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 belief that peoples 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. 460–377 BC), **Dioscorides** (1st Century AD), **Galen** (ca. 130–200 AD), and **Paracelsus** (1793–1541 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 who 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 greatest author of his time, he has created 500 treatise on medicine and around 250 treatise 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 diskoveries. He emphasized 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 were 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.

OATH OF A PHARMACIST

At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.

I will consider the welfare of humanity and relief of human suffering, my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.

I will keep abreast of developments and maintain professional competency in my profession of pharmacy. I will maintain the highest principles of moral, ethical and legal conduct.

I will embrace and advocate change in the profession of pharmacy that improves patient care.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

SCOPE OF PHARMACY

From ancient times pharmacy is known as a branch associated with healthcare services. The word Pharmacy has been derived from the Greek word "*Pharmakon*", meaning drug. Today, the diskipline of pharmacy has made enormous progress and has matured as a distinctly independent branch as pharmaceutical sciences, mainly through the acquisition of the wealth of knowledge, research and a vast array of drugs and therapeutic remedies. Unlike the other curricula, pharmacy is a product as well as service related diskipline, increasing its scope manyfold.

Pharmacy is involved in all the stages related to a drug, from its diskovery, development, action, safety, formulation, use, quality control, packaging, storage, marketing, etc. Thus, today's pharmacy professional is a "drug expert" in the real sense. The profession of pharmacy has transformed into a hub for the "global health care" and evolved as a multidisciplinary, versatile prospectus.

The drugs and pharma industry is a multibillion-dollar business. In the rapidly changing global scenario and the implementation of GATT and TRIPS in India, now a matter of only a couple of years, the pharmaceutical industry and professionals will play a vital role in shaping up our national economy. This new decade is thus, bound to have an ever-growing demand of pharmacy professionals not only in the country, but even worldwide. Anticipating this demand the government has taken special steps to boost this unique diskipline having a blend of both technology as well as health sciences.

Some of the Indian universities like NIPER, Chandigarh, BITS-Pilani, University of Pune, Vadodara, etc. have given a special status to the pharmacy education by setting up a separate faculty of pharmaceutical sciences. In India, Pharmacy Education is a two-tier system. After 12th Science of State Board one can opt for any of the two courses, namely Diploma (DPharm)

and Degree (BPharm). However, the diploma students can also be admitted in Degree course directly in Second Year BPharm. However, in the coming years the Government and Pharmacy Council of India is planning to abolish the DPharm course and make BPharm, the minimum qualification for any individual to become a registered pharmacist.

The regulatory bodies for pharmacy colleges are, namely All India Council of Technical Education (AICTE), Pharmacy Council of India (PCI) and the respective university to which the college is affiliated to. Today pharmacy education like the pharmaceutical industry is also in the process of globalization. In order to have uniformity in course contents, requisite standards of education, technical faculty, facilities and infrastructure at international levels, colleges are going for accreditation and certifications from internationally approved regulating agencies like NBA.

Career Opportunities

A career in pharmacy opens 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 diskussed 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 segments where opportunities exist are the field of dental products. Production of biological and biotechnological products, surgical dressings, medical devices and equipment, ayurvedic/homoeopathic/unani medicines also involve the presence of pharmacy professionals in its production. Other areas where pharmacy professionals are required in production are 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 M Pharm and PhDs are in a great demand in the various areas of pharmaceutical R&D. Other areas where professionals are required, are:

- **New drug diskovery research (NDDR):** Diskovering a new drug has assumed prime importance in the post-GATT era.
- **Process and 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. its 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 occur 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/Quality Assurance are highly preferred for this job.

Marketing

Any business is incomplete without the marketing and sales aspect, as the universal fact is that anything produced has to be sold. The Pharma: 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. The trend is already set in many hospitals in the country. This is a key position and the pharmacist plays an important role from preparing prescription to the patient's medical history after the medical doctor has diagnosed the disease. The pharmacist is the best-informed qualified drug expert whose advice is sought by everybody 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 services 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 M Pharm. 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 are Senior 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 foods and drugs control administration (FDA) 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), Senior 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.

