UNIT-I

Historical background and development of profession of pharmacy :-

Pharmaceutics

- The word pharmaceutics is used in pharmacy and pharmaceutical sciences to encompass many subject areas, which are all associated with the steps to which a drug is subjected towards the end of it's development i.e.

It is the stages that follow it's discovery or synthesis, it's isolation and purification and testing for advantageous pharmacological effect and the absence of serious toxicological problems.

- Put at it's most simplistic, pharmaceutics converts a drug into a medicine.
- Pharmaceutics is concerned with the scientific and technological aspects of the design and manufacture of dosage forms.
- Note :- medicines are drug delivery system that is they are a means of administering drugs to the body in a safe, efficient, reproducible and convenient manner.

History of profession of Pharmacy in India in relation to pharmacy education

- The allopathic system of medicine was introduced in India during the British rule.
- It was mainly meant for the ruling class.
- By the 19th century it became popular and was used for the common people also
- In the beginning the medicine were imported from Europe, later they were manufactured in India.
- The Bengal chemical and pharmaceutical works was setup by Acharya P.C. Ray in 1901 in Calcutta.
- Prof. T.K. Gujjar set up a small factory in Bombay at parel 1903 and the Alembic chemical works in 1907 at Baroda.
- The import of drugs was stopped during the first world war. It was resumed after the war. There was no restriction on the quality of the imported drugs so there were inferior quality drugs in the markets. Therefore a number of acts were passed to regulate the quality of drugs.
- In 1903 a comittee was appointed under the leadership of Col. R.N. Chopra to look into the issue related to the pharmacy in India.
- It reported that pharmacy did not exist as a specialized profession.
- After this prof. Mahadeva Lal Schroff started the pharmaceutical education in the Banaras Hindu University.

- The united province pharmaceutical association was set up in 1935 which later became the Indian pharmaceutical association.
- In 1939 prof. M.L Schroff started the Indian journal of pharmacy.
- The all India pharmaceutical congress association was set up in 1940 which held its session at various places and tried to publicize the idea of pharmacy.
- To regulate the manufacture, import, distribution and sale of drug, the drugs act of 1950 was adopted.

Industry and organisation

- It is well-known fact that because of the British rule, pharmaceutical industry couldnot be developed significantly in India.
- After Independence, the government declared its industrial policy in the year 1950.
- The government gave importance to the development of the pharmaceutical industry.
- During 1950, there were 65 domestic pharmaceutical units in India, while foreign units were 28 in number.
- In 1952 about 1,643 Unceses were issued under the drug act.
- In 1989, the no. has increased to 12000.
- Of there only 1554 were manufactering units.
- ~~Due to~~ In 1952, total investment in the pharmaceutical industry was only Rs. 24cr which increased to Rs. 1,175cr in 1984-85, and in 2000-05, it has reached over Rs. 15000 crores.

• Due to development of the pharmaceutical Industry, the average life expectancy of Indian Increased from 32 - 60 years.

• In fact, India has also made adequate research in this field.

• However, the multinationals have already entered the Indian market.

• These companies are competing with the Indian pharmaceutical companies.

Pharmacopoeia

→ Pharmacopoeia is accepted as a book of standards.

→ The word pharmacopoeia derived from Greek words phamacon (drug) and poeia (to make).

→ Pharmacopoeia contains —

* List of drugs and formula for medicinal substances and preparations.
* Description
* Tests &
* Standards.

→ It is issued under the authority of the government of country.

→ The countries don't have own pharmacopoeia can use pharmacopoeia of other countries.

* Pharmacopoeia is an official (set of simpler things) compendium containing list of established drugs with its nomenclature, molecular and structural formula, category/use, test for its identity, purity and potency (power of something to influence or make an impression) along with assay (determine the quality).

Indian Pharmacopoeia

It is an autonomous institution of the Ministry of Health and family welfare which sets standards for all drugs that are manufactured, sold and consumed in India.

* The set of standards are published under the title Indian Pharmacopoeia. (IP).

History

→ The history of IP is as old as BP.

→ The Bengal pharmacopoeia was published in 1844 (Nearly 20 year before first BP).

As on record, first pharmacopoeia of India published in 1868 under the authority of Her Majesty's, secretary of state for India in council.

