1 Introduction

History of Pharmaceutical Practice through Ages

Prehistoric Pharmacy

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

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

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

Antiquity

The advancement of societies also started influencing the fundamentals of disease and healing. The changes can be verified from the remains of the civilizations of Mesopotamia and Egypt. From ancient records of Egyptian civilization, it can be concluded that pharmaceutical sciences rose greater heights in these times, with more dosage forms compounded from more detailed formula. The Egyptian medical texts shows a close connection between supernatural and natural healing. Recipes usually began with a prayer or hymn and ended with plant drugs.

In ancient Greece, there was a similar connection of drugs or *pharmakon*, means magic spell, remedy, poison. Most Greek medicines were prepared from plants and the

first great study of plants was done by Theophrastus (370 – 285 BC), a student of Aristotle.

Middle Age

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

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

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

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

Indian Systems of Medicines

Indian Systems of Medicines includes the systems originated in India and the systems originated outside but adapted in India. These are Ayurveda, Unani, Siddha, Yoga, Naturopathy and Homeopathy.

Ayurveda

Ayurveda, the science of life, has arrived from the Vedas. Around 1000 BC, the knowledge of Ayurveda was comprehensively documented by Charak and Sushruta. Ayurveda considers both physical and spiritual aspects of man. According to the philosophy of Ayurveda, human being is a combination of the following structural and functional entities, three doshas, panchamahabhutas, sapta dhatu, panchaindriyas, manas, budhi and atman. Three doshas are vata (air), pitta (fire) and kapha (water and earth).

The principle of Ayurveda is to keep these structural and functional entities in a state of equilibrium to maintain a good health. The cause of illness is imbalance of these entities due to internal and external factors.

The diagnosis of any disease is done by questioning the patients and eight examinations, e.g. pulse, urine, faeces, tongue, eyes, visual examination and inference.

The factors, such as state of body, mind, temperament, sex, age, metabolic condition, etc,. are considered at the time of prescribing medicines. The system provides both preventive treatment and curative treatment.

Unani

This system was brought from Arab and Greece during 460-376 BC. According to this system the body has four humours-blood, phlem, yellow bile and black bile. Disease is a normal process of life and reactions of the body is symptom. The diagnosis and treatment are based on the principle of temperament, hot, cold, moist and dry. Any change in temperament is due to imbalance of humours. Medicines are made of herbal, animal and mineral origin. According to this system there is some natural self-preservation mechanism in human body. The function of the drugs is to stimulate and strengthen the defence mechanism and to normalise the imbalance in humours.

Siddha

Siddha means achievement or perfection. This system was originally practised in Tamilnadu. The manuscripts are written in Tamil. It is believed that eighteen Sidhars (saints or saintly persons), through the practice of yoga, developed this system of medicines which is mainly therapeutic in nature.

The principles of this system and of Ayurveda are similar. According to this system, the human body, the food and medicines are all replica of the universe. The concept of this system is based on tridosha and panchamahabhutas of Ayurveda. The method of diagnosis and treatment are similar to Ayurveda.

Homeopathy

The German physician Dr. Christian Frederic Sammuel Hahnemann introduced the basic principles of Homeopathy and translated Cullen's Materia Medica into German from English. Dr. Hahnemann discovered that any substance which produces artificial symptoms on healthy persons, can cure the symptoms in natural disease also. Thus, the concept of treatment is *Similia Similibus Curentur.* The symptoms disappear in the reverse order of their appearance. The doses sufficient to cure is administered. The treatment is done on individual symptoms basis, but not disease basis. Hence, detail study of symptoms in the patient and of the drug is of prime importance.

Yoga

Sage Patanjali proposed yoga. It contains eight components-restraint, observance of austerity, physical postures, breathing exercises, restraining of sense organs, contemplation, meditation and samidhi. Yoga is a way of life. Practice of yoga improves behaviour, keeps through better circulation of oxygenated blood in the body, restrain the

sense organs and mind, and induce tranquillity. It prevents psychosomatic disorders and improves the ability to overcome stress. It also improves the intelligence and memory.

Naturopathy

Treatment of disease without drug and application of simple laws of nature are the basic concepts of this system. The fundamental principle of this system is similar to that of Ayurveda. There are two groups-one believes in practising ancient Indian methods and the other believes in practising western methods similar to physiotherapy. The practitioner regulates the eating and living habits, methods of purification, hydrotherapy, fasting, cold packs, mud packs, baths, massages etc., and treat the patients.

Pharmacy in Relation to Allied Health Profession

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

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

Responsibilities of a pharmacist during a medical therapy:

1. To ensure safe procurement, storage, adequate dosage and dispensing of medicines as per the prescription,
2. To furnish information to the patients, which may include the name of the medicine, its purpose, potential interactions and side effects, correct usage and storage,
3. To review prescription orders to identify interactions, allergic reactions, contraindications and therapeutic duplications. Significant matters should be discussed with the prescriber (physician),
4. To consult with the physician for the preparation and revision of therapeutic plans of the treatment with the medicines,
5. To discuss medicine related problems or concerns with regard to the prescribed medicines, if requested by the patient,
6. To advise patients on the selection and use of non-prescription medicines and how to manage the minor symptoms or ailments,

