PHARMACEUTICS-I

PUNJAB PHARMACY COUNCIL, LAHORE

Chapter 1

PHARMACY

Definition

According to American college of pharmacy the word pharmacy defines as:

It is the branch of medical science that deals with the study of discovery, development, synthesis, manufacturing, action, quality assurance, distributing regulated affairs, clinical uses, and marketing patterns of drugs is called pharmacy.

According to American pharmacist association:

Pharmacy is a profession dedicated for the appropriate use of medication, devices and services to achieve optimal therapeutic out comes.

Types of Pharmacy (Specialties)

There are different specialties of pharmacy as following:

- Industrial Pharmacy
- Community Pharmacy → Retail pharmacy, wholesale pharmacy
- Hospital Pharmacy
- Forensic Pharmacy
- Clinical Pharmacy
- Compounding Pharmacy
- Dispensing Pharmacy

1. Industrial Pharmacy

Industrial pharmacy is the fundamental backbone of pharmacy profession it is an institution where medicines are manufactured on industrial scale.

Firstly in Pakistan the medicines are prepares manually. Due to recent scientific advances semi-automatic machines replace the manual work.

Any pharmaceutical industry mainly contains the following departments.

i. Production Section

It is the section of pharmaceutical industries where medicines are formulated and manufacture according to specification. Production section can be divided into following departments

- Tablet section
- Capsule Section
- Injectable section
- Syrup section

ii. Ware House

It is an important section of any industry where raw material and finished products are stored.

iii. Quality control section

It is the section of any industry where the quality of raw material and finished product are properly checked.

iv. Research and development Section

The basic function of this section in pharmaceutical industry is to discover, develop and synthesize new medicines or work on the improvement of existing medicines.

v. Administration

It is the section which is considers being the back bone of pharmaceutical industry. This section is responsible of managing all the matters of the industry.

2. Community Pharmacy

It is one of the pillars of pharmacy profession; in this specialty we provide the pharmaceutical services at community level.

Goals of any community pharmacy are:

- To provide quality medicine to general public
- Provide guidance and counseling regarding medication and vaccination
- Organized health camps
- Organized health talks and seminars

Community pharmacy divided into following parts

i. Retail Pharmacy

It is the business oriented type of pharmacy where medicines are taken from distributors or whole sellers and provided to general public on fixed percentage of profit.

ii. Whole Sale Pharmacy

It is the business oriented type of pharmacy where the medicines are taken from manufacturer and distribute to the medical stores, pharmacies and hospitals in bulk on a fixed percentage of profit.

3. Forensic Pharmacy

The branch of pharmacy that deals with the study of drug laws is known as forensic pharmacy. The forensic pharmacy deals with the legal aspects of pharmacy practice. The aspects on which forensic stress down are following.

- Duties and responsibilities of all government authorities.
- How to register new drug industry or institute
- How to obtain license to manufacturer purchase and sale drugs/medicine.

4. Hospital pharmacy

Hospital is an institute where ill patients are treated. The hospital pharmacy is the department or institution of any hospital where the pharmacy practice has been done. The pharmacist working in hospital pharmacy is known as hospital pharmacist.

Pharmacist

Any person that hold B-Pharm or Pharm-D from Pakistan pharmacy council recognized institution and furthermore he has a registration certificate from any provincial council of Pakistan is known as pharmacist. The provincial council of Pakistan enters the name of respective pharmacist in register A.

Assistant Pharmacist or pharmacy technician

Any person who holds diploma in pharmacy from any college or university which has been registered from Pakistan pharmacy council and furthermore he/she is registered under register B from provincial pharmacy council of Pakistan.

As assistant pharmacist the main working area of any hospital pharmacy is:

- Purchasing of quality medicines
- Medicine management
- Dispensing of medicine to in and out patient
- TPN total parental nutrition manufacturing
- Preparation of sterile solution
- Education and training of nurses and paramedics

5. Clinical Pharmacy

According to European society of clinical pharmacy

"Clinical pharmacy is the specialty of pharmaceutical sciences that deals with the study of drugs or medicines in contrast with their specific diseases."

The pharmacist working in the specialty of clinical pharmacy is known as clinical pharmacist and the main responsibilities of any clinical pharmacist are

- Medication review in comparison with the diagnosis
- Study about drug interaction for specific prescription
- Drug adverse reaction profiling
- Pharmaco-economic studies
- Drug formulary

Therapeutics

Therapeutics is the branch of medical science that deals with the treatment of diseases.

Chapter 2

DRUG

Definition

According to Ansel, the drug can be defined as "an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in humans or in other animals.