It contains —

* Vegetable
* Animal
* Distillations.
* Inorganic material & medica
* Products of fermentation.

↳ IIs supplement was published in 1869.

↳ It was the BP (A.H.) which was considered as the book of standards during the pre-Independence.

→ In 1902 Bose published - Official Indigenous Drugs of Indica. It was published as enlarge edition in 1932 as pharmacopoeia Indica.

After Independence

Indian pharmacopoeial committee was appointed in 1948 to prepare National Pharmacopoeia.

→ The first edition of IP was published in 1955.

British Pharmacopoeia

UK – United Kingdom – [England, Scotland, Wales]

Pharmacopoeias in UK

* British Pharmacopoeia (BP)
* British Pharmacopoeia (Veterinary)
* European Pharmacopoeia (Ph. Europe)

→ The BP provides comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products.

→ Important contribution to the role of the MHRA (Medicines & Healthcare Products Regulatory Agency).

→ BP publish every year in August.
Become effective on 1, January of the following year.

→ It incorporates all the Monographs and texts of the Ph. Europe.

→ It is vital reference tool for all individuals and organisations involved in Pharmaceuticals:-

R & D
Manufacturing
Quality control & Analysis.

The British Pharmacopoeia Commission:-

↳ Sponsored by Dept. of Health & Social care.

↳ Responsible for preparing New editions of the BP & BP(vet.)

↳ Established under the 1968 Medicine Acts.

↓

Superseded by the Human Medicines Regulations 2012.

BP contains:

* General Notices * General Monographs
* Specific Monographs – Provides mandatory standards for →
  - API
  - Excipients
  - Formulated preparations
  - Herbal drugs, Herbal drug products
  - Blood-related products
  - Immunological products.

History

1st ed. → 1864 → Part 1 : Materia Medica
2nd ed. → 1867 → Part 2 : Preparation & compounding
3rd ed. → 1884
4th ed. → 1898
5th ed. → 1914
6th ed. → 1953

After this it started to publish annually. (Every year)

United States Pharmacopoeia

→ USP-NF is combination of two compendia, United states Pharmacopoeia (USP) & National Formulary (NF)

→ USP-NF are the official standards for all prescription over the counter (OCT) medicines, dietry supplements, excipients and other healthcare product manufactured and sold in the United States (US).

→ US Federal food, drug and cosmetics act- designates the USP-NF as official Compendia in 1938.

USP-NF Components:

Monographs - About 4500

General Chapters - About 300

General Notices.

- Monographs → for drug substances, dosage forms and compound preparation.

→ Name of ingredients or prepartion.

→ The definition.

→ Packaging

→ Storage

→ Lebelling Requirements

→ Specification

↳ Specification consists:

→ Series of tests.

→ Procedure for the tests.

→ Acceptance critteria.

Excipients Monographs are in NF.

General Chapters :

→ Test and procedure referred in monographs are described in the detail.

General Notices

→ Defination of the terms used in the Monograph.

Publication Overview

→ United stated pharmacopoeial convention (Also called USP)

↳ Non-profit organization

↳ Owes the trademarks and copyrights to the USP-NF

→ Publish every year (Annually)

→ Volumes : 1st → General chapters

2nd & 3rd → Monographs.

History : 200 years

- 1820 : 1st edition published when group of 11 physician took action to protect patients from poor quality medicines by USP convention.
  - ↳ 217 drugs formula for preparation.
  - ↳ Written in English & Latin.
- 1888 : 1st NF appeared by American Pharmacist Association.
- 1975 : USP aquired NF from American Pharmacist Assn.

- 1980 : USP & NF published under same cover.
- 1992 : Electronic version of USP-NF on floppy disks was introduced.
- Current edition : USP 43 - NF 38 will become official on 1st November, 2020.

Note

* From 1820 to 1942, it was published at 10 year interval.
* 1942 to 2000 it was published at 05 year intervals.
* From 2002 it was published annually.

United Stats

Martindale : The Extra Pharmacopoeia

William Martindale (1840-1902), he was a pharmacy proprietor and an analyst in his pharmacy. He published the first edition under the title 'Martindale' The 'Extra' in the title was used in the sense of "outside", since the book aimed to describe drugs and medicines were not included in the current British Pharmacopoeia (BP) that time.