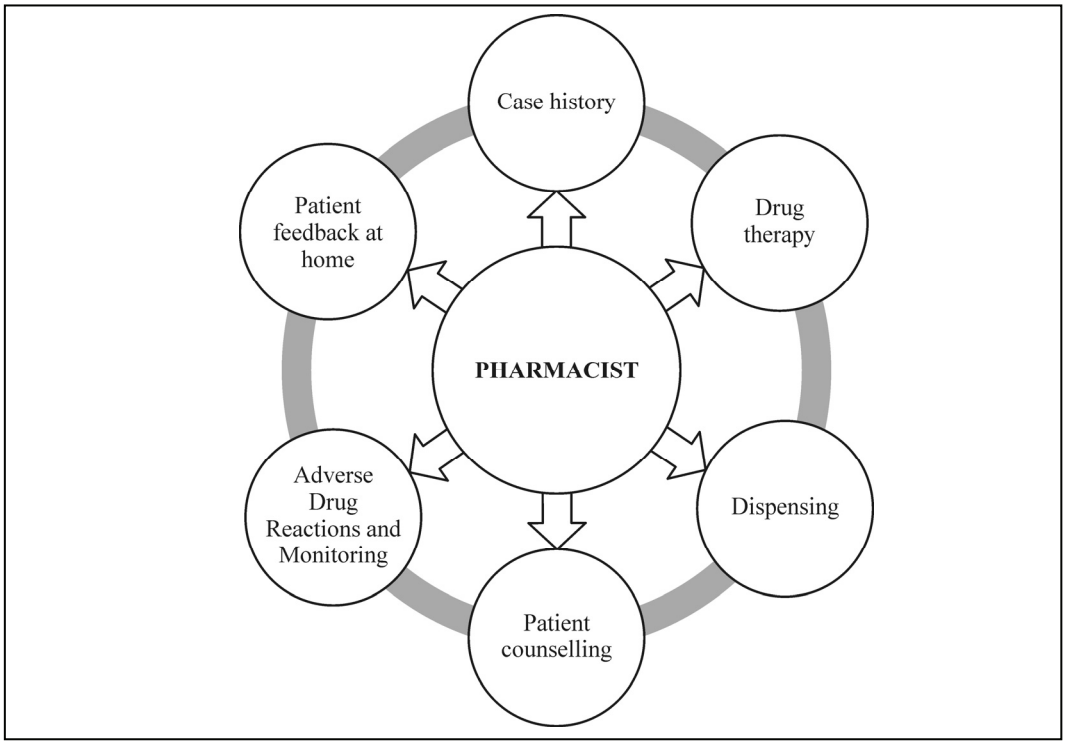
7. To advise the patient where self-medication is not appropriate and the respective physician to be consulted for diagnosis and treatment,
8. To report adverse reactions of medicines to health authorities, when necessary,
9. To provide and share general as well as specific medicine related information and to advise the public and health care providers,
10. To update the knowledge on medical therapy regularly through continuous professional development.

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

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

1. Proper administration of drugs i.e., to take right drug at right time. Whether the drug has to be administered before or after meals, frequency of administration, and dose of drugs to be administered in emergencies. All these are monitored by the pharmacist along with nurses,
2. A pharmacist also provides information to the nurse about the diet plan which should be followed by the patient during the drug therapy. A pharmacist is the best person who knows about the drug-food interactions and thus, he decides the diet plan which should be advised and monitored by the nurses.
3. The pharmacist also guides the nurses about the safe handling of drugs. He provides information regarding proper dispensing, storage of drugs and disposal of waste containers.
4. The pharmacist assists the nurses in documentation which includes recording of day to day and patient to patient plan of drug administration, recording of drug administered and to be administered. He can also assist in documentation of various clinical parameters at regular interval of time.
5. The pharmacist can also train the nurses about the use and sterilisation techniques of surgical instruments.
6. A pharmacist also acts as an active member of the health care team which includes physician and nurse, which can ultimately provide maximum benefits to the patients.

In the health care service the position of a pharmacist can be depicted as shown below.



Pharmacy as a Career

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

In the changing global scenario and in post implementation of GATT (General Agreement on Tariff and Trade) and TRIPS (Trade Related aspects of Intellectual Property Rights) in India, Indian pharmaceutical sector is witnessing tremendous growth with contract research and clinical trial business. The new patent regime is also opening avenues for Indian players. The Indian pharmaceutical industry presently has become the

front line player in the global pharmaceutical business. The sector is estimated to be worth of about 8 billion US$ with an annual growth of about 13%.

Indian pharmaceutical industry globally ranks 4th in terms of volume with about 8% share in global business, ranks 13th in terms of value. Indian pharmaceutical industry is now producing about 24% of the global generic drugs in terms of value. India is one of the 5 top producers of active pharmaceutical ingredients (API) with a share of about 6.5% globally. We are now supplying formulations to many countries of the world and catering about 70% of the demand for bulk drugs.

India ranks 17th with respect to exports value of bulk drugs and dosage forms. The factors that help Indian pharmaceutical industry to grow are, low cost of R&D, low cost of production, innovative scientific manpower and the strength of national laboratories.

With these advantages, India can now be able to export nearly 40% of the production which constitutes 55% of formulations and 45% of the bulk drugs.

According to Mckinsey report 'Indian pharmaceutical market will grow to USD 55 billion by 2020 driven by a steady increase in affordability and a step jump in market access. At the projected scale, this market will be comparable to all developed markets other than the US, Japan and China. In terms of volumes, India will be at the top, a close second only to the US market

