CHAPTER - 1

HISTORY OF PHARMACY PROFESSION IN INDIA

PART -I

Points to be covered in this topic

- 1.1 INTRODUCTION
- 1.2 HISTORY OF PHARMACY PROFESSION IN INDIA
  - 1.2.1 Pharmacy Education in India
  - 1.2.2 History of Pharmacy Profession in India in relation to industry
  - 1.2.3 Pharmacy Practice in India
  - 1.2.4 Pharmaceutical Association in India
- 1.3 PHARMACY AS A CAREER

HISTORY OF PHARMACY PROFESSION IN INDIA

1.1 INTRODUCTION

The pharmacy profession is **vital part** of the healthcare system. The pharmacy profession is an old profession worldwide. The profession of pharmacy has a **systematic and chronological development**. It is paramedical profession that links health sciences with basic sciences and works for safe and effective use of pharmaceutical drugs and dosage forms.

❖ Pharmacy

- The word **"pharmacy"** was coined from the Greek word **"Pharmakon"** meaning **"medicine"** or **"drug"**.
- Pharmacy is the art and science of manufacturing and dispensing of drugs prepared from natural and synthetic sources and using them for the treatment and prevention of diseases.

❖ Pharmacist

- Pharmacist is a **trained person** who is certified to make, sell or distribute medicine and medicine compounds.
- They are highly trained, skilled healthcare professionals with proper education and training.

❖ Pharmaceutics

- Pharmaceutics is a branch of pharmacy and is also called as **science of dosage form design**.
- It **involves the** design, development and evaluation of drugs in combination with an appropriate dosage form.

1.2 HISTORY OF PHARMACY PROFESSION IN INDIA

- The first college in India was **Madras Medical College** was established in 1835 where professional training for treating patients with drugs was given to students from 1870.

- The first college in India was started in Asia was started in Goa, India, 1842 by the Portuguese medical school known as "**Escola Medica de Goa**", Currently known as **Goa college of Pharmacy**.

Fig 1.1 Goa College of Pharmacy

- The systematic and well-defined university education in pharmacy was initiated in 1932 in the Banaras Hindu University under the leadership of **Professor Mahadev Lal Shroff.**

In 1937, BHU became the first university in India to start 3-year B. Pharm course.

- **In 1940,** a Master of Pharmacy research degree was started at BHU.
- **In 1943,** a committee appointed by Indian Government under the chairmanship of **Sir Joseph Bhore** recommended 3-tier system for pharmacy education.
- **In 1945,** PhD in Pharmaceutical Sciences was started at **BHU.**
- **In 1947,** Legislature brought the '**Pharmacy Bill**' to regulate, control and standardize pharmacy education in India. In the same year, **L.M. college of Pharmacy** was established in Ahmadabad (Gujarat).
- **In 1948,** the **Pharmacy Act** was enacted by PCI to regulate the practice, education and profession of pharmacy.
- **In 1996,** the M. Pharm program in pharmacy practice was introduced at JSS College of Pharmacy at Mysore and at Ooty in 1997.
- **In 1980**, there were 11 universities and 26 colleges for B. Pharma and M. Pharm.

- **In 2010,** there were less than 900 pharmacy colleges in country.
- **In 2014,** through PCI regulation, the B. Pharm and M. Pharma curriculum was made uniform throughout the nation.
- **In 2015,** the pharmacy colleges were increased from 2000 colleges to 6000 colleges with 4 lakh students.
- Now there are approximately **9000 pharmacy colleges** in India for diploma courses and degree courses.
- Indian Government has set up **7 National Institutes of Pharmaceutical Education and Research (NIPERs)** offering M.S. (Pharm), M. Tech. (Pharm) and higher-level degrees.
- National Pharmacy Education Day was celebrated on **March 6th**, in honour of the birth anniversary of Professor **Mahadeva Lal Schroff**, who established pharmacy education in India.

1.2.1 Pharmacy Education In India

❖D Pharm

- **Diploma in Pharmacy** is a 2-year-long career-oriented diploma course followed by 500 hours of practical training in hospital or community settings in the medical field of pharmaceutical sciences.
- D Pharm curriculum is framed through the **education regulations of the Pharmacy Act.**
- **Exit examination** for diploma students is supposed to be proposed by **PCI in 2024.**

❖B Pharma

- **Bachelor of Pharmacy** or B. Pharm is a 4 years undergraduate degree that teaches students about drug synthesis, dosage formulation, analyzing the chemical nature and preclinical testing of new drugs.
- B Pharma is a **major segment of the healthcare industry** contributing to research in medicinal drugs as well as the development, manufacturing, and supply of medicines in the market.

❖M Pharma

- **Master of Pharmacy** (M Pharm) is a 2-year post-graduate program of which second year is devoted to research in drug regulatory affairs, pharmaceutical manufacturing technology, pharmacognosy, pharmacology, pharmaceutics and many more.
- The eligibility to M. Pharm program is based on academic performance at B. Pharm or an **entrance test (GPAT)** or both.
- GPAT score qualifies a student to receive **government scholarship** during the period of their M. Pharm.

❖PhD

- **Ph. D (Pharmacy) is a doctoral pharmacy programme** that lays out the specialization in pharmaceutical science. It is outlined to fulfil the need of high-grade education, development and research work in the field of pharmaceutical industry.
- M Pharm students can work **for PhD** with an additional 3 years of study and research.

❖Pharm D

- **Pharm. D or Doctor of Pharmacy** is a professional degree in the pharmacy stream.
- Pharm D course duration is six years, including 5 years of learning and one year of internship for practical knowledge introduced in 2008.
- It **aims to educate** the fundamentals of analytical chemistry and the study of the monographs of certain inorganic chemicals.
- **B. Pharm degree holders** can join the **Pharm. D. program** at its fourth year.