History and editions

The book was successful start from a slim pocket volume of 313 pages. The 'EP' has grown to its current 4160 pages.

→ In 1883, 1st edition of Martindale: The Extra Pharmacopoeia (EP) was published.

→ In 1885, a 4th edition was published.

→ In 1901, a 10th edition was published.

⊛ William Martindale was in poor health and he committed suicide in February 1902. After death of William Martindale, his pharmacist son Dr William Harrison Martindale had taken over the responsibility of publication of Martindale extra pharmacopoeia in association with Dr Wynn Westcott at intervals of 2 to 3 years until Westcott's death in 1925.

→ In 1912, 15th edition was published with additional volume II containing the analytical and diagnostic material and continued until the 23rd edition in 1952.

→ After Harri's death in 1933, the Martindale businesses were split and the copyright of the EP was acquired by the Pharmaceutical Society of Great Britain (PSGB).

→ Latest edition is 37th in 2011.

** Martindale contains information on drugs in clinical use worldwide, as well as selected investigational & veterinary drugs, herbal & complementary medicines, pharmaceutical excipients, vitamins & nutritional agents, vaccines, radiopharmaceuticals, disinfectant & pesticides.

Dosage Forms

Introduction

Drug (Active pharmaceutical ingredients):
Chemical compound intended for used in diagnosis, treatment, prevention of disease.

(OR)

The API is the part of any drug that produces its effects.

Excipients:

→ Inactive ingredients may also be referred to as inert ingredients or excipients generally have no pharmacological effect.

→ Donot increase or affect the therapeutic action of the active ingredient.

→ Examples include binding materials, dyes, preservatives, flavoring agents, sweetening agents, coloring agents etc.

Dosage form (Medicines) = API + Excipients
The means (or the form) by which drug molecules are delivered to sites of action within the body.

Classification of Dosage forms

→ Based on Route of Administration.

→ Based on Physical form.

→ Method of manufacture

Based on Route of Administration

Oral
- Tablet
- Capsule
- Syrup
- Suspension

Topical
- Ointments
- Creams
- Gels
- Pastes

Opthalmic
- Eye drops
- Opthalmic ointments and gels.

Parenteral
- Intramuscular injection
- Intravenous injection
- Subcutaneous injection

Inhalation
- Aerosol
- Nebulizer

Otic
- Ear drops

Rectal
- Suppository
- Enema

Vaginal : Pessary

Classification (physical form)

Solid dosage forms

- Unit dosage forms
  - Tablets
  - Capsule
  - Powders
  - Pills
- Bulk
  - Parenteral
    - Fine Powders & granules
  - External
    - Dusting powders
    - Insufflations
    - Dentrifice
    - Snuffs
    - Ear powders

Liquid dosage forms

- Biphasic
  - Emulsion
  - Suspension
- Monophasic
  - Internal
    - Syrups
    - Elixir
    - Linctus
    - Drops
  - External
    - Liniments
    - Lotions
    - Gargles
    - Throat paints
    - Mouth washes
    - Sprays
    - Eye lotions
    - Eye drops
    - Nasal drops

Semi solid dosage forms

- Internal
  - Suppositories
  - Pessaries
- External
  - Ointment
  - Creams
  - Pastes
  - Jellies

Classification (Method & manufacture)

→ Aseptic - Sterile (Parenterals, Opthalmic)

→ Non aseptic - Non sterile (Solution, Tablet)

Solid dosage forms

Powders

→ A pharmaceutical powder is a mixture of finely divided drugs or chemicals in dry form.

→ These are solid dosage form of medicaments which are meant for internal & external use.

Tablets

→ Tablets are solid dosage forms of compressed powders intended for oral administration

→ They are unit dosage form of medication containing specific amount of drug.

→ They are prepared with/without the aid of pharmaceutical excipients.

→ They vary in size, shape, weight, hardness, thickness, disintegration and dissolution.

→ They are the most widely used and convenient dosage form.

Capsules

→ Capsules are solid dosage forms in which medicinal agents and pharmaceutical ingredients are enclosed within a small shell of gelatin.

