UNIT

1

History of the Profession of Pharmacy in India in Relation to Pharmacy Education, Industry, Pharmacy Practice, and Various Professional Associations

The history of pharmacy can be traced back thousands of years, with its origins deeply intertwined with the development of medicine and human civilization.

Ancient Times

Early civilizations in Mesopotamia, Egypt, and China, documented the use of various medicinal plants and herbs for treating diseases and ailments. The Ebers Papyrus, an ancient Egyptian medical text from around 1500 BCE, contains a wealth of information on pharmaceutical preparations and medicinal plants.

In India, the practice of Ayurveda, an ancient system of medicine, included the use of herbal remedies and the compounding of medicinal preparations.

Greek and Roman Period

The Greek physician Hippocrates, known as the 'father of Medicine', emphasized the importance of observing patients and using natural remedies for treatment. The Greek physician Galen made significant contributions to the pharmacy by developing pharmaceutical preparations and compounding techniques.

The Roman Empire established a network of pharmacies known as 'tabernae,' where drugs and medicinal preparations were dispensed.

Middle Ages

The Middle Ages saw the decline of pharmacy and the dominance of herbal medicine. Monasteries played a significant role in preserving medical and pharmaceutical knowledge during this period. Arab and Islamic civilizations made significant contributions to the pharmacy, translating and expanding upon Greek and Roman works.

Renaissance and Enlightenment

The Renaissance period marked a revival of scientific inquiry and the study of medicine and pharmacy. Pharmacopoeias, official books containing information on medicinal substances and preparations, were published during this time. The Enlightenment era brought about advancements in chemistry, leading to a better understanding of the chemical properties of drugs.

19th Century

The 19th century witnessed the emergence of scientific pharmacy and the development of professional organizations. The establishment of the American Pharmaceutical Association (1852) and the Pharmaceutical Society of Great Britain (1841) marked the professionalization of pharmacy.

20th Century and Beyond

The 20th century brought significant advancements in pharmaceutical research, drug development, and manufacturing processes. The discovery of antibiotics, vaccines, and other life-saving medications revolutionized healthcare.

Regulatory bodies and laws governing the quality, safety, and efficacy of drugs were established worldwide. Pharmacy education and training programs expanded, leading to the professionalization of the field.

THE HISTORY OF THE PROFESSION OF PHARMACY IN INDIA

The history of the profession of pharmacy in India dates back thousands of years. Here is a brief overview of the key periods and developments:

- *Ancient India:* The practice of pharmacy in ancient India can be traced back to the Vedic period (1500–600 BCE). Ayurveda, the traditional Indian system of medicine, played a significant role in shaping the concepts and practices of pharmacy. Medicinal herbs and plants were extensively used, and knowledge of their properties and preparation methods was documented in texts such as Charaka Samhita and Sushruta Samhita.
- *Buddhist and Jain Periods:* During the Buddhist and Jain periods (6th century BCE to 5th century CE), the use of medicinal plants continued to be prominent. Monasteries and universities played a key role in preserving and disseminating knowledge related to pharmacy.
- *Islamic Influence:* With the arrival of Islamic rulers in India, particularly during the Delhi Sultanate and Mughal Empire (13th to 18th centuries), the Unani system of medicine gained prominence. Unani medicine combined Greek, Persian, and Indian knowledge and emphasized the use of herbal remedies, minerals, and animal-derived substances. The establishment of Unani hospitals and dispensaries contributed to the growth of pharmacy practice.
- *Colonial Era:* The arrival of European powers, especially the Portuguese, Dutch, French, and British, in the 15th century marked a new phase in the history of pharmacy in India. The British East India Company established trading posts and introduced Western medicine. Western-style pharmacies were established, and indigenous practitioners had to adapt to the changing landscape.

Pharmacy Education

Pharmacy education in India can be traced back to ancient times when knowledge of medicinal plants and their preparations was passed down through traditional systems of medicine such as Ayurveda and Unani. Formal education in pharmacy started in the early 20th century with the establishment of the Banaras Hindu University College of Pharmacy in 1932, followed by other colleges and universities offering pharmacy programs. The Pharmacy Act of 1948 led to the establishment of the Pharmacy Council of India (PCI),

which is responsible for regulating pharmacy education in the country. The PCI sets standards for pharmacy curriculum, approves pharmacy colleges, conducts inspections, and grants licenses to pharmacists.

Over the years, the number of pharmacy colleges and the scope of pharmacy education have expanded significantly. Today, there are numerous diploma, undergraduate (B Pharm), postgraduate (M Pharm), and doctoral (Pharm D) programs offered by various institutions across India.

Pharmacy Organizations

Professional pharmacy associations started to emerge in the early 20th century. The United Province Pharmaceutical Association (later known as the Indian Pharmaceutical Association) was established in 1937. The association played a vital role in promoting the interests of the pharmacy profession and addressing the challenges faced by pharmacists. The Drugs Act of 1940 was a significant milestone in regulating the import, manufacture, and sale of drugs in India. The act led to the establishment of the Pharmacy Council of India (PCI) in 1948, which is responsible for regulating pharmacy education and the practice of pharmacy in the country.