1.2.2History of Pharmacy Profession In India In Relation To Industry

❖BEFORE-INDEPENDENCE

- The allopathic system of medicine was introduced in India during the British rule. It was mainly meant for the ruling class. By the 19th century it became popular and was used for the common people also.
- **1811: Scotch M Bathgate** opened a chemist shop in Kolkata, **Mr. Bathgate** came to India along with East India Company.
- **1899: Haffkine institute** was established at Mumbai which is one of the oldest biomedical research institutes in India
- **1901:** In Calcutta the first pharmaceutical company called **Bengal Chemicals and Pharmaceutical Works**, was set up by **Acharya P.C. Ray** which still is today as one of the fifth government-owned drug manufacturers was started.

- **1903: Prof. Tribhovandas Kalyandas Gajjar** established a small factory at Parel.
- **1907:** Alembic chemical Ltd. at Vadodara, Gujarat was established by **professor T.K Gajjar**.
- **1911:** This era was mainly dominated by the **Multi-National Companies** (MNC's) as it was governed by the Patent Act 1911 which prevented both process and product patent for 16 years which further can be extended for 10 years. It was **illegal for the indigenous firms** to manufacture the patented drugs.
- **1940:** The indigenous industry in India during **1940** and **1950** was largely unaffected by the new medicines marketed by MNCs.

❖**AFTER-INDEPENDENCE**

- **1950:** The **Indian Drugs and Pharmaceutical Limited** (IDPL) and **Hindustan Antibiotics Limited** (HAL) were established by the government with both indigenous and foreign technology collaboration.
- **1970:** This era was governed by **Indian Patent Act 1970** which encouraged procedure patent and not product patent secured for seven years.

- **1978:** The substantial price control through **the DPCO based National Drug Policy 1978** led to entry of large number of drugs into the firms.
- **1980:** The Indian generic industry increased the exports and became an important player globally.
- **1991:** India adopted the policy of globalization, liberalization, and privatization which had impact on almost all the sectors of the country.
- **1995:** India became the founder colleague of **World Trade Organization (WTO).**
- **2005:** It was known as **Patent Act 2005**, led to the implementation of product patents in India for the period of 20 years.
- Another policy was framed and implemented by the director of food and drugs, **New Drug price control Order 2013** which intended to reduce the price of the drugs.
- **2020:** In 1998 the domestic companies held 68% of the market share which grew to **77% in 2003** and **85% by 2020.**
- **2020:** The Indian pharma industry has grown from ₹237(1980) crores to about 1.6 lakh crores (2020).
- The domestic pharma industry has achieved historic milestones through world-class cost-effective drugs for AIDS and Covid-19 medicines.

❖Top five pharmaceutical industries in India 2023

Table 1.1: Top five Pharmaceutical Industry in India

RANK	INDUSTRY	FOUNDER
1.	Sun Pharmaceuticals (1983)	Dilip Shanghvi
2.	Cipla Ltd (1935)	Khwaja Abdul Hamied
3.	Dr. Reddy's Laboratory Ltd (1984)	Dr. Kallam Anji Reddy
4.	Torrent Pharmaceuticals Ltd (1959)	U. N. Mehta
5.	Zydus Lifesciences Ltd (1952)	Ramanbhai Patel

1.2.3Pharmacy Practice In India

- **Pharmacy practice** include interpretations, evaluation and implementation of medical orders and dispensing of prescriptions, Patient counseling, responsibility for compounding and labeling of drugs and devices in case of hospital manufacturing of drug and devices.
- It also **includes** the proper and safe storage of drugs and devices and maintenance of proper records.

❖ **History**

- In India, the pharmacy practice is governed by the **Drug and Cosmetic Act, 1940** and other related legislations regulatory officers appointed under the Act regulate the licensing and running of pharmacies.
- The profession of pharmacy practice has evolved through five stages as given in Table 1.2

Table 1.2: Stages of Pharmacy Practice

STAGES	DESCRIPTION
Traditional Era	In this era, the **pharmacist was involved in** formulation, dispensing, conducting animal experiments, systematic classification of drugs for treatment of diseases.
Scientific Era	In this era, pharmaceutical industries were emerged and drugs were manufactured by pharmacist in factories.
Clinical Era	It began with **second half of 20th century.** In this period, pharmacists were educated in the area of clinical pharmacy to study the pharmacokinetic parameter of a drug in the body.
Industrialization Era	This era was followed by **rapid mass production of medicines.** It includes standardization, chemical synthesis and increased use of parenteral medication.
Pharmaceutical Care Era	This era expanded the pharmacist role to includes medication use to achieve positive outcomes with prescribed drug therapy.

1.2.4 Pharmaceutical Associations In India

- Pharmacy organizations and association in India working for welfare of every individual.
- Here given description about all the pharmaceutical industries in Table 1.3

Table 1.3: Different Pharmacy organizations and association

YEAR	DESCRIPTION
1920	The 'Calcutta Chemist and Druggist Association' was formed which in 1926 changed their name to 'Bengal Chemist and Druggist Association'
1935	Qualified professionals at BHU formed 'BHU Pharmaceutical Society'
1940	'Allied Manufacturers and Distributors Association Ltd.' was formed in Mumbai
1948	'Indian Pharmaceutical Congress Association' (IPCA) was formed at Calcutta.
1963	'Indian Hospital Pharmacist Association' (IHPA) was formed in Delhi
1970	India joined 'Commonwealth Pharmaceutical Association' (CPA).
1973	'Indian Pharmacy Graduates Association' (IGPA) was established at New Delhi.
1979	All pharmacy associations merged to form 'All India Organization of Chemist and Druggist' (AIOCD).