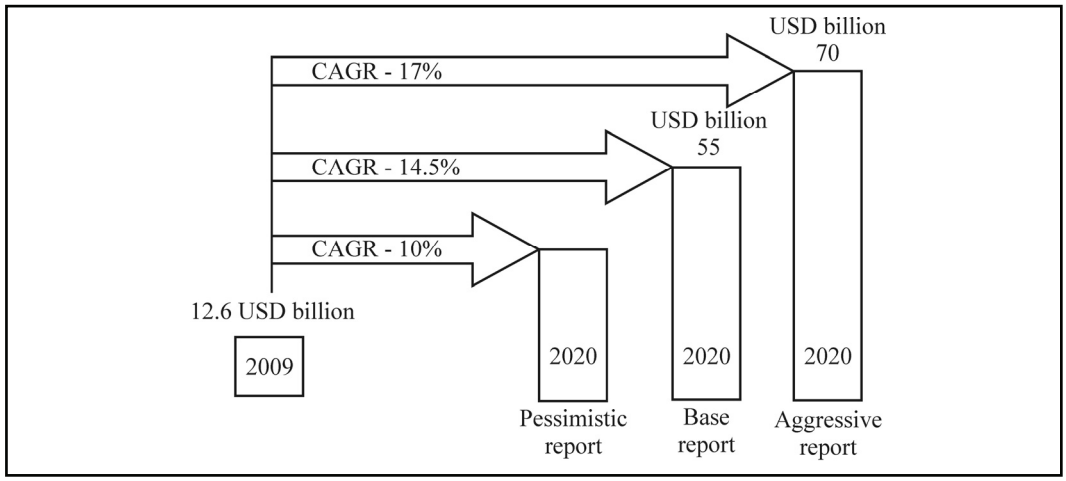


Figure 1.1 Projected size of Indian Pharma Market.

Source: Mckinsey analysis: secondary research

On account of inventory rationalization and reduction in Research and Development (R&D) budget by multinational pharmaceutical companies in the face of global slowdown the growth rate for Indian CRAMS (Contract Research and Manufacturing Services) players slowed down to 5-8% CAGR (Cumulative Annualised Growth Rate)

during 2009-2011. The industry has undergone tough times. However, in subsequent years the growth rate gradually picked up to low double digits. CARE Ratings expects gradual improvement (expected CAGR 18-20%) on the back of recovery signs witnessed in US markets. Some of the major drugs are going off patent during 2014-2020.

As per the report of a global pharmaceutical market intelligence company, IMS Health, the Indian Generic Manufacturers will grow to more than 70 billion US$ within couple of years as the patent of some drugs worth of 20 billion US$ annual sales value had expired in 2008 and the patent of some best selling drugs worth of about 80 billion US$ will expire by 2012.

Thus, it is clearly evident that the employment potential in pharmaceutical sector is growing faster in this country.

Career Opportunities

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

1. Pharmaceutical Industries
   Production – Manufacturing, Packaging, Store & Purchase
   Quality Control & Quality Assurance
   Research & Development
2. Pharmaceutical Marketing
3. Hospital & Clinical Pharmacy
4. Community Pharmacy
5. Regulatory Affairs
6. Academics
7. Consultancy
8. Library Information Service and Pharmaceutical Journalism
9. Opportunities Abroad

1. Pharmaceutical Manufacturing

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

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

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

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

Research and Development is heart of an industry. For sustenance and growth every industry should have its own R&D department. In pharmaceutical industry it is very much essential, because the discovery of a drug molecule and development of a suitable dosage form are continuous processes as the type of disease and its treatment are changing. Even for better treatment of the existing diseases the development of the drug delivery systems are necessary. Hence, a lot of job opportunity exist in this area and persons having M. Pharm or M. Pharm, Ph. D qualication are most suitable.

2. Pharmaceutical Marketing

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

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

3. Hospital and Clinical Pharmacy

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

4. Community Pharmacy

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

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

5. Regulatory Affairs

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

6. Academics

Excellent opportunities in teaching profession are available throughout the country. There are many Institutions in the country managed by government and private institutions where vacancies at different levels are still in existence. The minimum

eligible qualification at lecturer level is M.Pharm and with Ph.D one reach up to Professor level.

7. **Consultancy**

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

8. **Library Information Service and Pharmaceutical Journalism**

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

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

9. **Opportunities Abroad**

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

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

Pharmacy Education and Regulatory Bodies in India

Pharmacy education in India is a two-tier system. After 12^{th}, science students of state or central board one can opt for any of the three courses, D.Pharm, B.Pharm and M.Pharm. The duration of these courses are 2, 4 and 2 years respectively. After D.Pharm one can persue B. Pharm course being admitted to 2^{nd} year. After completion of M.Pharm course, one can persue Ph.D. Presently, the Pharm. D, a 6 years' course has been started which is a Doctorate course in pharmacy.

The pharmacy education in India is regulated by the All India Council for Technical Education (AICTE) and the Pharmacy Council of India (PCI). The Universities are affiliating bodies.

Dosage Forms

Drug is a substance which is used for diagnosis, mitigation, treatment, cure or prevention of a disease in human beings or in the animals.

Drug(s) are as such rarely administered but are administered as a particular form - known as *dosage form*, wherein certain substances which are non-toxic, therapeutically inactive and compatible with the drug(s) substances are mixed with the drugs to prepare the dosage forms. These substances are termed as *excipients or adjuvants or additives*. Each of these has a specific role or function for being used in a particular dosage form.

Hence, the term **Dosage form** may be defined as a pharmaceutical preparation designed for administration of a drug into the body through a suitable route.

Each dosage form must have the following characteristics:

- Therapeutic effectiveness,
- Physiochemical stability, ability to deliver the correct dose of the drug at the correct site and at the desired time,
- Acceptability to the patient and
- Reasonable cost.

The formulation or dosage form of a drug may be generic or branded. A drug which is

1. No longer under patent protection, which may be produced by any manufacturer following GMP,
2. Is sold under the generic name, is called as **generic product** and the label of the product shall mention only the official name of the drug and its formulation.

For example, if on the label the name of the product is given, *Paracetamol Tablets IP*, it is *generic*, but if any name other than this, is given to the formulation by the manufacturer for its promotional purpose, and the name of the drug (paracetamol, here) is only known through the composition, it is **branded**.