Pharmaceutical Industry

The pharmaceutical industry in India has a long history, dating back to ancient times when indigenous systems of medicine utilized herbal remedies and medicinal plants. With the advent of colonial rule, the influence of European medicine and the introduction of modern manufacturing techniques contributed to the growth of the pharmaceutical industry.

After India gained independence in 1947, the pharmaceutical industry witnessed significant growth. The government implemented policies to promote indigenous drug manufacturing, leading to the establishment of pharmaceutical companies and the development of a robust pharmaceutical sector.

Professional Associations

- *Indian Pharmaceutical Association (IPA):* The IPA, established in 1937, is one of the oldest professional associations in the

field of pharmacy in India. It aims to promote the interests of the pharmacy profession, encourage research and education, and facilitate networking among pharmacists.

- *Pharmacy Council of India (PCI):* The PCI, established in 1948, is the regulatory body for pharmacy education and practice in India. It sets standards for pharmacy education, maintains the pharmacy register, and regulates the pharmacy profession.
- *State-Level Associations:* Several state-level pharmacy associations exist across India, representing the interests of pharmacists at the regional level and organizing events, conferences, and professional development programs.

The pharmacy profession in India has witnessed tremendous growth and transformation in recent decades. Advances in pharmaceutical sciences, the growth of the pharmaceutical industry, and increasing recognition of the pharmacist's role in patient care have contributed to the evolution of the profession.

Today, the pharmacy profession in India is regulated by various acts, regulations, and bodies such as the Pharmacy Council of India (PCI) and the Indian Pharmaceutical Association (IPA). Pharmacists play a vital role in healthcare delivery, including the safe and effective use of medicines, patient counseling, drug information, and pharmaceutical research and development.

The history of pharmacy in India, particularly in relation to pharmacy education, industry, pharmacy practice, and professional associations, is marked by several significant developments and legislative measures. Here is a summary of the key events:

- *1930–1931:* The Indian government appointed the Drug Enquiry Committee under the chairmanship of Col RN Chopra to investigate pharmacy-related issues. The committee's report highlighted the need for a recognized specialized profession of pharmacy.
- *1935:* The United Province Pharmaceutical Association was established, which later transformed into the Indian

Pharmaceutical Association (IPA). The IPA played a crucial role in promoting the interests of pharmacists and advancing the field of pharmacy in India.

- *1937:* Prof ML Schroff initiated pharmaceutical education at the university level at Banaras Hindu University. He also started the Indian Journal of Pharmacy, providing a platform for scientific research and knowledge sharing.
- *1940:* The Drugs Bill was introduced by the government to regulate the import, manufacture, sale, and distribution of drugs in British India. This bill was eventually adopted as the Drugs Act of 1940.
- *1941:* The Drugs Technical Advisory Board (DTAB) was constituted under the Drugs Act of 1940. The Central Drugs Laboratory was established in Calcutta to ensure the quality and safety of drugs.
- *1945:* The Drugs Rules were established under the Drugs Act of 1940 to govern various aspects of drug regulation. The provisions of the Act also covered cosmetics, Ayurvedic, Unani, and Homeopathic medicines to some extent.
- *1945:* The Pharmacy Act of 1948 was published, providing a legal framework for the regulation of the pharmacy profession in India. The act established the Pharmacy Council of India (PCI) as the regulatory body for pharmacy education and practice.
- *1946:* The Indian Pharmacopoeial Committee was constituted under the chairmanship of Dr BN Ghosh. The committee published the Indian Pharmacopoeial List, which included drugs not covered by the British Pharmacopoeia.
- *1954:* The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 was enacted to prevent misleading advertisements related to drugs, including claims of cure-all remedies.
- *1955:* The Medicinal and Toilet Preparations (excise duties) Act, 1955 was introduced to enforce uniform duties on alcohol products across states. In the same year first edition of the Indian Pharmacopoeia was published, providing standards for drug quality, purity, and strength.
- *1985:* The Narcotic and Psychotropic Substances Act, 1985 was enacted to regulate and control narcotic and

psychotropic substances, addressing the issues of drug abuse and addiction.

The Government of India also controls the prices of drugs through the drugs price order, which is periodically revised.

These milestones in legislation and regulation have played a crucial role in shaping the pharmacy profession in India, ensuring the quality, safety, and accessibility of medications and promoting professional standards and ethics in pharmacy practice.

PHARMACY AS A CAREER

Pharmacy as a career offers a wide range of opportunities for individuals interested in the healthcare field. Pharmacists play a crucial role in promoting the safe and effective use of medications, providing patient care, and ensuring public health. There are various areas of pharmacy practice that pharmacists can specialize which are as follow.

1. Pharmaceutical Industries

Pharmaceutical industry offers opportunities to pharmacists of all educational levels. It provides jobs to a pharmacist in the following divisions of pharmaceutical industries:

- *Research and development (R&D):* This division focuses on discovering and developing new drugs or improving existing ones. Scientists and researchers in R&D conduct extensive studies, including preclinical testing and clinical trials, to ensure the safety, efficacy, and quality of drugs. They also explore new drug delivery methods and formulations.