The pharmacy professional association are as follows:

1. The Indian Pharmaceuticals Association (IPA)
2. The International Pharmaceutical Federation (IPF)
3. Indian Pharmacy Graduates Association (IPGA)
4. Indian Hospital Pharmacist Association (IHPA)
5. All India Drugs Control Officers Confederation (AIDCOC)
6. All India Organization of Chemist and Druggist (AIOCD))

7. All India Cosmetics Manufacturer Association (AICMA)

8. Association of Pharmacy Teachers of India (APTI)

9. Organization of Pharmaceutical Producers of India (OPPI)

10. Association of Community Pharmacist of India (ACPI)

1.The Indian Pharmaceutical Association (IPA)

- **Prof. M.L. Schroff**, established United Province Pharmaceutical Association (UPPA) at **Banaras Hindu University** in 1935.
- The **United Provinces Pharmaceutical Association** (UPPA) was renamed as Indian Pharmaceutical Association (IPA) in 1939 and the publication of Indian Journal of pharmacy started.
- The IPA headquarters was shifted to **Bombay on 1st January 1953**.
- The Pharma Times started in **1963** as professional monthly publication of IPA.
- The First Indian Pharmaceutical Congress was organized at Calcutta in December 1948 with **Prof. M.L. Schroff** as its First President.
- IPA is member of **Drug Technical Advisory Board** (DTAB), Ministry of Health and Family Welfare, Government of India.
- IPA is a recognized as the **leader of pharmacy at National level**.

2.The International Pharmaceutical Federation (IPF)

- **Federation (FIP)** is the global body representing pharmacy, pharmaceutical sciences and pharmaceutical education.
- It was founded in **1912**, it is a non-governmental organization with its head office in the Netherlands.

➢Partners of FIP

- World Health Organization
- UNESCO
- World Health Professions Alliance
- Regional pharmaceutical forums
- FIP Foundation for Education and Research
- International Pharmaceutical Students Federation (IPSF)

➢ **FIP works for**

- Pharmacy practitioners
- Pharmaceutical scientists
- Pharmaceutical educators, young pharmacist and new graduates

3. Indian Pharmacy Graduates Associations (IPGA)

- **'Indian Pharmacy Graduates Association'** (IPGA) was established in the year 1973.
- The association is registered as a society under the **Societies Registration Act, 1860**.
- At present IPGA has around **6100 life members in 21 state** branches all across the country.

4. Indian Hospital Pharmacist Association (IHPA)

- The **'Indian Hospital Pharmacists Association'** (IHPA) was formed on **29th December, 1963** at **Pilani** during the 15th Indian Pharmaceutical Congress with the foresightedness and able guidance of the founder **President Dr. S. Rohatgi** (Kanpur), organizing secretary **Dr. B.D. Miglani**, along with the support of **S.L. Nasa** and **Davinder K. Jain** and many other pharmacists.

5. All India Drugs Control Officers Confederation (AIDCOC)

- The **'All-India Drugs Control Officers Confederation'** (AIDCOC) was framed on **28th December, 1995 at Visakhapatnam** as a result of untiring efforts of many officers across the country and the initiative taken by the Andhra Pradesh Drugs Inspectors Association, the Kerala Drugs Control Enforcement Officers Association and Tamil Nadu Drugs Inspectors Association.

6. All India Organization of Chemist and Druggist (AIOCD)

- **'All India Organization of Chemist and Druggist'** (AIOCD) consists of retail and wholesale pharmacist as its members.

- It has its offices at Taluka, district and state level with the name 'Chemist and Druggist Association'.

7. All India Cosmetics Manufacturer Association (AICMA)

- Directors of 'All India Cosmetic Manufacturers Association' (AICMA) are **Kanubhai Talshibhai Vadher** and **Satish Mahadeo Thipsay**.
- This association promotes and protects the small-scale cosmetic industry in India.

8. Association of Pharmacy Teachers of India (APTI)

- **'Association of Pharmaceutical Teachers of India' (APTI)** is an organization of academics in India who teach in the area of pharmacy.
- It was established in **1966 by Prof. M. L. Schroff**, **Prof G.P. Srivastava** and others of pharmacy colleges.

9. Organization of Pharmaceutical Producers of India (OPPI)

- The **'Organization of Pharmaceutical Producers of India' (OPPI)** established in 1965, represents the research-based global pharmaceutical companies in India

10. Association of Community Pharmacist of India (ACPI)

- **Association of Community Pharmacist of India'** (ACPI) is a non-profit professional organization started with an aim to provide patient safety by pharmaceutical care.

  The **Membership consists of pharmacists**, pharmacy students, Nurses, Nursing student and patient groups in academic and non-academic settings.

