CHAPTER
1

History of Pharmacy and Pharmacopoeia

ORIGIN AND DEVELOPMENT OF PHARMACY

'**Bheshaj**' is the term used in India from the last four thousand years which is equivalent to Greek term '**Pharmacon**' meaning drug from which the term pharmacy has been derived. In ancient times pharmacist was responsible for making the drug into suitable dosage form acceptable to patient. Pharmacist was also involved in procurement of drug from various sources. Hence pharmacy is the branch that deals with identification, procurement, formulation and dispensing of drug. In ancient times there was a believe that people associated with this profession have some spiritual powers and hence the profession is treated in a different manner by the society. Throughout history, many individual have contributed to the advancement of the health sciences. Notable among those whose genius and creativeness had a revolutionary influence on the development of pharmacy and medicine were **Hippocrates** (ca. 460–375 BC), **Dioscorides** (1st Century AD), **Galen** (ca. 129–216 AD), and **Paracelsus** (1493–1541 AD).

Hippocrates, a Greek physician, is recognized for the introduction of scientific pharmacy and medicine. He streamlined medicine, systematized medical knowledge and put the practice of medicine on a high ethical place. His thinking on the ethics and sciences medicine dominated the medical writings of his and successive generations. His works included the descriptions of hundreds of drugs, and it was during this period that the term 'Pharmakon' came into existence which

means a purifying remedy for good only, excel the previous association of a charm or drug for good or for evil purposes, because of his revolutionary work in medical science and his motivation teachings and advanced philosophies that have become a part of modern medicine, Hippocrates is called the **father of medicine.**

Dioscorides, a Greek physician and botanist, was the first to used botany as an applied science of pharmacy. His work, ***De Materia Medica***, is considered a landmark in the development of pharmaceutical botany and in the study of naturally occurring medicinal materials. This area of study is today known as pharmacognosy, a term fomed from two Greek words, "pharmakon" meaning drug and "gnosis" means knowledge. Some of the drugs Dioscorides described, including opium, ergot, and hyoscyamus, continue to have use in medicine. His descriptions of the art of identifying and collecting natural drug products, the methods of their proper storage, and the means of detecting adulterants or contaminants were the standards of that period, established the need for additional work, and set guidelines for future investigators.

Claudius Galen, a Greek pharmacist–physician, created a perfect system of physiology, pathology, and treatment. Galen prepared doctrines that were followed for 1500 years. He was one of the most creative authors of his time or any other year, having been credited with 500 treatises on medicine and some 250 others on philosophy, law, and grammar. His medical writings include descriptions of numerous drugs of natural origin with a large amount of drug formulas and methods of compounding. He originated so many preparations of vegetable drugs by mixing or melting the individual ingredients that the field of pharmaceutical preparations was commonly referred to as "Galenic pharmacy" at that time.

Pharmacy always remained associated with medicine, pharmacy was officially separated from medicine for the first time in 1240 AD, when a declaration of **Emperor Frederick II** of Germany, regulated the practice of pharmacy within the part of his kingdom called the two sicilies. His announcement separating the two professions acknowledged that pharmacy

required special knowledge, skill, initiative, and responsibility. Pharmacists were obligated by oath to prepare reliable drugs of uniform quality according to their art. Any exploitation of the patient through business relations between the pharmacist and the physician was strictly prohibited.

Perhaps no person in history exercised such a revolutionary influence on pharmacy and medicine as did **Aureolus Theophrastus Bombastus von Hohenheim** (1493–1541), a Swiss physician and chemist who called himself **Paracelsus**. He was the first person who changes the pharmacy from a profession based primarily on botanical science to the one based on chemical science. Some of his chemical observations were astonishing for his time and they become landmark for further discoveries. He emphasize that it was possible to prepare a specific medicinal agent to combat each specific disease and introduced a host of chemical substances to internal therapy. Then further contribution was made by number of scientist by developing new drugs from different sources. In India, the ayurvedic medicine was used as per the ancient books written by **Charak**, a physician, which nowadays replaced by allopathic medicine during the British rule. After independence, a new revolutionary era of allopathic medicine leads to further development in pharmaceutical industry. Every person engage with profession of pharmacy has to abide with the pharmacy oath laid down below.

PHARMACIST OATH

I swear by the code of ethics of Pharmacy Council of India, in relation to the community and shall act as an integral part of healthcare team.

I shall uphold the laws and standards governing my profession.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system which I consider best for pharmaceutical care and counseling of patients.

I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity.

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.

I shall associate with organizations having their objectives for betterment of the profession of pharmacy and make contribution to carry-out the work of those organizations.

While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times !

Should I trespass and violate this oath, may the reverse be my lot!

PHARMACY AS A CAREER

A career in pharmacy, open out a view full of opportunities leading to a golden future for a young career aspirant. The job opportunities, working conditions, job satisfaction and monetary benefits are excellent.

The various careers, a pharmacy professional can opt, are discussed below.

