Historical background and development of profession of pharmacy

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PHARMAKON (Greek word) ➔ Pharmacy

Pharmakon means drug/ medicine.

Pharmacy is defined as the profession which is concerned with the art and science of **Identification, Selection, Preparation, Preservation & Standardization** of suitable drug substances from natural and synthetic sources and their formulations which are meant for administration for **Diagnosis, Prevention, Treatment of diseases.**

HISTORY OF PHARMACY

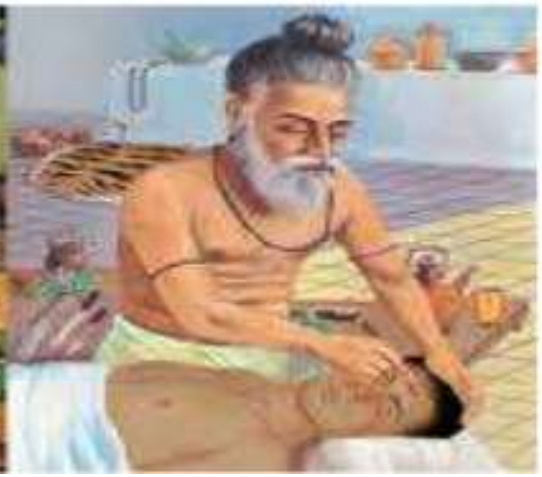
The evolution of the profession of pharmacy can be divided into five historical periods:

1. ANCIENT ERA-The beginning of time to AD 1600
2. EMPIRIC ERA-1600-1940
3. INDUSTRIALIZATION ERA-1940-1970
4. PATIENT CARE ERA-1970-present
5. BIOTECHNOLOGY AND GENETIC ENGINEERING ERA-The new horizon

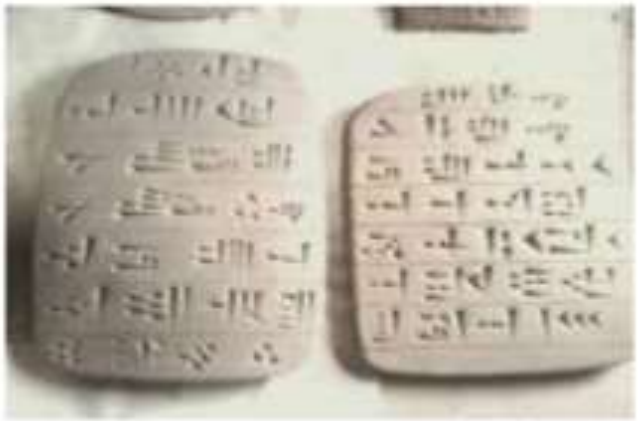
1.ANCIENT ERA

- Used leaves, mud, and cool water to stop bleeding and heal wounds
- They used these methods by observing how animals heal their wounds
- Documented experiences of healing onto clay tablets which provided the earliest known written record.
- In Babylonia the earliest record of the practice of pharmacy by the priest, pharmacist, and physician was kept. This is where the science of drugs, organized pharmacy and medicine had its beginnings.
- Chinese used herbs
- Hippocrates-The Father of Medicine
- Theophrastus-The Father of Botany-early scientist.
- Mithridates-Father of Toxicology-Studied the adverse effects of plants.

- Practised even in the ancient days but in a preliminary form.
- "Sushrutha samhitha" an ayurvedic monograph of medical substances complied in 6th century BC.(760 herbs)
- Charaka Muni(Charaka Sanhitha) **Classified herbs in 50 groups**
- Sharngadara Muni(Sharngadara Sanhitha)
- Vagbhata → Ashtanga Ayurveda- 7th century A.D



- 6th millennium BC to early 2nd millennium BC Sumerians used "Cuneiform clay tablets" to note the instructions given for the use of medicines.
- Engraving tablet an official monograph took birth before 500BC.
- 1st known trademark was 'Terra Sigillata'



- Theophrastus, a Greek philosopher around 300 BC studied plants, herbs shrubs etc.. Regarded as "Father of Botany".
- Mithridates VI contributed to Toxicology. Used to test toxins and their antidotes on himself and his prisoners. Came up with formula for universal antidote "Mithridatum"
- Egyptian medical document Papyrus Ebers and Papyrus Edwin Smith were written in 1550 BC and 16th century BC respectively. contains classification of medicaments.

- Greeks are 1st promoters of profession of pharmacy.
- Greek physician called Pedanios Diascorides wrote a book of 5 volumes on medicine & pharmacy book is translated in Latin entitled De Materia Medica it served as foundation for other books of medical profession

- Oldest Chainese literature work included a script named "Recipes for 52 Ailments" found in Mawangui tomb sealed in 168 BC.

- In Chaina during the Han Dynasty in the 1st century AD, a manuscript entitled Shennong Bencao Jing (*Divine Farmer)* dealing with medicinal substance was complied. By Shennong.
- He analysed bark, herb, root and their properties etc. Authorised the book Pen T Sao consisting about 365 drugs of natural and mineral sources.
- He considered as the Father of Chinese medicine.

- Galen (130-200 BC) was one of the greatest instructor and practitioners of medicine and pharmacy of his era in Rome.

- 1st formulated cold cream by him resembles present modernized product.
- His methods followed about 1500 years. Today also they serves as basis for preparing many medicaments.
- 1st to extract therapeutic constituents from plants. (Galenicals)

- During Islamic golden age in 754 pharmacy (Drug store) were set up 1st time in Baghdad, under the rule of Caliph Abbasid
- By 9th century pharmacy profession started. Regulated by state Govt. in Baghdad.

- Abu al- Qasim- Zahrawi (936-1013) innovated distillation and sublimation process. His manuscript named as 'Liber Servitoris'
- Sabur Ibn Sahi (689) has complied 1st Pharmacopoeia.
- Kitab al-Saydalah, the book on drugs is one of the most definite, specific best illustrated book on drug pharmacology by Al-Biruni (9973-1050)

(described drug properties, role of pharmacy & pharmacists)

- Book 'Canon of Medicine' by Ibn Sina. Explaind pharmacology of 700 medicinal preparations.

- In 10th century, in a book titled "The foundations of the true properties of remedies" by Al-Muwaffaq explained the distillation process of sea water so as to make it potable.
- Also gave information about properties of arsenious oxide combination with silicic acid.
- Informed about noxious characteristics of copper and lead compounds.

- After the fall of the Roman Empire, the division of pharmacy and medicine evolved. Three major advances in pharmacy occurred at this time:
- 1. The formulary –a continuation of the documentation of the knowledge of specific drug information to be used by pharmacists.
- 2. Dosage form-drugs were no longer harvested from herb gardens. They were incorporated into sweetened dosage forms, such as syrups, confections, and juleps, mixed with sugar and honey.
- 3. pharmacy shop-first appeared in Baghdad in about AD 762.

Between AD 1231 and 1240-The Holy Roman Emperor Frederick II issued an edict regulating medicine. For the first time, It legally recognized pharmacy as a separate profession in Western Europe.

- 1800 and early 1900's witnessed the rapid development in pharmacy field.

EMPIRIC ERA

- The Pharmacopeia became a regulatory tool for pharmacists.
- Benjamin Franklin started the first hospital in 1751. It had a pharmacy and the first hospital pharmacist was Jonathan Roberts.
- 1821 The Philadelphia College of Pharmacy was founded.
- William Proctor-The father of American Pharmacy. He devoted his time and attention to the advancement of pharmacy. He owned an apothecary shop.
- The major contribution of pharmacists to science was in the area of chemistry.

- 1st USP- 1820
- 1st pharmacy school- 1821 in philadelphia (US)
- American pharmacy association- 1852 by William Proctor. Regarded as father of pharmacy
- National Formulary-1888

- The year 1870 marked the birth of pharmacy in Madras state of India. Medical students use to practice.
- 1881 in Bengal institutes were started to train compounders.
- Banaras Hindu university started B.Pharmacy course in the year 1937 (Mahadeva lal schroff)
- Punjab university in 1944
- 1st Indian pharmacopoeia- 1955

Mahadeva Lal Schroff (1902-1971)

INDUSTRIALIZATION ERA

The development of manufacturing pharmacy began.

Rapid mass production of medicines followed.

Standardization,

biologically prepared products,

complex chemical synthesis,

increased use of parenteral medications were all part of this period.

THE PATIENT CARE ERA

- The beginning of this era concentrated on research to develop new medicines. Research on medication s was done.
- New drugs were developed. Had a lot of adverse reactions to drugs so drug review and monitoring resulted. Pharmacists began to take a more hands on role in dispensing medications and patient education.

