

WELCOME TO



Drx Notes

Pharmaceutics | Chapter-1

History of the profession of Pharmacy in India in relation to
Pharmacy education, industry

History of the Profession of Pharmacy in India: In Relation to Pharmacy Education

- Pharmacy education in India at the certificate level, was started in 18/42 in Goa by the Portuguese. Formal training of the compounds was started in 1881 in Bengal and as a university level program in 1937 at the Banaras Hindu University (Varanasi). In Baghdad the first pharmacies or drug store, were established in 754.
- The revolution in the development of science and technology in post-world war-2 starter the change in pharmacy profession.
- Pharmacy being a health care profession, the independent government of India enacted 'The Pharmacy Act' to control the pharmacy profession as well as education, in 1948.
- Father of Pharmacy: 'William Procter Jr.' (American Pharmacist)
- Father of Indian Pharmacy: 'Mahadev Lal Schroff'
- Traditionally pharmacy has been known as an art and science of making drug/medicine. The word Pharmacy is derived from the Greek word 'PHARMAKON' meaning drug.
- In the ancient period, the physician themselves practiced pharmacy and it is believed that Hippocrates, the great Greek physician, regard as father of Medicine, used to make his own prescription or at least, supervise their preparation.
- Apothecary is a historical name of a medicine professional who, formulates and dispense medicine to physicians and patients, now this role served by the pharmacist. The earliest pharmacies were known as Apothecary shops.
- Pharmacist play a role in, compounding most of the medicine needs of the people. Here the medicinal professional prepared and dispensed medicines to physicians and mixtures, ointments, pills, tincture, syrups, elixirs, powder etc. in their pharmacy, based on the prescriptions given by physicians. They

packed them suitably labeled them and dispensed them along with appropriate advice for consuming them.

- In old time, direct crude drugs are used in the diagnosis by the physicians and require herbs and drugs are provided by pharmacist. At that time drugs are identified by their morphological appearance and organoleptic characters.
- Like other, countries In India too, pharmacy was part of medicine in our Ayurvedic, and Siddha system of medical practice.
- Pharmacy is a versatile, dynamic, growing and increasingly diverse professions, one which creates an excitement because there are so many opportunities for services. it is an old age profession which has transformed into a hub for 'Global health Care' and evolved as multidisciplinary and multifaceted field in recent times.

Pharmacy relation in Industry:

- In industry pharmacist perform many works in many ways.
1. **Formulation development**— Commercial drug production is a difficult task for any pharmaceutical companies. Due to involvement of pharmacy in pharmaceutical, it is easy way to developed commercial formulation and developing a complete understanding of the form and structure of the drug substance and drug products.
 - Pharmacist also involved in the formulation testing and make a successful pharmaceutical formulation requires the combination of the Active Pharmaceutical Ingredients (API) with inactive excipients.
 - Physicochemical analysis can aid excipient selection, enable the stability of the drug substance and drug product to be assessed, and also ensure the critical material attributes (CMAs) relating to formulation performance are identified as part of the design space definition applied for downstream manufacturing controls.
 2. **Manufacturing department**— Proper equipment, proper procedure and suitable conditions are the necessary conditions for any manufacturing units. In pharmaceutical it is also decided by the pharmacist. Pharmacist developed and maintain Standard Operation Procedure (SOP) and provide effective training to products staffs.

- Proper sanitation and hygiene conditions are also developed by the pharmacist and it is also decided the safety area and safety environment for the manufacturing units.
 - Assist and review production batch records have all the necessary information for final approval and release decision and also conduct and support companies research and development projects
3. **Quality control and Quality assurance:** The main function of quality control is to test and verify the products quality according to pharmacopeial standards.
- In Quality Control sampling inspection and testing of raw material and packaging material, release and documentation are control by the high skilled person (Pharmacists). QC department also define the stability testing and evaluation of self-life product and also monitor the microbial activity of raw materials and finished products.
 - Quality Assurance (QA) department execute the systemic monitoring and evaluation of the various expects of a project service or facility to ensure that standards of quality of the drugs. It also responsible of maintenance of a desired level of quality in as service or product, especially by means of a attention to ever stage of the process of delivery or production. It also assured the doses and formulations of drugs according to patients need and convenience.
4. **Drug Information:** Pharmacists are also known as drug experts because it gains a lot of knowledge during the academic session. In industry it informed the drugs composition and formulation and also defined the drug advantage (useful effect) and disadvantage (Harmful or adverse effect). chemically drugs are active or inactive it is decided by the pharmacists and also provided the drugs reaction with other drugs.
- Drug are the chemical substances, which are design for treating the disease. It is also providing the complete information about suitable excipients (coloring agent, flavoring agent etc).
5. **Regulatory affairs:** In industry, regulatory affairs are a profession developed from the desire of governments to protect public health by controlling the

safety and efficacy of medicinal products like veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. Regulatory department responsible for the discovery, testing, manufacture and marketing of pharmaceutical products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.