Production and manufacturing: A pharmacy professional can work as a production person (chemist, officer, executive, manager, vice-president), involved in the production of bulk drug and intermediates or formulations and dosage forms. Industries in the cosmetics, soaps, toiletries segment also hire pharmacy professionals.Other areas, where pharmacy professionals are required, are in production of veterinary medicine, perfumery, fragrances, and nutraceuticals.

Research and development: This forms the heart of any industry, as it is the key to growth and nutrition. Mainly MPharm and PhDs are in great demand in the various areas of pharmaceutical R&D. Other areas, where professionals are required are:

- New Drug Discovery Research (NDDR): Discovering a new drug has assumed prime importance in the post-GATT era.

- Process development (P&D): One of the important areas in bulk drugs industry is developing workable processes for the manufacture of drugs and intermediates for their commercial production.
- Formulation and development (F&D): The success of any pharma company lies in the quality of its products, i.e. formulations and dosage forms.
- Clinical trials, bioequivalence studies, toxicological studies: These are some of the areas of clinical research which are in high demand as they are involved in the systematic evaluation of potential drug substances prior to getting them approved by the authorities.

Analysis and Testing

Any drug or dosage form for human use has to be of excellent quality and purity, free from any impurities. The permitted limits of impurities, which either occurs through the manufacturing process, equipment, raw materials, handling or storage, are very strict. Therefore, quality control (QC) and quality assurance (QA) are the most integral areas of the drug and pharmaceutical industry. Highly specialized and trained staff is required to handle sensitive analytical procedures and sophisticated equipment. MPharm and PhDs in pharm analysis /QA are highly preferred for this job.

Marketing

Any business is incomplete without the marketing and sales aspect, as the universal fact is that any thing produced has to be sold. The pharmacy sales and marketing is a highly technical field and offers excellent opportunities for the pharmacy graduates. Additional qualification like MBA adds to their arsenal. An aspirant of a highly bright future can enter through various openings like starting his own retail or wholesale drug store or becoming a professional sales representative (known as medical sales representative or MR) to the levels of international marketing and exports. The financial rewards and perks are the best.

Hospital Pharmacy

Another opening for a pharmacy professional is as a "registered pharmacist" in the hospitals or drug stores. This is a very sought after professional especially in countries like the USA and Canada. This is a key position and the pharmacist plays an important role form preparing prescription to the patient's medial history after the medical doctor has diagnosed the disease. The pharmacist is the best-informed qualified drug expert whose advice is sought by every body regarding the dosage, incompatibilities and side effects of drugs.

Community Pharmacy

This concept, which is already very old in developed Western countries, is rapidly catching up the healthcare service in our country. Through the services of community pharmacy a pharmacist becomes a vital link between the patients and the products, i.e. drugs. The pharmacist also serves a vital link between the patients and other healthcare professionals, especially the medical experts.

- Counseling the patients regarding the use of the drugs and dosage forms
- Providing up-to-date information on drugs/dosage forms to the patients, as well as, medical staff.
- Maintaining patient records and history
- Involved in the usage of self-diagnostic kits by the patients for disorders like diabetes, hypertension, etc.
- Providing supply of home care dosage forms.

Academics

Excellent opportunities for the professionals are available in teaching profession also. As per the AICTE norms the minimum entry-level qualification as lecturer is MPharm. This is a profession associated with job satisfaction and social status as teaching is considered to be noble profession. The higher posts in the hierarchy and Sr. Lecturer, Reader, Assistant Professor, Professor, Principal, etc. The emoluments are satisfactory.

Besides teaching academic related opportunities involve positions on research posts and training programs.

Regulatory Affairs

Locally the FDA (foods and drugs control administration) is the main regulatory body governing and implementing the rules and regulations for the drug and pharma industry. The FDA has state branches and sub-branches all over the country. The job opportunities for pharmacy graduates are excellent and range from the levels of a Drug Inspector (DI), Sr. DI, Deputy Drug Controller, Assistant Drug Controller, Drug Controller and finally DCI (Drug Controller of India). This is highly respected and sought after profession. A graduate in pharmacy is the minimum eligibility.

In order to enter into trade with the foreign countries it is compulsory to get the necessary approvals and sanctions as per the formats given by local regulatory authorities, e.g. approvals to be obtained from USFDA for USA, TGA for Australia and New Zeeland, MCA and MCM for UK and European countries and ICH guidelines going to be uniform for international levels. Similarly, patents and trademarks, IPR experts are also in high demand as far as the pharmaceutical industry is concerned.

Opportunities Abroad

Golden opportunities galore for qualified pharmacy professionals in various courtiers including the USA, Canada, European countries like UK, France, Germany, African countries like South Africa, Nigeria, Yemen, Gulf countries like Saudi Arabia, Kuwait, South-East Asian countries like Singapore, Korea, Japan, etc. and the Australian continent including New Zealand.