With globalization process reaching out to India, the geographical barriers have become outdated. Any country will have to compete and trade globally in order to progress and survive in the years to come. The major drugs and pharma companies have realized this fact and have stepped into the global area of competitive trade. If an Indian manufacturer wants to sell his drug or formulation to a foreign country, it is mandatory that he has to fulfill all the statutory requirements laid by the regulatory authorities of that country. Also, his product needs to be perfectly as per the specifications laid down by the concerned regulatory authority. Thus, 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 the USA, TGA for Australia and New Zealand, MCA and MCM for the UK and the European countries and ICH guidelines going to be uniform for international levels.

Since the business involved is worth multibillion dollars, this branch has assumed tremendous significance and is bound to grow enormously, in the Post-GATT era. Many big players in

the drugs and pharmaceutical field have already established separate regulatory affairs departments in a their companies. Regulatory experts are thus in a great demand.

Similarly, patents and trademarks, IPR experts are also in high demand as far as the pharmaceutical industry is concerned.

Documentation, Library Information Services and Pharmaceutical Journalism

The regulatory affairs as well as patenting processes and issues involve a lot of documentation works to be done and submitted to the concerned regulatory authorities in a highly specialized and technical manner. Pharmacy professionals are again fitting in the bill. Most of the major Indian pharmaceutical companies have established separate documentation departments with a highly technical and skilled staff for this purpose.

Similarly, the R&D and QC departments of the pharmaceutical companies need a wealth of technical information, which needs to be updated regularly, in order to match the pace of global competition. Therefore, library information services are another field in much demand as far as the pharmaceutical industry is concerned. Furthermore, with the advent and boom of the Information Technology, Bio-informatics and Electronic Data Retrieval Systems, this field is already scaling new heights.

Pharma journalism is another area filled with a great potentialities. This requires specialist technical personnel like pharmacy graduates on the editorial staff to cover the various aspects. There is already a very profitable business in this field.

Consultancy

This is an ideal opportunity for highly technical and experienced pharmacy professionals to earn handsomely as self-employed entrepreneurs, even after the age of retirement. Consultancy services in pharmacy are offered in various fields against very attractive financial fees

- Regulatory affairs
- Documentation
- Approvals
- Manufacturing processes

- Analytical series
- Research
- Market surveys and sales promotion
- Information retrieval
- Data management.

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 S 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 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 diskussed 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".

History of Pharmacopoeia

Some of the earliest pharmacopoeia books were written by Muslim physicians. These included *The Canon of Medicine* of

Avicenna in the 1020s and other pharmacopoeia books by Abu-Rayhan Biruni in the 11th century, Ibn Zuhr (Avenzoar) in the 12th century (and printed in 1491), and Ibn Baytar in the 14th century. The first work of the kind published under government authority appears to have been that of Nuremberg in 1542; a passing student named Valerius Cordus showed a collection of medical receipts, which he had selected from the writings of the most eminent medical authorities, to the physicians of the town. An earlier work, known as the *Antidotarium Florentinum*, had been published under the authority of the college of medicine of Florence. The term *pharmacopoeia* was first given by **Dr A. Foes** in 1561 in a work published at Basel.