→ They are manufactured using Gelatin which is made up of proteins extracted from animal collagen.

Types

- Hard gelatin Capsules & Soft gelatin capsules

Pills : These are small, rounded solid dosage forms containing medicaments intended for oral use.

→ Now a days pills are outdated preparations because of number of disadvantages such as Disintegration time of pill is uncertain means freshly prepared pills disintegrates readily than old dried pills.

→ It is difficult to prepare pills of uniform size & weight.

Suppositories

→ A suppository is a medicated solid dosage form generally intended for use in rectum, vagina and to lesser extent, the urethra.

→ The medicament is incorporated into the suppository base and the product is formulated in such a way that they will either melt or dissolve in the body cavity fluid to release the medicament.

→ Produce local or systemic effects

→ Used for - Emolients, astrigents, antibacterial agents, hormones, steroids, local anaesthetics.

Liquid Dosage Forms

Biphasic : The liquid which consist of two phases are known as a biphasic liquid dosage forms.

→ They are sub categorized into two diff. forms - Emulsion & Suspension.

→ In emulsion, both phases are available in liquid whereas in suspension, finely divided solid particles are suspended in liquid medium.

Emulsions: Biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other.

Types

→ Water in oil (w/o)

→ Oil in water (o/w)

Suspension: Biphasic liquid dosage forms of medicament in which finely divided solid particles ranging from 0.5 – 5 micron are dispersed in a liquid.

→ In which solid particles act as disperse phase where as liquid vehicle acts as continuous phase.

→ These are taken orally, parenterally or externally.

Prescription

Prescription is a written order from a registered medical practitioner to a pharmacist to compound and dispense a specific medication for the patient.

→ The prescriptions are generally written in the English language but Latin words or abbreviations are frequently used in order to save time.

Parts of a Prescription

1. Date
2. Name, age, sex, and address of the patient.
3. Superscription
4. Inscription
5. Subscription
6. Signatura
7. Renewal Instructions
8. Signature, address and registration no. of the prescriber.

1. Date: It helps a pharmacist to find out the date of prescribing and date of presentation for filling the prescription. The prescription which prescribe narcotic or other habit forming drugs, must bear the date, so as to avoid the misuse of prescription if it is presented by the patient, a number of times for dispensing.

2. Name, age, sex and address of the patient: Must be written in the prescription because it serves to identify the prescription.

→ Also used in dose calculation of children.

3. Superscription: It is represented by a symbol Rx which is written before writing the prescription, which means you take.

→ In olden days, the symbol was considered to be originated from the sign of Jupiter, God of healing.

→ Employed by the ancient in requesting God for the quick recovery of the patient.

4. Inscription: This is the main part of the prescription order, contains the names and quantities of the prescribed ingredients.

→ The names of ingredients are generally written in English language but common abbreviation used can be written both in English and Latin languages.

5. Subscription: This comprises direction to the pharmacist for preparing the prescription and number of doses to be dispensed.

6. Signatura: This consists of the direction to be given to the patient regarding the administration of the drug.

→ It is usually written as 'sig' on the prescription.

The instruction may include the following :-

(a) The quantity to be taken.

(b) The frequency of administration or application.

(c) The mode of administration.

(d) The special instructions such as dilution direction.

7. Renewal instructions : The prescriber indicate on every prescription order, whether it may be renewed and if so, how many times.

→ It is very important particularly in the prescription containing the narcotic and other habit forming drugs to prevent its misuse.

8. Signature, address & Registration no. of the prescriber : The prescription must bear the signature of the prescriber along with its registration number and address.

Handling of Prescription

The following procedure should be adopted by the pharmacist while handling the prescriptions for compounding and dispensing :-

1. Receiving
2. Reading and checking
3. Collecting and weighing the materials
4. Compounding, labelling and packaging.

1. Receiving

→ The prescription should be received from the patient by the pharmacist himself.

→ While receiving a prescription, a pharmacist should not change his facial expression which gives an impression to the patient that he is surprised or confused after seeing the prescription.

2. Reading and checking

→ On receiving a prescription, always check it that it is written in a proper format ie doctor's pad or OPD slip of the hospital.

→ In case of any difficulty in reading or any doubt regarding the prescription, pharmacist should consult the other pharmacist or prescriber.

