Chapter 1

Historical Background Development of the Profession of Pharmacy

History of Profession of Pharmacy in India in Relation to Pharmacy Education, Industry and Organization, Pharmacy as a Career

Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

Defining the Project

Pharmacy has been a part of everyday life since ancient times. Excavations, such as Shanidar (30000 B.C.E) support this fact. The ancient tribal healers, also called as Shamans often guarded this knowledge of healing properties of certain natural substances. But, the recognition of the medicinal plants was so widespread that it obstructed any necessity for a special class of drug gatherers. Earlier people used to describe diseases in supernatural terms. They believed the beneficial medicines worked in supernatural ways. The magical medicines for curing were part of the duty of Shamans. Usually they were in charge of all supernatural things in a tribe, and hence, they diagnosed and treated most serious and chronic diseases. These remedial medicines connected with supernatural world for thousand years continue to fascinate us all even today. Thus, we can conclude that drugs have a dual heritage, a simple curing tool and special substance with supernatural powers.

Though the ancient people discovered a small number of drugs that heals human diseases, but this discovery can be considered as one of the humanity's greatest advances.

Afterwards, settled cultures provided tools (such as writings, weights, measures) to mushroom this rationale method of medical treatment, without which pharmaceutical sciences may have failed to progress.

Antiquity: The advancement of societies also started influencing the fundamentals of disease and healing. The changes can be verified from the remains of the civilizations of Mesopotamia and Egypt. From ancient records of Egyptian civilization, it can be concluded that pharmaceutical sciences rose greater heights in these times, with more dosage forms

compounded from more detailed formula. The Egyptian medical texts show a close connection between supernatural and natural healing. Recipes usually began with a prayer or hymn and ended with plant drugs.

In ancient Greece, there was a similar connection of drugs or *pharmakon*, means magic spell, remedy, poison. Most Greek medicines were prepared from plants and the first great study of plants was done by Theophrastus (370 – 285 BC), a student of Aristotle.

Middle Age: Traditionally, middle Ages refer to the period from the first fall of Rome (400 AD) to the fall of Constantinople (1453). Now the use of drugs went another shift. Rational drug treatment was replaced by Church's teaching that sin and disease were related intimately. Monasteries became centres for healing, both spiritual and physical. Now monks planted gardens to grow medicinal herbs, and inclined to credit their cures to the God, rather to their medical resources.

There were many cultures that dealt with medicines but there was no significant change that occurred in this period.

In Western Europe, teachings of Mohammed were followed. Greek writings in medicines were translated into Arabic. As Arabs conquered this region, they brought new medicines with them. They rejected the idea that foul testing medicines worked best. Arabic culture returned the classical knowledge of medicine to Europe. The debate on medicine among European academics was based on speculation but not on observation.

Hence observation methodology was to be followed to bring down a significant change in the medical practice. This new experimental period was called *Renaissance*.

History of Pharmacy Profession in India

In earlier times vegetables, animal and mineral had been used as a source of drug in India. Few experienced persons called Vaidya used to process and prepare medicines from these materials. The knowledge of collecting, processing and preparing the medicines had been kept secret within the family. No scientific method of standardization of drugs was available. India has been ruled by various invaders. However, the Indian system of medicines was influenced during these rules. For example, during Muslim rule in India the Indian system of medicines declined but, the Arabic or Unani-Tibbi system grew. During the British rule the Allopathic or English system of medicines came to India. In fact, during 19^{th} century this system became more popular. Till early nineteenth century all the drugs had been imported into the country from Europe.

After 1900 the development of the system started. Some facts are mentioned below chronologically for information to the readers.

- In 1901 the Bengal Chemical & Pharmaceutical Works was established in Calcutta by Acharya Prafulla Chandra Roy.
- In 1903 a small factory was set up by Prof. T.K. Gujjar at Parel, Bombay.
- In 1907 Prof. T.K. Gujjar set up Alembic Chemical Works at Baroda.

During World War-I (1914 – 1920) the imports of drugs were cut off. Before that war crude drugs were mostly exported and imported in finished form. Import of drug became regularized after the War. Since there was no check on the quality of the imported drugs, the manufacturers took advantage of the situation and as a result

(i) Foreign manufacturers started dumping the inferior quality and adulterated medicines in India.

(ii) Indian market became full of useless and deleterious drugs and these were sold by unqualified people.

As a result of these conditions (1) poisoning due to quinine, (2) selling of chalk powder in place of quinine, (3) in place oil atropine solution, croton oil was instilled into the eye, and (4) compounds of antimony and arsenic, and digitalis (potent drugs) were dispensed without any standard.

The necessity of controlling such situation was felt and following laws framed earlier were reframed and imposed.

Year	Act	Purpose
1878	Opium Act	To deal with cultivation of poppy and the manufacture, transport, export, import and sale of opium.
1889	Indian Merchandise Act	To misbrand the goods in general
1894	Indian Tariff Act	To levy of customs duty on goods including foods, drinks, drugs, chemicals and medicines imported into India or exported there from.
1898	Sea Customs Act	To prevent Goods with 'false trade description' from importing under this act.
1919	Poisons Act	To regulate the import, possession and sale of poisons.
	Indian Penal Code	To make provision for punishment for intentional adulterations as per Sections of IPC.

Some laws were also imposed at state level as indirect reference to drugs; these laws were too superficial and had very less direct link to drugs. For example;

Year	Act	Remarks
1884	Bengal Municipal Act	
1901	City of Bombay District Municipal Act	Concerned with food
1909	Bengal Excise Act	.
1911	Punjab Municipal Act	
1912	United Provinces (now Uttar Pradesh) Prevention of Adulteration Act	Refers to adulteration of foods and drugs.
1914	Punjab Excise Act	
1916	United Provinces Municipalities Act	Inspection of shops and seizure of adulterated substances.
1919	Bengal Food Adulteration Act	
1919	Bihar and Orissa Prevention of Adulteration Act	
1919	Madras Prevention of Adulteration Act	Chiefly concerned with food adulteration
1922	Bihar and Orissa Municipal Ac	
1922	Central Provinces Municipalities Act	
1925	Bombay Prevention of Adulteration Act	
1929	Punjab Pure Food Act	

To assess the status of the Pharmacy profession in the country the Govt of India appointed a committee under the chairmanship of Late Col. R. N. Chopra and recommend the measures to be taken.