1.3 PHARMACY AS A CAREER

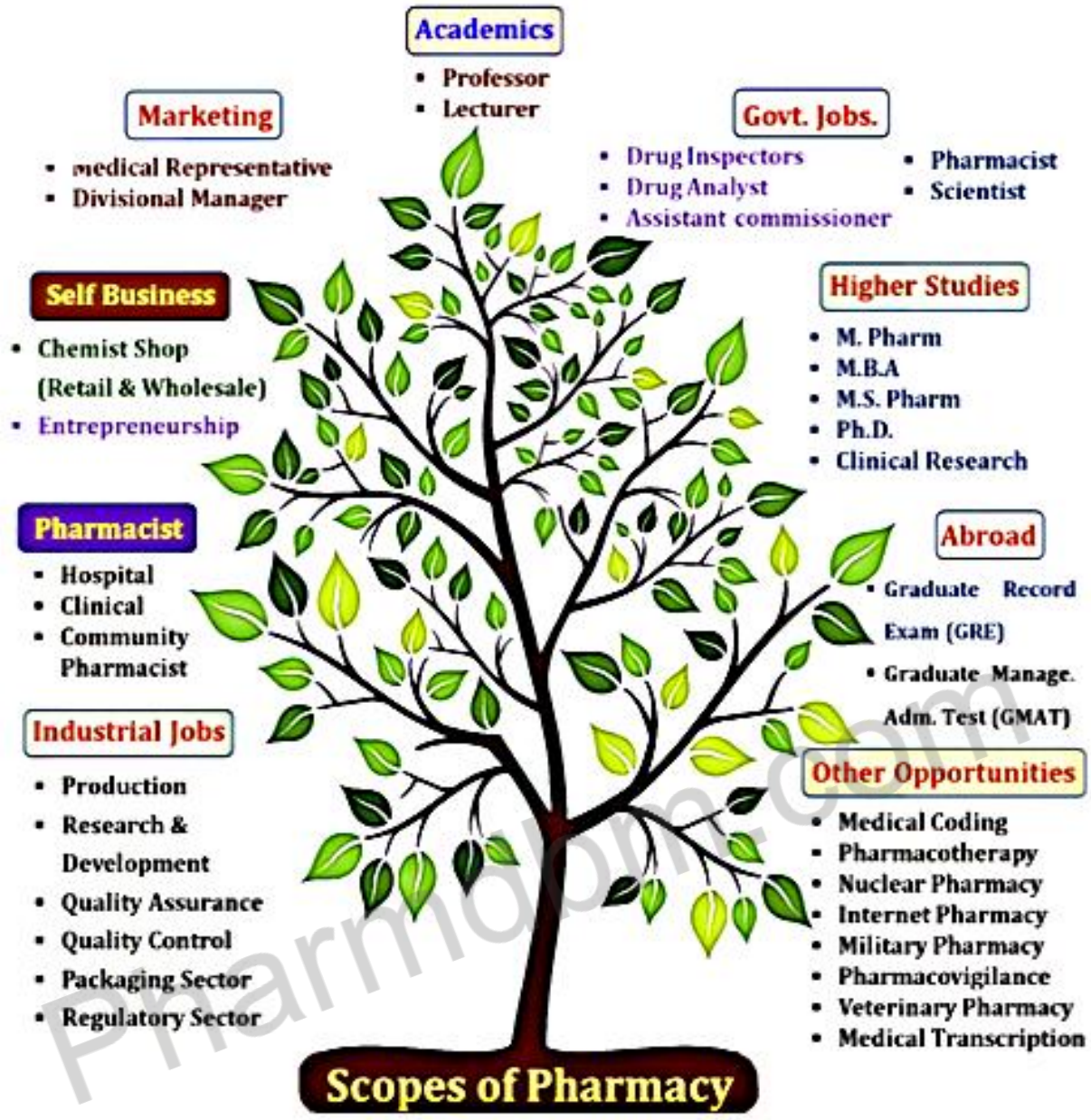

Fig 1.2 Scopes of Pharmacy

(A) Academics

- Academic Pharmacists are **full-time faculty members** of an educational Institute (e.g., University). They are involved in **teaching and training** of the future generations of pharmacists and pharmaceutical scientists.

1. **Professor - Professor (commonly abbreviated as Prof.)** is an academic rank at universities and other post-secondary education and research institutions in most countries. Literally, professor derives from **Latin** as a **"person who professes."** Professors are usually experts in their field and teachers of the highest rank.

2. **Lecturer** - A **lecturer** is a teacher at a university or college. **As per the AICTE norms** the minimum entry- level qualification as lecturer is M. Pharma.

(B)Government Jobs

1.**Drug Inspectors** - Drug Inspectors are specialists who **monitor a drug's safety, utility performance, and consistency** from the time it is manufactured until it is sold in a retail outlet. They are employed by the **state governments.**

2. **Drug Analyst** - A drug analyst is a professional who **is responsible for ensuring that the quality of all the drugs** produced in the pharmaceutical industry, whether it is for domestic or export, is up to the marks.

3. **Assistant Commissioner** - Candidates applying for the post of Assistant Commissioner must have a degree in Pharmacy or **Pharmaceutical Chemistry or Degree in Pharmacology**.

4. **Pharmacist** - A Pharmacist is a health professional who has special training in **preparing and dispensing** (giving out) prescription drugs.

5. **Scientists** - Pharmaceutical scientists usually specialize in one aspect of the drug development process. They may **design new drug therapies** using natural or synthetic (man-made) ingredients.

(C) Higher studies

1.**Master of Pharmacy** - **(M Pharm) is a 2-year post-graduate program** which is one of the pharmacy courses to enter the pharmaceutical industry. M. Pharm contains **10 specialization subjects** in (Cosmetics, Industrial pharmacy, pharmaceutical analysis, Pharmaceutical Biotechnology, Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Pharmacy practice, pharmaceutical quality assurance and Pharmaceutical regulatory affairs).

2.**MBA** - MBA in Pharmaceutical Management is a **2-year postgraduate degree course** which focuses at producing skilled professionals for managerial level positions in areas like Drug Manufacturing, Production Management, Pharmaceutical Marketing, Brand Management etc.

3.**Master of Science** - **(MS) Pharma** in Pharmaceutics is a full-time two-year post-graduate course degree offered by National Institute of Pharmaceutical Education and Research, Ahmedabad.

(D)Aboard

1.Graduate Record Exam

- **The Graduate Record Examination (GRE)** is taken by a huge number of students every year, who wish to pursue higher studies outside India after completing their undergraduate degree here.
- In (GRE), General Test for students from all over the world who wish to enroll in a master's programme, a business-specific master's programme, a JD programme, an MBA programme, or a general master's programme must take the **GRE general test.**
- The **purpose of this exam** is to evaluate a student's verbal reasoning, analytical writing, and critical thinking abilities.