Advantages of Dosage Forms

- Through a dosage form accurate dose of the drug can be administered.
- It can protect the drug from its degradation.

- The unpleasant odour and taste can be masked.
- Depending on the requirement a drug can be formulated as solid, semisolid, liquid or gaseous dosage form.
- The palatability of a liquid dosage form can be improved by addition of suitable excipient.
- The therapeutic action of a drug can be modified through a formulation, e.g. sustained, delayed, controlled release formulation.
- A properly designed formulation can be inserted into any part of the body for desired therapeutic action, e.g. suppositories, inserts and dental cones etc,.
- For dispensing to various category of patients, e.g. children, adult, elderly, bed ridden, a drug can be formulated differently.

Classification of Dosage Form

The dosage forms may be classified on the basis of their routes of administration, the physical state and method of manufacture.

Physical state	Dosage form
Solid	Tablet, Capsule, Granules and Powders.
Semi-solid	Ointment, Cream, Paste, gel.
Liquid	Solution, Suspension, Emulsion.
Gas	Inhalations.

Route of administration	Dosage form
Oral	Tablet, Capsule, Granules, Powders, Solution, Syrup, Elixir, Suspension, emulsion, Gel.
Parenteral	Injection (in the form of solution, suspension, emulsion), Implant.
Topical	Ointment, Cream, Paste, Lotion, Gel, Solution, Aerosol.
Eye	Solution, Ointment.
Ear	Solution, Suspension, Ointment.
Nasal	Solution, Inhalation.
Lung	Aerosol (in the form of solution, suspension, powder), sprays, Gases, Inhalation.
Rectal/Vaginal	Suppositories, Ointment, Cream, Powder, Lotion.

Method of Manufacture	Dosage form
Aseptic	Sterile (Parenterals, Opthalmics)
Non-aseptic	Non-sterile (Solutions, syrups and others)
Special	Novel Drug Delivery systems (Controlled drug delivery)

Routes of Drug Administration

The routes through which a drug may be administered are: oral, buccal or sublingual, inhalation, rectal, parenteral and topical. The route of administration is selected on the basis of necessity and convenience.

Oral Route

This is the most convenient route because a patient does not require anybody to take a dose of a drug. Only a child, very elderly or bed ridden cannot take the drug without the help of anybody. Most of the drugs are capable of reaching systemic circulation adequately within a reasonable time limit and can elicit expected therapeutic effect. Most of the drugs are absorbed from the gastrointestinal tract. However, there are certain exceptions.

Buccal or Sublingual Route

Although by swallowing a dosage form, adequate plasma concentration of a drug is achieved within a reasonable time, sometimes for faster response and to avoid degradation of the drug in the liver, a drug may be given through buccal or sublingual route. For example, in case of angina pectoris a patient can get relief by taking drug through this route and parenteral route may by avoided. Limited drugs are administered by this route.

Inhalation Route

This route is used to deliver either the gaseous or volatile drug substances or through a gaseous or volatile carrier into the systemic circulation. For example general anaesthetics. The drug is administered through lungs to the alveoli. As the alveolar and vascular membrane are penetrable to the drugs, flow of blood is abundant and the surface area is large, the absorption of drug is also high. Because of certain problems this route is not used largely. It is mostly useful when the drug is supposed to act on the respiratory tract.

Rectal Route and Vaginal Route

Usually the drugs which are administered orally can be administered rectally also. It has three distinct advantages:

1. The drug administered rectally can exert a direct action on the rectum,
2. It can evacuate the bowel, and
3. Can provide a systemic effect.

In earlier days, rectal suppositories and retention enemas were more popular, but due to improvement in parenteral preparations their popularity has been decreased. Still with certain limitation this route is in use and, sometimes, very important for administration of

drugs, particularly in paediatrics and geriatrics. In some cases, the retention enemas become very useful substitute for oral route.

Parenteral Routes

There are various routes of administration of a drug parenterally. Depending on the need and the drug, the solution of a drug is injected through one of the following parenteral routes.

1. ***Intracutaneous or Intradermal Injection:*** The drug solution is injected into the skin, between the epidermis (outer layer of the skin) and dermis (inner layer). The volume of injection, usually small, 0.1 to 0.2 ml and normally the skin of left forearm is the site. Main purpose of such injection is diagnostic or investigation of immunity or allergy.
2. ***Subcutaneous or Hypodermic Injection:*** This is given under the skin. That is, into the subcutaneous tissue, and the maximum volume of injection is up to 1 ml. Oily solution or suspension in oil or water cannot be given through this route as these cause pain or irritation.