- In 1931 this committee published its report and reported that in the country there was no recognized and specialized profession of Pharmacy. The functions were being done by a group of people known as Compounder. After publication of the said report, Prof. Mahadeva Lal Schroff (Prof. M.L. Schroff) took initiative to start Pharmacy education in the Banaras Hindu University (BHU), Allahabad, U.P.
- In the year 1935 United Province Pharmaceutical Association was established which was later on converted into Indian Pharmaceutical Association (IPA).
- In 1937 the 3-years B. Pharm course was started in BHU under the leadership of Prof. M.L. Schroff who published a journal in name of Indian Journal of Pharmacy in 1939.

- In 1940 the All India Pharmaceutical Congress Association (IPCA) was started and to popularize the profession of Pharmacy as a whole IPCA started holding the pharmaceutical conference at various places in the country. Since then the yearly conference has been held at different parts of the country.
- In 1937, the Govt of India brought 'Import of Drugs Bill' which was later on withdrawn.
- In 1940, to regulate the import, manufacture, sale and distribution of drugs in British India the Govt brought 'Drugs Bill'. This was later on adopted as 'Drugs Act of 1940'.
- In 1941, the Drugs Technical Advisory Board (D.T.A.B.) was constituted under this act.
- In 1945, Central Drug Laboratory was established in Calcutta under 'Drugs Act of 1940'.

The Drugs Act has been modified from time to time and presently the provisions of the Act cover Cosmetics and Ayurvedic, Unani and Homeopathic medicines in certain respects.

- In 1945 to standardize the Pharmacy Education in India the Govt brought the Pharmacy Bill.
- In 1946 the Indian Pharmacopoeial List was published under the chairmanship of late Col. R. N. Chopra. The list contained the drugs used in India at that time but not included in British Pharmacopoeia.
- In 1948, the Pharmacy Act was published and in the same year Indian Pharmacopoeial Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.
- In 1949, the Pharmacy Council of India (P.C.I.) was established under Pharmacy Act 1948.
- In 1954, the Education Regulation came in force in some states but other states lagged behind.
- In 1954, the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements such as Cure all pills.
- In 1955, Medicinal and Toilet Preparations (Excise Duties) Act 1955 was introduced to enforce uniform duty for all states for products containing alcohol.
- In 1955 the first edition of Indian Pharmacopoeia was published.
- In 1985, to protect the society from dangers of addictive drugs the Narcotic and Psychotropic Substances Act was enacted.

The price of drugs in India is controlled by Drugs Price Order and the Govt of India changes the price from time to time.

Development of Pharmacy Education

The origin of pharmacy education in India dates back to 1899. At that time, training of pharmacists was mostly conducted at Madras (present name Chennai). In 1928 the State Medical Faculty of Bengal followed this pharmacy training procedure by starting a similar programme. However, this has been mentioned above that in 1937 Prof. M.L. Schroff started 3-year degree course (B. Pharm) in pharmacy at Banaras Hindu University, Allahabad. At that time, the curriculum was a combination of pharmaceutical chemistry, analytical chemistry, and pharmacy. The graduates could work as specialists in quality control and standardization of drugs for pharmaceutical companies, but not for pharmacy practice. Thereafter and before independence 2 more institutions were set up to impart pharmacy degree programs; in 1944, the Punjab University started a pharmacy department and in 1947 L.M. College was established in Ahmadabad. After independence and till 1963 six more states Govt Universities and one private university, Birla Institute of Technology, Pilani started offering the course. Afterwards various institutions across the country have been imparting the education in pharmacy.

This has also been mentioned earlier that in 1949, the Pharmacy Council of India (P.C.I.) was established under the Pharmacy Act 1948. The Govt of India established the PCI with the objective of regulation of

- The Pharmacy Education in the country for the purpose of registration as a pharmacist under the Pharmacy Act.
- Profession and Practice of Pharmacy

Hence the functions and duties of the Pharmacy Council of India are;

- To prescribe minimum standard of education required for qualified pharmacist.
- To frame Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy throughout the country.
- Inspection of Pharmacy Institutions seeking approval under the Pharmacy Act, monitoring and grant of approval as per the prescribed norms.
- To withdraw the approval, if the approved course of study or an approved examination does not fulfil the educational standards prescribed by the PCI.
- To approve foreign qualifications granted outside the territories of the Pharmacy Act.
- To maintain Central Register of Pharmacists.

Presently, there are more than 3000 institutions imparting various pharmacy training programmes across the country and about 150,000 students are being enrolled in different courses of pharmacy every year. The pharmacy degree programs offered in India include: Diploma in Pharmacy (D. Pharm), Bachelor of Pharmacy (B. Pharm), Master of Pharmacy (M. Pharm), Master of Science in Pharmacy [MS (Pharm)] and Master of Technology in Pharmacy [M Tech (Pharm)], Doctor of Pharmacy (Pharm D), and Doctor of Philosophy in Pharmacy (PhD). Integration of two courses like B. Pharm + MBA or M. Pharm + MBA has also been initiated by some institutions. There are six National Institutes of Pharmaceutical Education and Research (NIPERs) in India offering MS (Pharm), M. Tech (Pharm), and doctoral-level degrees.