THE FUTURE OF PHARMACY

Research in the area of biotechnology and gene therapy is being conducted.

Medications are being produced through recombinant DNA technology.

New therapies for cancer, anemia, and hepatitis are being introduced.

PHARMACEUTICAL INDUSTRY

1. Before independence
2. Post independence
3. Present scenario
4. Pharma industry in 21th century.

BEFORE INDEPENDENCE

In ancient India the sources of drugs were of vegetable, animal and mineral origin.(Ayurveda).They were prepared empirically by few experienced persons. Knowledge of that medical system was usually kept secret within a family (Folkore).There were no scientific methods of standardization of drugs.

Muslim rule in India

The Indian system of medicine declined during the Muslim rule while the Arabic or the Unani-Tibbi system flourished.

British rule in India

The western or the so-called Allopathic system came into India with the British traders who later become the rulers.

Before 1940

Initially all the drugs were imported from Europe. Later some drugs of this system began to be manufactured in this country.

Bengal Chemicals & Pharmaceuticals Ltd.
(A Government of India Enterprise)

- The beginning of the Modern Pharmaceutical Industry can be traced back to the early part of the 20th century with the starting of the 1st Indian owned drug firm.
- The "Bengal Chemical and Pharmaceutical Works" in kolkata in 1901 by Proff. P.C Ray.

1903: A small factory at Parel (Bombay) by Prof. T.K. Gujjar.

Alembic
Touching Lives over 100
Nurturing global well being...Since 1907

- 'Alembic Chemical works' was set up in 1907 in Baroda.

- Other big units during early part of century were Sarabhai Chemical works, The Bengal Immunity Laboratory and few Govt. laboratories for the manufacture of vaccines and sera.

Drugs were mostly exported in crude form and imported in finished form.

During World War-I (1914 – 1920) the imports of drugs were cut-off.

Imports of drugs were resumed after the War.

- World War-I: Simple cough syrups, tablets, capsules.

- Quinine- By Govt. in Darjeeling and Nilgiris.

- By 1930- sera, vaccines, anaesthetics like ether, chloroform, few simple drugs based on coal-tar distillation products began in the country.

- Modern drug research in India started in 1920 when Sri Ram Nath Chopra set up active centre of research on Indian medicinal plants at the school of Tropical Medicine, Kolkata.

- Dr. Upendranath Brahmachari at the Campbell Medical school, Kolkata introduced Urea Stibamine in 1922 for the treatment of Kala-azar.

- World war-II: Plant based synthetic drugs and biologics.

- Manufacture of anti dysentery drugs like Iodochlor, Chemotherapeutic drugs like Arsenical, Anti Leprotic drugs, colloidal preparations of calcium, silver Iodine etc. was started during this period.

- Production of biologics like Liver extracts, pituitary extracts, Adrenaline solution was taken up.

Manufacturer abroad took advantage of the situation. The consequences were as follows

(i) Foreign manufacturers dumped inferior quality medicines and adulterated drugs.

(ii) Markets were full of all sorts of useless and deleterious drugs were sold by unqualified men.

Examples

- Poisoning due to quinine.
- Putting of croton oil into eye instead of atropine solution.
- Selling of chalk powder tablets in place of quinine.
- Potent drugs like compounds of antimony and arsenic and preparations of digitalis were dispensed without any standard.

Few laws were there having indirect bearing on drugs, but were insufficient.

1878	Opium Act	Dealt with cultivation of poppy and the manufacture, transport, export, import and sale of opium.
1889	Indian Merchandise Act	Misbranding of goods in general
1894	Indian Tariff Act	Levy of customs duty on goods including foods, drinks, drugs, chemicals and medicines imported into India or exported there from.
1898	Sea Customs Act	Goods with 'false trade description' were prevented from importing under this act.
1919	Poisons Act	Regulated the import, possession and sale of poisons.
	Indian Penal Code	Some sections of IPC have mention of intentional adulterations as punishable offence.

Some state-level law had indirect references to drugs

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

The laws were too superficial and had indirect link to drugs.

Drug enquiry committee

Government of India on 11th August 1930 , appointed a committee under the chairmanship of Late Col. R.N.Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken.

The committee gave report in 1931 and recommended following acts to be enacted to improve pharma industry in India.

1937: Government of India brought 'Import of Drugs Bill'; later it was withdrawn.

1940: Govt. brought 'Drugs Bill'to regulate the imort, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as 'Drugs Act of 1940'.

1941: The first Drugs Technical Advisory Board (D.T.A.B.) under this act was constituted. Central Drugs Laboratory was established in Calcutta

1945: 'Drugs Rule under the Drugs Act of 1940' was established.

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

1945: Govt. brought the Pharmacy Bill to standardize the Pharmacy Education in India

1946: The Indian Pharmacopoeial List was published under the chairmanship of late Col.R.N. Chopra. It contains lists of drugs in use in India at that time which were not included in British Pharmacopoeia.

1948: Pharmacy Act 1948 published.

1948: Indian Pharmacopoeial Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.

1949: Pharmacy Council of India (P.C.I.) was established under Pharmacy Act 1948.

1954: Education Regulation have come in force in some states but other states lagged behind.

1954: Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements

1955: Medicinal and Toilet Prepartions Act 1955 was introduced to enforce uniform duty for all states for alcohol products.

1955: First Edition of Indian Pharmacopoeia was published.

1985: Narcotic and Psychotropic Substances Act has been enacted to protect society from the dangers of addictive drugs.

Govt. of India controls the price of drugs in India by Drugs Price Control Order (DPCO) changed from time to time.

- "Council of Scientific and Industrial Research" was registered in March 12, 1942 to coordinate various activities of Industrial research and development.

- Today C.S.I.R is premier research organization with 39 laboratories and 101 extension centres.

- When India became independence total production was worth of Rs.10 crores.

Post Independence development:

- Realising the crucial role of the pharmaceutical industry, the Govt. of India paid a special attention to the needs of this industry.

- In 1948, a survey was undertaken of the country's industrial potential in all the sectors and a programme of development was undertaken in the first 5 years, subsequently followed every 5 years.

Hindustan
Antibiotics LTD

- In order to reduce the dependency on imports and increase the production of Abs (specially penicillin and streptomycin) 'Hindustan Antibiotic Limited' set up in 1954 at Pimpri near Pune.

- Private enterprises were encouraged to enter into production of sulpha drugs.

- In the early 1960's, the indigenisation of the industry started with R&D collaboration b/n the industry and National Laboratories and academia.

- Indian Drug and Pharmaceutical Limited was set up by Govt. in 1964 to provide a boost to the production of bulk drugs and formulations.

In Hyderabad & Rishikesh.

- The 1970's saw an upsurge of R&D within the industry because of the encouragement provided by the Govt. to establish R&D units within the industry in the form of liberal tariff and tax concessions and financial incentives.

- Special provision given in Patent act-1970 to exclude the product patent for drugs and medicines, food and chemicals provided the right climate for innovation in the development of alternative routes for the synthesis of existing drugs.

- The 1980's and 1990's saw setup of number of manufacturing units.

- Near self-reliance was achieved in the production of bulk drugs and formulations.

Present Scenario:

- The Indian Pharmaceutical Industry, today is one of the largest and most advanced among the developing countries.

- Indian Pharmaceutical Industry today has the capability to manufacture all the needed formulations and 70% of its bulk drugs requirements.

- The Pharmaceutical industry in India is the world's third-largest in terms of volume and stands 14th in terms of value.

- According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry is US$21.04 billion.

- Mumbai, Hyderabad and Ahmedabad are the major pharmaceutical hubs of India.

- Except some Anti-cancer drugs and few antibiotics all the products are currently manufactured in India for the domestic market as well as for export.

- The value of Indian pharmaceutical market for formulation today is around 14,000 crores and is growing steadily at the rate of 13-15% /A.

- Pharmaceutical export have risen from Rs. 46 crores in 1980 to Rs. 5000 crores.

INDIAN PHARMA PRODUCTION:

1948 – 10 crores
1968 – 175 crores
1992-93 – 6,000 crores
1997 – 12,000 crores.
2008-09 – US $ 21.04 billions
2015 -- US $ 30 billions
2020 -- US $ 55 billions (estimated)

Indian pharmaceutical industry fulfills 70% of national needs.

The pharmaceutical industry in India ranks **3rd** in the world terms of volume and **14th** in terms of value.