  In this section following positions are available for the job:

  a. *Pharmaceutical scientist/researcher:* Conducts research to discover and develop new drugs or improve existing ones.
  b. *Formulation scientist:* Formulates and develops pharmaceutical products, ensuring their stability, effectiveness, and safety.

c. *Analytical scientist:* Performs analysis and quality control testing of pharmaceutical products to ensure their compliance with regulatory standards.
d. *Clinical Research Associate (CRA):* Coordinates and monitors clinical trials to evaluate the safety and efficacy of pharmaceutical products.

- *Manufacturing and production:* This division is responsible for the large-scale production of pharmaceutical products. It involves processes such as formulation development, drug synthesis, quality control, packaging, and distribution. Manufacturing facilities follow strict regulations to ensure the consistency, purity, and safety of the manufactured drugs. In the manufacturing sector following opportunities are:
  a. *Production supervisor:* Manages the manufacturing processes, ensuring efficient production and adherence to quality standards.
  b. *Supply chain manager:* Oversees the procurement, inventory management, and distribution of pharmaceutical products.
  c. *Quality assurance manager:* Ensures compliance with quality standards and regulatory requirements in the manufacturing process.
  d. *Packaging engineer:* Designs and develops packaging solutions for pharmaceutical products, considering safety, preservation, and regulatory compliance.
- *Quality assurance and quality control:* These divisions are responsible for maintaining and ensuring the quality of pharmaceutical products. They establish and implement quality control procedures, conduct regular inspections and audits, perform product testing, and monitor compliance with regulatory standards. Quality assurance and control departments play a critical role in upholding product quality and safety.
- *Regulatory affairs:* This division handles the regulatory requirements for drug development, approval, and marketing. Regulatory affairs professionals work closely with regulatory authorities to navigate the complex regulatory landscape, prepare regulatory submissions, and

ensure compliance with relevant laws and regulations. In the regulatory affair following posts are available:

a. *Regulatory affairs specialist:* Ensures compliance with regulatory requirements and submits applications for product approvals to regulatory agencies.
b. *Regulatory compliance manager:* Oversees regulatory compliance activities and ensures adherence to relevant regulations and guidelines.
c. *Pharmacovigilance specialist:* Monitors and reports adverse drug reactions and ensures drug safety throughout its lifecycle.

- *Medical affairs:* Medical affairs professionals work to bridge the gap between pharmaceutical companies and healthcare professionals. They provide scientific and medical information about products to healthcare providers, conduct clinical research collaborations, organize educational programs, and engage in medical communication and publications.
- *Supply chain and logistics:* This division manages the flow of pharmaceutical products from manufacturing to distribution. It involves procurement of raw materials, inventory management, logistics planning, warehousing, and coordination with distributors and retailers to ensure the timely and efficient delivery of products.
- *Pharmacovigilance and drug safety:* This division is responsible for monitoring and evaluating the safety of pharmaceutical products throughout their lifecycle. They collect, analyze, and report adverse drug reactions and other safety-related data to regulatory authorities. Pharmacovigilance ensures the ongoing safety and risk management of marketed drugs.
- *Medical affairs and scientific research:* This division focuses on scientific research, clinical trials, and providing medical expertise. Medical affairs professionals collaborate with healthcare providers, conduct clinical studies, generate scientific evidence, and provide medical information to support the safe and effective use of pharmaceutical products.

- *Marketing and market access:* This division is involved in developing marketing strategies, conducting market analysis, and ensuring market access for pharmaceutical products. They work on pricing, reimbursement, and market penetration strategies, considering regulatory, economic, and competitive factors.
- *Business development and licensing:* This division explores opportunities for collaborations, partnerships, and licensing agreements with other pharmaceutical companies. They identify potential acquisition targets, negotiate deals, and foster strategic alliances to expand the company's portfolio and market presence.
- *Regulatory compliance:* This division ensures compliance with various regulatory requirements and guidelines. They monitor changes in regulations, develop policies and procedures to meet regulatory standards, and provide training and support to ensure adherence to applicable laws and regulations.
- *Information technology (IT) and data management:* IT departments in pharmaceutical companies manage information systems, software applications, and databases to support various functions, including research, development, manufacturing, quality control, and sales. They also play a crucial role in data management, data security, and digital innovation.
- *Human resources and talent development:* This division is responsible for managing human resources, recruitment, training, and development of employees. They ensure compliance with labor laws, foster a positive work environment, and support employee growth and career progression.
- *Corporate affairs and public relations:* This division handles external communications, public relations, and corporate social responsibility initiatives. They manage relationships with stakeholders, engage with the public, and promote the company's reputation and corporate values.

2. Academics

Due to rapid growth of pharmaceutical industry and expansion of health services in the country, there is steep increase in the

number of pharmacy teaching institutions in the country. To fulfill the demand, there is a need for qualified and experienced faculty members. So, there is more scope for fresh pharmacy graduates to be absorbed as faculty members in these teaching institutions.