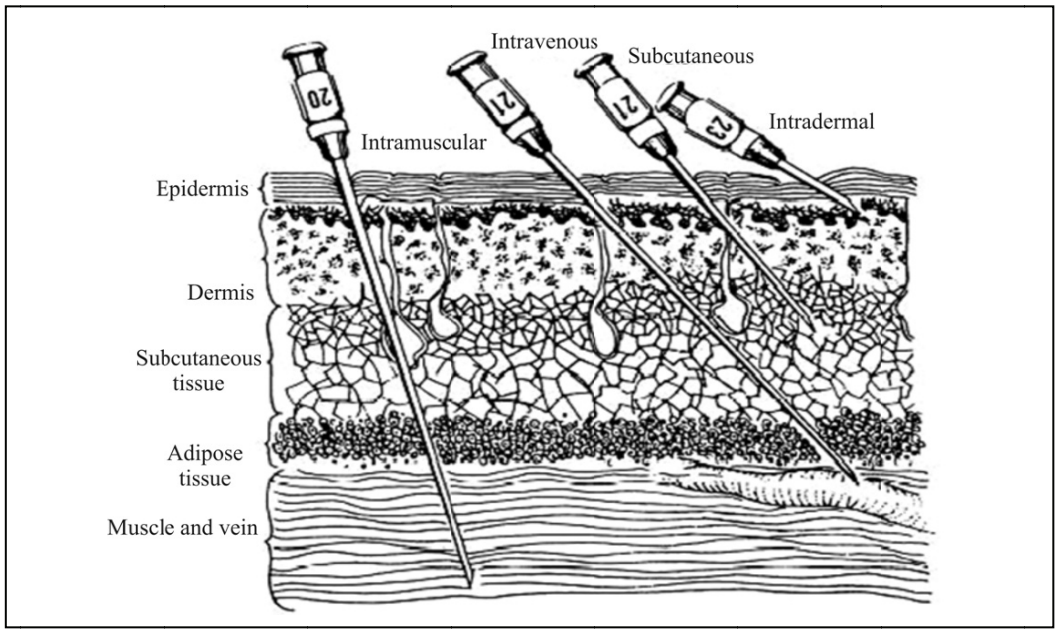


Figure 1.2 Routes of Parenterals Administration.

3. ***Intramuscular Injection:*** These injections are given inside a muscle penetrating the subcutaneous tissue and muscle membrane. The common sites are muscles of shoulder, thigh or of buttock. The maximum volume injected is 4-5 ml. As the muscle can tolerate pain, irritation and there is little fear of blockage, the oily solution or suspension in oil or water can be administered

through this route in small volumes. The rate of administration should be slow in such cases.

4. ***Intravenous Injection:*** These are given to the vein and hence, directly to the blood stream. This is the route of choice when immediate response is desired. Most common site of injection is the median basilic vein, near anterior surface of the elbow. The volume of injection may range from 1 ml to 500 ml or more. For immediate therapeutic action the small injections are given. Large volume is given usually for replacement of body fluids or eletrolytes.
5. ***Intra-arterial Injection:*** This is almost similar to intravenous injection. This is given when immediate effect is required in peripheral area. For example, in early gangrene when arterial flow is restricted, this injection is given to improve the flow.
6. ***Intracardiac Injection:*** In emergency only, this is given into the heart muscle or ventricle. For example, in cardiac arrest injection of adrenaline or isoprenaline sulphate is given through this route.
7. ***Intrathecal Injection:*** This is given into the subarachnoid space surrounding the spinal cord. That is the space, between arachnoid and pia matter, containing a fluid known as cerebrospinal fluid. Such injection requires special skill so that the injection is made without entering the spinal cord and causing serious damage. The volume injected normally within 20 ml and in extreme cases like in spinal anaesthesia, tubercular meningitis the drug is given in this route. In the same way the cerebrospinal fluid is taken for diagnostic purpose also.
8. ***Peridural Injection:*** The injection is made into the peridural space between the dura matter and the inner aspect of the vertebrae. The peridural space is narrow but extended throughout the spinal column length wise. Hence, a special skill is necessary for injection.
9. ***Intracisternal Injection:*** This is another special route and requires special skill, used either to withdraw the cerebrospinal fluid or to inject a dye for investigation purpose, or to administer an antibiotic for treatment. The needle is inserted between the first and second vertebrae, and into the cisterna magna. This is done when intrathecal route is failed.
10. ***Intra-articular injection:*** This injection is made into the synovial fluid that lubricates the articulating ends of bones in a joint. Usually anti-inflammatory drugs are administered through this route.

Topical Route

This route refers to the application of a drug over the skin either for its local effect or for systemic effect. For example, a dermatological preparation is meant for treating skin disorder, the skin is the target organ. A transdermal preparation is intended to deliver the drug to the systemic circulation through the skin, skin is not the target organ.

Pharmacopoeia

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

Indian Pharmacopoeia

The Indian Pharmacopoeia originated in the year 1844 in the name of Bengal Pharmacopoeia and General Conspectus of Medicinal Plants commonly known as Bengal pharmacopoeia. It was prepared by William Brooke O'Shaughnessy and published by the order of the Government. The principal focus of this was on indigenous drugs along with some products imported from Europe.

Later in the year 1865 the Indian Pharmacopoeia Committee was constituted, which in the year 1868 published the first Pharmacopoeia of India under the authority of the Secretary of State for India in Council. The Pharmacopoeia was edited by Edward John Waring. It contained the drugs, official in the British Pharmacopoeia 1867 along with some indigenous drugs. A Supplement to the Pharmacopoeia of India was prepared by Moodeen Sheriff which was published in 1869. Till 1885 the Pharmacopoeia of India had been in use. When British Pharmacopoeia 1885 was published, the Government made this Pharmacopoeia the sole authority on all matters relating to pharmacy in India. In 1900, the Indian and Colonial Addendum to the British Pharmacopoeia 1898 was published and in 1901, it was published as the Government of India Edition with certain minor modifications. The important articles of this Addendum were subsequently included into the general body of the British Pharmacopoeia 1914. The British Pharmacopoeia Commission also made provision for publication of Supplement or Addenda according to the local requirements and the Indian Pharmacopoeia List 1946 was accordingly prepared to serve as the Indian Supplement to the British Pharmacopoeia 1932. After independence, in the year 1948 an Indian Pharmacopoeia Committee was constituted for preparation of the Pharmacopoeia of India (The Indian Pharmacopoeia) 1955. In 1960, a Supplement to it was published. This Pharmacopoeia contained western as well as traditional drugs. The Indian Pharmacopoeia 1966 and its Addenda 1975 were prepared as per the same policy. Next edition of the Pharmacopoeia of India 1985 and its Addenda 1989 and 1991 also did not include the traditional drugs in general. The traditional drugs were considered separately and only those herbal drugs having definite quality control standards were included.