INDIAN PHARMA EXPORTS:

The Indian Pharmaceutical Industry has witnessed a robust growth over the past few years. In the year **1990** the turnover is approximately **US $ 1 billion.**

By 2001 pharma exports growth was 20.73%.

In 2005 **GATT & TRIPS** were enacted which expanded export to Asian, Gulf countries.

In **2015** the export turnover is approximately **US $ 15 billion**. India's pharmaceutical exports stood at **US$ 16.4 billion** in **2016-17** and are expected to grow by 30 per cent over the next three years to reach **US$ 20 billion** by **2020**.

Indian Pharmaceutical Industry in the 21st Century:

- To provide healthcare for all at an affordable cost, Indian pharmaceutical industry has the obligation to discover, develop, produce and distribute new drugs for which no therapy is currently available.

- Industry has also to develop better diagnostic tools as well as prophylactics for diseases which are preventable.

Top 10 Publicly Listed pharmaceutical companies in India by Market Capitalization as of July 2015

Rank	Company	Market Capitalization 2015 (INR crores)
1	Sun Pharmaceutical	2,17,636
2	Lupin Ltd	84,193
3	Dr. Reddy's Laboratories	63,779
4	Cipla	52,081
5	Aurobindo Pharma	42,454
6	Cadila Healthcare	38,677
7	Glenmark Pharmaceuticals	29,047
8	GlaxoSmithKline Pharmaceuticals Ltd	28,587
9	Divis Laboratories	24,847
10	Torrent Pharmaceuticals	22,320

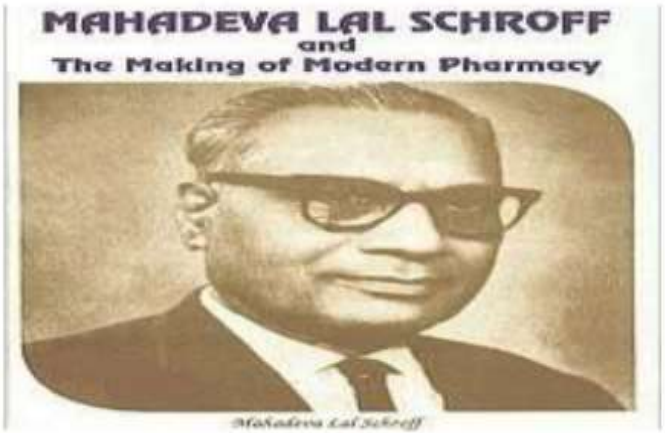
Top 20 Biotechnology companies in India,

Rank	Company
1	Serum Institute of India
2	Biocon
3	Nuziveedu Seeds Private Limited
4	Novo Nordisk
5	Syngene International
6	Reliance Life Sciences
7	Eli Lilly and Company
8	Bharat Serums
9	Biological E. Limited
10	Fortis Clinical Research

Rank	Company
11	Novozymes South Asia
12	Ankur Seeds
14	Indian Immunologicals Limited
15	GlaxoSmithKline Pharmaceuticals Ltd
13	Bharat Biotech International
16	Tulip Group
17	Hafkine Biopharmaceutical
18	Mahyco
19	Advanced Enzymes
20	Raasi Seeds

PHARMACEUTICAL EDUCATION

- In ancient times **physician** has to do diagnosis, compounding and dispensing.
- In European middle ages there were physician, **apothecaries (pharmacist)** & drug merchant (druggist- supply drugs).
- In early days pharmacy as a part of health care services was studied in medical colleges and hospitals.
- In 1870 MADRAS MEDICAL COLLEGE conducted **licentiate exam** for chemist and druggist.



Drug enquiry committee

Government of India on 11th August 1930 , appointed a committee under the chairmanship of Late Col. R.N.Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken.

This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy. A set of people known as compounders were filling the gap.

Just after the publication of the report Prof. M.L.Schroff (Prof. Mahadeva Lal Schroff) initiated pharmaceutical education at the university level in the **Banaras Hindu University.**

Other universities in India which provided pharma education were **Andhra University, Madras University, Bombay University, Punjab University and L.M. College.**

Table 1. First 10 Pharmacy Colleges/Universities Offering Degree Programs in India

Year of Inception	Colleges/Universities	Category	Current Degrees Offered
1937	Department of Pharmaceutical Engineering, Institute of Technology, Banaras Hindu University, Varanasi	Central University	BPharm, MPharm, PhD
1944	University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh	State University	BPharm, MPharm, PhD
1947	L. M. College of Pharmacy, Ahmedabad	Private College	BPharm, MPharm, PhD
1950	Department of Pharmacy, Madras Medical College, Chennai	Medical College	BPharm, MPharm
1950	Birla Institute of Science and Technology, Pilani	Private University	BPharm, MPharm, PhD
1951	College of Pharmaceutical Sciences, Andhra University, Visakhapatnam	State University	BPharm, MPharm, PhD
1952	Department of Pharmaceutical Sciences, Dr. H.S. Gour University, Sagaur	Central University	BPharm, MPharm, PhD
1956	Department of Pharmaceutical Sciences, Nagpur University, Nagpur	State University	BPharm, MPharm, PhD
1958	Pharmaceutical Department, University Institute of Chemical Technology, Mumbai University, Mumbai	State University	BPharmSci, MPharmSci, PhD (Tech)
1963	Department of Pharmaceutical Technology, Jadavpur University, Kolkata	State University	BPharm, MPharm, PhD

Pharmacy Council of India (PCI)

Introduction

Pharmacy Act, 1948 was passed by the Central Government for the constitution of Pharmacy Council of India (PCI) which was constituted on March 9, 1949 to ensure uniform education and training to individuals throughout the country who are interested in the profession of pharmacy.

Objectives

- To regulate the pharmacy education in the country
- To allow the registration as a pharmacist under the pharmacy Act
- To regulate the profession and practise of pharmacy

- In **July 1937** pharmaceutical education was started in India.
- In 1953 PCI developed Education Regulation **(ER-53)** stating that minimum qualification for registration as pharmacist is

10^{th} + 2 yr D-Pharm + 1 yr experience.

- To increase professional standards patient oriented subjects like health education, community pharmacy, hospital pharmacy and business management were added.
- In 1991 PCI developed Education Regulation **(ER-91)** stating that minimum qualification for registration as pharmacist is

10^{th} +2yr intermediate + 2 yr D-Pharm.

- In 2001 PCI developed Education Regulation (ER-2001) to improve pharmacy education to world standards.
- According to **ER-2001** the minimum qualification for registration as pharmacist is **10^{th} +2yr intermediate + 4yr B-Pharm**. But, till date this regulation has not got clearance from Indian government.
- The pharmacy degree programs offered in India include:

(D. Pharm), (B. Pharm), (M. Pharm), (PharmD),

Master of Science in Pharmacy **[MS (Pharm)]** and

Master of Technology in Pharmacy **[MTech (Pharm)],**

Doctor of Philosophy in Pharmacy **(PhD)** .

Integration of two courses like **B. Pharm+MBA** or **M. Pharm+MBA** has also been initiated by some institutions

➢Until the early **1980's**, only 11 universities and 26 colleges offered pharmacy degree programmes in India.

➢Currently, there are more than **1500 institutions** with an annual enrolment of around 1,00,000 students.

Year	No. of colleges	No. of students
2005- as per PCI	220	12,506
2005- as per AICTE	445	24,672
2007	854	52,000
	583 (D-Pharm)	34,000

➢There are six **National Institutes of Pharmaceutical Education and Research (NIPERs)** these are the prime institutions in the country for pharmaceutical education and research

PHARMACY as CARRER

Production & Manufacturing

A B. Pharm graduate has a lucrative career in the production of pharmaceutical products

Formulation Development

A B. Pharm graduate plays a significant role in the formulation of an accurate dosage form

Quality assurance & Quality Control

The success of any Pharmaceutical industry is in the quality of its products which lies in the hands of a B.Pharm graduate

Drug Regulatory Affairs

A B.Pharm graduate is the minimum eligibility for governing the laws and regulations such as the Federal Food Drug and Cosmetics Act, Patents, Trademarks and Intellectual Property Rights of the pharmaceutical industry

Pharmaceutical Packaging technology

Life of any pharmaceutical product depends upon its packing

Research & Development

Discovering a new drug has assumed prime importance in the pharmaceutical industry

Hospital Pharmacy

The Pharmacist is the qualified drug expert whose advice is sought by everybody regarding the dosage, incompatibilities & side effects of drugs