Growth of Pharmaceutical Industry in India

The pharmaceutical education being imparted to students in India focuses towards self-employability, and entry into academia and the pharmaceutical industry. In July 2010, Her Excellency Smt. Pratibha Devi Singh Patil, the former President of India, in a speech on "Recent Trends in Pharmacy Education and Practice", mentioned that the Indian pharmaceutical industry has a wide range of capabilities and is ranked amongst one of the foremost industries of the country. It has grown from a meagre turnover of US$ 0.32 billion in 1980, to about US$ 21.3 billion in 2009-10, and it is poised to grow at a compounded annual growth rate of 19 percent. The growth of the pharmaceutical industry, of course, indicates the employment of able and competent pharmacists, and this seems to be one of the major reasons for the growth of pharmacy colleges in India. However, apart from the pharmaceutical industry-related employment, practicing pharmacists are also supposed to cater to the needs of general public and patients. But the latter aspect is lacking in the country. The medical stores are being handled primarily by diploma holders; but patient counselling or patient-pharmacist interaction is rarely taking place. To bridge this gap, the courses or curriculum needs to be designed accordingly. In addition, the students entering into pharmacy institutions have to expand their areas and look beyond the industrial employment to the wider fields of public healthcare. Already, some institutions have started Pharmacy Practice courses; but this initiative is very less than actual requirement. Expansion of training programmes by the teachers and greater acceptance by the students is necessary to cater to the health care needs of patients.

Code of Ethics

Code of ethics has been drafted by Pharmacy Council of India according to the work being done by the pharmacist such as job, trade, medical profession, and profession. Ethics is defined as code of moral principles. It

highlights 'what is right and what is wrong'. It is a noble profession; accordingly, there are differences in code of ethics based on type of work being done.

A young prospective pharmacist should feel no hesitation in assuming the following pharmacist's oath:

- I promise to do all I can do to protect and improve the physical and moral well-being of society, holding the health and safety of my community above other considerations. I shall uphold the laws and standards governing my profession, avoiding all forms of misinterpretation, and I shall safeguard the distribution of medical and potent substances.
- Knowledge gained about patients, I shall hold in confidence and never divulge unless compelled to do so by the law.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancements of pharmacy and the public health.
- I furthermore promise neither to maintain my honour in all transactions and my conduct never bring discredit to myself or neither to my profession nor to do anything to diminish the trust reposed in my professional brethren.
- May I prosper and live long in favour as I keep and hold to this, my Oath, but if violated these sacred promises, may the reverse be my lot.

The goal of medical therapy is to improve the patients' health and quality of life. Optimal medical therapy should be safe, effective and appropriate. Accurate and up to date information are necessary to provide best medical care for the patients as well as for the providers.

The responsibilities of physicians and pharmacists are complementary and supportive to meet the goal of providing optimal medical therapy. This requires communication, respect, trust and mutual recognition of each other's professional competence. During counselling the patients, the physician may focus on the goal of therapy, the risks and benefits and side effects. The pharmacists on the other hand may focus on correct usage, treatment adherence, dosage, precautions and storage information.

Responsibilities of a pharmacist during a medical therapy

1. To ensure safe procurement, storage, adequate dosage and dispensing of medicines as per the prescription
2. To furnish information to the patients, which may include the name of the medicine, its purpose, potential interactions and side effects, correct usage and storage

3. To review prescription orders to identify interactions, allergic reactions, contraindications and therapeutic duplications. Significant matters should be discussed with the prescriber (physician)
4. To consult with the physician for the preparation and revision of therapeutic plans of the treatment with the medicines
5. To discuss medicine related problems or concerns with regard to the prescribed medicines, if requested by the patient
6. To advise patients on the selection and use of non-prescription medicines and how to manage the minor symptoms or ailments
7. To advise the patient where self-medication is not appropriate and the respective physician to be consulted for diagnosis and treatment
8. To report adverse reactions of medicines to health authorities, when necessary
9. To provide and share general as well as specific medicine related information and to advise the public and health care providers
10. To update the knowledge on medical therapy regularly through continuous professional development.

When the pharmacist and physician start exchanging information, each provider can understand other's performance. Such understanding ultimately helps to recognize each other's value, to build mutual trust and to develop satisfaction with the relationship. The net benefit of each exchange among service partners adds value to professional collaboration. Similarly, when expectations are met, the satisfaction with exchange partners may result. The continued meeting of expectations also can contribute to the development of trust.

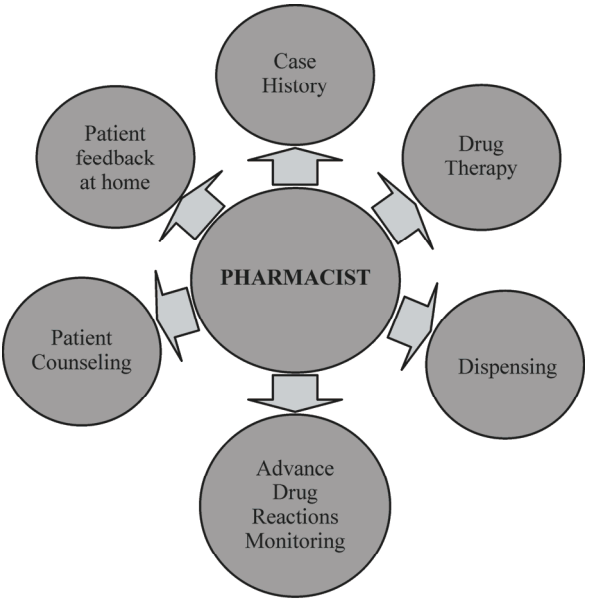
Apart from the above discussed responsibilities, a pharmacist also coordinates with and assists the nursing staff at different levels or stages of therapy.

1. Proper administration of drugs i.e. to take right drug at right time. Whether the drug has to be administered before or after meals, frequency of administration, and dose of drugs to be administered in emergencies. All these are monitored by the pharmacist along with nurses,
2. A pharmacist also provides information to the nurse about the diet plan which should be followed by the patient during the drug therapy. A pharmacist is the best person who knows about the drug-food interactions and thus, he decides the diet plan which should be advised and monitored by the nurses.
3. The pharmacist also guides the nurses about the safe handling of drugs. He provides information regarding proper dispensing, storage of drugs and disposal of waste containers.