There are several career opportunities in academics within the field of pharmacy. Here are some common roles:

- *Faculty member/professor:* Pharmacy schools and colleges hire faculty members to teach and educate aspiring pharmacists. As a faculty member, you would deliver lectures, lead laboratory sessions, facilitate discussions, and assess students' progress. They may also be involved in research activities and scholarly work, such as publishing papers and conducting studies in area of expertise.
- *Researcher:* Many academic institutions have research departments or centers focused on pharmaceutical sciences. As a researcher, they would be involved in conducting scientific studies, developing new drugs or therapeutic approaches, investigating drug interactions, analyzing data, and publishing research findings. This role often requires advanced degrees such as a PhD or Pharm D/PhD dual degree.
- *Department chair/head:* In larger academic institutions, there are administrative positions available such as department chairs or heads. These individuals oversee the overall functioning of the pharmacy department, manage faculty and staff, develop curriculum, and contribute to strategic planning and decision-making.
- *Preceptor/supervisor:* Academic institutions often collaborate with healthcare facilities and community pharmacies to provide experiential education to pharmacy students. As a preceptor or supervisor, they would guide and mentor students during their pharmacy practice experiences, ensuring they gain practical skills and knowledge in a real-world setting.
- *Continuing education coordinator:* Many pharmacy schools offer continuing education programs for licensed pharmacists to enhance their knowledge and skills. As a coordinator, they would develop and organize these

programs, collaborate with industry experts, and ensure compliance with accreditation requirements.

- *Academic advisor:* Academic advisors play a crucial role in guiding students throughout their pharmacy education. They provide support, advice, and guidance on course selection, career paths, and professional development. They may also assist students in navigating licensing and certification processes.
- *Program director:* Some academic institutions offer specialized pharmacy programs, such as residency programs or postgraduate training. As a program director, they would oversee the development, implementation, and evaluation of these programs, ensuring they meet educational standards and prepare students for their desired career paths.
- *Curriculum development specialist:* With the evolving landscape of pharmacy practice, there is a need for professionals who can develop and update curricula to align with emerging trends and advancements in the field. Curriculum development specialists collaborate with faculty and stakeholders to design comprehensive and relevant educational programs.

3. Pharmacy

There are several different types of pharmacies that cater to specific areas of healthcare and serve distinct purposes. Here are some examples of different types of pharmacies:

- *Retail or community pharmacy:* These are the most common type of pharmacies that are located in community settings, such as drugstores or supermarkets. They provide prescription medications, over-the-counter drugs, and health-related products. Retail pharmacies also offer services like medication counselling, immunizations, and health screenings.
- *Hospital pharmacy:* Hospital pharmacies operate within healthcare facilities and are responsible for managing medication distribution within the hospital setting. They work closely with healthcare providers to ensure safe and appropriate medication use for inpatients and outpatients.

Hospital pharmacists may also participate in clinical rounds, provide drug information, and collaborate with other healthcare professionals to optimize patient care.

- *Clinical pharmacy:* Clinical pharmacies are often integrated within hospitals or healthcare institutions. Clinical pharmacists work directly with patients and healthcare teams to provide specialized pharmaceutical care. They contribute to medication therapy management, conduct medication reviews, and provide recommendations to optimize patient outcomes. Clinical pharmacists may work in specialized areas such as critical care, oncology, cardiology, or infectious diseases.
- *Compounding pharmacy:* Compounding pharmacies prepare customized medications to meet the unique needs of individual patients. They can create medications in different forms, strengths, or combinations that are not commercially available. Compounding pharmacies often cater to patients with specific requirements, such as those with allergies, paediatric patients, or individuals needing personalized formulations.
- *Specialty pharmacy:* Specialty pharmacies focus on providing medications and support services for patients with complex or chronic conditions, such as cancer, HIV/AIDS, multiple sclerosis, or organ transplants. These pharmacies offer specialized medications, patient education, and comprehensive medication management to ensure patients receive appropriate therapy and ongoing support.
- *Long-term care pharmacy:* Long-term care pharmacies primarily serve patients residing in long-term care facilities such as nursing homes, assisted living facilities, or rehabilitation centres. They provide medication dispensing services, medication management, and consultation to meet the unique needs of elderly or chronically ill patients in long-term care settings.
- *Research pharmacy:* Research pharmacists work in academic or research institutions, pharmaceutical companies, or government agencies. They conduct research studies to explore new drugs, evaluate the effectiveness and safety of medications, and contribute to scientific advancements in the field of pharmacy.

- *Nuclear pharmacy:* Nuclear pharmacists specialize in the preparation and dispensing of radioactive materials used in diagnostic imaging and nuclear medicine procedures. They follow strict safety protocols, ensure accurate dosing, and collaborate with healthcare providers to support the diagnosis and treatment of various conditions.

4. Pharmaceutical Sales and Marketing

Pharmacists can pursue careers in pharmaceutical sales and marketing, promoting and selling medications and healthcare products to healthcare professionals. They provide information on drug benefits, efficacy, and safety, and build relationships with healthcare providers.

These roles require a combination of scientific knowledge, communication skills, and business acumen. Here are some common job positions in pharmaceutical sales and marketing:

a. *Pharmaceutical sales representative:* Sales representatives are responsible for promoting pharmaceutical products to healthcare professionals, such as doctors, pharmacists, and hospital staff.
b. *Medical science liaison (MSL):* MSLs are field-based professionals who serve as scientific experts and provide clinical and scientific support to healthcare professionals.
c. *Product manager:* Product managers oversee the marketing and promotion of specific pharmaceutical products.
d. *Marketing manager:* Marketing managers have a broader role in planning and executing marketing initiatives for pharmaceutical products or therapeutic areas.
e. *Market research analyst:* Market research analysts collect and analyze data to assess market trends, customer preferences, and competitive landscapes.
f. *Brand manager:* Brand managers are responsible for managing the branding and positioning of pharmaceutical products.
g. *Market access manager:* Market access managers focus on ensuring that pharmaceutical products are accessible to patients through reimbursement, pricing, and regulatory strategies.