Community Pharmacy

The pharmacist serves a vital link between the patients and other healthcare professionals, especially the medical experts

Academics

As per the AICTE norms the minimum qualification for B.Pharm colleges as lecturer is M. Pharm,

Marketing

Pharmaceutical production unit is incomplete without marketing & sales, anything produced has to be sold

Govt. Jobs

- Drug Inspector
- Drug Controller
- Scientist in CSIR, ICMR
- Govt. Analyst

Regulatory Bodies

Members of PCI, AICTE

Chemist Shop

Entrepreneurship

Establishment of a new pharmaceutical industry is another challenging area

Opportunities abroad

Golden opportunities galore for qualified Pharmacy professionals in various countries

Higher Studies

A B. Pharm candidate can opt for M. Pharm, MBA, MS-NIPER, Clinical Research

Other Opportunities

- Nuclear pharmacy
- Pharmacotherapy
- Forensic Pharmacy
- Armed Services
- Pharma Consultancy
- Medical Transcription

THE PHARMA TREE

AREA OF PHARMA INDUSTRY

- Hands on / supervisory role of *pharmacists*

RESEARCH AND DEVELOPMENT	• Drug discovery, reverse engineering, formulation and process development, upscaling from pilot to manufacture, troubleshooting, stability, packaging development.
PRODUCTION/ MANUFACTURING	• Production/manufacture of bulk drugs & intermediates, finished medicines, vaccines & other biological products, veterinary medicines, ayurvedic medicines, diagnostic products & medical devices.
PACKAGING	• Various stages of packaging of pharmaceuticals.

QUALITY CONTROL	• Product testing throughout the life cycle of the drug and finished product (from raw materials, packing material to finished goods / stability, etc.)
QUALITY ASSURANCE	• Preparing, reviewing & submitting documents, conducting trainings, internal audits etc., hence assuring overall quality management
SALES AND MARKETING	• Strategic planning, team management and marketing of pharmaceuticals. • Working as a medical representative.
REGULATORY AFFAIRS	• Preparing, reviewing, communicating, submitting registration documents on pharmaceuticals to regulatory agencies to get R & D, testing, production & marketing approvals, issues related to patents.

Area Of Practice	Hands On Role/Supervisory Role
COMMUNITY (RETAIL) PHARMACY *(Medical Store/ Chemist & Druggist)* 	Employed as a *pharmacist*, or can start his own pharmacy. Managing inventory and storage of medicines and allied products. Prescription handling, checking for correctness, safety Dispensing of medicines Patient counselling, demonstration of medical devices Maintaining patient medication records Health promotion (disease prevention), nutrition advice Doing screening tests (blood pressure, blood sugar, height-weight, peak flow, etc) Responding to symptoms and recommending medicines for simple ailments

Area Of Practice	Role/Supervisory Role
HOSPITAL PHARMACY *[In Private Hospitals, Public Hospitals (PHCs (Primary Health Centres), CHCs (Community Health Centres), District Hospitals, Tertiary & Teaching Hospitals, other public sector hospitals]*	Medicine selection Managing inventory and storage of medicines and allied products. Small scale manufacturing/compounding, sterile supplies Dispensing of medicines Patient counselling Health promotion Taking part in National Health Programmes
CLINICAL PHARMACY *(In patient care settings – both in hospitals and community pharmacy)*	ADR (Adverse Drug Reaction) prevention, detection, monitoring. Reducing drug interactions and drug related problems. Taking patient medication history Taking part in ward rounds along with doctors and nurses Deciding/adjusting medication dosing for patients Providing drug information

Academics :

- Pharmacists as teachers have various roles to play in the teaching institutions/pharmacy colleges: **teaching** students, and also carry out continuing upgradation and **research work**, liaison with **industry** and pharmacy.
- One needs to be a **postgraduate** in pharmacy to qualify as a Lecturer and in order to climb up the academic ladder, a Ph.D. is very much essential.
- There is a lot of demand for qualified teachers in the country and even in some countries in Asia.
- Teachers make time to get exposure to the pharmaceutical industry and the practice settings to keep themselves **updated**.

Regulatory (Government) :

Pharmacists work in the Drug Control Department in various sections. The **CDSCO** (Central Drugs Standard Drug Control Organization) is the central body in India for drug control.

Their task is to ensure that the pharmaceuticals in the market - right from raw material to finished product and the distribution from the manufacturing facility to the customer is regulated, so as to ensure the **safety, efficacy and quality** of pharmaceuticals.

Drug Inspectors, Assistant Drug Controllers, Drug Controller, carry out inspections, are involved in giving clinical trial approvals, manufacturing approvals, market approvals, etc.

They work in the **drug testing laboratories** associated with the Drug Control Department (Pharmaceutical Chemist/Analyst).

Clinical Research :

Clinical Research Organizations (CROs) in India offers ample job opportunities.

CROs in India are staffed with a highly skilled clinicians, **Pharmacologists,** Post Doctorates, **Pharmacists**, Toxicologists, Chemists, Analysts.

Services provide by CROs :

- Undertaking clinical studies from Phase 1 to Phase 4
- Feasibility studies
- Protocol development
- Case Report Form review and designing
- Report writing
- Monitoring
- Bio-analytical services
- Quality assurance and data management
- Conduction of bioavailability studies
- Data management for global trials

Pharmacy education and job opportunities outside India:

Learning opportunities for higher studies exist in both the practice as well as research streams.

Generally, one needs to answer one or more of the following entrance/qualifying exams **GRE** (Graduate Record Exam)

TOEFL (Test of English as a Foreign Language)

IELTS (International English Language Testing System).

In order to work as a registered pharmacist in a particular country, one will have to answer **registration exams** (USA-**FPGEE, NAPLEX**)

Ample job opportunities await qualified pharmacy professionals in various countries. The pharmaceutical career is one of the highest rewarding careers especially in the developed countries.

Quality Assurance Health Manager – The Pharmacy graduate can play an important role in the development of clinical care plans, can investigate adverse medication events and in some cases can suggest preventive measures.He can play a key role in spreading awareness amongst the people about AIDS and the preventive measures to be taken.

Medical Transcription – The B Pharm graduate can work with medical practitioners to maintain the patient treatment history, the drug to which he/she is allergic etc

Nutritionist and Dietician :Pharmacy graduates with sound knowledge of Nutrition can join various Nutraceutical companies with good packages.Dietician is responsible for preparing appropriate diet charts for various patients like that of Diabetes, Hepatitis, B.P. Patients etc.

Sales and Marketing – Ambitious achievers with pleasant personality and good communication skills can opt for the job of Medical Sales Representative. The companies prefer pharmacy graduates for this job, as they have a good knowledge about the drug molecules, their therapeutic effects and the drug –drug interactions.

Data Manager – A pharmacist can seek employment as "Data Manager" to store the data in the computer and process it using software developed for the purpose.

Pharmacy is a rewarding career, in terms of personal satisfaction and financial compensation, as well as service to the people. So start planning from today

PHARMACOPOEIA

- I.P
- B.P
- U.S.P
- EXTRA PHARMACOPOEIA

PHARMACOPOEIA

- Derived from Greek word **'Pharmakon'** means **drug** and **'Poiea'** means **to make**.
- It is a legal and official book issued by recognized authorities usually appointed by **Government of each country**.
- It comprises list of pharmaceutical substances, formulae along with their description and standards.

- **List of Pharmacopeias:**

  a) Argentine b) Austrian c) Belgian d) Brazilian e) **British**
  f) Chinese g) Egyptian h) **European** i) French j) German
  k) Hungarian l) **Indian** m) **International** n) Italian o) Japanese
  p) Yugoslavian q) Mexican r) Netherlands s) Nordic t) Polish
  u) Portuguese v) Rumanian w) Russian x) Spanish y) Turkish
  z) **United state.**

INDIAN PHARMACOPOEIA

HISTORY OF THE PHARMACOPOEIA OF INDIA

The Government of India through its letter No. 2338 H(C)/43 dated 26 January, 1944, directed the Drugs Technical Advisory Board list the drugs used in India, which are not mentioned in British Pharmacopoeia and also recommend the standards to be prescribed to maintain uniformity and the chemical tests to be used to establish identity and purity. The Government of India published the Indian Pharmacopoeial List in 1946, as a supplement to the British Pharmacopoeia. The term "List" in the title was "misleading" in that, the book not only contained a list of drugs which were of substantial medicinal value but also laid down standards.