2. Graduate Management Admission Test

- The **Graduate Management Admission Test (GMAT)** is a graduate admissions entrance exam designed specifically for students who want to go to graduate school for business.
- A GMAT score is often required when submitting a graduate program application for an MBA, Master of Accountancy, or Master of Finance.

(E)Marketing

1.Medical Representatives - Medical Representatives are sales people who are **brand ambassador** for their respective companies. These are the primary point of communication for pharmaceutical and medical firms as well as healthcare providers.

2. Divisional Manager - **Divisional Manager develop** a strategic direction and drive the development of their companies products. The product manager ultimately owns the product's success or failure in the market.

(F)Self-Business

1. **Chemist Shop** - A store that sells medicines and various other pharmaceutical products is known as **Chemist Shop.**

2. **Entrepreneurship** - **Entrepreneurship** is generally associated with the establishment of community pharmacy and business management.

(G) Pharmacist

1. **Hospital Pharmacist** - Hospitals have a pharmacy department which are **controlled** and **managed by a pharmacist.** They undertake responsibility for stock control, storage, placing orders, labelling and financial budgeting and account keeping for the dispensary.
2. **Clinical Pharmacist** - Clinical pharmacist is a branch of pharmacy that involves the **provision of patient care** with the use of medications to optimize the health outcomes of patients. This includes promoting wellness and preventing disease.
3. **Community Pharmacist** -Community pharmacist, also known as **retail pharmacist**, is the most common type of pharmacy that allows the public access to their medications and advice about their health. They help in **managing inventory** and **storage of medicines** and allied products.

(H) Industrial Jobs

1. Production and Manufacturing

- A production pharmacist in the **pharmaceutical industry** is responsible for overseeing the production of pharmaceutical products, including ensuring that products are manufactured according to **good manufacturing practices (GMP)** and other regulatory guidelines.
- Pharmacist work as a trainee, chemist, production executive, Officer, Manager, director, Vice president, President in production of bulk drugs and dosage form.

2. **Research and Development** - The areas of research include **New Drug Discovery Research (NDDR),** Process Development, Formulation and Development. Standardization of dosage etc.

✓ **Formulation** - Pharmaceutical formulation is the **multistep process** where the active drug is mixed with all other components by considering the factors of particle size, polymorphism, pH, and solubility and becomes the final beneficial medicinal product.

✓ **Bulk drugs** - A bulk drug, also known as an **Active Pharmaceutical Ingredient (API)** is the chemical molecule in a pharmaceutical product that lends the product the claimed therapeutic effect

3. Quality Assurance

- **Quality assurance (QA)** is any systematic process of determining whether a product or service meets e specified requirements.

4. Quality Control

- Quality Control (QC) is a procedure or **set of procedures** that ensure that a manufactured product specified to a defined set of quality criteria or meets the requirements of the client or customer.
- **Chemist are responsible for** the biological and chemical testing of product, raw, material and intermediate product

5. Packaging Sector –

- The **personnel are responsible for** proper packing, recording, unacceptable wastage, proper cleaning and delay in the work process due to negligence.

6. Regulatory Sector –

- **Regulatory professionals** help to ensure that the public has access to safe and effective drugs.
- They make sure that drugs meet certain federal and state guidelines.
- The work that **pharmaceutical regulatory professionals** do is vital and has a range of implications.

(I)Other Opportunity

1. Medical Coding

- Medical coding analyzes **medical records** and identifies **documentation deficiencies.** It serves as resource and subject matter expert to other coding staff.
- It **reviews and verifies documentation** supports diagnoses, procedures and treatment results.

2. Pharmacotherapy –

- **Pharmacotherapy** is the treatment of health conditions by using pharmaceutical products (drugs).
- Pharmacotherapy involves replacing the drug of dependence with a legally prescribed substitute.

3. Internet Pharmacy –

- An **Internet Pharmacy**, or **online pharmacy**, or **mail-order pharmacy** is a pharmacy that operates over the Internet and sends orders to customers through mail, shipping companies, or online pharmacy web portal.

4. Military Pharmacy –

- A pharmacist in the military is responsible for **ensuring enlisted members in all military branches** receive medication and therapy treatments. Pharmacists also offer services to retired personnel with chronic health situations resulting from their active duties.

5. Pharmacovigilance

- Pharmacovigilance is the **science and activities** relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.
- The word **"pharmacovigilance"** is derived from **Pharmakon** (means drug) and **vigilar** (to keep watch).

6. Veterinary Pharmacy –

- Veterinary pharmacy is a **field of pharmacy practice**, in which veterinary pharmacists may compound medications, fill prescriptions, and manage drug therapies for animals.

7. Medical Transcription –

Medical Transcription is the manual processing of voice reports dictated by physicians and other healthcare professionals into text format. This field gives you an **opportunity to earn** and **gain more experienced** and to become a good medical transcriptionist.

1.4 PHARMACOPOEIA

❖ **Definition**

- The Pharmacopoeia derived from the **Greek** word **'Pharmakon'** means **'drug' and 'poeia'** means **'make'**.

1.4 PHARMACOPOEIA

- **Pharmacopoeia** is a book describing drugs, chemicals, and medicinal preparations especially one issued by an officially recognized authority and serving as a standard.
- These **regulations are presented in** separate articles, general and specific, relating to individual drugs, and are published in the form of a book called a Pharmacopoeia.
- Pharmacopoeia is an official book **published by the Ministry of Family and Health Welfare** containing the approved list of drugs with description, preparation, tests for identification, purity & potency.
- The head office of Indian Pharmacopeia Commission is situated at **Ghaziabad**.