The term 'Pharmacopoeia' was first used in 1580 in a book on drug standards printed in Bergamo, Italy. After that a number of national pharmacopoeia were published by various European Pharmacopoeias of London, Edinburgh and Dublin. Until 1617 such drugs and medicines as were in common use were sold in England by the apothecaries and grocers. The apothecaries obtained a separate charter and it was enacted that no grocer should keep an apothecary's shop. The preparation of physicians' prescriptions was thus confined to the apothecaries, this was then their responsibility to make and dispense medicines accurately, by the issue of a pharmacopoeia in May 1618 by the College of Physicians, and by the power which the wardens of the apothecaries received in common with the censors of the College of Physicians of examining the shops of apothecaries within 7 m of the London and destroying all the compounds which they found unfaithfully prepared. Then, the first authorized London Pharmacopoeia was selected chiefly from the works of Mezue and Nicolaus de Salerno, but it was so full of errors that the whole edition was cancelled, and a fresh edition was published in the following December. At this period the compounds employed in medicine were often heterogeneous mixtures, some of which contained from 20 to 70, or more, ingredients, while a large number of samples were used in consequence of the same substance being supposed to possess different qualities according to the source from which it was derived. Although other editions of the London Pharmacopoeia were issued in 1621, 1632, 1639 and 1677, it was not until the

edition of 1721, published under the guidance of Sir Hans Sloane, when all important alterations were made. In the edition published in 1788, the tendency to simplify was carried out to a much greater extent, and the extremely compound medicines which had formed the principal remedies of physicians for 2000 years were diskarded, while a few powerful drugs which had been considered too dangerous to be included in the pharmacopoeia of 1765 were restored to their previous position. In 1809, the French chemical nomenclature was adopted, and in 1815, a corrected impression of the same was issued. Subsequent editions were published in 1824, 1836 and 1851.

Pharmacopoeia were officials throughout the United Kingdom. Each pharmacopoeia described different strength and method of preparation for the same preparation. Hence, there was a lot of confusion. To overcome this difficulty, the first British Pharmacopoeia came into existence in 1864. In the United States, the first pharmacopoeia was published in December 1820 both in English and in Latin. Later on a national formulary was also published in addition to the United States Pharmacopoeia (USP). The object of first USP was to select from substances the ones which possess medicinal power, converted them into preparations of suitable composition in order to enhance their power to the maximum advantage. The first international pharmacopoeia was published by the World Health Organization in 1951 (volume 1) and in 1955 (volume 2).

These books are revised from time to time so as to introduce the latest information available as early as possible after they become established in order to introduce new products, and to keep the size of book within reasonable limits, it becomes necessary to omit certain less frequently used drugs and pharmaceutical adjuvant from each new edition of the book. Therefore, in each new edition of these books certain new monographs are added while the older once are deleted.

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 their origin.

Official compendia include British Pharmacopoeia, British Pharmaceutical Codex, Indian Pharmacopoeia, the United States Pharmacopoeia, national formulary, the state pharmacopoeia of USSR and pharmacopoeia of other countries.

2. Non-official Compendia

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

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. The term "list" in the title was "misleading" in that, the book not only contained a list of drugs which were of substantial medicinal value but also laid down standards. The Indian Pharmacopoeial list contained about 180 monographs and a no. of appendices prepared on the lines of the British Pharmacopoeia.

Approximately 100 monographs were on vegetable drug growing in India and on their galenicals. For example, berberis, cannabis, ispaghula, rauwalfia, vasaka, digitalis, etc. were included in it. Similarly, several oils such as *chaulmoogra*, *neem*, and *pudina*, were included in it. The Pharmaceuticals and Drug Research Committee of the Council of Scientists and Industrial Research decided in February 1947 to compile a "Brochure" to highlight the information and clinical uses of the important

indigenous drugs of India, in the form of a "codex". The first Indian pharmaceutical codex was published in 1953. The codex consists of two parts: The first part carried about 190 general monographs on natural products and drugs of vegetable and animal origin, and a few chemicals. The second part consisted of formulary of galenicals and other preparations.