- Regulatory department promote strategic and technical advice at the highest level in their industries, making an important contribution both commercially and scientifically development.
- Keeping track of the ever-changing legislation in all the regions in which a company wishes to distribute its products and give advice on legal and scientific restraints and requirements.

6. Sales and marketing: For any industry growth and development sales and marketing is a very important factor. Pharmaceutical marketing is presently the most organized and comprehensive information system for updating physicians about the availability, safety, efficacy, hazards, and techniques of using medicines.

- Marketing is a process that starts with identifying and understanding the needs and wants of the customer (demand) and then fulfilling those needs and wants (supply). An effective marketing plan offers a solution to fulfill the needs and wants of society (individuals and organizations), while achieving the goals of the organization.
- In addition, marketing can create new needs or reformat existing needs. Both customers (demand) and organizations (supply) have objectives.
- In marketing, pharmacists are direct attached to the patients and physicians so it provided the complete information about the public need and requirements.

Management: Marketing management is the analysis, planning, an implementation the control over actions, aimed on an establishment, fastening and support of favorable exchanges with target buyers for the achievement of certain problems of the organization, such, as profit reception, sales volume growth, increase market share, etc.

- **Pharmacy Practice and Various Professional Associations Or Pharmacy as a Career**

Introduction: Pharmacy are developed to organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/ materials. Pharmacists is the first person of health care system by playing various roles like academic pharmacists, industrial pharmacist, community pharmacists, clinical pharmacists, hospital pharmacists, veterinary pharmacist etc. All pharmacists working in different fields of the profession are directly or indirectly related to nation's health. Finally, pharmacists are responsible for insuring that "Right drug to right patient at right time in right dose through right route in right way." So that pharmacists are an integral part of health care system.

General/ clinical practice:

- Clinical pharmacists often apply their knowledge of medications in the medication plan of a particular patient and evaluate the appropriateness of the dose, side effects, efficacy and drug interactions.
- In many cases, the clinical pharmacist with work directly with patients to help them understand the medications they take and encourage them to take the medications as directed.
- Pharmacists are monitoring patient progress with medications and making relevant recommendations to change and evaluating medication therapy and making appropriate recommendations to patients or health practitioners. Pharmacists are also called as primary informers in the medical department.
- According to new authority by government pharmacists are also open our own clinics and provide the primary treatment to the patient and also treat the emergency condition in the absence of doctors.

Academic practice:

- In academic pharmacist focus on teaching, research and training of the upcoming pharmacist. On the basis of knowledge and skill pharmacists are appointed for different-different post in the academic institute.
- By arranging seminar, project, or system academics, pharmacist plays valuable role in health care system. Education motivates the professionals in the health care system.
- From their basic education training and pre-registration training, students acquire a broad understanding of the scientific principles and techniques of the pharmaceutical sciences and

the ability to keep pace throughout their careers with developments in medicine and pharmacy.

- Pharmacist also gave the knowledge about preparation, distribution, action and uses of drug. Educational training programs helps to professionals for their current knowledge. Pharmacist gets a specialized knowledge regarding to drugs and therapeutic action through there practical training overall we can say academic pharmacist preliminary part in pharmacy profession.

In Health program

- According to WHO "Health is complete physical, mental and social well-being and not merely absence of disease. According to Ayurveda swath's health is defined as "well balance metabolism. In spite of short coming in the WHO difference the Concept of the health is wide and positive and provides an overall goal towards which nations.
- Health is an integral part of the development and health is central to the concept of quality of life hence, health is world Wide social-goal. To achieve this goal every nation sets professional persons in healthcare System Pharmacist, Physician/doctors, Nurses, Compounder, Dispenser. Health related other service provide by pharmacists that is.

i. Health missions

ii. Health consultant

iii. Doctor's assistant.

In Hospital Pharmacy:

- Hospital pharmacists are playing the key role in monitoring the supply of all medicines used in the hospital and are in charge of purchasing, manufacturing, dispensing and quality testing their medication stock along with help from pharmacy assistants and pharmacy technicians.
- Hospital pharmacists can offer information on potential side effects and check that medicines are compatible with existing medication.
- They will often also monitor the effects of treatments to ensure that they are proving effective, safe and appropriate to the user, like doctors, pharmacist regularly attends wardrounds and more involved in selecting treatments for patients.
- Some pharmacists specialize as consultant in many areas as Hematology (blood), Nephrology (kidneys), Cardiology (heart), Urology (urinary), pediatrics (children), Diabetes and infectious disease etc. it also participates in.