There are plenty of higher education and research opportunities in the developed western countries along with excellent job openings. The pharmaceutical career is one of the highest rewarding careers in these countries.

The monetary job benefits abroad are highly exciting, job profiles in African countries like, and Nigeria, Yemen and Gulf countries like Saudi Arabia, Kuwait, mainly as pharmacists in drug stores and hospitals.

In developed western countries the job opportunities are manifold and almost in any one of the ten vocations discussed above.

INTRODUCTION TO PHARMACOPOEIA

The term pharmacopoeia comes from Greek word ***"Pharmakon"*** meaning 'drug' and ***"Poein"*** meaning 'make', and the combination means any recipe or formula or other standard required to make or prepare a drug.

"Pharmacopoeia (literally, the art of the drug compounder), in its modern technical sense, is a book containing directions for the identification of samples and the preparation of compound medicines, and published by the authority of a government or a medical or pharmaceutical society. The name has also been applied to similar compendiums issued by private individuals".

Each country has legislation on pharmaceutical preparations which sets a standards and required quality indices for medicament, raw materials and preparations employed in the manufacture of drugs. These regulations are presented in separate articles. General and specific matters relating to individual drugs are published in the form of a book called a **pharmacopoeia**.

On 15th December **1820**, the first United States Pharmacopoeia (USP) was released.

In **1864**, the first British Pharmacopoeia (BP) was published.

In **1955,** the first Indian Pharmacopoeia (IP) was published.

The History of Pharmacopoeia of India

The Government of India through its letter No. 2338H(C)/43 dated 26 January, 1944, directed the Drugs Technical Advisory Board to list the drugs in use in India, which are not mentioned in British Pharmacopoeia and also recommend the standards to be prescribed to maintain uniformity and the chemical tests to be used to establish identity and purity. The Government of India published the Indian Pharmacopoeial list in 1946, as a

supplement to the British Pharmacopoeia. **British Pharmacopoeia** was utilized as the **official book of standards in India before independence**.

i. The first Indian Pharmacopoeia started in the year 1944 under the chairmanship of Col. RN Chopra.
ii. The Indian Pharmacopoeia list was first published in the year 1946.
iii. The government of India constituted a permanent Indian Pharmacopoeia Committee in 1948 for the preparation of the Indian Pharmacopoeia and established a central Indian Pharmacopoeia Laboratory at Ghaziabad, Uttar Pradesh, to keep it uptodate. The first edition of Pharmacopoeia of India was compiled and then published in 1955.
iv. After independence, the **first edition of the Indian Pharmacopoeia** (IP) was published in the year **1955** under the chairmanship of **Dr BN Ghosh**. Supplement for first edition of Indian Pharmacopoeia was published in the year 1960.

The Indian Pharmacopoeia Commission (IPC) has been established in the year 2005. The IPC provided a systematic approach and practices for publication of Indian Pharmacopoeia, 5th edition, with a focus on those drugs and formulations that over the national healthcare programs and the national essential medicines.

For the preparation of these books the expert opinion of medical practitioners, teachers and pharmaceutical manufacturers is obtained.

The drug compendia are classified as:

1. Official compendia
2. Non-official compendia.

1. Official compendia

Official compendia are the compilations of drugs and others related substances which are recognized as legal standards of purity, quality and strength by a government agency of respective countries of there origin.

Official compendia's include British Pharmacopoeia, British Pharmaceutical Codex, Indian Pharmacopoeia, United States Pharmacopoeia, National formulary, the State Pharmacopoeia of USSR and pharmacopoeia of other countries.

2. Non-official compendia

The books other then official drug compendia which are used as secondary reference source for drugs and other related substances are known as non-official drug compendia. Example like Merck index, Remington's pharmaceutical sciences, etc.

INDIAN PHARMACOPOEIA

Main Features of First Edition of Pharmacopoeia of India (1955)

1. The title of monograph was given in Latin language and abbreviated titles for use of prescription were given immediately below the Latin line.
2. The English title were also given below the abbreviation title.
3. The weights and measures were given in metric system.
4. All statements given in the individual monographs were considered as constitute standards for official substances.
5. Doses were expressed both in the metric system as well as in the English system.
6. A list of preparation was given at the end of some of the monographs.
7. The temperature was expressed in Celsius.
8. The descriptive terms (very soluble, freely soluble, sparingly soluble, slightly soluble, very slightly soluble, practically insoluble) have been used where the exact solubility of a pharmacopoeial substance is not known.

The tenure of the Indian Pharmacopoeial Committee expired in 1954, and the committee was reconstituted under the chairmanship of Dr BN Ghosh, Professor of Pharmacology, RG Kar Medical College, Calcutta. The committee compiled a

supplement to the first edition of the Indian Pharmacopoeia. The supplement was published in 1960. The composition of the committee was as follows:

1. Chairman 1
2. Members 11
3. Member Secretary 1
4. Assistant Secretary 1

The second edition of the pharmacopoeia of India, was published in 1966 and later on its supplement was published in 1975.