Classification of drugs

On the Basis of Sale

1. Over The Counter Drugs

OTC is the group of drug that does not required any prescription for their dispensing. This group contains the following drugs

- Multivitamin
- NSAIDS (non-steroidal anti-inflammatory drugs) Aspirin, Paracetamol.
- Laxatives
- Oral contraceptives

2. Prescription Drugs

These drugs can only be dispensed on the physician`s prescription.
Following drugs are included:

- Antibiotics
- Steroids
- Benzodiazepines
- Barbiturates
- Hypoglycemic Agents
- Anti-hypertensive

On The Basis of Sources

The classification of drug on the basis of their source as following

i. Natural sources
ii. Semi synthetic sources
iii. Synthetic sources

i. Natural Sources

Plant source **Animal source** **Microbial source** **Mineral source**

A. Plant sources /drug

This is the group of drug that obtained from plants e.g.

i. **Reserpine** is obtained from *Rauwolfia serpentina*
ii.Cinamaldehyde obtained from *Cinnamomum loureirii.*
iii. **Digoxin** is obtained from *Digitalis lanata*

B. Animal Sources /Drugs

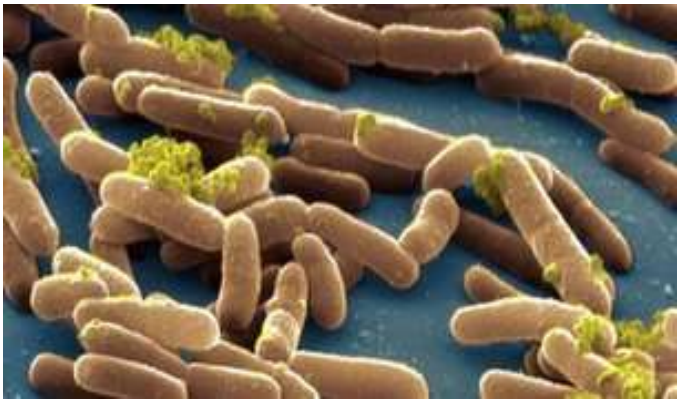
Many animals are involved in the production of many important drugs

ii. Insulin
iii. Sex hormones
iv. Thyroxin

C. Microbial Source/drug

This is the group of medicines /drugs that are synthesized by using different micro-organisms this group include the following drug.

- Antibiotics
- Insulin
- Vaccines



D. Mineral Source

Zinc
Iodine

ii. Semi-synthetic Drugs

Semi synthesis drugs are the group of drugs/ medicines that are synthesized by using combine sources of natural and synthetic world.
Example

- Amoxicillin
- Cefixim
- Ceftriaxone

iii. Synthetic Drugs

Synthetic drugs are the group of drugs/ medicines that are totally synthesized in laboratory by using chemicals or substances.
Example

- Paracetamol
- Aspirin
- Ciprofloxacin
- Sulphonamide group

Generic Name.

These are the names of drugs that are given to them on scientific basis. This is the official name of the drug.
Example

- Paracetamol
- Aspirin
- Ciprofloxacin

Brand Name/Trade Name

These are the names of medicines that are given on the basis of the proprietorship. These names are given to identify the one product from the other.

Example

1. Paracetamol

- Panadol
- Calpol
- Disprol

2. Diclofenic sodium

- Dicloran
- Voltral

3. Aspirin

- Dispirin
- Loprin

Chemical Name

These are the names which are given to the drugs on the basis of presence of different atoms or molecules and their inter-relationship. This name reveals every part of the compounds molecular structure.

Examples

- Acetylsalicylic Acid (Aspirin)
- Acetyl Para aminophenol (Paracetamol)

Strength

The strength is the amount of drug in the dosage form or a unit of the dosage form (e.g. 500 mg capsule, 250 mg/5 mL suspension).

CHAPTER NO. 3

Books in Pharmacy/ Pharmacopoeias and Formularies

The books containing the standards for drugs and other related substances are known as pharmacopoeias and formularies. They contain a list of drugs and other related substances regarding their source, tests, formulas for preparation, action and uses, doses, storage conditions.
Literally it means that it is a list of medicinal substances, crude drugs and formula for making preparations from them.

There are fundamentally two types of books in pharmacy
1. Official Books
2. Non Official Books

OFFICIAL BOOKS
These are the books that are written compile and publish under the strict supervision of Government agency of respective countries is known as official book.
Example

- British Pharmacopoeia (B.P)
- British pharmaceutical codex (BPC)
- British National Formulary(BNF)
- United State Pharmacopoeia (USP)
- National Formulary
- Pakistan Pharmacopoeia
- International Pharmacopoeia

NON-OFFICIAL BOOKS
These are the books which are written compile and published locally. Which are used as secondary reference sources for drugs and other related substances.
Example

- Remington Pharmaceutical sciences
- Merck Index
- Applied and Clinical pharmacology by Katzung
- Tutorial pharmacy

Official Books

British Pharmacopoeia (BP)

British Pharmacopoeia is the most abundantly used pharmacopoeia in the world, today it is mostly used because of their up to date monograph regarding the drug. .The fundamental responsibility of B.P is on the General Medical Council which was given to it in 1858.