INDIAN PHARMACOPOEIA

Edition	Year	Addendum/Supplement
1st Edition	**1955**	Supplement 1960
2nd Edition	**1966**	Supplement 1975
3rd Edition	**1985**	Addendum 1989
		Addendum 1991
4th Edition	**1996**	Addendum 2000
		Vet Supplement 2000
		Addendum 2002
		Addendum 2005
5th Edition	**2007**	Addendum 2008
6th Edition	**2010**	Addendum 2012
7th Edition	**2014**	Addendum 2015
		Addendum 2016

INDIAN PHARMACOPOEIA

- First official Pharmacopeia of India appeared in **1868** which was edited by **Edward John Waring.**
- In preindependence days, British Pharmacopeia was used in India.
- The colonial addendum of **BP 1898** was published in **1900** appeared as Government of India edition in **1901.**
- In **1946** Government of India issued one list known as **'The Indian Pharmacopeial list'**
- Committee under chairmanship of **Sir R. N. Chopra** alongwith other nine members prepared **'The Indian Pharmacopeial list'**
- It was prepared by **Dept. of Health, Govt. of India, Delhi** in **1946.**
- In **1948** Government of India appointed an Indian Pharmacopeia committee for preparing **'Pharmacopeia of India'**
- Tenure of this committee was **five years.**
- Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published **first edition of IP** in **1955.**

INDIAN PHARMACOPOEIA

- It is written in **English** & official titles of monographs given in **Latin**.
- It covers **986** monographs.
- Supplement to this edition was published in **1960**.
- Second edition of **IP** was published in **1966** under the chairmanship of **Dr. B. Mukkerji**.
- Official titles of monographs given in **English**.
- Dose were expressed in **Metric system**.
- For **Tablets and Injections** **"USUAL STRENGTH"** have been given.
- Formulations of the drugs were given immediately after the monograph of drugs.
- **274** monographs from IP 55 & their supplement were deleted.
- **93** new monographs were added.
- Supplement to this edition was published in **1975.**
- **126** new monographs have been included & **250** monographs have been amended.
- **Cholera vaccine** has been deleted.

INDIAN PHARMACOPOEIA

- Third edition of **IP** was published in **1985** with two volumes & nine appendices.
- **261** new monographs have been added.
- **450** monographs were deleted.
- Addendum I to IP was published in **1989** were **46** new monographs added and **126** amended.
- Addendum II was published in **1991** were **62** new monographs added and **110** amended.
- Fourth edition of **IP** was published in **1996** under the chairmanship of **Dr. Nityanand**.
- It has been made effective from **1st December 1996.**
- It covered **1149** monographs and **123** appendices.
- It includes **294** new monographs & **110** monographs have been deleted.
- Addendum I has been made effective from **31st December 2000** were **42** new monographs have been added.
- Addendum II has been made effective from **30th June 2003** were **19** new monographs have been added.
- The veterinary supplement to **IP 1996** contains **208** monographs & **four** appendices.

INDIAN PHARMACOPOEIA

- Fifth edition of **IP** was published in **2007** & addendum to this edition was published in **2008.**
- **IP 2007** is presented in **Three Volumes**.
- Volume **One** contains general notices & general chapters.
- Volume **Two & Three** contains general monographs on drug substances , dosage forms & Pharmaceutical aids.

INDIAN PHARMACOPOEIA 2010

- 6th editionof IP is published in 2010.
- The 6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeia Commission (IPC) Ghaziabad in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.
- It supersedes the 2007 edition but any monograph of the earlier edition that does not figure in this edition.
- This edition would be effective from 1st September, 2010.
- The Indian Pharmacopoeia 2010 is presented in three volumes.
- Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters.
- Volume II contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (A to M).

INDIAN PHARMACOPOEIA 2010

- **Volume III** contains Monographs on drug substances, dosage forms and pharmaceutical aids **(N to Z).**
- Followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products.
- The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a day are omitted from this edition.

INDIAN PHARMACOPOEIA 2010

- The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of Vaccines and Immunosera are also upgraded in view of development of latest technology in the field.
- A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
- A chapter on NMR is incorporated in Appendices.
- The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

Seventh Edition of Indian Pharmacopoeia

- The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.

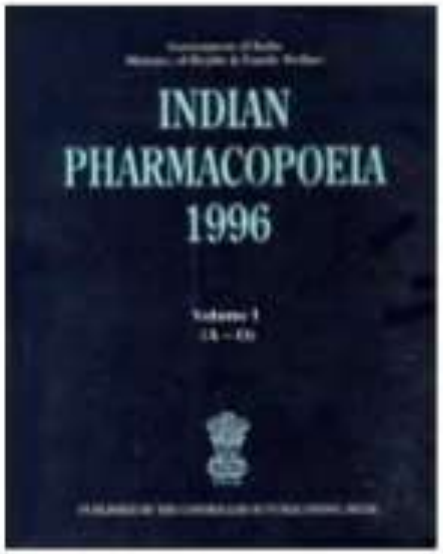
Seventh Edition of Indian Pharmacopoeia

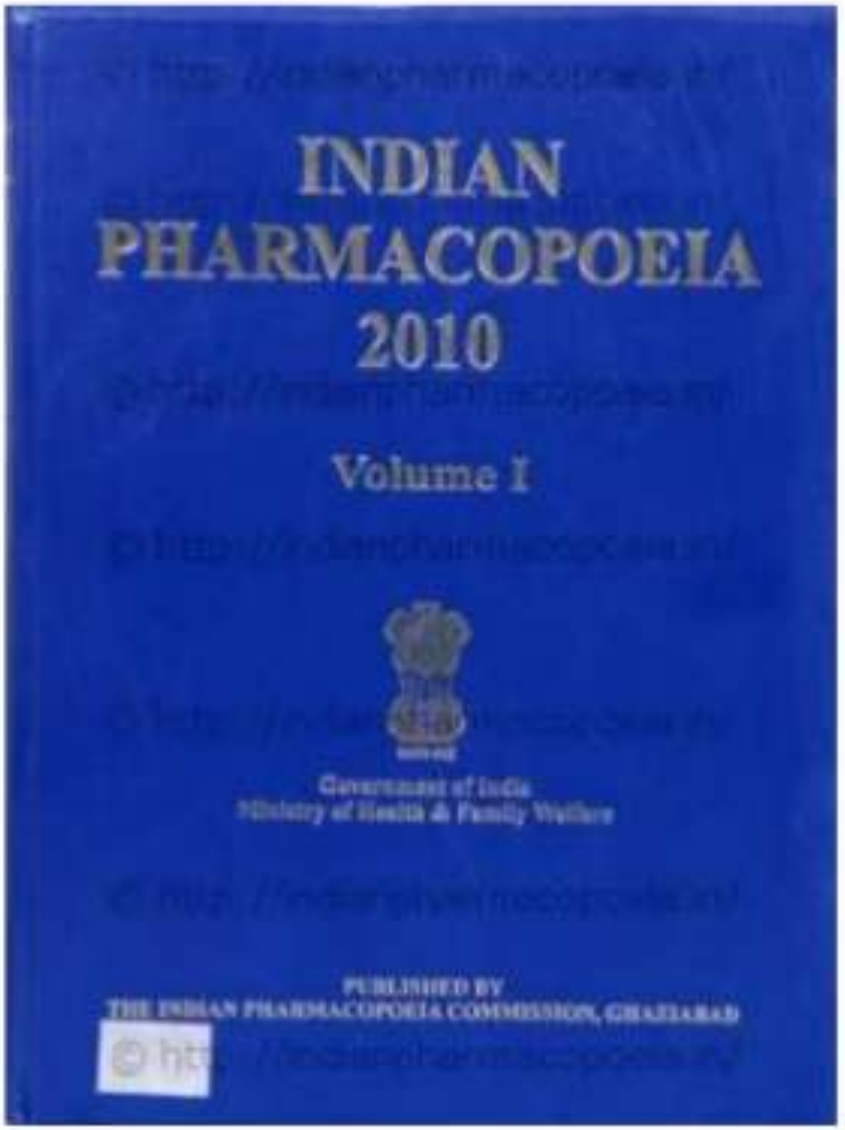
- A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 313 New Monographs on drug substances, Dosage forms & Pharmaceutical aids (A to Z), 43 New Drugs Substances Monographs, 10 Antibiotic Monographs, 31 Herbal Monographs, 05 Vaccines & immunosera for human use, 06 Insulin Products, 07 Biotechnology Products etc. along with the 19 new General Chapters.
- 19 New Radiopharmaceutical Monographs & 1 General chapter is first time being included in this edition.