- i. Prescribing
- ii. Dispensing
- iii. Administration
- iv. Documentation
- v. Monitoring

Pharmacovigilance: Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. The word "*pharmacovigilance*" are- **pharmakon (means drug)** and **vigilar (to keep watch)**. Pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients.

Research and development:

- Pharmacist contributes to research, and their expertise in formulation development is of particular relevance to the biological availability of active ingredients. Pharmacists perform the many experiments and develop the drug formulation and develop the convenient dosages form according to demands and need and maintain the resister of the drugs. It also decided the suitable excipients for APIs. It also helps in the development of combination drugs.
- Pharmacists are also involved in the vaccine preparation.

Pharmaceutical marketing and Management:

- Pharmacist are participating in the marketing and distribution by provide the knowledge about the drugs to the physicians.
- Advertisement, news, and multimedia are also the components of the pharmaceutical marketing.
- Management, is the key features of any jobs and companies. In the pharmaceutical regular checkup of drug, temperature maintaining, moisture regulation, light availability etc. are include in management. In any job regular practice and time management is very important factors. The inclusion of pharmacist in all levels of management promotes an ethical approach within management policies.

Chemist shop and medical store:

- Pharmacists are also authorizing to open our own chemist shop and checking, dispensing of prescription drugs and providing advice on drug selection and usage. It also called community pharmacist. Community pharmacist are directly closed with the public and provide the complete information about disease.

- Community pharmacist is also taking on more of the clinical roles that have traditionally been undertaken by doctors, such as the management of asthma and diabetes as well as blood pressure testing.
- They also help people give up smoking, alter their diets to make them healthier and advise on reproductive health matters.

In Industry:

Pharmacists are involved and responsible for wide area activities in industry. Pharmacists are involved in drug discovery process, drug safety studies, formulations of dosage forms, clinical trials, marketing and management.

Role of pharmacist in industry:

- ✓ **Formulation development.**
- ✓ **Manufacturing department.**
- ✓ **Quality control and Quality assurance.**
- ✓ **Sales and marketing.**
- ✓ **Management.**

Pharmacopoeia

Introduction of Pharmacopoeia:

Pharmacopoeia has been the authoritative organization working to ensure the consistency and quality of medicines.

Pharmacopoeia is the formulation of drugs. It is the standard book for preparation of drugs.

The book is published in a country under the authority of its own government.

Pharmacopoeia is derived from Greek word

Pharmakon - Drugs

Copoeia - Means to make

Type of Pharmacopoeia / List of Pharmacopoeia:

- We cannot call it a specific type because every country has an own Pharmacopoeia.

- DRx Notes will discuss Pharmacopoeia of some countries. First of all, let's know about our Indian Pharmacopoeia. When did this book become public, which edition of it is running now?

- **Indian Pharmacopoeia**
- **British Pharmacopoeia**
- **United States Pharmacopoeia**

Indian Pharmacopoeia:

The Indian Pharmacopoeia is published by the Indian Pharmacopoeia commission (IPC) on behalf of the ministry of health and family welfare Government of India.

- **Bengal Pharmacopoeia 1844 - But this book was not made public, just this name was kept.**
- **Legal and official book published by IPC-1945.**

- Indian Pharmacopoeia Headquarter - Ghaziabad (Uttar Pradesh)
- Indian Pharmacopoeia commission (IPC) regulated by Ministry Of Health And Family Welfare.

- Indian Pharmacopoeia is written in English and official title of monographs given in Latin.

- The Indian Pharmacopoeia is being processed to fulfill the requirement in the Drug And Cosmetics Act 1940 and rules 1945.
- In 1946 the government of India published the Indian Pharmacopoeia list which served as the supplement to British Pharmacopoeia.
- After publication of list the government of India constituted a permanent Indian Pharmacopoeia committee in 1948.

- **Indian Pharmacopoeia committee under chairmanship of Dr. B.N. Ghosh published First Edition of Indian Pharmacopoeia in 1955.**
- (Dr. B.N. Ghosh professor of pharmacology. R.Gkar medical College Kolkata who died 1958. After Dr. B.N. Ghosh, Dr. B Mukerji Director Central Drug Research Institute Lucknow (CDRI) was appointed as chairman of the Indian Pharmacopoeia committee.)

- **Second Edition of Indian Pharmacopoeia was published in 1966. Supplement to this edition was published in 1975.**
- (On 30 June 1978 the Indian Pharmacopoeia committee was reconstituted by the government of India Ministry of Health and Family Welfare) under the Chairmanship Dr. Nityanand Director of Central Drug Research Institute Lucknow (CDRI).