→ Pharmacist should never guess about the meaning of any illegal or confused word.

3. Collecting and weighing the material:

→ Before compounding the prescription, all the materials required for it, should be collected on the left hand side of the balance.

→ After weighing the material it should be shifted to right hand side of the balance.

→ This gives a check of ingredients which have been weighed.

4. Compounding, labelling and packaging

→ Compounding should be carried out in a neat place.

→ All the equipments etc. required should be thoroughly cleaned and dried.

→ Only one prescription should be compounded at one time.

→ All the ingredients should be compounded according to the directions of the prescriber or according to to pharmaceutical art.

→ The compounded medicaments should be filled in suitable containers depending on its quantity & use.

→ The filled containers are suitably labelled.

Errors in Prescription

1. Abbreviation:

→ Extreme care should be taken by pharmacist in interpreting the abbreviation.

→ Pharmacist should not guess at the meaning of an ambiguous abbreviation.

2. Name of the drug

→ There are certain drugs whose name look or sound like those of other drugs.

Digitoxin	Digoxin
Robalate	Robalate
Ananase	Orinase

3. Strength of the preparation

→ The strength of the preparation should be stated by the prescriber.

→ It is essential when various strength of a product are available in the market.

4. Dosage form of the drug prescribed

→ Many medicines are available in more than one dosage form. eg. liquid, capsule, tablet.

→ The pharmaceutical form of the product should be written on the prescription in order to avoid ambiguity.

5. Dose:

→ Unusually high or low doses should be discussed with the prescriber. Paediatric dosage may present.

→ So pharmacist should consult paediatric posology to avoid any error.

→ Sometimes a reasonable dose is administered too frequently.

6. Instructions for the patient

The quantity of the drug to be taken, the frequency and timing of administration and route of administration should be clearly given in the prescription so as to avoid any confusion.

7. Incompatibilities

It is essential to check that there are no pharmaceutical or therapeutic incompatibilities in a prescribed preparation and that different medicines prescribed for the same patient do not interact with each other to produce any harm to the patient.

Posology

→ The word posology is derived from the Greek words 'posos' meaning how much and 'logos' meaning science.

→ So posology is a branch of medical science which deals with dose or quantity of drugs which can be administered to a patient to get the desired pharmacological actions.

→ The dose of a drug cannot be fixed rigidly because there are so many factors which influence the doses.

Factors Influencing Dose

1. Age

→ The pharmacokinetics of many drugs changes with age.

→ So while determining the dose of a drug, the age of an individual is of great significance.

→ Children and old people need lesser amount of drug than the normal adult dose, because they are unable to excrete drugs to that extent as adult.

→ Children can tolerate relatively larger amounts of belladonna, digitalis whereas, elderly patients are more sensitive to some drug effects.
eg- hypnotics and tranquillizers may produce confusion states in them.

2. Sex

→ Women donot always respond to the action of drugs in the same manner as it is done in men.

→ Morphine and barbiturates may produce more excitement before sedation in women.

→ Special care should be taken when drugs are administered during menstruation, pregnancy & lactation.

→ There are certain drugs which on administration to the mother are capable of crossing the placenta and affecting the foetus. eg- alcohol, barbiturates.

→ During lactation, the drugs like antihistamines morphine and tetracycline which are excreted in milk should be avoided or given very cautiously to the mothers who are breast feeding the babies.

3. Body weight

→ The average dose is mentioned either in terms of mg per kg body weight or as a total single dose for an adult weighting between 50-100 kg.

→ However, the dose expressed in this fashion may not apply in cases of obese patients, children and malnourished patients.

→ It should be calculated according to body weight.

4. Route of administration

→ Intravenous doses of drugs are usually smaller than the oral doses, because the drugs administered intravenously enter the blood stream directly.

→ Due to this reason the onset of drug action is quick with intravenous route and this might enhance the chances of drug toxicity.

→ The effectiveness of drug formulation is generally controlled by the route of administration.

5. Time of administration

→ The presence of food in the stomach delays the absorption of drugs.

→ The drugs are more rapidly absorbed from the empty stomach.

→ So the amount of drug which is very effective when taken before a meal may not be that much effective when taken during or after meals.