5. Jobs

Government job opportunities in the field of pharmacy are available in various sectors and departments. Here are some common government job opportunities for pharmacy graduates:

- *Drug inspector:* Drug inspectors work under the regulatory authority to ensure compliance with drug laws and regulations. They inspect manufacturing facilities, review drug samples, and monitor the quality and safety of pharmaceutical products.
- *Pharmacist in government hospitals:* Pharmacists play a crucial role in government hospitals by dispensing medications, providing drug information, and monitoring patients' medication therapies. They work closely with healthcare professionals to ensure safe and effective use of medications.
- *Research scientist:* Government research organizations and institutes hire pharmacy graduates as research scientists. They conduct research on drug development, formulation, drug delivery systems, and other areas of pharmaceutical sciences.
- *Drug control officer:* Drug control officers are responsible for enforcing drug laws and regulations. They conduct inspections, investigate illegal drug activities, and collaborate with law enforcement agencies to control the illicit drug trade.
- *Pharmacovigilance officer:* Pharmacovigilance officers monitor and report adverse drug reactions and ensure the safety of drugs in the market. They work in government agencies responsible for drug safety and regulatory affairs.
- *Government analyst:* Government analysts work in laboratories and testing facilities to analyze drugs and pharmaceutical products for quality control purposes. They perform tests, verify compliance with standards, and generate reports.
- *Central and state government health departments:* Various central and state government health departments hire pharmacists for public health programs, drug distribution, and pharmacy services in government healthcare facilities.

PHARMACOPOEIA

The books containing the standards for drugs and other related substances are known as pharmacopoeia and formularies, collectively these books are known as the drug compendia.

The pharmacopoeias or formularies contain a list of drugs and other related substances regarding their source, descriptions, standards, tests, formulae for preparing the same, action and uses, doses, storage conditions etc.

These books are prepared under the authority of the government of the respective countries. The word 'pharmacopoeia' is derived from the Greek words '*pharmacon'* meaning 'drug' and '*poieo'* means 'make'. Literally it means that it is a list of medicinal substances, crude drugs and formulae for making preparations from them.

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

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

Classification

The drug-compendia are classified as:

- Official compendia
- Non-official compendia

1. *Official compendia:* Official compendia are the compilations of drugs and other related substances which are recognized as legal standards of purity, quality and strength by a government agency of respective countries of their origin. These are:
   - British Pharmacopoeia (BP)
   - British Pharmaceutical Codex (BPC)

- Indian Pharmacopoeia (IP)
- United States Pharmacopoeia (USP)
- National Formulary (NF)
- The State Pharmacopoeia of USSR

2. *Non-official compendia:* The book other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia. e.g.
   a. Merck Index
   b. Extra Pharmacopoeia (Martindale)
   c. United States Dispensatory, etc.

NATIONAL PHARMACOPOEIAS

National pharmacopoeias are official compendia of standards and specifications for the quality, purity, and labelling of medications used in a particular country or region. They provide guidelines and requirements for the identification, strength, dosage forms, and quality control of drugs and pharmaceutical substances. Pharmacopoeias are generally prepared under the authority of the government of the respective countries.

Example: Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia, etc.

The drugs used may vary from nation to nation so, the respective pharmacopoeia includes those drugs or dosage forms which are frequently used in that very country at that time.

INDIAN PHARMACOPOEIA

The Indian Pharmacopoeia (IP) is an official compendium of quality standards for drugs and pharmaceutical substances in India. It is published by the Indian Pharmacopoeia Commission (IPC), which operates under the Ministry of Health and Family Welfare, Government of India. The IP provides guidelines and specifications for the quality, safety, and efficacy of drugs used in healthcare.

The main objectives of the Indian Pharmacopoeia are as follows:

- *Setting standards:* The primary objective of the IP is to establish standards for the quality, purity, and strength of drugs and pharmaceutical substances used in healthcare. It ensures that the drugs produced and sold in India meet the required quality standards.
- *Ensuring safety:* The IP aims to ensure the safety of drugs by providing guidelines for the control of impurities, contaminants, and potentially harmful substances. It sets limits for heavy metals, microbial contamination, and other harmful elements to protect the health of patients.
- *Promoting efficacy:* The IP defines standards for drug potency, dissolution rates, and bioavailability. It helps ensure that drugs are effective in treating the conditions they are intended for. By providing these standards, the IP helps healthcare professionals make informed decisions about drug selection and dosage.
- *Facilitating quality control:* The IP serves as a reference for quality control laboratories, both in the government and private sector, to test and analyze drugs. It provides methods and specifications for testing drug samples to ensure their compliance with the defined standards.
- *Supporting regulatory authorities:* The IP supports regulatory authorities in their role of ensuring the quality, safety, and efficacy of drugs. It provides a basis for regulatory decisions, inspections, and approvals related to drug manufacturing, import, and sale.
- *Harmonizing standards:* The IP aligns with international pharmacopoeial standards to promote harmonization and facilitate trade in pharmaceutical products. It helps in maintaining consistency with global standards and facilitates acceptance of Indian drugs in international markets.
- *Providing information:* The IP serves as a valuable source of information for healthcare professionals, manufacturers,

and researchers. It includes monographs, general methods, and guidelines on drug quality, identification, dosage forms, and related topics.

