter paper or charcoal are routinely used in the manufacturing plants. The regular monitoring of fibers and black particles in the bulk drugs is essential to avoid these impurities.

3. Residual Solvents:

These are organic volatile chemicals used during the manufacturing process are classified into 3 classes:

Class I solvents includes Benzene & CCl_4,these to be avoided because of their carcinogenic and toxic activity.

Class II solvents includes methylene chloride, methanol, acetonitrile, etc.

Class III solvents are acetic acid, acetone, isopropyl alcohol, ethanol, etc.

SOURCES OF IMPURITIES

1. **During manufacturing**
2. **During Purification and Processing**
3. **During storage**

1. During manufacturing:

(a) Raw Materials employed : Impurities present in raw materials may be carried through the manufacturing process to contaminate the final product. Impurities such as Pb, heavy metals, chlorides associated with Na compounds, H_2SO_4 with $CuSO_4$ and HCl with $FeCl_3$

(b) Reagents used in manufacturing process : If reagents used in the manufacturing process contain some impurities these may find entry into the final product. For e.g. Sulphuric acid is used in many chemical processes. This acid often has lead present in it.

(c) Solvents used in the manufacturing process : The manufacturing processes may involve a single step or multiple steps (unit operations). If proper quality/purity of solvents is not assured, they may add to the impurities. e. g. Solvents like toluene, n-butanol contain water as an azeotrope. Alcoholic solvents also may be contaminated with water

(d) Reaction vessels: The reaction vessels in the manufacturing process may be metallic (cast iron, mild steel, stainless steel) or mild steel with glass lining. Some solvents and reagents employed in the process may react with the metals of the reaction vessels, leading to their corrosion and passing traces of metal impurities into the solution, contaminating the final product. Similarly, glass vessels may leach traces of alkali into the solvent.

(e) Intermediate products in manufacturing process : Some intermediates which are produced during the manufacture may be carried out through the final product as impurities. Intermediates are products of -

(I) incomplete conversion of reactants to final products or

(ii) side or competing reactions or

(iii) decomposition of products formed due to poor process control.

e.g. In the manufacturing process of KI, the intermediate iodate is the main impurity.

(f) Defects in manufacturing process : Defects like imperfect mixing, non–adherence to optimum reaction conditions (proper temperature, pressure and pH) may lead to impurities. E.g., Improper heating in process of manufacture of Zinc Oxide can lead to un oxidized metallic Zn as an impurity.

$$2\ Zn + O_2\ ¾ \rightarrow 2\ ZnO + Zn\ (impurity)$$

(g) Manufacturing hazards : In industrial areas, the atmosphere is contaminated with dust particles (Al_2O_3, silica glass, carbon, gases like H_2S, SO_2, CO_2, CO etc.). During the manufacture of pharmaceutical products, these impurities may enter the final product.

2. During purification and Packaging:

(a) Reagents used to remove other impurities : Sometimes some chemicals are added to remove or to precipitate another substance. This may be also give rise to source of impurity. For e.g. $BaCl_3$ is added to remove excess of Sulphate in $AlCl_3$, hence $AlCl_3$ is likely to contain Ba as an impurity.

(b) Solvents used in process of purifications : Often the solvents used for purification can be sources of impurities. These solvents range from organic solvents to acids (organic as well as mineral) and of course water. Types of water used are:

(i) Tap water : It contains impurities of Na+, Ca2+, Mg_2+, CO_2−3 , SO_4-

(ii) Softened water : It contains Na^+ and Cl^- ions as impurities may appear as impurities.

(iii) Demineralized water : Though it is free from all above inorganic ion- impurities it still contains organic impurities like salts of carboxylic acids, N and S etc.

(iv) Distilled water : Considered to be the best. It is pure water and is free from all inorganic and organic impurities but the cost of it's production is very high.

(c) Contamination due to vessels and equipment used for purification : During the purification processes, if the vessels are defective or not perfectly cleaned and dried they may add impurities like metallic ions, rust, glass particles, moisture etc. The other equipment mainly the filters, centrifuges, dryers etc., also need to be clean and dry.

3. During Storage:

(a) Errors in the packaging or use of substandard packaging material :

During the process of packaging or filling and sealing which can ensure complete foolproof packaging without access to atmosphere and light will ensure the stability of the product. Thus, quality and strength of packaging material is very important. E.g., if the aluminum foil for tablet strip or cap for a liquid formulation bottle is of substandard quality it can add to impurities.

(b) Faulty packaging processes : Most of the pharmaceutical packaging processes are assembly lined automated process, generally involving pressing and sealing with heat. If the process parameters are not optimized or are tampered with, then it may lead to contaminations.

e.g. Nowadays most of the parenteral products are in polymer containers using FFS (Form-Fill-Seal) processes which involve proper heating, filling, sealing and congealing cycles. Any changes in process parameters can be hazardous.

(c) Microbial Contamination : Microbial contaminations, mainly in the form of fungal and bacterial growth may be due to the result of improper storage conditions as well as faulty packaging. The products for parenteral administration and ophthalmic preparations have to undergo sterility tests.

Effects of Impurities in Pharmaceuticals

1. Some impurities if present beyond certain tolerance limits can cause untoward side effects that can lead to unpleasant reactions. For example, Heavy metals like; Pb, Fe and As salts.
2. Some impurities which are otherwise harmless in nature and without any therapeutic effect, if present in considerable proportions dilute the active strength or potency of the drug substance. For example, Na, K, Cl, SO_4, CO_3 salts.
3. Some impurities may be able to catalyze the degradation, thereby shortening the shelf life of the drug substance.
4. Some impurities by their chemical nature can interact with the drug substance to affect its purity and potency. Such impurities are said to be incompatible with the drug substance/s.
5. Some impurities by virtue of their unstable nature like; hygroscopic nature, oxidizable nature, etc., can bring about change in the physical properties like; change in appearance, taste, odour, stability, etc., of the drug substance causing technical difficulties in its use as well as formulation.

Pharmaceutical	Raw materials	Impurities present
Bismuth compounds	Bismuth salts	Lead, copper, and silver
Copper compounds	Copper turnings	Arsenic and iron
Zinc compound	Zinc metal or oxide	zinc Aluminum, copper, manganese,Mg,
		arsenic, iron and nickel.

Question Bank

1. Briefly explain the history of Indian Pharmacopoeia.
2. Define and classify different types of impurities.
3. Discuss various sources of impurities in pharmaceutical substances.
4. Write in brief the content of Monograph.
5. Explain the terms “Pharmacopoeia” and “Monograph”. Enlist different Pharmacopoeia and discuss salient features of monograph.
6. Explain ash value and its significance.
7. Explain control of impurities.

Thank you