Main Features of the Second Edition of Pharmacopoeia of India (1975)

1. The titles of monographs were changed from Latin to English.
2. The name of the drug was given first, e.g. injection of ranitidine has been changed to ranitidine injection.
3. Doses were expressed in the metric system only.
4. Solubility is expressed in parts of solvent per unit part of solute.
5. The preparations of a drug have been given immediately after the monographs on the parent drug.
6. For the detection of fungi apart from aerobic and anaerobic bacteria The test for sterility was included.
7. New analytical techniques such as non-aqueous titrimetry, column chromatography, HPLC were added
8. In the monographs of "tablets" and "injection", a new subheading "usual strength" has been given to represent the strength of the tablet or injection.
9. Some drugs were renamed in this edition, e.g. 'acetylsalicylic acid' has been changed to 'aspirin'.

The Government of India, Ministry of Health and Family Welfare, vide their resolution No. X 19014/1/77-D and MS, dated 30th June,1979, reconstituted the Indian Pharmacopoeia Committee for a period of five years for the preparation of the

edition of Pharmacopoeia of India. The composition of the committee was as follows:

i. Chairman 1
ii. Members 13 from academic, research and industry.
iii. Member Secretary 1
iv. Assistant Secretary 1

The committee appointed the subcommittees and working groups in order to expedite the preparation of the new edition of the Indian Pharmacopoeia.

The monographs, appendices and general notices are prepared by the "working group" and finalized by the committee were then published in the form of third edition of Pharmacopoeia of India in 1985 by the Government of India.

Main Features of Third Edition of Pharmacopoeia of India (1985)

1. The newer analytical techniques like flame photometry, flurimetry, electrophoresis were introduced for certain analytical methods
2. For certain tablets, dissolution test was introduced.
3. Disintegration test was modified regarding the design of the apparatus and method of testing.
4. Microbial limit test was prescribed for various pharmaceutical aids and oral liquid dosage form.
5. In spite of shivering response for rabbit the pyrogen test was introduced.
6. GLC (gas liquid chromatography) was introduced for analytical purposes of alcohol concentration detection.
7. Ostwald viscometer was used to determine the viscosity.
8. The new appendix on "Water for Pharmaceutical Use" has been introduced for purified water, water for injection and sterile water for injection.
9. Drugs were renamed, e.g. 'acetylsalicylic acid' has been changed to 'aspirin'.
10. New drugs were added and some drugs were omitted from the third edition.

The Government of India, Ministry of Health and Family Welfare vide their resolution No. X19020/1/89-DMS and PFA dated 12th August, 1991, reconstituted the Indian Pharmacopoeia Committee for a period of five years for the preparation of the fourth edition of Pharmacopoeia of India. The composition of the committee was as follows:

1. Chairman 1
2. Members 18 in number representing academic, research and industry.
3. Member Secretary 1
4. Assistant Secretary 1

The committee appointed the subcommittees and working groups in order to expedite the preparation of the new edition of the Indian Pharmacopoeia.

The monographs, appendices and general notes as prepared by the "working group" and finalized by the committee were then published in the form of fourth edition of the pharmacopoeia of India in 1996 by the Government of India.

Main Features of the Fourth Edition of Pharmacopoeia of India (1996)

1. It contains 1149 monographs and 123 appendices in two volumes.
2. It contains computer-generated structural formulae
3. Some titles were changed to include the more commonly accepted names, e.g. hyoscine hydrobromide for scopolamine hydrobromide.
4. Infrared and ultrared adsorption spectrophotometric tests for identification of drug substance were added. The infrared reference spectra of a number of drug substances were also included in an appendix.
5. The high performance liquid chromatography (HPLC) has been widely used as a method to analyze many formulations which can otherwise be analyzed only by more difficult and less accurate method, e.g. biological assay of insulin has been replaced by HPLC.

6. Bacterial endotoxins test for pyrogens has been introduced.
7. A number of general monographs, e.g. eye drops; eye ointments, nasal preparation, oral liquids, pessaries, suppositories, etc. have been included.
8. A quantitative method for determining particulate matter in injectable preparations has been replaced by the qualitative test.
9. The specific biological assays and tests provided for vaccines; hormones, blood products and enzymes have been transferred to the individual monograph.
10. In the monograph of oral rehydration salts (ORS), ORS – bicarbonate formula was omitted due to its stability problem, whereas ORS-citrate formula recommended by WHO is added.

Main Features of the Fifth Edition of Pharmacopoeia of India (2007)

The Indian Pharmacopoeia, 2007 is presented in three volumes. Volume I contains the general notes, preface, the structure of the IPC, introduction and general chapters. Volume II deals with the general monographs on drug substances, dosage forms and pharmaceutical aids. Volume III contains monographs on drug substances, dosage forms, pharmaceutical aids, vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products.