SALIENT FEATURES OF IP

The Indian Pharmacopoeia (IP) has several salient features that distinguish it as a comprehensive reference for drugs and pharmaceutical substances in India. Some of these salient features include:

- *Standards and monographs:* The IP provides standards and monographs for drugs, excipients, pharmaceutical formulations, and herbal products. It includes detailed specifications regarding the quality, purity, strength, and identity of these substances.
- *Inclusion of herbal drugs:* The IP acknowledges the importance of traditional medicine in India by including a significant number of monographs on herbal drugs and formulations derived from Ayurveda, Siddha, and Unani systems of medicine.
- *Legal authority:* The IP is published under the authority of the Ministry of Health and Family Welfare, Government of India. It is legally enforceable and serves as a reference for the Indian pharmaceutical industry, regulatory authorities, healthcare professionals, and quality control laboratories.
- *Official compendium:* The IP is recognized as the official compendium of standards for drugs and pharmaceuticals in India. It sets the benchmark for drug quality, safety, and efficacy, and helps ensure uniformity and consistency in the pharmaceutical sector.
- *International harmonization:* The IP aligns with international pharmacopoeial standards, particularly those of the Pharmacopoeial Discussion Group (PDG), which includes the pharmacopoeias of the United States, Europe, Japan, and the United Kingdom. This harmonization promotes global compatibility and facilitates the acceptance of Indian drugs in international markets.

- *Up-to-date revisions:* The IP undergoes regular updates to incorporate advancements in scientific knowledge, changes in regulatory requirements, and emerging trends in the pharmaceutical industry. These revisions ensure that the standards remain current and relevant.
- *Quality assurance:* The IP provides guidelines and methods for quality assurance of drugs, including testing procedures, reference standards, and specifications for various tests. It helps pharmaceutical manufacturers and quality control laboratories in ensuring the quality and safety of their products.
- *Reference for drug registration:* The IP serves as a crucial reference for the registration of drugs in India. It provides the necessary information and requirements for the submission of drug dossiers and facilitates the regulatory approval process.
- *Inclusion of pharmacovigilance guidelines:* The IP includes guidelines for pharmacovigilance, which focus on the monitoring and reporting of adverse drug reactions to ensure drug safety.
- *Educational resource:* The IP serves as an educational resource for students, researchers, and healthcare professionals by providing information on drug quality, standards, analytical methods, and related topics.

These salient features make the Indian Pharmacopoeia an essential tool for maintaining drug quality, ensuring patient safety, and promoting the rational use of drugs in India.

The Indian Pharmacopoeial List, 1946, was prepared by the Department of Health, Government of India.

HISTORY OF INDIAN PHARMACOPOEIA

The development of the Indian Pharmacopoeia (IP) has undergone several stages and editions over the years. Here is a timeline of the major events in the history of the Indian Pharmacopoeia:

- *1946:* The Government of India published the Indian Pharmacopoeial List, which served as an initial compilation of drugs and their standards. The committee, chaired by

Col. Sir RN Chopra, and consisting of nine other members, compiled the list of drugs. It included the following details:

- *1948:* The Government of India established the Indian Pharmacopoeia Committee, a permanent committee tasked with the preparation and maintenance of the Indian Pharmacopoeia.
- *1955:* The first edition of the Indian Pharmacopoeia (IP) was published, providing official standards for drug quality, purity, and strength.
- *1960:* A supplement to the 1955 edition of IP was published.
- *1966:* The second edition of IP was published.
- *1975:* A supplement to the 1966 edition of IP was published.
- *1978:* The Indian Pharmacopoeia Committee was reconstituted under the chairmanship of Dr Nitya Nand, Director of the Central Drug Research Institute.
- *1985:* The third edition of IP was published in two volumes, Volume I and Volume II, covering a wide range of monographs and standards.
- *1989 and 1991:* Addendum (I) and Addendum (II) to the 1985 edition of IP were published.
- *1996:* The fourth edition of IP was published, providing updated monographs and standards. It was divided into two volumes, with Volume I covering monographs from A to O, and Volume II covering monographs from P to Z, along with appendices and an index.
- *2007:* The fifth edition of the Indian Pharmacopoeia was published in 2007. It introduced expanded monographs, the extended use of chromatographic methods in assays, and provided solubility information, among other updates.
- *2010:* The sixth edition of the Indian Pharmacopoeia was published in 2010.
- *2014:* The seventh edition of the Indian Pharmacopoeia was published in 2014.
- *2018:* The eighth edition of the Indian Pharmacopoeia was published in 2018.
- *2022:* The most recent edition of the Indian Pharmacopoeia was published in 2022. It includes updated monographs, standards, and guidelines for drugs, excipients, and dosage

forms, reflecting the latest advancements in pharmaceutical sciences.

Each edition of the Indian Pharmacopoeia contains monographs for various drugs, including their chemical structures, physical descriptions, solubility, identification tests, standards, assay methods, storage conditions, and more. The appendices of the IP include additional information on tests, assays, apparatus, reference substances, reagents, and other relevant data.