➢The **addendums** of I.P 7th edition (2014) was released in 2015 & 2016.

➢**8th edition** of I.P (2018) will be released soon with 4 volumes.

INDIAN PHARMACOPOEIA





SALIENT FEATURES of I.P

INDIAN PHARMACOPOEIA

In order to expedite the compilation of the second edition of Pharmacopoeia, the Indian Pharmacopoeia Committee constituted a "Working Group" to examine the comments received on the draft monographs and then submitted suitable recommendations to the Committee in the light of their comments. The second edition of the Pharmacopoeia of India was published in 1966 and later on its supplement was published in 1975.

Salient Features of the Second Edition of Pharmacopoeia of India (1966)

1. The titles of monographs have been changed from Latin to English.
2. The words of the title have been transposed to give the name of the drug first e.g. Injection of Aminophylline has been changed to Aminophylline Injection.
3. Doses are expressed in the metric system only.
4. Solubility is expressed in parts of solvent per unit part of solute.
5. The preparations of a drug have been given immediately after the monograph on the parent drug.
6. The test for sterility has been modified to provide for detection of fungi in addition to aerobic and anaerobic bacteria.
7. New analytical techniques such as non-aqueous titrimetry, column chromography have been included.
8. In the monographs of "Tablets" and "Injections", a new sub-heading "Usual Strength" has been given to represent the strength of the tablet or injection in which it should be generally marketed.

INDIAN PHARMACOPOEIA

Salient Features of the Third Edition of Pharmacopoeia of India (1985)

1.The new analytical techniques such as Flame Photometry, Flurometry, Electrophoresis and Photometric Haemoglobinometry have been introduced as official method for certain chemical analysis.
2.Dissolution Test has been introduced in the case of certain tablets.
3.Disintegration Test has been amended by modifying the design of the apparatus and method of testing.
4.A microbial limit test has been prescribed for certain pharmaceutical aids and oral liquid preparations.
5.The Pyrogen Test has been revised to make the test less time-consuming than the previous method.
6.Gas Liquid Chromatography has been recognized as an alternative method for the determination of alcohol concentration in various preparations.
7.The test for determination of viscosity has been modified by the introduction of other methods involving the use of Ostwald Viscometer.
8.The new appendix on "Water for Pharmaceutical Use" use been introduced to clearly indicate the different official standard in respect of purified water, water for injection and sterile water for injection.
9.Some of the drugs have been renamed in this edition e.g. "Acetylsalicylic Acid" has been changed to "Aspirin".
10.Many drugs have been omitted from the third edition and many new drugs have been included in the third edition.

INDIAN PHARMACOPOEIA

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

1.It contains 1149 monographs and 123 appendices and available in two volumes.
2.The computer-generated structural formulae have been introduced.
3.Some titles have been changed to include the more commonly accepted names of India. E.g. Hyoscine Hydrobromide for Scopolamine Hydrobromide
4.Infra-red and ultra-red absorption spectrophotometric tests for identification of drug substance have been introduced as alternative tests to the classical chemical tests. The infra-red reference spectra of a number of drug substances has been included in an appendix.
5.The high performance liquid chromatography (HPLC) has been widely used as a method to analyse many formulations which can otherwise be analysed only by more difficult and less accurate method e.g. biological assay of Insulin has been replaced by HPLC.
6.The test for bacterial endotoxins as a more suitable substitute for the test for pyrogens has been introduced for some articles.
7.A quantitative method for determining particulate matter in injectable preparations has been replaced by the quantitative test of the previous edition. The test is applicable solutions that are supplied in containers with 100 ml or more.
8.The specific biological assays and tests provided for a vaccines; hormones, blood products and enzymes have been transferred from an appendix to the individual monographs.
9.In the monographs for Oral Rehydration Salts (ORS), ORS-Bicarbonate formula has been dropped due to its stability problem, whereas ORS_Citrate formula recommended by WHO is retained.

INDIAN PHARMACOPOEIA

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

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

2.General chemical tests for identification have been almost eliminated and more specific infrared and ultraviolet spectrophotometric tests have been given.

3.The test for pyrogens involving the use of animals has been virtually eliminated. The test for bacterial endotoxins has been introduced.

4.The test for abnormal toxicity is now confined to certain vaccines.

5.The use of chromatographic methods has been extended in assays to large number of pharmaceutical products.

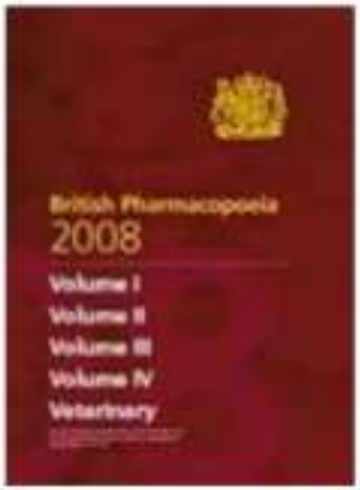
6th Edition
INDIAN PHARMACOPOEIA 2010

- The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of Vaccines and Immunosera are also upgraded in view of development of latest technology in the field.
- A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
- A chapter on NMR is incorporated in Appendices.
- The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

Seventh Edition of Indian Pharmacopoeia

- The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.

BRITISH PHARMACOPOEIA



BRITISH PHARMACOPOEIA

- First edition of **BP** was published in **1864**.
- It consist of two sections
- Part I:- **Materia Medica** & Part II:- **Preparation & compounds.**
- Second edition of **BP** was published in **1867**.
- Fourth edition of **BP** was published in **1898**.
- Fifth edition of **BP** was published in **1914**.
- Eighth edition of **BP** was published in **1953**.
- In this edition titles of drugs & preparations were in **English** instead of **Latin** and **metric system**.
- It has been published **annually.**
- In **BP 2007** monographs has been introduced for material specifically used in preparation of Traditional Chinese medicines.
- Term **'Prolonged release'** has been replaced the term **'Slow'** and the term **'Gastro-resistant'** has been replaced with **'Enteric coated'** in number of monographs.

BRITISH PHARMACOPOEIA

- BP **2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.
- It has been made effective from **1st January 2008**.
- **BP 2007 -2009** were given in Six Volumes i.e. **Volume I to Volume VI.**
- **Volume I & II** contains medicinal substances.
- **Volume III** contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.
- **Volume IV** contains supplementary chapters, IR spectra etc.
- **Volume V** contains veterinary.
- **Volume VI** contains CD ROM version.

THE BRITISH PHARMACOPOEIA 2010

TSO (The Stationery Office), on behalf of the British Pharmacopoeia Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA), has recently published the British Pharmacopoeia (BP) 2010.

The British Pharmacopoeia (BP) is the official collection of standards for UK medicinal products and pharmaceutical substances. Published annually, the BP contains monographs for pharmaceutical substances, formulated preparations and other articles used in the practice of medicine. The standards in the BP 2010 are legally effective in the UK from 1 January 2010.

The BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864. Today, it is used in almost 100 countries worldwide and remains an essential reference for any individual or organisation working within pharmaceutical research and development, manufacturing and testing across the globe.

New to the BP 2010 are 40 monographs for formulated preparations, including veterinary medicines and additional standards for widely used unlicensed formulations. All European Pharmacopoeia 6th edition material up to and including Supplement 6.5 is integrated into the text of the BP 2010. In addition to the expanding number of monographs for licensed formulated products, the BP supports the regulatory work in the fields of herbal and complementary medicines by providing additional new and revised monographs for herbal medicinal products and for homeopathic stocks and mother tinctures.

The print edition of the BP 2010 comprises four volumes of the BP 2010 and a single volume of the BP (Veterinary) 2010.

THE BRITISH PHARMACOPOEIA (BP) 2013

The BP 2013 package includes:

Six volume printed edition including the BP (Veterinary) 2013

New for 2013:

41 new BP monographs

40 new European Pharmacopoeia monographs

619 amended monographs

6 new and 1 amended Infrared Reference Spectra

THE BRITISH PHARMACOPOEIA 2014

The only official source of British pharmaceutical standards

Produced by the British Pharmacopoeia Commission Secretariat of the Medicines and Healthcare Products Regulatory Agency, and updated annually, the British Pharmacopoeia (BP) is the official, authoritative collection of standards for UK medicinal substances for human and veterinary use.

The 2014 edition includes almost 3500 monographs which are legally enforced by the Human Medicines Regulations 2012.

Global standards

Now used in over 100 countries, the BP remains an essential reference for all individuals and organisations working within pharmaceutical research and development, manufacture and testing around the globe.