4. The pharmacist assists the nurses in documentation which includes recording of day to day and patient to patient plan of drug administration, recording of drug administered and to be administered. He can also assist in documentation of various clinical parameters at regular interval of time.
5. The pharmacist can also train the nurses about the use and sterilisation techniques of surgical instruments.
6. A pharmacist also acts as an active member of the health care team which includes physician and nurse, which can ultimately provide maximum benefits to the patients.

Pharmacy as a Career

Pharmacy is a word derived from the Greek word *pharmakon* meaning drug. Pharmacy is a branch of science related to healthcare services and Pharmacist is a core healthcare professional. Today, the discipline of pharmacy has made enormous progress and is a distinctly independent discipline, known as pharmaceutical sciences & technology with the wealth of knowledge, research and art of technology. Unlike other curricula, pharmacy is a product as well as service-related discipline. Pharmacist works in all stages related to drug, starting from drug discovery, development, safety, quality control, packaging, storage, use, marketing, and sale and also in governing the manufacture, sale, export and import of drugs in the country, i.e. in drug control administration. Precisely, in the real sense, pharmacist is a drug expert.



The position of a pharmacist in health care profession

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, and it accounts for 20 per cent in the volume terms and 1.4 per cent in value terms of the Global Pharmaceutical Industry as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented.

India plays an important role in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to move the industry ahead to higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical companies.

The UN-backed Medicines Patent Pool has signed six sub-licences with Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs, and allowed them to make generic anti-AIDS medicine Tenofovir Alafenamide (TAF) for 112 developing countries.

Indian pharmaceutical sector is estimated to account for 3.1 – 3.6 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. It is expected to grow to US$100 billion by 2025. The market is expected to grow to US$ 55 billion by 2020; thereby emerging as the sixth largest pharmaceutical market globally by absolute size, as stated by Mr Arun Singh, Indian Ambassador to the US.

Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues). The sector is expected to generate 58,000 additional job opportunities by the year 2025.

According to the report given by the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL), India’s pharmaceutical exports stood at US$ 16.8 billion in 2016-17 and are expected to grow by 30 per cent by next three years to reach US$ 20 billion by 2020.

Indian companies received 305 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2017. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market.

India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected grow at an average growth rate of around 30 per cent a year and reach US$ 100 billion by 2025. Biopharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues at Rs 12,600 crore (US$ 1.89 billion).

The Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector in order to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions.

According to data released by the Department of Industrial Policy and Promotion (DIPP), the drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US$ 15.570 billion between April 2000 and September 2017.

Some of the major investments in the Indian pharmaceutical sector are as follows:

- The exports of Indian pharmaceutical industry to the US will get a boost, as branded drugs worth US$ 55 billion will become off-patent during 2017-2019.
- Private equity and venture capital (PE-VC) investments in the pharmaceutical sector have grown at 38 per cent year-on-year between January-June 2017, due to major deals in this sector.
- The Indian pharmaceutical market size is expected to grow to US$ 100 billion by 2025, driven by increasing consumer spending, rapid urbanisation, and raising healthcare insurance among others. Pharma sector's revenues are expected to grow by 9 per cent year-on-year through fiscal 2020.
- Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the rise.
- The Indian government has taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

Career Opportunities

There are various options a pharmacy professional do have for their career growth.

1. Pharmaceutical Industries
   Production – Manufacturing, Packaging, Store & Purchase
   Quality Control & Quality Assurance
   Research & Development
2. Pharmaceutical Marketing

3. Hospital & Clinical Pharmacy
4. Community Pharmacy
5. Regulatory Affairs
6. Academics
7. Consultancy
8. Library Information Service and Pharmaceutical Journalism
9. Opportunities Abroad

1. Pharmaceutical Industries

Manufacturing: Whether it is allopathic, ayurvedic or homoeopathic drug manufacturing unit. Each manufacturing unit comprises various major sections like production, packaging, inventory and purchase. Based on type of dosage forms being manufactured the number of sections vary. A pharmacy professional is most desired technical person for production of bulk drugs, intermediates and formulations. The job is supervisory in nature and the initial designation, chemist, supervisor, executive, etc varies from company to company. Based on efficiency and experience the candidate can become Manager, General Manager, Vice-President and President, the top most position.

In cosmetic, soaps & toiletries industry the pharmacy professionals are also preferred as suitable technical persons. For production of Blood and Plasma products pharmacy professionals are appointed as supervisors.

Packaging of pharmaceutical products is of great importance and requires technical supervision. Similarly store & purchase are two major operations associated with production on which the quality of a product depends. Hence, many pharmaceutical companies appoint pharmacy professional for supervising these activities.

Quality Control and Quality Assurance are two major departments of any manufacturing industry. Of course there are official standards for drugs and drug products with permissible limits of impurities and purities for every raw material and finished product, but most of the pharmaceutical industries have their own internal standards for input materials and products, which are more specific and process based. Hence, it is very essential to adhere to established methods and standards, so that the final quality of the manufactured products is achieved consistently. Highly specialised and trained staff is required to operate most sensitive and sophisticated analytical instruments. In general professionals with M. Pharm or M. Pharm, Ph. D are most preferred.

Research & Development is heart of an industry. For sustenance and growth every industry should have its own R&D department. In

pharmaceutical industry it is very much essential, because the discovery of a drug molecule and development of a suitable dosage form are continuous processes as the type of disease and its treatment are changing. Even for better treatment of the existing diseases the development of the drug delivery systems are necessary. Hence, a lot of job opportunity exists in this area and persons having M. Pharm or M. Pharm, Ph. D qualification are most suitable.