→ The irritating drugs are better tolerated if administered after meals. eg - Iron, arsenic & cod-liver oil should always be given after meals.

6. Emotional factors

→ The personality and behaviour of a physician may influence the effect of drug especially the drugs which are intended for use in a psychosomatic disorder.

→ The females are more emotional than males and requires less dose of certain drugs.

7. Presence of disease

→ Drugs like barbiturates and chlorpromazine may produce unusually prolonged effect in patients having liver cirrhosis.

→ Streptomycin is excreted mainly by the kidney of the may prove toxic if the kidney of the patient is not working properly.

→ During fever a patient can tolerate high doses of antipyretics than a normal person.

8. Accumulation

→ Some drugs produces the toxic effect if it is repeatedly administered for long time.
eg- digitalis, emetine, heavy metals because these drugs excreted slowly.

→ This occurs due to accumulative effect of the drug.

9. Additive effect

→ When the total pharmacological action of two or more drugs administered is equivalent to sum of their individual pharmacological action.

→ For example, combination of ephedrine and aminophylline in the treatment of bronchial asthma.

10. Synergism

→ When two or more drugs are used in the combination form, their action is increased.

→ Synergism is very useful when desired therapeutic result needed is difficult to achieve with a single drug.

→ eg- procaine and adrenaline combination, increases the duration of action of procaine.

11. Antagonism

→ When the action of one drug is opposed by the other drug on the same physiological system.

→ The use of antagonistic responses to drugs is valuable in the treatment of poisoning.

→ eg- Milk of magnesia is given in acid poisoning where alkalaine effect of milk of magnesia neutralise the effect of acid poisoning.

12. Idiosyncrasy

→ An extraordinary response to a drug which is different from its characteristic pharmacological action is called idiosyncrasy.

→ The word idiosyncrasy has now been replaced by the term drug allergy.

→ For example, small quantity of aspirin may cause gastric haemorrhage and a small dose of quinine may produce ringing in the ears.

13. Tolerance

→ When an unusually large dose of a drug is required to elicit an effect ordinarily produced by the normal therapeutic dose of the drug.

→ eg.: Smokers can tolerate nicotine, alcoholic can tolerate large quantity of alcohol.

True tolerance: produced by oral and perenteral administration of the drug.

Pseudo tolerance: produced only to the oral route of administration.

14. Tachyphylaxis

→ When certain drugs are administered repeatedly at short intervals, the cell receptors get blocked up and pharmacological response to that particular drug is decreased.

→ Decreased response cannot be reversed by increasing the dose.

→ eg.: Ephedrine when given in repeated doses at short intervals in the treatment of bronchial asthma may produce very less response due to tachyphylaxis.

15. Metabolic disturbances

→ Changes in water electrolyte balance and acid base balance, body temp^r and other physiological factor may modify the effects of drugs.

→ Salicylates reduce body temp^r only in case an individual has rise in body temp^r.

→ They have no antipyretic effect if the body temp^r is normal.

→ The absorption of iron from G.I.T is maximum if the individual has an iron deficiency anaemia.

Calculations of Doses

① Doses proportionate to age

There are number of methods by which the dose for a child can be calculated from the adult dose.

(i) Young's formula

$$\text{Dose for the child} = \frac{\text{Age in years}}{\text{Age in years} + 12} \times \text{Adult dose}$$

The formula is used for calculating the doses for children under 12 years of age.

(11) Dilling's formula

$$\text{Dose for the child} = \frac{\text{Age in years}}{\text{Age in years} + 12} \times \text{Adult dose}$$

→ The formula is used for calculating the doses for children in between 4 to 20 years of age.

→ This formula is considered better because it is easier and quick to calculate the dose.

2. Doses proportionate to body weight

Clark's formula is used to calculate the dose for the child according to body weight.

Clark's formula

$$\text{Dose for the child} = \frac{\text{Child's weight in kg}}{70} \times \text{Adult dose}$$

3. Doses proportionate to surface area

→ The calculation of child dose according to surface area is more satisfactory and appropriate rather than the method based on age.

→ The method is more complicated than the method based on age.

$$\text{Percentage of adult dose} = \frac{\text{Surface area of child}}{\text{Surface area of adult}} \times 100$$

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