1. General chemical tests for identification have been almost eliminated and more specific infrared and ultraviolet spectrophotometric tests have been given.
2. The test for pyrogens involving the use of animals has been virtually eliminated. The test for bacterial endotoxins has been introduced.
3. The test for abnormal toxicity is now confined to certain vaccines.
4. The use of chromatographic methods has been extended in assays to large number of pharmaceutical products.

5. Labeling and storage are featured at the end of a monograph.
6. The general monographs for dosage forms of active pharmaceutical ingredients are grouped together at the beginning of volume II followed by the monographs for active pharmaceutical ingredients, pharmaceuticals aids and individual dosage forms, all in alphabetical order. Monographs for other articles of a special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products are given in separate section in Volume III of IP.
7. Limit of bacterial contamination has been introduced for controlling the microbial quality of all medicinal products.
8. Analytical methods are in general in harmony with those adopted internationally for monitoring the quality of drugs.

Main Features of the Sixth Edition of Pharmacopoeia of India (2010)

The sixth version of Indian Pharmacopoeia was published in 2010. IP-2010 has more than 2000+ drug monographs. New methods have been introduced for analysis of herbals, biologicals and veterinary products.

It replace the 2007 edition but any monograph of the earlier edition which was not mentioned in this edition continues to be official at as specified in the second schedule of the Drugs and Cosmetic Act, 1940. This edition would be effective from 1st September 2010. The Indian Pharmacopoeia 2010 is presented in three volumes.

i. Volume I contains the notices, preface, the structure of the IPC, acknowledgements, introduction and the general chapters.
ii. Volume II contains the general notice, general monographs on dosage forms, monographs on drug substances, dosage forms and pharmaceutical aids (A-M).

iii. Volume III contains monographs on drug substances, dosage forms and pharmaceutical aids (N-Z) followed by monograph on vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products.

The scope of 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 dosage combinations. Standards for new drugs and drugs used under national health programs are added and the drugs as well as their formulations not in use nowadays are omitted from the edition. The number of monographs of excipients, anti-cancer drugs, herbal products and antiretroviral drugs have been increased in this edition. Monograph of vaccines and immunosera are also upgraded in view of development of latest technology in this field. A new chapter on liposomal product and a monograph of liposomal amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery. 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.

Main Features of the Seventh Edition of Pharmacopoeia of India (2014)

1. It is effective from 1st January, 2014
2. Presented in 4 hard bound volumes with DVD
3. Total monographs 2548, 577 new monographs included.
4. For the first time in this edition 19 new radiopharmaceutical monographs and 1 general chapter is included
5. Presented in user friendly format and cross referencing has been avoided
6. Veterinary products monographs are the integral part of this edition
7. Use of chromatographic methods has been greatly extended

8. More specific IP and UV spectrophotometer tests have been introduced and classical chemicals tests for identification of an article have been almost eliminated.
9. Test for pyrogen almost eliminated.
10. Obsolete monographs have been omitted.
11. More herbal drugs monographs has been added
12. Included several new monographs not included in any other major pharmacopoeias of the world.

Main Features of the Eighth Edition of Pharmacopoeia of India (2018)

The eighth edition of the Indian Pharmacopoeia (IP, 2018) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health and Family Welfare. The Indian Pharmacopoeia (IP) is published in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of this pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing units, inspection and distribution of medicines.

The new 2018 IP consists of 4-volume print edition plus a DVD. It contains:

i. New monographs: 220
ii. Revisions: 366
iii. Omissions: 07
iv. 170 New chemical monographs
v. 49 API
vi. 64 formulations
vii. 53 fixed dose formulations
viii. 02 excipients
ix. 02 antibiotics
x. 15 new herbs and herbal products monographs
xi. 03 new radiopharmaceutical monographs
xii. 14 new veterinary non-biological monographs
xiii. 18 new biological monographs

xiv. 02 vaccines and immunosera for human use
xv. 06 biotechnology derived therapeutic products
xvi. 10 blood and blood related products

Standards for new drugs, drugs under National Health Programme and drugs in national list of essential medicines have been included for ease of access and to make pharmacopoeia more user friendly index has been incorporated in volume 1 along with that already existing in Volume IV of IP.

Table 1.1: Editions of Indian Pharmacopoeia

Edition	*Year of publication*	*Year of addendum released*	*Features of edition*
First	1955	1960	Contains both western and traditional system drugs commonly used in India
Second	1966	1975	Contains both western and traditional system drugs commonly used in India
Third	1985	1989 (1st) 1991 (2nd)	Addition of traditional system of drugs was limited. However, most of the new drugs manufactured and/or marketed were included
Fourth	1996	2000 (1st) 2002 (2nd) 2005 (3rd)	Included a large number of antiretroviral drugs, The Indian Pharmacopoeia Committee decide to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medicinal need
Fifth	2007	2008	Contains monographs on antiretroviral, anticancer, anti-tubercular and herbal drugs. It further emphasized on biological monographs such as vaccines, immunosera for human use, blood products, biotechnological and veterinary (biological and non-biological) preparations.
Sixth	2010	2012	Consists of three volumes Volume I comprises notices, preface, about Indian Pharmacopoeia Commission, acknowledgements, introduction, general chapters and reference data.