The Government of India Ministry of Health & Family Welfare, vide their Resolution No. X.19020/1/89-DMS & PFA dated 12th August, 1991 reconstituted the Indian

Pharmacopoeia Committee for a period of five years for preparation of the next edition of the Indian Pharmacopoeia under the Chairmanship of Dr. Nityanand, Ex-Director, Central Drug Research Institute, Lucknow.

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

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

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

The full name or title of the Pharmacopoeia including Addenda there to, has been changed to Indian Pharmacopoeia 1996 and abbreviated to IP 1996 because of convenience to all and the initial name, Pharmacopoeia of India has been dropped. Current edition of Indian Pharmacopoeia is its 7th edition which has been published in 2014.

United States Pharmacopoeia

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

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

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

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

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

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

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

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

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

Since 2002, the USP-NF has been revised and published annually. The current edition USP 39-NF 34 was published on 1, May 2016.

National Formulary

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

Hence, in 1852, the American Pharmaceutical Association (APhA) organised and prepared a Formulary containing some drugs and formulas which were not included in the USP. In 1888 the first edition of the Formulary was published under the title, National Formulary of Unofficial Preparations. The term unofficial indicated a kind of protest and to distinguish it from the USP in which the term official was used. In 1906 the title was changed to National Formulary (NF) and both USP and NF were made legal books of

standards as per the first federal Pure Food and Drug Act under the signature of the then president, Theodore Roosevelt. Hence, according to the law the formulations carried the name USP or NF in their labels were bound to conform to the physical and chemical standards mentioned in the respective monographs.

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

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

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

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

Since 2002 the USP-NF has been revised and published annually. The current USP33-NF28 shall be published in the year 2010. Currently USP 39 NF 34 is available.

British Pharmacopoeia

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

The 1968 Medicines Act established the legal status of the British Pharmacopoeia Commission and of the British Pharmacopoeia as the standards for medicinal products in

the United Kingdom under the section 4 of the Act. Since then, the British Pharmacopoeia Commission continued the work of the earlier Commissions appointed by the General Medical Council and was responsible for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping those up-to-date. Since 1864, the distribution of BP has grown throughout the world and is now used in more than 100 countries. Australia and Canada have adopted the BP as their national standard and in other countries, e.g. Korea, BP is recognized as an internationally acceptable standard.

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

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

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

Till 1996, the British Pharmacopoeia has been revised and published every 5 years. Since 1998 it has been revised and published annually.

International Pharmacopoeia

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

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

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

The third World Health Assembly held in May, 1950, formally approved the publication of the *Pharmacopoea Internationalis*. This was not intended to be legal pharmacopoeia in any country unless adopted by the pharmacopoeial authority of that country. From that time WHO constituted a permanent International Pharmacopoeial Secretariat. Accordingly, the first edition of International Pharmacopoeia was published in 2 volumes, one in 1951 and the other in 1955. In 1959, a supplement was published. These were published in English, French and Spanish, subsequently translated into German and Japanese languages. Altogether, it included 344 monographs on drug substances, 183 monographs on dosage forms and 84 tests, methods and general requirements. A large number of national pharmacopoeias and official lists were examined and assistance from International Pharmaceutical Federation (FIP) was also obtained to select substances and products for their inclusion in the pharmacopoeia.

The second edition was published in 1967, the third edition in 1975, and in 2006 the forth edition was published. The current edition is published in 2015 and this is the fifth edition. This serves as the source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements.

European Pharmacopoeia

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

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

On 16th November, 1989, a protocol to this convention was signed in order to enable the European community to accede to it and since 1st November 1992, it was entered into force.

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

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

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

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

The current edition is the 8th edition, published in the year 2014 and consists of a two-volume main edition with supplements. But since 1st January 2017 the 9th edition shall be effective.

The texts and monographs of the European Pharmacopoeia form an integral part of the British Pharmacopoeia.

Extra Pharmacopoeia

It was published in 1883 under the title, Martindale: *The Extra Pharmacopoeia*. Presently it is being published as Martindale : *The Complete Drug Reference*. It is a reference book with information of about 6000 drugs and medicines, and 146000 proprietary preparations. It also includes 668 disease treatment reviews along with some selected investigational and veterinary drugs, herbal and complementary medicines, pharmaceutical excipients, vitamins and nutritional agents, vaccines, radio-pharmaceuticals, diagnostic agents, contrast media, medicinal gases, drugs of abuse, recreational drugs, toxic substances, disinfectants and pesticides.

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

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

Martindale has two main parts, Monographs and Preparations plus two extensive indexes, Directory of manufacturers and General index.

Monographs on drugs and ancillary substances, - about 5827 monographs are arranged in 53 chapters based on clinical use with reference to disease treatment reviews. Monograph contains nomenclature, properties and actions of each substance. A chapter on supplementary drugs and other substances covers about 980 monographs on new drugs, not easily classified, herbals and drugs which are not even clinically used, but reported to be of clinical interest. Monographs of some toxic substances are also included.

Preparations about 1,46,000 preparations from various countries of the world are included in this portion.

Directory of Manufacturers contains about 13,000 names of manufacturers.

General index contains approved names, synonyms and chemical names.

In the digital version, additional 1000 drug monographs, 30,000 preparation names and 5000 manufacturers are provided.

Some Important Compendial Terms

Monographs: The format of the text given in a Pharmacopoeia containing the official title, the primary informations and the all the requirements given under the heading, **STANDARDS** for a pharmaceutical ingredient or for a formulation.