After the publication of Indian Pharmacopoeial list, the Government of India constituted an eleven-member Indian pharmacopoeial Committee in 1948, in their notification No. F.1–1/48-DS dated 23rd November, 1948, for preparing the Pharmacopoeia of India. The tenure of the office of the members of committee was five years. It was extended by one year vide Government notification No. F.6–10/53-DS dated the 21st November, 1953. In compiling the monographs of the first Pharmacopoeia of India, help was taken from all available established scientific data in modern pharmacopoeia, such as British Pharmacopoeia, the United States Pharmacopoeia, International Pharmacopoeia, and from scientific institutions interested in drugs and pharmaceutical products. The first edition of Pharmacopoeia of India was compiled and then published in 1955.

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, Kolkata. 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

A subcommitte was appointed by the committee to help in the compilation work. The following subcommittes were made.

1. Pharmacology and Bioassay Subcommittee
2. Biological Product Subcommittee
3. Antibodies, Vitamins and Hormones Subcommittee
4. Pharmacognosy Subcommittee
5. Pharmacy Subcommittee
6. Pharmaceutical Subcommittee
7. General Chemistry Subcommittee
8. Analytical Subcommittee
9. Physical Standards, Weights, Measures and Nomenclature Subcommittee
10. Indian Medical Plants Subcommittee.

A coordination subcommittee consisting of the chairman and secretary of the Indian Pharmacopoeia Committee and the chairman of the various subcommittees was also constituted to coordinate the work of various subcommittees. 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 & 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 following subcommittees:

1. Clinical Medicines and Pharmacology Subcommittee
2. Biological Products and Bioassay Subcommittee
3. Antibiotics Subcommittee
4. Synthetic Drugs Subcommittee
5. Medicinal Plants, Galenicals and Surgical Dressing Subcommittee
6. Chemicals and Sterile Products Subcommittee
7. Parenteral and Sterile Products Subcommittee
8. Non-parenteral Products Subcommittee
9. Analytical Methods, Reagents, Diagnostic Aids and Containers Subcommittee
10. Nomenclature and Formulae Subcommittee.

The Indian Pharmacopoeia Committee also constituted a "Working Group" for the purpose of preparing draft

monographs and appendices, to examine the comments received on these from various sources and then make suitable recommendations to the committee.

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, Fluorimetry, 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. Gas liquid chromatography (GLC) 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 ultra-red 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.

British Pharmacopoeia

The British Pharmacopoeia (BP) is a collection of quality standards for the 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.

In 1907, the British Pharmacopoeia was supplemented by the British Pharmaceutical Codex, which gave information on drugs and other pharmaceutical substances not included in the BP, and provided standards for these.

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 current edition of 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 online 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 1,30,000+ 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.

British Pharmaceutical Codex

It was in 1903 that the Council of the Pharmaceutical Society of Great Britain decided to prepare a reference book for the use of medical practitioners and dispensing pharmacists. The first edition of the British Pharmaceutical Codex was published in 1907. The subsequent revisions of this codex were published in 1911, 1923, 1934, 1949, 1954, 1959, 1963, 1968, and 1973.

On the request of British Pharmacopoeia Commission, the Council of the Pharmaceutical Society agreed in 1959 for the publication of codex to coincide with that of the British Pharmacopoeia, so that these two books, i.e. British Pharmaceutical Codex and British Pharmacopoeia should come into effect on the same dates.

The British Pharmaceutical Codex differs from British Pharmacopoeia in that:

1. It contains many new drugs and preparations; some were included in advance, which were in the pipeline of clinical trials or synthesis.
2. It provides standards for drugs, surgical dressings and pharmaceutical preparations not included in the British Pharmacopoeia.
3. It provides information on the actions and uses of drugs, their undesirable effects, precautions and the treatment of poisoning.
4. It contains formulae, method of preparation, dose, container and storage conditions of majority of pharmaceutical preparations, e.g. mixtures, powders, eye drops, ear drops, liniments, lotions, ointments, creams, pastes, suppositories, etc.

United States Pharmacopoeia

The United States Pharmacopoeia is an official public standards setting authority for all prescription and over-the-counter medicines and other health care 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 health care 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's, 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 health care 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 health care 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.