Flexible access options

The BP 2014 package comprises five volumes of the British Pharmacopoeia 2014 and a single volume of the British Pharmacopoeia (Veterinary) 2014, along with a fully searchable CD-ROM and online access to provide you with flexible resources.

New for 2014

Legally effective from 1 January 2014

40 new BP monographs

272 amended monographs

Three new Supplementary Chapters

Four new BP (Vet) monographs

One new BP (Vet) Supplementary Chapter

BRITISH PHARMACOPOEIA 2016

The BP 2016 includes almost **4,000 monographs** which are legally enforced by the Human Medicines Regulations 2012, and becomes legally **effective on 1 January 2016.**

This is **6-volume** printed edition, including the BP (Vet) 2016

New for 2016:

- 37 new BP monographs
- 142 amended monographs
- one new BP appendix for the DNA identification of herbs
- all European Pharmacopoeia monographs from the 8th edition, as amended by supplements 8.1 to **8.5**

BRITISH PHARMACOPOEIA 2017

The British Pharmacopoeia (BP) 2017 becomes legally effective on **1 January 2017.**

Also included is new information for **unlicensed medicines** and DNA barcoding.

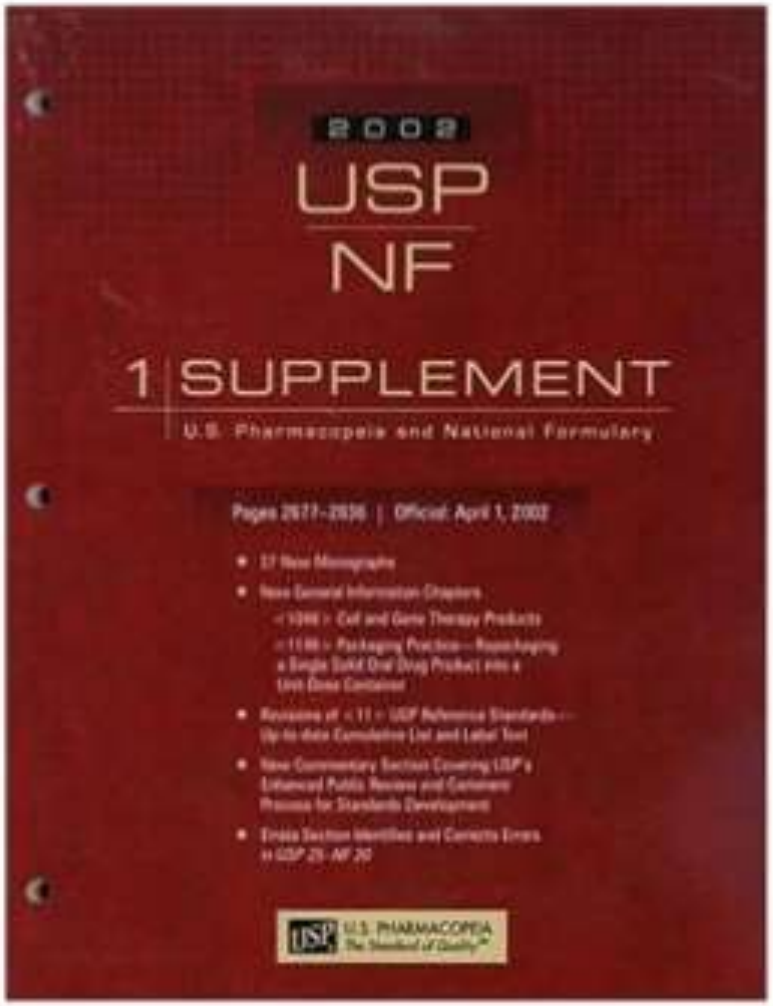
A **six-volume** printed edition, including the BP (Veterinary) 2017

New for 2017:

- 29 new BP monographs
- 234 amended monographs
- Four new formulated preparation monographs for biological medicines
- Two new monographs for unlicensed formulations
- A new Supplementary Chapter on **DNA barcoding**
- A new Supplementary Chapter on the **Aseptic Preparation** of Unlicensed Medicines
- All European Pharmacopoeia monographs integrated (8th Edition as amended by Supplements 8.1 to **8.8**)

UNITED STATE PHARMACOPOEIA

U.S. Pharmacopeia
The Standard of Quality™



UNITED STATE PHARMACOPOEIA

- **First edition** of United state Pharmacopeia was published on 15th **December 1820** in both ***Latin & English***.
- From 1820 to 1942 it was published at **Ten years** intervals.
- From 1942 to 2000 it was published at **Five years** intervals.
- From 2002 it was published **annually**.
- First ***National Formulary*** of the united state appeared in **1888**.
- **USP21-NF16** have eight supplements.
- First appeared in **January 1985** & last in **November 1988**.
- **USP22-NF17**, **1990** is the third revision that consolidates USP & NF into a single volume.
- Electronic version of ***USP-NF*** on floppy disks was introduced in **1992**.
- **USP23-NF18**, was published in Mumbai as an Asian edition at the end of **1994**.

UNITED STATE PHARMACOPOEIA

- *USP23* has ten supplements.
- First supplement was published in **January 1995** & Last in **May 1999**.
- ***USP24-NF19***, appeared from first **January 2000**.
- ***USP30-NF25***, appeared from **May 2007**.
- It contains Scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.
- It contains **4,100** monographs and **200** general chapters.
- It has been printed in **three volume** set.
- **Volume I** contains general chapters & **Volume II & III** contains monographs.
- First supplement to ***USP30-NF25***, appeared from **August 2007** & second supplement from **November 2007** which will be considered official from **May 2008**.
- From 2006, Spanish edition of USP is also being published.

- **UNITED STATES PHARMACOPOEIA 30 – NATIONAL FORMULARY 25**

Highlights include:

- New heavier paper stock
- Complete table of contents and index in each volume
- Special 'Using the New USP-NF Print' tutorial CD
- Convenient slipcase for easy access and storage (English edition only).
- **UNITED STATES PHARMACOPOEIA 31 - NATIONAL FORMULARY 26**
- The USP-NF is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP. Excipient monographs are included in the NF.

- **UNITED STATES PHARMACOPOEIA 32 - NATIONAL FORMULARY 27**

The USP 32-NF 27 Contains :

- More than 4,200 monographs
- Includes over 200 general chapters, covering general tests and assays
- Displays helpful guides and charts that make it easy to find focus-specific information
- Includes information on emerging areas of science and medicine
- Helps ensure compliance with official standards
- Enables validation of test results against proven benchmarks
- Creates in-house standards for operating procedures and specifications
- Expedites new product development and approvals.

- **UNITED STATES PHARMACOPOEIA 33 - NATIONAL FORMULARY 28:**

The USP 33-NF 28 Contains:

- More than 4,400 monographs
- Over 200 general chapters covering general tests and assays
- A new, easy-to-read format and monograph layout
- Helpful guides and charts that make it easy to find focus-specific information
- Ensures compliance with official standards
- Establishes in-house standard operating procedures and specifications
- Facilitates new product development and approval.

- **UNITED STATES PHARMACOPEIA 34 - NATIONAL FORMULARY 29:**

  USP 34-NF 29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics. USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.

- **UNITED STATES PHARMACOPEIA 35 - NATIONAL FORMULARY 30:**

  The 'United States Pharmacopeia 35 - National Formulary 30' (USP-NF) is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from **1 May, 2012 to 30 April, 2013.**

USP 40 & NF 35 (2017)