General Monographs are the monographs which describe official preparations, requirements of general application and requirements of tests applicable to all monographs for the relevant dosage forms, unless otherwise mentioned in the individual monograph.

Official Standards: It refers to the requirements mentioned in a monograph of the Pharmacopoeia applicable for a substance or its product intended for medicinal use, not for other purpose. A monograph shall be construed according to any general monograph, notice, note, any appendix, or any other explanatory material given in the Pharmacopoeia and those shall be applicable to that monograph.

Under the heading **STANDARDS** in a monograph all the statements shall refer to as standards, if there is no specific general notice indicating otherwise is given and no material can be considered as of *pharmacopoeial quality* unless it comply with all the requirements stated in the monograph. The monograph limits the presence of potential impurities only. Any material, if found to contain any impurity, contaminant or adulterant which cannot be detected by the prescribed tests, cannot be declared as *not of pharmacopoeial quality* unless the nature and amount of such substance is found objectionable under the conditions of use or is incompatible with good pharmaceutical practice.

Usual Strength: In any individual monograph of a preparation the strength is mentioned as a general information to the pharmacist or the medical practitioner and does not prevent any manufacturer from manufacture and market the formulation of different strength with the approval of appropriate authority.

Storage: The storage conditions mentioned in a monograph are not mandatory, only a advice type to maintain the appropriate conditions to protect a substance or a product from the effects of atmosphere, moisture, heat, light and to prevent deterioration and contamination. The terms mentioned as storage condition with respect to temperature are;

Cold**:** Any temperature within the range from $2^{o} – 8^{o}$C, a refrigerator is a cold place.

Cool**:** Any temperature within the range from $8^{o} – 25^{o}$C, unless otherwise mentioned, a refrigerator can be used as a cool place.

Room temperature**:** The temperature prevailing in a particular place of work.

Warm: Any temperature within $30^{o} – 40^{o}$C.

Excessive heat**:** Any temperature more than 40^{o}C.

Protection from freezing**:** Where it is known that freezing may cause breakage of the container, alter the characteristics of the contents in terms of strength or potency or any other, the precautionary note is provided in the monographs.

Storage under non-specific conditions**:** Where there is no specific storage condition is mentioned in the monograph, the material is to be kept away from moisture, freezing and excessive heat.

Containers: Container is a device to hold a material. The closure is a part of container. The immediate container is that which always remains in direct contact with the material, e.g., an ampoule, bottle, etc. Since it has a role in protecting the material from contamination and deterioration, requirements and guiding information are provided in the Pharmacopoeia. Despite that in certain individual monographs requirements for containers are also provided. However, any other newly developed or designed container which satisfy the requirements and serve the purpose, but not included in the pharmacopoeia, can be used with the permission of the appropriate authority.

The primary functions of a container are;

- To provide the required degree of protection to the contents from the environment,
- To provide convenient transfer of the content from the container,
- To ensure that the safety and quality of the contents are not changed,
- There should be no interaction between the container and contents,
- To ensure that no extraneous material is introduced into or onto the contents.

Thus, the container should be properly cleaned.

Light-resistant Container means a container that protects the contents from the effects of actinic light by means of,

- Light resistant property of the container itself,
- By wrapping the container with an opaque cover,
- Storing the container in dark place.

In the later cases the label on the container should clearly mention the instructions for storage.

Well-closed Container should ensure - protection of the contents from extraneous solids and liquids, and – no loss of content under normal conditions of, handling, shipment and distribution, storage.

Tightly-closed Container should ensure - protection of the contents from extraneous solids, liquids, or vapours, – no loss or deterioration of content from effervescence, deliquescence or evaporation under normal conditions of, handling, shipment and distribution, storage.

A tightly-closed container should be capable of being closed tightly after opening the container.

Where a tightly-closed container is specified, a hermetically sealed container can be used for a single dose of a formulation.

Hermetically Sealed Container is a container impervious to air or any other gas under normal condition of handling, shipment, distribution and storage. It may be closed either by fusion of the material of the container, e.g. ampoule, or by any other means, e.g. sealed container used for powder for injection as mentioned in an individual monograph of the Pharmacopoeia.

Single Unit Container is designed to hold a single dose of a preparation and intended for use immediately after opening the container. The immediate container and/or outer container or protective packaging is also designed in such a way that any tampering with the contents can be seen.

Single Dose Container is intended for holding a single dose parenteral preparation or an amount of a drug sufficient for its single dose.

Unit Dose Container is a container to hold a single dose of a non-parenteral preparation which can be administered directly from the container.

Multiple Unit Container is a container which holds multiple doses of a preparation and allows withdrawal of contents repeatedly without affecting the strength, quality or purity of the remaining portions in the container.

Multiple Dose Container is a multiple unit container intended for holding multiple doses of a parenteral preparation.

Tamper-evident Container is a container fitted with a device or mechanism that reveals irreversibly whether the container has been opened.

Labelling: The labelling of drugs and pharmaceuticals, in general, is governed by the Rules made under the Drugs and Cosmetics Act, 1940 and a drug or its product must bear a label stating the information necessary for it. No deviation is permitted. In the pharmacopoeial monograph the statement given under the heading Labelling is mere a recommendation.

General Guidelines for Manufacturing

The experiment may be performed either on the basis of an established formula (composition and method of manufacture) or after designing a formula. The former will be a demonstration or practice case while the latter shall be considered as a project work.

In either case the following procedures must be followed to approach a *zero-error* result.