❖History of pharmacopoeia

- **Pharmacopoeia Augustana** was probably the first Pharmacopoeia which appeared in 1601. It was the official pharmacopoeia of **Augsburg in Bavaria**.
- **Edinburgh Pharmacopoeia** was published in 1699 by college of physicians Edinburgh.
- **Dublin- Pharmacopoeia** published by college of physicians for the first time in 1809 and its first publication in English was published in 1850.
- **Pharmacopoeia Londinensis** published in 1918 by college of physicians written entirely in Latin.
- Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published first edition of IP in 1955.
- First official Pharmacopeia of India appeared in 1868 which was edited by **Edward John Waring**.
- The **first British Pharmacopoeia** (B.P.) was published in 1864. It includes monographs on benzoic acid, gallic acid, tartaric acid, tannic acid, camphor, lactose, sucrose.

- The first **United State Pharmacopoeia** (U.S.P.) was released on **15th December, 1820.**

✓ Monographs

Official drugs and other details about them are gives in **"Monographs".** Pharmacopeial monographs give the following details, in the order given below:

- Name of the drug (Main Title).
- Other names of the drug (Subsidiary Titles).
- Chemical formula, Molecular weight and Systematic chemical name.
- Standards of purity or strength.
- **Description** - Gives details about appearance, odor and taste.
- Solubility in various solvents.
- **Identification** - Gives specific tests.
- **Tests of Purity** - Gives maximum limit of impurities that may be present in drug.

❖ Classification of Pharmacopoeia

1. **Official Compendia:** These are the **collections of the drug** and other **related substances** which are categorised as good standard of purity, quality and strength by a government.
2. **Non-Official Compendia:** These are the books which are **used as secondary reference sources** for drugs and other related substances.

❖ Objectives of Pharmacopoeia

- Each country has its own pharmacopoeia to maintain **the uniformity** and **standard of drugs in country.**

- **Pharmacopoeia** is used to avoid the adulteration of drug.
- It provides all the information about the **drug in monograph.**
- Its standard is applied throughout **the shelf life of dosage form.**
- It solves the **dispute** and **conflicts about drug** and medicinal product.
- It **plays important role** in generic drug manufacturing, contract research and production for export purpose.
- It is amended time to time in the form of addenda where monograph can be added and outdated can be removed.
- It is used in laboratory, industry, academic institution.

❖ **Types Of Pharmacopoeias**

Fig 1.3 Types of Pharmacopoeias

1.4.1 Indian pharmacopoeia

✓ **History of Indian Pharmacopoeia**

- The **Indian pharmacopeial list 1946** was prepared by the department of Health, Government of India.
- Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the **ministry of Health and Family Welfare** which sets standards for all drugs that are manufactured, sold and consumed in India.

- The IPC was formed according to the **Drug and Cosmetics Act 1940** and established by executive orders of the **gov. of India in 1956.**
- The actual process of publishing the first Indian Pharmacopoeia started under the Chairmanship of **Col. R. N. Chopra.**

Table 1.4: Different Edition of Indian Pharmacopoeia

EDITION	SUPPLEMENT	FEATURES
1st - 1955	1960	• Covers 986 monographs • Titles of monograph in Latin language • Weight and measure in metric system
2nd - 1966	1975	• Titles of monograph in Latin language given in English • New analytical technique was added
3rd. - 1985 (2 Volume)	1989 and 1991	• Dissolution had been added • Microbial limit test prescribed for liquid preparation • Flame photometry electrophoresis, fluorometry was added
4th - 1996 (2 Volume) (Blue)	2000, 2002 & 2005	• Computer generated formulae was used • IR and UV spectrophotometry test was added • Contain 1149 monographs and 123 appendices
5th - 2007 (3 Volume) (Blue)	2008	• Volume one contains general notice, structure of I PC • Volume two contains general monographs • Volume three contains vaccines, immunosera for human use.
6th – 2010 (3 Volume) (Blue)	2012	• Products of biotechnology, herbal products were added • Antiretroviral drug was added
7th- 2014 (4 Volume) (Red)	2015 and 2016	• Contain 2567 monographs • Radiopharmaceutical monographs was added

8th – 2018 (4 Volume) (Orange)	2019	• General chemical test and TLC were eliminated • More specific test like IR, UV Spectrophotometer was added • Pyrogen test replaced by Bacterial Endotoxin Test
9th - 2022 (Orange)		• Launched in 1st July 2022 at Vigyan Bhawan, New Delhi • 92 new monographs including 60 Chemical, 21 Vitamins, Minerals, Amino acids, Fatty acids etc. • This has led to the total number of 3152 monographs in the current edition of IP.

✓ Salient Features of Indian Pharmacopoeia

I. I.P 1st edition - 1955

1. 1st edition of IP was published under the chairmanship of **Dr. B. N. Ghosh.**
2. It was published in **1955** and written in **English**.
3. The official titles of the monographs are given in Latin and covered total **986 monographs**.
4. It includes crude drugs, chemicals, biological and several formulae.

II. I.P 2nd edition - 1966

1. 2nd edition of IP was published under the chairmanship of **Dr. B. Mukherjee.**
2. 2nd edition of IP consists of **274 monographs** from I.P 1955 and its supplement of 1960 were deleted in the second edition of I.P.
3. In the 2nd edition of I.P **93 new monographs** were added.
4. The supplement to this edition was published in 1975 and it contains **126 new monographs** and **250 monographs** were amended.