The Indian Pharmacopoeia serves as a crucial reference for ensuring the quality, safety, and efficacy of drugs used in India, and it plays a vital role in the regulation of the pharmaceutical industry and pharmacy practice in the country.

IP published by the Controller of Publications, Delhi, on behalf of Govt of India, Ministry of Health and Family Welfare.

Example of a Monograph of an Official Drug

- The word '*Monograph*' means the written study of a subject. The pharmacopoeial monographs (for example in IP) give the following information about the drugs and pharmaceutical aids
- *Example monograph:* Aspirin (acetylsalicylic acid)
- *Main title:* Acetylsalicylic acid (aspirin).
- *Synonym:* None mentioned.
- *Chemical formula and molecular weight:* $C_9H_8O_4$; 180.2.
- *Category:* Analgesic, antipyretic, anti-inflammatory.
- *Doses:* The average adult dose is 300–900 mg orally every 4–6 hours, not exceeding 4 g per day.
- *Description:* Acetylsalicylic acid is a white crystalline powder with a slightly acidic taste.
- *Solubility:* Sparingly soluble in water; soluble in alcohol, ether, and fixed oils.
- *Standards:* Acetylsalicylic acid should contain not less than 99.5% and not more than 100.5% of $C_9H_8O_4$, calculated with reference to the dried substance.
- *Identification:* Specific tests are provided to confirm the identity of acetylsalicylic acid.

- *Tests of purity:* The monograph includes tests for the melting point, heavy metals, chloride, sulfate, loss on drying, and other relevant parameters.
- *Method of assay:* The assay method is described for the quantitative determination of acetylsalicylic acid in the substance or its formulations.
- *Storage:* It is recommended to store acetylsalicylic acid in a well-closed container, protected from light and moisture, and at a temperature not exceeding 25°C.
- Please note that this is a general example, and the specific monograph for acetylsalicylic acid in the Indian Pharmacopoeia (IP) may contain additional or slightly different types of information. The IP should be referred to for accurate and up-to-date monographs.

The International Pharmacopoeia

The International Pharmacopoeia is published by the World Health Organization and is particularly used in developing countries. The object of this was to provide a uniform list which would avoid the confusion caused by different national standards, strengths and names. This pharmacopoeia prepared by WHO Expert Advisory Panel on the International Pharmacopoeia.

The International Pharmacopoeia includes monographs on pharmaceutical substances, excipients, and dosage forms. These monographs provide detailed information on the identity, purity, strength, and quality control tests for each substance or formulation. The pharmacopoeia also includes general chapters that cover topics such as analytical methods, quality assurance, and packaging requirements.

- *First edition (1951):* The first edition of the International Pharmacopoeia was published in 1951. It aimed to establish a uniform list of standards, strengths, and names for drugs and pharmaceutical preparations to avoid confusion caused by different national standards.
- *Second edition (1967):* The second edition of the International Pharmacopoeia was published in 1967. It focused on quality control of pharmaceutical preparations and introduced

new analytical techniques such as infrared spectroscopy, chromatography, non-aqueous titration, and radioactivity.

- *Third edition (1975):* The third edition of the International Pharmacopoeia was published in 1975. It included updated quality specifications for essential drug substances listed in the WHO Model List of Essential Drugs.
- *Fourth edition (2003):* The fourth edition of the International Pharmacopoeia was published in 2003. It expanded the scope of quality specifications for pharmaceutical substances, excipients, and dosage forms. It also included a section on antimalarial drugs and their widely used dosage forms.
- *Fifth edition (2016):* The fifth edition of the International Pharmacopoeia was published in 2016. It introduced new monographs, updated quality specifications, and incorporated the latest scientific advancements in pharmaceutical analysis and quality control.

Extra Pharmacopoeia (Martindale)	
History	The Extra Pharmacopoeia was first produced in 1883 by William Martindale and is still known as 'Martindale'
Produced by	The Royal Pharmaceutical Society of Great Britain
Meant for	Medical practitioners and pharmacists all over the world
Sources of information	Journals and periodicals, licensed product literature, WHO publications, government reports and legislation and other official and standard publications
Contains information of	Drugs and medicines, selected investigational and veterinary drugs, herbal medicines, pharmaceutical excipients, vitamins and nutritional agents, vaccines, radiopharmaceuticals, contrast media and diagnostic agents, medicinal gases, drugs of abuse and recreational drugs, toxic substances, disinfectants, and pesticides
Monograph headings	Definitions and descriptions, pharmacokinetics, adverse effects and treatments, uses, precautions, administration, interactions, trade names of preparations
Additional information	• Disease treatment reviews that provide overviews of diseases and the choice of treatments available • Details of commercial preparations from a wide range of countries • Directory of drug-manufacturers and their addresses worldwide

The British Pharmacopoeia (BP)

The British Pharmacopoeia (BP) is an official compendium of quality standards for medicinal substances and pharmaceutical products in the United Kingdom. It provides guidelines and specifications for the identification, quality, and purity of drugs that are used in healthcare. The BP is published by the British Pharmacopoeia Commission, which is a part of the Medicines and Healthcare products Regulatory Agency (MHRA).