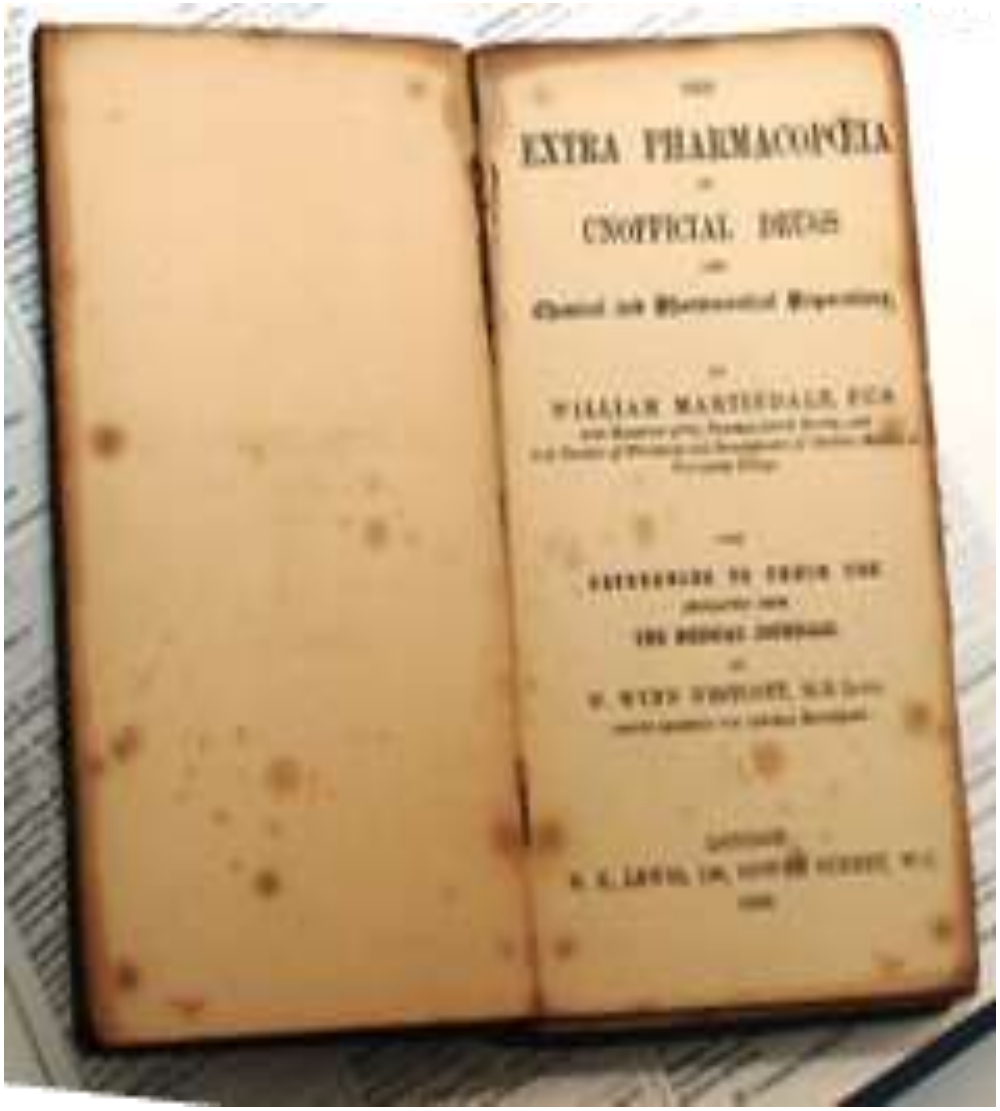
4 Volumes with 2 Supplements

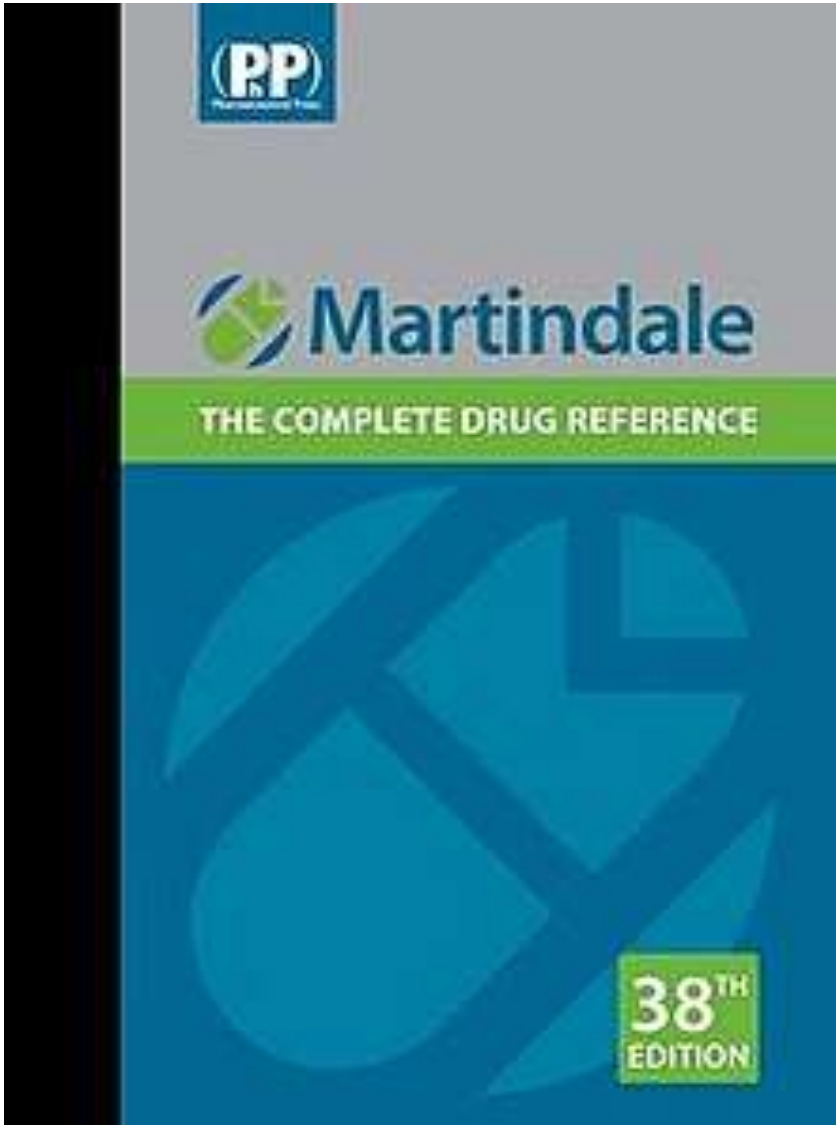
becomes official August 1, 2017.

Features:

- More than 4,900 monographs with specifications for identity, strength, quality, purity, packaging, and labeling for substances and dosage forms. View a sample USP-NF monograph.
- More than 300 general chapters providing clear, step-by-step guidance for assays, tests, and procedures
- Focus-specific charts and a combined index help you find the information you need
- Helpful sections on reagents, indicators, and solutions, plus reference tables
- Includes new General Chapter <800> Hazardous Drugs-Handling in Healthcare Settings

EXTRA PHARMACOPOEIA





➢**Martindale: The Complete Drug Reference** is the alternate reference book for drugs and medicines.

➢The Extra Pharmacopoeia, originally produced by **William Martindale in 1883** and now published by the Pharmaceutical Society of Great Britain, contains information on the drugs presently used in Great Britain.

➢**Aim:**

1. To update information for pharmacist, physician in all subjects.
2. To provide information of official, un official, proprietary preparations currently in use.

➢The general section contains about 1,400 pages of drug descriptions listed in alphabetical order under English titles.

➢ Monographs include Chemical Abstracts Service (CAS), Anatomical Therapeutic Chemical Classification System (ATC) numbers and FDA Unique Ingredient Identifier (UNII) codes to help readers refer to other information systems.

➢*Martindale* contains **information on drugs** in clinical use, as well as selected investigational and veterinary drugs, herbal and complementary 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.

38th edition of *Martindale: The Complete Drug Reference*.

This was published in **June 2017.**
Martindale is arranged into **two main parts followed by three extensive indexes**:

- **Monographs on drugs and ancillary substances**, listing over **6,000** monographs arranged in **49 chapters** based on clinical use with the corresponding disease treatment reviews.
- Monographs summarize the nomenclature, properties, and actions of each substance.
- A chapter on supplementary drugs and other substances covers some **1190 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.

Preparations - including over 1,80,000 items from 43 countries and regions, including China.

Directory of Manufacturers listing some 20,000 entries.

Pharmaceutical Terms in Various Languages: this index lists nearly 5,600 pharmaceutical terms and routes of administration in **13 major European languages** as an aid to the non-native speaker in interpreting packaging, product information, or prescriptions written in another language.

General index: prepared from **1,75,000 entries** it includes approved names, synonyms and chemical names; a separate Cyrillic section lists nonproprietary and proprietary names in Russian and Ukrainian.

Digital versions :include an additional 1,000 drug monographs, 60,000 preparation names, and 5,000 manufacturers.

USE:

- *Martindale* aims to **cover drugs** and related substances reported to be of clinical interest anywhere **in the world**.
- It provides a useful source of information for patients arriving from abroad to **identify their existing medication**.
- This may reveal that a currently taken proprietary preparation is available under **another brand name**.
- Alternatively if the drug is not available, the class of agent can be determined allowing a pharmacist or doctor to determine which **alternative equivalent drugs** can be substituted.


THE END