2. Pharmaceutical Marketing

Without marketing and sales of its products no business can be viable. The pharmaceutical marketing and sales are highly technical in nature, the prescribing physician needs to be aware of the dose, use and contraindication of every drug product. And this is done by the representative of the manufacturer visiting the doctor. Hence, this is a specialised job and needs a person who is fully aware of the subject. Pharmacy professional can do this successfully. Even the retailer needs to be trained on proper storage of a particular drug product and how the patient should take the preparation. This is field job. Scope of promotion is maximum and within short period one can reach to top position with basic qualification only.

Product management is another area of marketing where the person having some field experience can do excellently. This is not field job. Great scope of earning exists if the person has innovative ideas.

3. Hospital & Clinical Pharmacy

For pharmacy professionals this is one more opportunity to work as *Registered Pharmacist* in the hospitals or drug store. In fact, in most of the countries abroad this is a prestigious job and the pharmacist is the only authorized person to prescribe a medicine. The physician only diagnoses the disease but cannot prescribe a medicine. This requires the knowledge of drug-drug interaction, drug-food interaction, pharmacokinetics of the drug. After careful consideration of the patient's medical history, disease state, health condition, incompatibility with other medicines, if being taken, etc the pharmacist selects the suitable drug, decides the proper dose and its administration schedule.

4. Community Pharmacy

As such this concept is existing in developed countries. Through the community pharmacy a pharmacist plays a vital role during treatment of a patient. The pharmacist through his service becomes a link between the patient and treating physician, i.e. as a link between the patient and drug. The duties of the pharmacist in a clinical pharmacy are,

- Counselling the patients regarding the use of the drugs and dosage forms,
- Providing up-to-date information about the drug/dosage form to the patient, as well as to the medical staff,
- Maintaining the patient record and disease-treatment history,
- Training of the patient regarding use of self-diagnostic kits for certain disease like diabetes, hypertension, etc.
- Providing supply of Home care dosage forms.

5. Regulatory Affairs

In India Drugs Control Administration is the main regulatory body that governs the manufacture, sale, import and export of drug and drug products. Every state has its own Directorate of Drug Control Administration, over and above there is Central Drug Control Administration. In each set up there are Inspectors of Drugs who visit the retail counters, manufacturing units, etc and draw samples for quality check. The state directorate is headed by State Drugs Controller and the central administration is headed by the Drugs Controller of India. In between the Director and Drug Inspector, the Deputy Director and Assistant Directors are there. The minimum eligible qualification for such job is B. Pharm.

6. Academics

Excellent opportunity in teaching profession is there throughout the country. There are many Institutions in the country managed by government and private where vacancies at different levels are still in existence. The minimum eligible qualification at lecturer level is M. Pharm and with Ph.D one reach up to Professor level.

7. Consultancy

For highly technical and experienced pharmacy professional this is an ideal opportunity to earn handsomely as a self-employed entrepreneur. There is no age limit for this profession. The consultancy fees depend on the type of service and field, like regulatory affairs, documentation, approval, manufacturing process know-how, analytical technique, research, market survey and sales promotion, information retrieval, data management, turn key project, etc.

8. Library Information Service and Pharmaceutical Journalism

In the recent times the regulatory affairs and patenting processes involve a lot of documentation work to be done and submitted to the concerned Regulatory Authorities within a definite time schedule, for which a special work force is necessary. Hence, most of the large scale companies have separate department for this purpose and pharmacy professional are best suited for such activities.

Similarly, the Research & Development and Q.C departments need to collect technical information across the world. This needs to be regularly updated to match the pace of global competition. So, library information service is another area of growing demand in pharmaceutical industries. Moreover, Bioinformatics and Electronic Data Retrieval systems are also promising area where a pharmacy professional can find growth.

9. **Opportunities Abroad**

   There are golden opportunities for pharmacy professional to work abroad. Countries like USA, Canada, UK, France, Germany, Australia, African countries; Saudi Arabia, Japan, etc still importing pharmacy professionals for different types of jobs like industrial, academics and clinical pharmacy.

   One with B. Pharm degree can pursue higher education in developed western countries and can find highest career growth.

Pharmacopoeia

The term Pharmacopoeia came from two Greek words, *Pharmakon* (means drug) and *Poiein* (means make). In Bergamo, Italy in the year 1580 this term Pharmacopoea was first used for a book on the standards of drugs. Subsequently many countries started using this word for their books on drug standards. Now almost every country of the world has its own national Pharmacopoeia. This is the official book of standards for drugs and their formulations.

Indian Pharmacopoeia

In the year 1833 a committee of the East Indian Company's Dispensary recommended the Publication of a Pharmacopoeia. The Bengal Pharmacopoeia and General Conspectus of Medicinal Plants were published in 1844. This mainly listed most of the commonly used indigenous remedies. In 1868 IP was published. This covered both the drugs of British Pharmacopoeia (BP) 1867 and indigenous drugs used in India. A supplement containing the vernacular names of indigenous drugs and plants was published in 1869. However, from 1885 the BP was made official in India. A drug Enquiry Committee was appointed in 1927 by the government. The committee recommended the publication of a National Pharmacopoeia.

In 1900, the Indian and Colonial Addendum to the British Pharmacopoeia 1898 was published and in 1901, it was published as the Government of India Edition with certain minor modifications. The important articles of this Addendum were subsequently included into the

general body of the British Pharmacopoeia 1914. The British Pharmacopoeia Commission also made provision for publication of Supplement or Addenda according to the local requirements and the Indian Pharmacopoeia List 1946 was accordingly prepared to serve as the Indian Supplement to the British Pharmacopoeia1932. After independence, in the year 1948 an Indian Pharmacopoeia Committee was constituted for preparation of the Pharmacopoeia of India (The Indian Pharmacopoeia) 1955. In 1960, a Supplement to it was published. This Pharmacopoeia contained western as well as traditional drugs. The Indian Pharmacopoeia 1966 and its Addenda 1975 were prepared as per the same policy. Next edition of the Pharmacopoeia of India 1985 and its Addenda 1989 and 1991 also did not include the traditional drugs in general. The traditional drugs were considered separately and only those herbal drugs having definite quality control standards were included.