III. I.P 3rd edition – 1985

1. 3rd edition of I.P was published under the chairmanship of **Dr. Nityanand.**
2. It has been published in **1985** in 2 volumes along with 9 appendices.
3. **261 new monographs** were added.
4. IUPAC system of nomenclature of organic chemical drugs has been used.
5. Pharmaceutical containers, water for pharmaceutical use and pharmaceutical aids and some oral liquid preparations, analysis of biological assay have been annexed.

IV. I.P 4th edition - 1996

1. It contains **1149 monographs** and 123 appendices & available in 2 volumes.
2. It included 294 new monographs and 110 included in edition were deleted.
3. The **computer-generated structural formula** has been introduced.
4. A number of general monographs e.g., eye drops, eye ointment nasal preparations, oral liquids, pessaries, suppositories etc have been included.
5. After the publication of 4th edition Indian Pharmacopoeia in 1996, **two addendum was published**
   Addendums 2002
   Addendums 2005

V. I.P 5th edition - 2007

- The Indian pharmacopoeia 2007 was published in **3 volumes**.
  - **Volume 1** contains the general notes, preface, and the structure of the I.P.C.
  - **Volume 2** deals with the general monograph on the drug substance, dosage forms and pharmaceutical aids.

- **Volume 3** contains aids, vaccines, immunosera for human use herbs and herbal product contains monographs on the drug substance, dosage forms, pharmaceuticals, blood and blood related products.

2. **General chemical tests** for identification have been almost eliminated and more specific infrared and ultra violet spectrophotometric test has been given.
3. **Test for Pyrogen, abnormal toxicity** is confined in this edition.

VI. I.P 6th edition - 2010

1. This pharmacopoeia is presented in 3 volumes.
   - **Volume 1st** contain notices, structures of I.P.C, acknowledgement, introduction and general chapters.
   - **Volume 2nd** contains general notice, general monograph on dosage form, & monograph on drug substance, dosage form and pharmaceutical aid (A to M).
   - **Volume 3rd** contains monographs on dosage forms (N to Z) followed by Monograph on vaccines, herbal products, blood and blood related products, biotechnology products and veterinary products.
2. A **chapter on NMR** is added in appendices.

VII. I.P 7th edition - 2014

1. The Indian pharmacopoeia was published in **four volumes**.
2. It consists of **2548 monograph of drugs**, out of which 577 are new monographs consisting of APLS, excipients, dosage forms and herbal products.
3. Accordingly, it has **19 new chapters** based on current technologies used by the stakeholders and harmonized with other international pharmacopoeias; like mass spectroscopy, inductively coupled mass spectroscopy and polymorphism etc.

4. It has **more essentials monographs**; crude herbal drugs and their extracts have been incorporated.

5. **IP 2014 contains** new chemical monographs, new herbal monographs, new human vaccines monographs, radiopharmaceutical monographs, revised monographs, revised tests, and new IR spectra.

VIII. I.P 8th edition - 2018

1. The IP has been released in **2018 by C K Mishra**, Secretory Union Ministry of Health.
2. The Indian pharmacopoeia was published in **four volumes**.
3. It is of orange color. IP-2018 has been brought out in 4 Volumes incorporating **220 new monographs** that is **170 Chemical Monographs**, **15 Herbal Monographs**, **10 Blood and Blood related products**, **2 Vaccines** and Immunosera for Human use monographs, **3 Radiopharmaceutical monographs**, **6 Biotechnology** Derived Therapeutic Products, **14 Veterinary monographs**.

IX. I.P 9th edition - 2022

1. The 9th edition was launched in 1st July 2022 at Vigyan Bhawan, New Delhi by **Union Minister for Health and Family Welfare and Chemicals and Fertilizers.**
2. **Dr. Mansukh Mandaviya** was chairman of IPC Conference 2022 and released 9th edition of Indian Pharmacopoeia.
3. IP 2022 contains a total of 92 new monographs including 60 Chemical, 21 Vitamins, Minerals, Amino acids, Fatty acids etc,3 biotechnology-derived therapeutic products, 4 human vaccines, 2 blood and blood related products, 2 herbs and herbal related products, and 7 phytopharmaceutical ingredient category monographs.

4. It includes **92 new monographs for drugs**, 12 new general chapters, monographs for active pharmaceutical ingredients (APIs) as well as dissolution specifications for all prolonged release formulations.

1.4.2 British Pharmacopoeia

✓ Introduction and History of British Pharmacopoeia

- The British Pharmacopoeia (BP) is the **National Pharmacopoeia** of the United Kingdom. It is an annually published collection of quality standard for UK medicinal substances, which is used by individuals and organizations involved in pharmaceutical research, development, manufacture and testing.
- First **"Pharmacopoeia Londinensis"** was published in Britain in year 1684.
- First **"Edinburgh Pharmacopoeia"** was published in 1699 and the last in 1841.
- First **"Dublin Pharmacopoeia"** in 1807 and the last in 1850.

✓ Monographs

- In **BP 2007 monographs** has been introduced for material specifically used in preparation of Traditional Chinese Medicines.
- The term **"Prolonged release"** has been replaced with the term **"Slow"** and the term **"Gastro-resistant"** has been replaced with "Enteric coated" in number of monographs.
- BP 2007-2009 were given in 06 Volumes i.e., **Vol. I to Vol. VI**.

Table 1.5: Different volume of BP 2007-2009

VOLUME	CONTENT
Volume I and II	Medicinal substances
Volume III	• Formulated preparations • Blood related products • Immunological products • Homeopathic preparations
Volume IV	• Appendices • Infrared reference spectra • Index
Volume V	British Pharmacopoeia (Veterinary)
Volume VI	British Pharmacopoeia (Veterinary) British Pharmacopoeia

- **BP 2016** includes almost **4,000 monographs** which are legally enforced by the Human Medicines Regulations 2012, and becomes legally effective on 1st January 2016.
- **BP 2022** contains 25 new BP monographs, 38 new Ph. Eur. monographs.133 amended BP monographs.
- **BP 2023** contains 23 new BP monographs, 59 new Ph. Eur. monographs.151 amended BP monographs.