(Contd.)

Edition	*Year of publication*	*Year of addendum released*	*Features of edition*
			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	2015	It is presented in four volumes. Included products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. The IP 2014 incorporates 2548 monographs of drugs among this 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotic monographs, insulin products and herbal products etc.**New radiopharmaceutical monographs and 1 general chapter is first time being included in this edition**.
Eighth	2018	2019	General chemical tests and TLC for identification of an article have been almost eliminated and more specific infrared, ultraviolet spectrophotometer and HPLC tests have been given emphasis. Use of chromatographic methods has been greatly elaborated. Most of the existing assays and related substances test methods are upgraded by liquid chromatographic technique. Pyrogen test have been replaced by bacterial endotoxin test (BET) in parenteral preparations and other

BRITISH PHARMACOPOEIA

The British Pharmacopoeia (BP) is a collection of quality standards for UK medicinal substances. It is used by individuals and organizations involved in pharmaceutical research, development, manufacturing and testing. The British Pharmacopoeia is an important statutory component in the control of medicines which complements and assists the licensing and inspection processes of the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom. It is published every year.

The British Pharmacopoeia is published by the health ministers of the United Kingdom, on the recommendation of the Commission on Human Medicines in accordance with Section 99(6) of the Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC.

The first publication of British Pharmacopoeia was in 1864 and has grown throughout the world. It is now used in over 100 countries. Australia and Canada are two of the countries that have adopted the BP as their national standard alongside the UK, and in other countries (e.g. Korea) it is recognized as an internationally acceptable standard. The BP is prepared by the Pharmacopoeial Secretariat working in collaboration with the BP laboratory, the British Pharmacopoeia Commission (BPC) and its Expert Advisory Groups (EAG) and Advisory Panels. The development of pharmacopoeial standards receives input from relevant industries, hospitals, academia, professional bodies and governmental sources, both within and outside the UK. The BP laboratory provides analytical and technical support to the British Pharmacopoeia.

The British Pharmacopoeia comprises six volumes which contain nearly 3,000 monographs for drug substances, excipients and formulated preparation, together with supporting general notices, appendices (test methods, reagents, etc.) and reference spectra used in the practice of medicine, all comprehensively indexed and cross-referenced for easy reference.

BP, Volumes I and II contain:

- Medicinal substances

BP, Volume III contains:

- Formulated preparations
- Blood related preparations
- Immunological products
- Radiopharmaceutical preparations
- Surgical materials
- Homeopathic preparations

BP, Volume IV contains:

- Appendices
- Infrared reference spectra
- Index

BP, Volume V contains:

- British Pharmacopoeia (Veterinary)

BP, Volume VI (CD-ROM version) contains:

- British Pharmacopoeia
- British Pharmacopoeia (Veterinary)
- British approved names

The BP is available as a printed volume and electronically in both on-line and CD-ROM versions, the electronic products use sophisticated search techniques to locate information quickly. For example, pharmacists referring to a monograph can immediately link to other related substances and appendices referenced in the content by using 130,000+ hypertext links within the text.

The major functions of BP are:

1. Development of new pharmacopoeial monographs
2. Development and validation of qualitative and quantitative test methods for new BP monograph specifications
3. Refining and revalidating test methods for existing BP monographs.

The current edition of the British Pharmacopoeia, i.e. British Pharmacopoeia, 2014 comprises five volumes and a single volume of the British Pharmacopoeia (Veterinary) 2014, along

with a fully searchable CD-ROM and online access to provide with flexible resources.

Highlights of British Pharmacopoeia 2014

i. Legally effective from 1 January 2014
ii. 40 new BP monographs are included
iii. 272 amended monographs
iv. Three new supplementary chapters are included
v. Four new BP (Vet) monographs are included
vi. One new BP (Vet) supplementary chapter is included
vii. Free in-year updates in April and July to harmonise with the European Pharmacopoeia.

UNITED STATES PHARMACOPOEIA

The United States Pharmacopoeia is an official public standards–setting authority for all prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. USP also sets recognized standards for food ingredients and dietary supplements. These standards help to ensure the quality, purity, strength, and consistency of products made for public consumption. USP's standards are recognized and used in more than 130 countries around the globe. The United States Pharmacopoeia and the National Formulary (USP-NF) are recognized as official compendia and are used as reference books for determining the strength, quality, purity, packaging and labeling of drugs and other related articles.

The United States Pharmacopoeia was originally published in 1820 under the authority of the United States Pharmacopoeial convention and the National Formulary was published in 1888 under the guidance of the American Pharmaceutical association. In 1974, the National Formulary was purchased by the United States Pharmacopoeial Convention and from 1980 onwards only one official book of Drug Standards was published under the heading, the United States Pharmacopoeia and the National Formulary (USP-NF).