The Government of India Ministry of Health & Family Welfare, vide their Resolution No. X.19020/1/89-DMS & PFA dated 12.8.1991 reconstituted the Indian Pharmacopoeia Committee for a period of five years for preparation of the next edition of the Indian Pharmacopoeia under the Chairmanship of Dr. Nityanand, Ex-Director, Central Drug Research Institute, Lucknow.

To expedite the preparation of the new edition of the Indian Pharmacopoeia, the Committee constituted various Sub-Committees, Working Groups having expert representatives from the Pharmaceutical industries, Drug control laboratories, Research and Teaching Institutions of the country for preparation of draft monographs and appendices, for examination of the comments received on those and for suitable recommendation there on to the Committee.

It was also felt necessary to prepare a Veterinary Supplement to this new edition. Since the drugs for veterinary use needed specialised information, a Group was formed for this purpose.

Accordingly, the Committee finalised the monographs, appendices and general Notices prepared by the Working Groups and in 1996 the Indian Pharmacopoeia was published. For the said purpose other Pharmacopoeias like the British Pharmacopoeia (BP), European Pharmacopoeia (EP), the United States Pharmacopoeia (USP), National Formulary, the Pharmacopoeia of Japan, the Pharmaceutical Codex, the International Pharmacopoeia, the Marck Index and the standards published by the Bureau of Indian Standards were also consulted.

The full name or title of the Pharmacopoeia including Addenda there to, has been changed to Indian Pharmacopoeia 1996 and abbreviated to IP 1996 because of convenience to all and the initial name, Pharmacopoeia of India has been dropped.

Indian Pharmacopoeia (IP) is an official document meant for overall Quality Control and Assurance of Pharmaceutical products marketed in India by way of contributing on their safety, efficacy and affordability. IP contains a collection of authoritative procedures of analysis and specifications for Drugs. The IP, or any part of it, has got legal status under the Second Schedule of the Drugs & Cosmetics Act, 1940 and Rules 1945 there under.

IP prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals. IP standards are authoritative in nature. They are enforced by the Regulatory authorities for quality control of medicines in India. During Quality Assurance and at the time of dispute in the court of law the IP standards are legally acceptable.

The fifth edition of IP was published in 2007 and in 2008 an addendum was published. In 2010 the sixth edition of IP and in 2012 its addendum were published. The seventh edition was published in the year 2014. The current eight edition of IP has been published in 2018 and its addendum is scheduled to be published in 2019.

United States Pharmacopoeia

In January 1817, Dr. Lyman Spalding of New York City of the United States submitted to the Medical society of the Country a proposal to develop a national Pharmacopoeia. He proposed, -

(1) to divide the country into four districts - northern, southern, western and middle, (2) to call for *Convention* in each district with delegates from all medical societies and medical schools of the respective district, (3) to prepare a draft for pharmacopoeia and, (4) to appoint delegates for *General Convention* to be held later in Washington, D.C.

Accordingly, the drafts were submitted only by the northern and middle districts.

In the General Convention held in January,1820 these drafts were thoroughly reviewed and consolidated. In December 1820, the first United States Pharmacopoeia was published in two languages, English and Latin. Latin was the then international language of medicine. It was of 272 pages and 217 drugs were included. The convention also resolved that the USP would be revised every 10 years. Because of the extensive efforts extended for preparing the USP, Dr. Spadling is called as the *Father of the USP*.

In 1900 the Pharmacopoeial Convention decided to issue Supplements to the USP as and when necessary to maintain satisfactory standards. In 1940, the Convention decided to revise the USP every 5 years with periodic issuance of Supplements.

The USP is a non-governmental, non-profit public health organisation which independently works to set scientific and recognized standards.

In more than 130 countries across the globe USP's standards are recognized and used. To ensure quality medicines, food ingredients and other health care products USP establishes documentary and reference standards. These documentary standards and references are used by regulatory agencies and manufacturers of pharmaceuticals, dietary supplements and food ingredients to ensure appropriate strength, quality and purity of the ingredients and the products.

USP develops information relating to various aspects of drug-use and circulates this information to physicians, pharmacists and others who are associated with health care profession.

USP also acts to improve health and promote optimal public health care delivery around the world by running operations at various places like Europe, middle East, Africa, India, China and at brazil.

Since 2002 the USP-NF has been revised and published annually. The current edition of USP, USP33-NF28 shall be published in the year 2010. The current edition of the USP-NF was published in 2017.

National Formulary

Till 1852 the third revision of USP was the only recognized and authoritative book of drug standards in the United States. The drugs having established therapeutic value were included in the USP. Many drugs and formulas being used by the medical practitioners were not included in the USP due to strict selectivity.

Hence, in 1852 the American Pharmaceutical Association (APhA) organised and prepared a Formulary containing some drugs and formulas which were not included in the USP. In 1888 the first edition of the Formulary was published under the title, National Formulary of Unofficial Preparations. The term unofficial indicated a kind of protest and to distinguish it from the USP in which the term official was used. In 1906 the title was changed to National Formulary (NF) and both USP and NF were made legal books of standards as per the first federal Pure Food and Drug Act under the signature of the then president, Theodore Roosevelt. Hence, according to the law the formulations carried the name USP or NF in their labels were bound to conform to the physical and chemical standards mentioned in the respective monographs.

The initial editions of NF provided uniform names of the drugs, their preparations and working directions as a convenient means to the practicing pharmacists and to the small scale manufacturers of popular preparations prescribed by the physicians.

Till 1940, like USP, the NF had been revised every 10 years and thereafter every 5 years with periodical issuance of supplements as and when necessary.

In 1975 both USP and NF were unified and the first combined compendium USPXX-NF XV was published in 1980. The USP section contained all monographs on the drug substances and the NF section contained the monographs on pharmaceutical agents. The USP25-NF20 became an annual publication in 2002. The next edition of USP26-NF21 with about 4000 drug monographs was published and made available in both hard and soft copy.