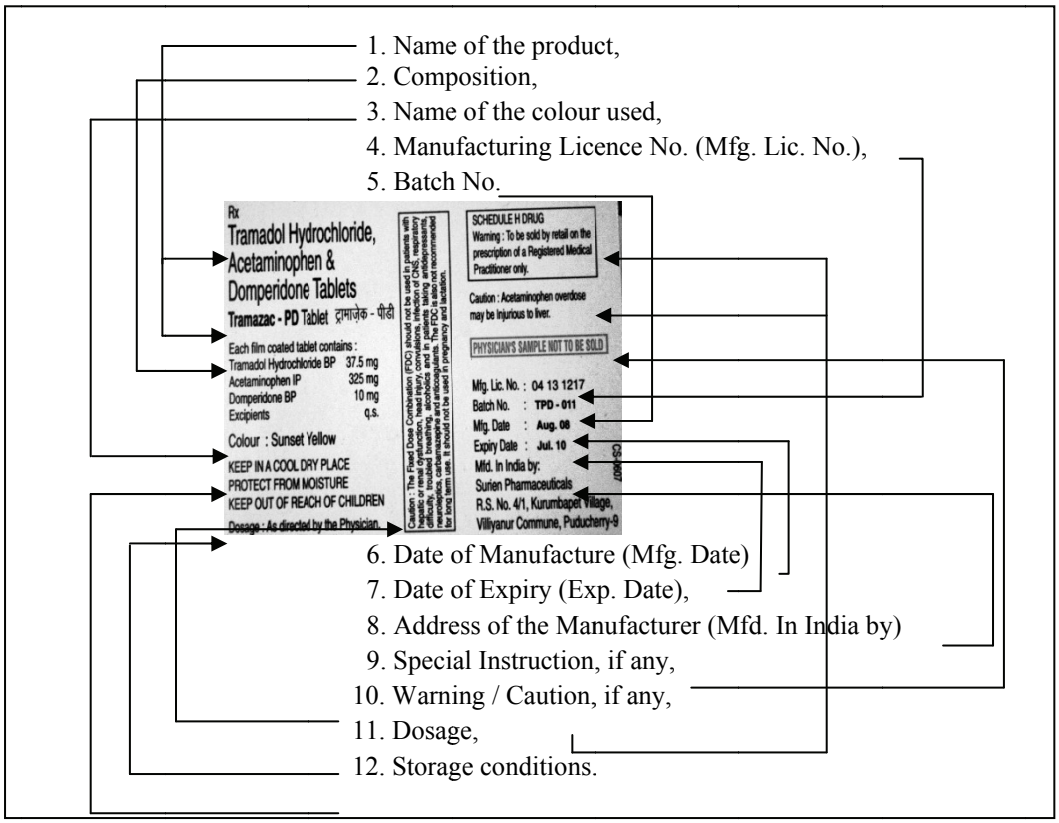
1. Fix up the *lot size* of the product to be manufactured.
2. Decide which method is to be followed.
3. Accordingly make a list of ingredients both *active ingredients* and *excipients,* necessary for the lot.
4. Write down the different *steps* of manufacturing.
5. Make a list of *machineries*, *equipments* and *apparatus* required for the experiment.
6. *Clean* each equipment and machine, *calibrate* each of these.
7. Clean the *work place*.
8. Examine all the materials required for the experiment with respect to their *appearance*, *assay* and *impurities*.
9. The materials to be used as *dried form*, dry them properly at a temperature quite below their melting point; if to be *sieved* or *filtered,* sieve or filter before *weighing*

the required quantity for the lot. While calculating the required quantity take the *purity (assay value)* of the *drug substance(s)* into consideration.

10. Make *list of tests* to be carried out during processing (*process control test*) and after completion (*final tests*). Ensure the availability of *testing facility* and *calibrate* the *instruments* accordingly.
11. Also, check the *working environment*, e.g. room temperature, humidity, sterility, etc., as appropriate to the product being manufactured, is maintained.

Record all the *information* properly and sequentially in the practical note book.

Contents or Parts of a Label



Exercises

Short Questions

1. (a) What do you mean by Shanidar and Mangical medicines?
   (b) How the pharmacy had been practiced during middle age?
   (c) Which period is called Renaissance and why?
   (d) What are other professionals related to health care system?
   (e) What are in-patient and out-patient counselling?
   (f) What is community pharmacy?
   (g) Name the bodies who regulate pharmacy education in India.
   (h) Define drug, dose, dosage form and excipient.
   (i) Write down the characteristics of a dosage form.
   (j) What are generic and branded dosage forms?
   (k) How can a generic product be identified from the label?
   (l) What is a Pharmacopoeia?
   (m) What are full form of IP, USP, BP, EP, NF, BPC?
   (n) Define the term Monograph.
   (o) What do you understand by Official Standard?
   (p) What are temperatures referred to as cold, cool and warm?
   (q) What are single dose container and unit dose container?
2. Discuss how the pharmacy has been developed.
3. Enumerate the role of pharmacist in health care system.
4. How can a pharmacist assist a nursing staff during various stages of therapy?
5. What are the career opportunities in pharmacy?
6. Classify the dosage forms according to their method of manufacturing, physical state and route of administration.
7. Discuss briefly the developmental history of IP/BP/USP/Extra Pharmacopoeia.
8. Explain briefly the importance of a Pharmacopoeia in a country. What does it contain? How it is related to pharmacy?
9. Present a label and mention the various parts.
10. Briefly write down the measures to be taken during manufacture of a dosage form.

11. Write short notes on:

(a) Parenteral Route of Administration
(b) Antiquity
(c) Patient counselling
(d) Dosage Forms
(e) Community Pharmacy
(f) International Pharmacopoeia
(g) National Formulary
(h) AICTE,
(i) PCI
(j) Importance of a label