✓ **Edition of BP**

- 1st edition of BP was published in **1864** and consist of two sections **(a) Part I- Materia Medica (b) Part II- Preparation & compounds**
- 2nd edition of BP was published in **1867**
- 3rd edition of BP was published in **1885**
- 4th edition of BP was published in **1898**
- 5th edition of BP was published in **1914**
- 6 th edition of BP was published in **1932**
- 7th edition of BP was ready in **1946** but not published until **1948**

- 8th edition of BP was published in **1953**
- 9th edition of BP was published in **1958**
- 10th edition of BP was published in **1963**
- Titles of drugs & preparations were in English instead of Latin and metric system.

- The latest edition of British Pharmacopoeia (BP) **2022** and **2023** is the most comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products.

✓ **Salient features of British Pharmacopoeia**

- British Pharmacopoeia includes **30 new BP monographs, 20 new monographs.**
- It includes around 4000 monographs including BP (veterinary) and all **European Pharmacopoeia** monographs. It amended 171 BP monographs.

1.4.3 United States Pharmacopeia

✓ **Introduction and History of United State Pharmacopoeia**

- The **United States Pharmacopeia** is a pharmacopeia for the United States published annually by the United States Pharmacopeia Convention, a non profit organization that owns the trademark and also owns the copyright on the pharmacopeia itself. **1820:** The first edition of USP was published by United States Pharmacopeial Convention on **December 15th, 1820** in both Latin and English language.

- **1830:** The 1st revision of USP was published in 1830 and **was resolved to revise USP** at 10 years intervals.
- **1850:** In 1850, the colleges of pharmacy in USA were invited to participate in revision of USP.
- **1860 and 1860: USP 4th** and **USP 5th** edition were published which includes newer medicines and remedies.
- **1880 and 1890: USP 6th** and **USP 7th** editions were published respectively.
- **On 5th July 1974,** unification of USP and NF was announced.
- **1995:** The first edition of USP23-NF18 was published in 1995 and its **10th supplement** was published in 1999.
- **2019:** USP43-NF38 was published in 2019 and includes more than 5000 monographs for finished drug products.
- **2023:** USP46NF41 was published in 2023 and was the latest edition that *contains* procedures, tests and acceptance of criteria that help ensure identity, strength, quality, and purity articles.
- USP covers all the drug substances and drug product and NF covers only pharmaceutical ingredients. Since **1940**, it is revised after every 5 years.

✓ **Salient features of United State Pharmacopoeia**

- USP was earlier revised every **10 years but after 1940**, the convention decided that it must be revised after every 5 years.
- Interim supplements were issued whenever necessary to maintain satisfactory standards.
- USP XIX (1975) was the last USP to be published individually as subsequent editions were published in combination with the **National Formulary.**

1.4.4 National Formulary

✓ Introduction and History of National Formulary

- A NF contains a **list of medicines** that are approved for prescription throughout the country, indicating which products are interchangeable.
- **It includes** key information on the composition, description, selection, prescribing, dispensing and administration of medicines.
- **1960:** The 1st edition of National Formulary was published by the Government of India, Ministry of Health.
- **1966:** The 2nd edition of National formulary committee was published by the chairmanship of Dr. B. B. Yodh consulting physician.
- **1979:** The 3rd edition of National Formulary was published.
- **2011:** The 4th edition of National Formulary was published with large numbers of additions and deletions.
- **2016:** The 5th edition of National Formulary was published to promote the rational use of medicine in India.
- **2021:** The 6th edition of NFI has been drafted by adopting the principle 'do not miss critical and do not overload' the information by revising the appendices, chapters and drug monographs.

✓ Salient features of National Formulary

- **NF contains 521 drug monographs**, 20 immunological, 12 vitamins, 8 drug monograph.
- It provides practical clinical information like schedule **H and H1 drugs**, their indication, availability, dose, precautions, adverse effects.
- It contains 22 appendices, focused on Adverse Drug Reaction reporting and causality assessment drug causing severe allergic reactions, drug banned in **India since 2008, NLEM 2011**.

1.4.5 Extra pharmacopoeia (Martindale)

✓ Introduction and History of Extra Pharmacopoeia

- **Martindale contains information** on drugs in clinical use worldwide, as well as selected investigational and veterinary drugs, herbal and Complementary medicines, pharmaceutical excipients, vitamins & nutritional agents, vaccines, radiopharmaceuticals, contrast
- It is published by the **Royal Pharmaceutical Society of Great Britain** a by William Martindale.
- It aims to provide practicing pharmacists and physicians with up-to-date information on all drug substances, official, unofficial & propriety that are currently used in pharmacy.

- It aims to provide practicing pharmacists and physicians with up-to-date information on all drug substances, official, unofficial & propriety that are currently used in pharmacy.
- There were 40 editions of 'Martindale'.
- **1883:** 1st edition of Martindale was published.
- **2014:** 38th edition was published in 2014.
- **2020:** Latest edition (40th edition) of Martindale was published and includes over 6,300 drug monographs (and over 7,500 online, accessible via a Medicines Complete subscription) and over 185,000 pharmaceutical preparations.

✓ Salient Features of Extra Pharmacopoeia

- **Monographs on drugs and ancillary substances**, listing over 6,400 monographs arranged in 49 chapters based on clinical use with the corresponding disease treatment reviews.
- A chapter on supplementary drugs and other substances **covers monographs on new drugs**, those not easily classified, herbals, and drugs no longer clinically used but still of interest. Monographs of some toxic substances are also included..