All the members related to health care including pharmacists, physicians, dentists, veterinarians, nurses, manufacturers and suppliers of bulk drugs, chemicals and pharmaceutical products, public health agencies, drug regulatory and enforcement agencies and others were made responsible to adhere to the norms and standards mentioned in the USP-NF.

Since 2002 the USP-NF has been revised and published annually. The current USP33-NF28 shall be published in the year 2010. In the 2017current 40th edition of the USP-NF was published.

British Pharmacopoeia

Since 1491 – 1547 the regulation of medicinal products had been regulated by officials in the United Kingdom. Physicians of The Royal College, London were empowered to inspect the products of apothecaries in the London area and to destroy the defective stocks. The first list of approved drugs and their manufacturing guidelines was published in London in 1618 as London Pharmacopoeia. In Great Britain, there were three city-pharmacopoeias – the London, the Edinburgh and the Dublin. These were official till the first British Pharmacopoeia (BP) was published in 1864 and all those three pharmacopoeias were merged. In 1907, a Commission was appointed by the General Medical Council and the body was made responsible statutorily under the Medical Act, 1858 to produce a British Pharmacopoeia on national basis. In 1907 the British Pharmaceutical Codex was published with the information and standards for drugs and other pharmaceutical substances not included in the BP.

The 1968 Medicines Act established the legal status of the British Pharmacopoeia Commission and of the British Pharmacopoeia as the standards for medicinal products in the United Kingdom under the section 4 of the Act. Since then, the British Pharmacopoeia Commission continued the work of the earlier Commissions appointed by the General Medical Council and was responsible for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping those up-to-date. Since 1864, the distribution of BP has grown

throughout the world and is now used in more than 100 countries. Australia and Canada have adopted the BP as their national standard and in other countries, e.g. Korea, BP is recognized as an internationally acceptable standard.

The British Pharmacopoeia is prepared by the Pharmacopoeial Secretariat in collaboration with the BP Laboratory, the British Pharmacopoeia Commission and its Expert Advisory Groups and Advisory Panels. The input information is collected from relevant industries, hospitals, academia, professional bodies and governmental sources, inside and outside the UK.

The current edition of the British Pharmacopoeia contains six volumes with about 3000 monographs for drug substances, excipients and formulations along with supporting General Notices, Appendices and Reference Spectra used in the practice of medicines. BP (Veterinary) contains all items used exclusively in veterinary medicines in the UK.

Volume I and II contain medicinal substances, Volume III contains formulations, blood related products, immunological products, radio-pharmaceutical preparations, surgical materials and homeopathic preparations. Volume IV comprises Appendices, Infrared Reference Spectra and Index. Volume V is British Pharmacopoeia (Veterinary), Volume VI contains CD-ROM version of British Pharmacopoeia, British Pharmacopoeia (Veterinary) and British Approved Names.

Till 1996 the British Pharmacopoeia has been revised and published every 5 years. Since 1998 it has been revised and published annually. In 2017 the BP had been published which superseded the BP 2016.

International Pharmacopoeia

The history of the International Pharmacopoeia dates back to 1874. The first conference was called by the Belgian Government in Brussels in 1902 and an Agreement for the Unification of the Formula of Potent drugs which was ratified by 19 countries in 1906.

A second agreement, the Brussels Agreement, was drawn up in 1925 and ratified in 1929. It was resolved that the League of Nations would be responsible for the administrative work to produce a unified Pharmacopoeia, and a permanent secretariat of an international organisation would coordinate the work of National Pharmacopoeial Commissions. General principles for the preparation of galenicals, maximal doses, nomenclatures and biological testing of arsenobenzones were included in the articles of this agreement along with a table of dosage strengths and descriptions for 77 drug substances and preparations.

In response to the repeated calls from pharmaceutical experts in various countries, the health organisation of the League of Nations set up a Technical Commission of Pharmacopoeial Experts in 1937. In 1947, the Interim commission of WHO (World Health Organisation) took over the work of pharmacopoeias and in 1948, the first World Health Assembly approved the establishment of the Expert Committee on the International Pharmacopoeia.

The third World Health Assembly held in May1950 formally approved the publication of the *Pharmacopoea Internationalis*. This was not intended to be legal pharmacopoeia in any country unless adopted by the pharmacopoeial authority of that country. From that time WHO constituted a permanent International Pharmacopoeial Secretariat. Accordingly, the first edition of International Pharmacopoeia was published in 2 volumes, one in 1951 and the other in 1955, In 1959, a supplement was published. These were published in English, French and Spanish, subsequently translated into German and Japanese languages. Altogether, it included 344 monographs on drug substances, 183 monographs on dosage forms and 84 tests, methods and general requirements. A large number of national pharmacopoeias and official lists were examined and assistance from International Pharmaceutical Federation (FIP) was also obtained to select substances and products for their inclusion in the pharmacopoeia.

The second edition was published in 1967, the third edition in 1975, and in 2006 the fourth edition was published. In 2008, a supplement has been published. This is the current edition of the International Pharmacopoeia. It has two volumes and one supplement. This serves as the source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements. The International Pharmacopoeia published in 2016 is the current edition.

European Pharmacopoeia

In the year 1964, a Convention was organised by the European countries-Belgium, France, Germany, Italy, Netherlands, Switzerland, Luxembourg and United Kingdom under the banner of Council of Europe and decided to prepare a European Pharmacopoeia. The objectives were to make uniform specifications for medicinal substances of general interest to the people of Europe and to prepare the specifications for the growing number of new medicinal substances coming to the market.

Based on these objectives the European Pharmacopoeia was created and published in the year 1967 comprising monographs and became official standards applicable to the territories of the countries which were contracting parties to the convention. The second edition was published in 1980.

On 16th November1989, a Protocol to this Convention was signed in order to enable the European Community to accede to it and since 1st Nov'92 it was entered into force.