The British Pharmacopoeia (BP) has undergone several editions since its first publication in the 19th century. Here are some key editions of the BP:

- First edition (1864): This was the inaugural edition of the BP, published by the British Pharmacopoeia Commission. It laid the foundation for standardizing the quality and purity of medicinal substances and preparations in the United Kingdom.
  Subsequent editions: The BP has been regularly revised and updated, with new editions published approximately every ten years. Here are some notable editions:
- Second Edition (1867)
- Third Edition (1874)
- Fourth Edition (1885)
- Fifth Edition (1898)
- Sixth Edition (1907)
- Seventh Edition (1914)
- Eighth Edition (1932)
- Ninth Edition (1932)
- Tenth Edition (1948)
- Eleventh Edition (1953)
- Twelfth Edition (1963)
- Thirteenth Edition (1973)
- Fourteenth Edition (1980)
- Fifteenth Edition (1993)
- Sixteenth Edition (2013)
- Seventeenth Edition (2021)

British Pharmacopoeia (BP) and National Formulary (NF): From 1948 to 1973, the BP and the National Formulary (NF) were merged into a single publication known as the British

Pharmacopoeia and National Formulary (BP-NF). This combined the standards for drug substances (BP) and practical prescribing information (NF).

National Formulary of India

The National Formulary of India (NFI) is an official document that provides standards for the quality and therapeutic use of medicines in India. It is a reference book that contains a list of formulations, their ingredients, dosages, and other relevant information. The NFI is developed and published by the Indian Pharmacopoeia Commission (IPC), which is responsible for establishing and maintaining pharmacopoeial standards in the country.

The primary objective of the NFI is to promote the rational use of medicines and ensure their quality, safety, and efficacy. It serves as a guide for healthcare professionals, including physicians, pharmacists, and other healthcare providers, in prescribing and dispensing medications. The NFI includes a wide range of formulations, covering various therapeutic categories, including but not limited to antibiotics, analgesics, antidiabetics, cardiovascular drugs, and more.

The NFI provides detailed information about each formulation, including its composition, dosage forms, strengths, indications, contraindications, precautions, and side effects. It also includes guidelines on the appropriate use of medicines, such as dosage recommendations, administration routes, and storage conditions. The NFI helps healthcare professionals make informed decisions in selecting the right medicines for their patients based on standardized formulations and recommended dosages.

In year 1960, the first edition was published by Government of India, Ministry of Health. Union Minister for Health and Family Welfare, launched the sixth edition of National Formulary of India (NFI) on October 25, 2021.

British Pharmaceutical Codex (BPC)

The British Pharmaceutical Codex (BPC) was first published in 1907 as a reference book for medical practitioners and

dispensing pharmacists. It was created by the Council of the Pharmaceutical Society of Great Britain. In 1959, the British Pharmacopoeia Commission requested the publication of the Codex to coincide with the British Pharmacopoeia (BP) so that they would come into effect on the same date.

The BPC has some differences compared to the BP:

- It includes a larger number of drugs and preparations. Some of these may be included in advance of the pharmacopoeia, while others may have been included in previous editions of the pharmacopoeia but are now retained in the Codex because they are still commonly used.
- It provides information on the actions and uses of drugs, their undesirable effects, precautions, and the treatment of poisoning. This additional information helps healthcare professionals understand the drugs better and use them safely.
- It contains formulae, methods of preparation, container and storage conditions for many preparations that are still extemporaneously prepared in the pharmacy. This information is valuable for pharmacists who need to prepare medications on-site according to specific formulations.

Overall, the BPC complements the British Pharmacopoeia by offering additional drug information, guidance on drug actions and uses, and details on extemporaneous preparations commonly performed in pharmacies.

The United States Pharmacopoeia (USP)

The USP was originally published in 1820 under the authority of United States Pharmacopoeial Convention. The National Formulary (NF) was published in 1888 under the guidance of American Pharmaceutical Association.

In 1974, the NF was purchased by the United States Pharmacopoeial Convention and from 1980 onwards only one official book of drug standards was published under the heading The United States Pharmacopoeia and The National Formulary (USP-NF). The USPNF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). The current version, USP–NF 2023, Issue 1, was official on May 1, 2023.

The Merck Index

It is an encyclopaedia of chemicals, drugs and biologicals. The first edition was published in 1889 and the 15th and latest edition was published in year 2013 by Royal Society of Chemistry.

Some important key features about the Merck Index are:

- *Chemical and drug information:* The Merck Index contains detailed information about thousands of chemicals, drugs, and substances. It provides data on their chemical structures, physical properties, synthesis methods, therapeutic uses, toxicity, and other relevant information.
- *Reference for researchers:* Researchers often rely on the Merck Index as a trusted source of information when studying or working with specific chemicals or drugs. It helps them understand the properties, characteristics, and potential applications of these substances.
- *Drug identification:* The Merck Index is valuable for identifying unknown drugs or substances.
- *Safety and handling information:* The index includes safety and handling information for various chemicals and drugs.
- *Pharmaceutical development:* The Merck Index is useful in the pharmaceutical industry for drug development and formulation.
- *Educational resource* The Merck Index is also used as an educational resource in academic settings.
- *Updated editions:* The Merck Index is regularly updated to incorporate new compounds and discoveries.