The four main programs that USP promotes are:

i. Ensuring drug quality by working with local governments, USAID missions, the World Health Organization (WHO), and other partners to evaluate a country's readiness and capacity to provide necessary drug quality assurance.
ii. Providing continuing education for physicians, pharmacists and nurses in drug information and pharmacovigilance to help improve drug dispensing and ensure competence and accountability.

iii. Developing and disseminating evidence-based drug and therapeutic information through targeted drug and therapeutic information materials for healthcare providers based on specific needs.
iv. Establishing regional and international cooperation through USP's system of open conferences, internet-based communications, and regular publications.

5. USP's Global presence

Activities at USP are focused on promoting the public health by disseminating authoritative standards and information for over-the-counter medicines, dietary supplements, food ingredients and other health care technologies, and related practices used to maintain and improve health and promote optimal healthcare delivery around the world.

The International Pharmacopoeia

The International Pharmacopoeia (Ph.Int.), is issued by the World Health Organization.

The aim is to achieve a wide global uniformity of quality specifications for selected pharmaceutical products, excipients, and dosage forms.

High priority is given to medicines that are important to WHO health programs, and which may not appear in any other pharmacopoeias, e.g. new antimalarial drugs.

The International Pharmacopoeia (Ph. Int.) comprises a collection of quality specifications for pharmaceutical substances (active ingredients and excipients) and dosage forms together with supporting general methods of analysis that is intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements.

The activities related to the International Pharmacopoeia are an essential element in the overall quality control and assurance of pharmaceuticals contributing to the safety and efficacy of medicines. The International Pharmacopoeia recognizes the needs of specific disease programs and the essential medicines nominated under these programs; it is based primarily on those substances included in the current WHO Model

List of Essential Medicines. The work on the International Pharmacopoeia is carried out in collaboration with members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and with other specialists. The process involves consultation of and input from WHO Member States and drug regulatory authorities.

PRACTICE QUESTIONS

Very Short Answer Type Questions

1. What does the term 'Pharmacon' mean?
2. Name the scientist who made major contribution in the development of pharmacy profession.
3. Define the term Pharmacopoeia.
4. In which year, the first British Pharmacopoeia was published?
5. Give the year of publication of first USP.
6. In which year, the first pharmacopoeia of India came 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 came out?
12. When was the first Indian Phrarmaceutical Codex published?
13. When was the term "Pharmacopoeia" used for the first time?
14. When was the First International Pharmacopoeia published?

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. Give the reasons for the publication of International Pharmacopoeia by WHO.

5. Why did publication of Indian pharmacopoeial List in 1946 become necessary?
6. 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 become 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 States Pharmacopoeia.

OBJECTIVE TYPE QUESTIONS

Multiple Type Questions

1. The new edition of British Pharmacopoeia is published after every:
   (1) 4 years (2) 5 years
   (3) 6 years (4) Alt. year
2. The first edition of the Pharmacopoeia of India was published in:
   (1) 1947 (2) 1955
   (3) 1966 (4) 1946
3. The supplement to second edition of Pharmacopoeia of India was published in:
   (1) 1981 (2) 1975
   (3) 1985 (4) 1966

4. The first USP was published in:
   (1) 1820 (2) 1830
   (3) 1845 (4) 1855
5. The Indian Pharmacopoeial List was published as a supplement to:
   (1) British Pharmacopoeia (2) USP
   (3) Pharmacopoeia of India (4) IPC
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 …….....
13. 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 …….....……
18. Match the following:
    Name of the scientist Time period

1. Hippocrates	a. First century AD
2. Dioscorides	b. a.c 130–200 AD
3. Galen	c. 1793–1541 AD
4. Paracelsus	d. a.c 460–377 BC

ANSWERS

1. (4)
2. (2)
3. (3)
4. (1)
5. (1)
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. 1-d, 2-a, 3-b, 4-c