In 1996 the European Directorate for the Quality of Medicines & Health Care (EDQM) came into force. It is an organ of the Council of Europe. It consists of the Technical Secretariat of the European Pharmacopoeial Commission, set up in 1964 by the European Pharmacopoeia Convention.

The EDQM is in charge for

- Preparing and publishing adopted text (printed, CD-ROM, and Internet version) and distributing the European Pharmacopoeia and other publications.
- Checking the text experimentally in the laboratory, the laboratory also carries out analytical studies and organises collaborative studies to establish European Pharmacopoeia chemical or biological reference substances or preparations.
- Preparing, managing and dispatching European Pharmacopoeia reference substances.
- Organising regularly congresses on new scientific and technical subjects, as well as seminars and training sessions on subjects related to European Pharmacopoeia.

The European Pharmacopoeia currently has 37 European Members including the European Union (EU). There are 21 observer countries for European Pharmacopoeia including the WHO.

The 2005 edition, the 5th edition, includes 1800 specific and general monographs, including various chemical substances, antibiotics, biological substances; Vaccines for human or veterinary use; Immuno-sera; Radiopharmaceutical preparations; Herbal drugs; Homoeopathic preparations and Homoeopathic stocks. It also contains Dosage forms, General monographs, Materials and Containers, Sutures; 268 General methods with figures or chromatograms and 2210 reagents are described.

The current edition is the 6th edition, published in the year 2008 and consists of a two- volume main edition with supplements.

The texts and monographs of the European Pharmacopoeia form an integral part of the British Pharmacopoeia. The 9th edition published in 2016 is the current edition of European Pharmacopoeia.

Extra Pharmacopoeia

It was published in 1883 under the title, Martindale: *The Extra Pharmacopoeia*. Presently it is being published as Martindale: *The Complete Drug Reference*. It is a reference book with information of about

6000 drugs and medicines, and 146000 proprietary preparations. It also includes 668 disease treatment reviews along with some selected investigational and veterinary drugs, herbal and complementary medicines, pharmaceutical excipients, vitamins and nutritional agents, vaccines, radiopharmaceuticals, diagnostic agents, contrast media, medicinal gases, drugs of abuse, recreational drugs, toxic substances, disinfectants and pesticides.

The purpose of Martindale is to provide information on drugs and related substances reported to have clinical value anywhere in the world. It is also a source of useful information for patients arriving from different country to search their existing medication, available in different brand name; if not available, their substitutes.

The monographs include Chemical Abstract Services (CAS) and Anatomical Therapeutic Chemical Classification System (ATC) numbers, so that a reader can refer to other information system.

Martindale has two main parts, Monographs and Preparations plus two extensive indexes, Directory of manufacturers and General index. The 37th edition of *Martindale: The Complete Drug Reference,* is available in 2 volumes. The beauty of this work is that it is the most stupendously comprehensive work in its field. To provide more up-to-date information, the interval between print editions has been reduced over successive editions, and the book is now produced about every two years.

Exercise

A. Multiple Choice Questions Carrying 01 Mark

1. Opium Act was enacted in the year
   (a) 1878 (c) 1879
   (b) 1880 (d) 1890
2. Poisons Act was enacted in the year
   (a) 1920 (b) 1919
   (c) 1918 (d) 1921
3. Bengal Food Adulteration Act was enacted in the year
   (a) 1915 (b) 1920
   (c) 1919 (d) 1921
4. Drugs Act 1940 was first amended in the year
   (a) 1943 (b) 1944
   (c) 1945 (d) 1946

5. Which statement is correct?
   (a) Pharmacy Council of India was established under Pharmacy Act 1948
   (b) Pharmacy Council of India was established under Pharmacy Act 1945
   (c) Pharmacy Council of India was established under Pharmacy Act 1947
   (d) None
6. Indian Government brought the Pharmacy Bill in the year
   (a) 1942 (b) 1946
   (c) 1940 (d) 1945
7. B. Pharm course was started first in India at
   (a) Birla Institute of Technology, Pilani
   (b) Banaras Hindu University, Allahabad
   (c) Jadavpur University, Kolkata
   (d) Hari Shankar Gaur University, Sagar
8. The first edition of Indian Pharmacopoeia was published in the year
   (a) 1962 (b) 1960
   (c) 1955 (d) 1967
9. Which organisation is responsible to publish IP in India?
   (a) Indian Pharmaceutical Association
   (b) Indian Pharmacopoeia Committee
   (c) Pharmacy Council of India
   (d) None
10. Since which year USP-NF was being published
   (a) 2000 (b) 1990
   (c) 2001 (d) 2002

B. Question Carrying 05 Marks

1. Write down briefly the history of Pharmacy profession during ancient times.
2. How the education in Pharmacy has been developed in India?
3. Write down the code of ethics.

4. Write down briefly the history of the United States Pharmacopoeia.
5. Describe about the British Pharmacopoeia.
6. Describe about the International Pharmacopoeia.
7. Describe brief note on the European Pharmacopoeia.
8. Describe about the Extra Pharmacopoeia.
9. Write a brief note on National Formulary.
10. Write a brief note on Indian Pharmacopoeia.

C. Question Carrying 10 Marks

1. Discuss how the Pharmacy profession has been developed in India.
2. Write down the responsibilities of Pharmacist during medical therapy.
3. Discuss about the career in Pharmacy.
4. Write down the historical development of Indian Pharmacopoeia.
5. Write down the historical development of National Formulary.
6. Write down the historical development of the United States Pharmacopoeia.
7. Describe how the education in Pharmacy has evolved in India.
8. Discuss on Extra Pharmacopoeia and European Pharmacopoeia.

Answers

A. Multiple Choice Questions

1. (a)	**2. (b)**	**3. (c)**	**4. (c)**	**5. (a)**
6. (d)	**7. (b)**	**8. (c)**	**9. (b)**	**10. (d)**