USP is a non-governmental, not-for-profit public health organization whose independent, volunteer experts work under strict conflict-of-interest rules to set its scientific standards. USP's work is aided by the participation and oversight of volunteers representing pharmacy, medicine, and other healthcare professions as well as academia, government, the pharmaceutical and food industries, health plans, and consumer organizations.

Main Features of USP

1. Product Quality—Standards and Verification

USP establishes documentary and reference standards to ensure quality medicines, food ingredients, and other healthcare products. Prescription and over-the-counter medicines available in the United States, must by federal law, meet USP's public standards, where such standards exist. Many other countries require the use of high-quality standards such as USP to assure the quality of medicines and related products. USP also conducts verification programs for dietary supplement ingredients. Much like food ingredients, USP's standards for dietary supplements have no legal recognition in the United States, but involve independent testing and review to verify ingredient and product integrity, purity, and potency for manufacturers who choose to participate.

2. Healthcare Information

USP develops information relating to various aspects of drug use and disseminates this information to practitioners, pharmacists, and others who make decisions about healthcare around the world. Significant among USP's healthcare information initiatives is the development of a drug classification system that medicare prescription drug benefit plans may use to develop their formularies. USP also partners with the US. Agency for International Development, the World Health Organization and others in worldwide projects that help to assure drug quality and proper drug use in many developing countries.

3. Patient Safety

USP operates two programs to promote safer care of patients who take medications and stay in hospitals. The Medication Errors Reporting Program allows healthcare professionals to directly report medication errors to USP. MEDMARX®, an Internet-based medication error and adverse drug reaction reporting program, is designed for use in hospitals and health systems. USP also uses its knowledge base to provide information that supports the healthcare community in the research and development of patient safety initiatives.

4. Drug Quality and Information

USP's Drug Quality and Information (USP DQI) Program is a cooperative agreement with the United States Agency for International Development (USAID). The USP DQI program has established a presence in USAID–priority countries on four continents advancing strategies to improve drug quality and the appropriate use of drugs.

NATIONAL FORMULARY OF INDIA

National Formulary of India is formulated to help medical practitioners, medical students, pharmacists, and buyers in hospitals and sales departments. Originally published by the health ministry of the government of India in 1960, this book went through several digital revisions in the 1980s. A second edition appeared in 1966. The third edition came out in 1979. Information is provided regarding drug interactions, resistances, cumulative effects, drug dependence, and prescription writing, among others.

EXTRA PHARMACOPOEIA

The Extra Pharmacopoeia, originally published in 1883 by William Martindale, is still known today as Martindale. This is a comprehensive guide to drugs, making it one of the most widely used reference books in the world. All kinds of information about medications and drugs can be found in it.

Royal Pharmaceutical Society of Great Britain, under the direction of its council, publishes this journal, which is prepared by its Department of Pharmaceutical Sciences.

ISOLATED KEY POINTS

- '**Bheshaj**' is the term used in India from the last four thousand years, which is equivalent to Greek term '**Pharmacon**' meaning drug from which the term pharmacy has been derived.
- Pharmacy is the branch that deals with identification, procurement, formulation and dispensing of drug.
- Throughout history, many individual have contributed to the advancement of the health sciences.
- Notable among those were **Hippocrates** (ca. 460–375 BC), **Dioscorides** (1st Century AD), **Galen** (ca. 129–216 AD), and **Paracelsus** (1493–1541 AD).
- Hippocrates is called the **father of medicine.**
- **Dioscorides,** a Greek physician and botanist, was the first to used botany as an applied science of pharmacy. His work, **De Materia Medica**, is considered a landmark in the development of pharmaceutical botany and in the study of naturally occurring medicinal materials.
- **Claudius Galen**, a Greek pharmacist-physician, created a perfect system of physiology, pathology, and treatment. Pharmaceutical preparations were commonly referred to as "Galenic pharmacy" at that time.
- **Career options in pharmacy are:**
  i. Production and manufacturing
  ii. Research and development:
  iii. Analysis and testing
  iv. Marketing
  v. Hospital pharmacy
  vi. Community pharmacy
  vii. Academics
  viii. Regulatory affairs