- **Third Edition of Indian Pharmacopoeia was published in 1985.**
- This Pharmacopoeia include two Addendum with two Volumes.
- Addendum (Volume-1) to Indian Pharmacopoeia published in 1989. They contain legal notice prephase acknowledgement, Introduction, General notice and monographs from A to P.
- They contain 46 new monographs added and 126 amended.
- Addendum (Volume-2) was published in 1991 contain monographs from Q to Z and they contain 62 new monographs added and 110 amended.

- **Fourth edition of Indian Pharmacopoeia was published in 1996 under the chairmanship of Dr. Nityanand.**
- In Fourth edition addendum from veterinary product in 2002, 2005 and supplement volume-1 A to P, Volume-2 Q to Z.
- The veterinary supplement to Indian Pharmacopoeia 1996 contain 208 monographs.

- **Fifth Edition of Indian Pharmacopoeia was published in 2007 and addendum to this edition was published in 2008.**
- Fifth Edition Indian Pharmacopoeia is presented in three (3) Volume.
- Volume-1st contains general notices and general chapters.
- Volume-2nd contains general monographs on Drugs substances Dosage forms and Pharmaceutical Aids.

- **Sixth edition of Indian Pharmacopoeia was published in 2010.**
- The 6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeia commission (IPC).
- The Indian Pharmacopoeia 2010 is presented in 3 volumes.
- Volume-1st contains the notices, Preface the structure of the IPC, Acknowledgements, Introduction and the general chapters.

- Volume-2nd contains the General notice, monographs on Dosage forms and monographs on Drug substances, dosage forms and Pharmaceutical Aids (A to M).
- Volume-3rd contains monographs on Drug substances, dosage forms and Pharmaceutical Aids (N to Z) followed by monographs on Vaccines and Immunoserum for human use.
- Herbs and Herbal products. Blood and blood related products biotechnology product and veterinary products.

- The seventh edition of the Indian Pharmacopoeia was published in 2014 by the Indian Pharmacopoeia commission (IPC) on behalf of the Government of India Ministry of Health and Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four Volumes.
- The Indian Pharmacopoeia 2014 incorporates 2550 monograph of drugs out of which 577 are new monographs consisting of APIs, Excipients, Dosage forms and herbal products etc.

- The Eight edition of Indian Pharmacopoeia was published in 2018 by the IPC on behalf of the Ministry of Health and Family Welfare, Government of India.

Indian Pharmacopoeia 2018 salient features-

- Incorporating with 4 volumes.
- 220 New monographs
- 170 New chemical monographs
- 49 API
- 64 Formulation
- 53 Fixed dose formulations
- 02 Excipients
- 02 Antibiotics
- 15 New herbs and Herbal products monographs
- 03 New Radiopharmaceutical monographs.
- 14 New veterinary non-biological monographs.
- 18 New Biological monographs
- 02 Vaccines and Immunoserum for human use
- 06 Biotechnology derived therapeutic products.
- 10 Blood and Blood related products.

Silent features of Indian pharmacopoeia

- ❖ I.P is published in continuing pursuit of the mission of I.P.C to improve the health of the people through ensuring the quality, safety and efficacy of medicines.

- ❖ I.P contains procedures for analysis and specifications for the determination of quality of pharmaceutical substances, excipients, and dosage form.
- ❖ General chapter on volumetric glassware, conductivity, dissolution test, disintegration test, dimensions of hard gelatin capsule shell etc. have been revised.
- ❖ I.P has been extended to include products of biotechnology indigenous herbs and herbals products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed dose combinations (FDC).
- ❖ I.P contains the 170 chemical monographs, 15 herbal monographs, 10 blood and blood related products monographs, 6 biotechnology monographs, 3 pharmaceuticals monographs, 2 vaccines and immune-sera monographs, 14 veterinary and non-biological products monographs.
- ❖ I.P monograph for an official substances or preparation includes the articles definition, description, identification, packaging, storage, specifications, impurities, assay and specific tests, one or more analytical procedures for each test, acceptance criteria, other requirement etc.
- ❖ General chemical tests and TLC for identification of an article have been almost eliminated and more specific infrared, ultraviolet spectrophotometer and HPLC tests have given emphasis.
- ❖ The uses of chromatographic methods have been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.



Drx Notes

Edition	Year	Addendum/ Supplement	Chairmanship	Volume
1 st	1955	1960	Dr B N Ghose	1
2 nd	1966	1975	Dr B Mukherjee	1
3 rd	1985	1989/1991	Dr Nityanand	2
4 th	1996	2000/2002/2005	Dr Nityanand	2
5 th	2007	2008	Dr Nityanand	3
6 th	2010	2012	Shri K Chandramauli	3
7 th	2014	2015/2016	Nabi Azad (Health Minister)	4
8 th	2018	2019/2021	Dr C K Mishra	4

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