- Documentation, Library Information Services and Pharmaceutical Journalism
- The term pharmacopoeia comes from Greek word **"Pharmakon"** meaning 'drug' and **"Poein"** meaning 'make', and the combination means any recipe or formula or other standard required to make or prepare a drug.
- The drug compendia are classified as: i. Official compendia, ii. Non-official compendia.
  i. **Official compendia:** Official compendia are the compilations of drugs and others related substances which are recognized as legal standards of purity, quality and strength by a government agency of respective countries of there origin. Official compendia's include British Pharmacopoeia, British Pharmaceutical Codex, Indian Pharmacopoeia, United States Pharmacopoeia, National formulary, the state Pharmacopoeia of USSR and Pharmacopoeia of other countries.
  ii. **Non-official compendia:** The books other then official drug compendia which are used as secondary reference source for drugs and other related substances are known as non-official drug compendia. Example like Merck index, Remington's pharmaceutical sciences, etc.
- **Indian Pharmacopoeia:** The India Pharmacopoeia (IP) is a collection of quality standards for Indian medicinal substances. It was first published in 1955.
- **British Pharmacopoeia:** The British Pharmacopoeia (BP) is a collection of quality standards for UK medicinal substances. The British Pharmacopoeia is published by the health ministers of the United Kingdom, on the recommendation of the Commission on Human Medicines in accordance with section 99(6) of the Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC. The first publication of British Pharmacopoeia was in 1864
- **United States Pharmacopoeia:** The United States Pharmacopoeia is an official public standards—setting

authority for all prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. USP's standards are recognized and used in more than 130 countries around the globe.

- **National Formulary of India:** National Formulary of India is formulated to help medical practitioners, medical students, pharmacists, and buyers in hospitals and sales departments. Originally published by the health ministry of the government of India in 1960, this book went through several digital revisions in the 1980s.
- Extra Pharmacopoeia: **The Extra Pharmacopoeia, originally published in 1883 by William Martindale, is still known today as Martindale.**

PRACTICE QUESTIONS

Very Short Answer Type Questions

1. What does the term "Pharmacon" means?
2. Name the scientist who made major contribution in the development of pharmacy profession?
3. Define the term pharmacopoeia.
4. In which year was the first British Pharmacopoeia published?
5. Give the year of publication of first USP.
6. In which year did the first pharmacopoeia of India come out?
7. How many monographs are there in Indian Pharmacopoeial list?
8. When was the first International Pharmacopoeial list published?
9. Who was publisher of Indian Pharmacopoeia?
10. When was Indian Pharmacopoeial list published?
11. In which year the various editions of the pharmacopoeia of India come out?
12. When was the term "Pharmacopoeia" used for the first time?

Short Answer Type Questions

1. Define the term pharmacopoeia.
2. Name the various pharmacopoeias commonly used in India
3. Name the various standards reference books on pharmacy in common use in our country.
4. Why did publication of Indian Pharmacopoeial list in1946 became necessary?
5. Differentiate between official and non-official compendia?

Long Answer Type Questions

1. Describe in detail the various stages, which ultimately led to the development of first pharmacopoeia of India?
2. Write in brief about history of pharmacopoeia.
3. Discuss briefly the scope of pharmacy.
4. Write in detail about the origin and development of pharmacy.
5. Give the salient features of the second edition of Pharmacopoeia of India.
6. What are the salient features of the third edition of pharmacopoeia of India?
7. Why did the publication of British Pharmacopoeia became necessary?
8. Give, in brief, the history of the pharmacopoeia of India.
9. Differentiate between BP and BPC.
10. Write in brief about the International Pharmacopoeia of India.
11. Write in brief about the United State Pharmacopoeia-India?

Multiple Choice Questions

1. The new edition of British Pharmacopoeia is published after every:
   a. 4 years b. 5 years
   c. 6 years d. Alternate year

2. The first edition of the Pharmacopoeia of India was published in:
   a. 1947 b. 1955
   c. 1966 d. 1946
3. The supplement to second edition of Pharmacopoeia of India was published in:
   a. 1981 b. 1975
   c. 1985 d. 1966
4. The first USP was published in:
   a. 1820 b. 1830
   c. 1845 d. 1855
5. The Indian Pharmacopoeial List was published as a supplement to:
   a. British Pharmacopoeia
   b. USP
   c. Pharmacopoeia of India
   d. IPC

Fill in the Blanks

6. "*De Materia Medica*" was written by .....
7. ..... is the father of medicine.
8. ..... made major contribution for "*Galenic Pharmacy*"
9. Father of ayurveda is .....
10. FDA stands for .....
11. AICTE stands for .....
12. PCI stands for .....
14. TRIPS stands for .....
14. DI stands for .....
15. ICH stands for .....
16. Term pharmacopoeia comes from ..... word ..... meaning ..... and poein meaning .....
17. The term pharmacopoeia was first given by ..... in his work published at .....

Matching Type Question

18. Match the following:

Name of the scientist	Time period
i. Hipocrates	a. First century AD
ii. Dioscorides	b. c.a 129–216 AD
iii. Galen	c. 1493–1541 AD
iv. Paracelus	d. c.a 460–375 BC

Answers

1. d
2. b
3. c
4. a
5. a
6. Dioscorides
7. Hippocrates
8. Claudius Galen
9. Charak
10. Food and Drug Administration Act
11. All India Council for Technical Education
12. Pharmacy Council of India
13. Trade related intellectual property and rights
14. Drug inspector
15. International conference on Hormonisation
16. Greek, Pharmacon, drug, to make
17. Dr. A Foes, Basel
18. i. b, ii. d, 3. c, 4. a