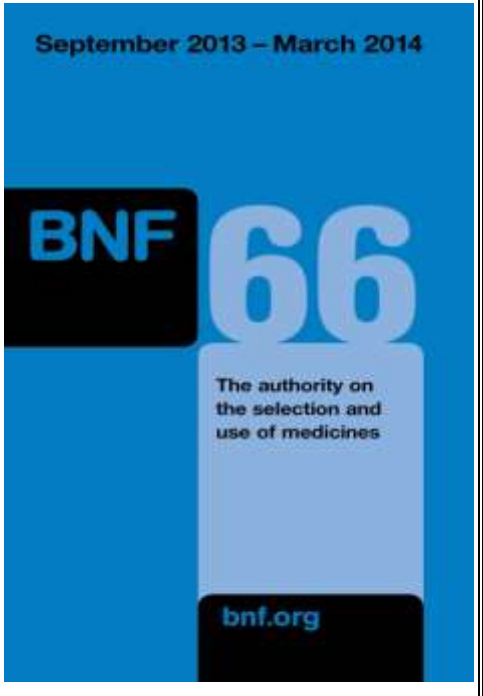
This book contain the following data

i. Complete monograph of drugs.

ii. Quality control and quality assurance of pharmaceutical production sections of pharmaceutical industries.

iii. Quality control test of dosage form

iv. Identification and analytical test of drugs



British Nation Formulary (BNF)

It is the national formulary of medicines that are being use in United Kingdom. It is written compiled and published under the co supervision of GMC (General Medical Council) and Royal Pharmaceutical society of Great Britain. This book is largely being used as a text book for registration examination in UAE and in UK

This book contains following information

i. Detail knowledge regarding the clinical and pharmacological aspects of drugs /medicines

ii. Detail note on prescription policy

iii. Knowledge regarding the refilling and prescription handling

British Pharmacopoeia Codex

In 1903 first time the Royal Pharmaceutical society of Great British realized the importance of another Pharmacopoeia which is specially made for medical practitioners and dispensing pharmacists.

This book contain the knowledge and articles on the following issue of pharmaceutical sciences

i. Regarding the dispensing method of medicines specific to their nature

ii.The techniques of dispending e.g. unit dose dispensing and multi-dose dispensing

iii. A thorough knowledge regarding the Pharmacological aspects of drugs
iv. Manufacturing and formulation techniques of drugs

International Pharmacopoeia (IP)
International pharmacopoeia is the official book that has been written, published and compiled by the WHO (world Health Organization)
WHO is a sub -office of united Nation that concerned with the health education and other health problems.
Mainly IP contain following information
i. Pharmaceutical technological techniques for the development of drugs
ii. Drug formulation and manufacturing processes
iii. Controlling the quality of medicines

United States Pharmacopoeia (USP)
This is an official book of pharmacy. It is one of the leading and important pharmacopoeias of the world. Firstly written, compiled and published under the supervision of a government agency of United States, named United State pharmaceuticals convention. USP can be used to determine the strength, Quantity, Quality, Purity and labeling of drug.

United State National Formulary (UNF)
In 1888 the first National Formulary of United States was published under the supervision of American Pharmaceutical Association. But in 1974 the right of UNF was given to united state Pharmaceutical Convention so from 1980 the UNF is published with USP –NF.

(Non-Official Books)

Remington Pharmaceutical Science
This book contain a detail knowledge regarding all the aspects of pharmacy .It is available in two volumes

Applied and Clinical Pharmacology by Katzung
This book contains a detail knowledge regarding drug and their actions on humans.

Tutorial Pharmacy
This book contains a detail knowledge regarding the physical pharmacy

CHAPTER NO. 4

HISTORY OF PHARMACY

Regarding the Muslim Scientist

Pharmacy is a word which had been derived from a Greek word "Pharmakon" which means drug or medicine.
The Muslim scientists play a significant role in the discovery, development, formulation, manufacturing and the use of drugs in according with the specific diseases. There are the following Muslim Scientists

1. AL-KINDI (801-873 A.D)

Al-Kindi was a great Muslim philosopher, **scientist, physician and psychologist**. He was born in Kufa **Iraq**. He got his early education from Baghdad.
He plays a significant role in the development of many branches of science e.g. Pharmaceutical chemistry, medicine, Psychology and cosmetics.

His notable work include:

1. Al Kindi was a first person who uses music for the treatment of Psychological problems.
2. He describes the isolation process of alcohol to form pure wine.
3. He describes how to make perfumes.
4. He describes in detail regarding cosmetics formulation
5. In his book "Treaties of disease caused by phlegm "he describes the epilepsy.

Phlegm
It is a viscous liquid produce in the living system by the mucous membrane.

2. IBN-AL-NAFIS (1213-1288 A.D)

Ibn-al-Nafis was the one of the greatest physician, **Anatomist, Physiologist, Pharmacologist,** Sociologist and Islamic scholar of his time. He was born in Damascus, **Syria** and later he moved to Cairo, **Egypt**. and done his research work here. He was renowned for the following work

- He was first person who describe the pulmonary circulation
- He describe regarding capillary and coronary circulation
- He describes in detail the anatomy and physiology of respiratory system, genitourinary system and GIT.
- He was the first person who writes about pulse rate.
- He has worked in the development of over 100 drugs.

3. IBN-ZUHAR (1091-1161 A.D)

Ibn- Zuhar was the great Muslim scholar, physician, **surgeon and pharmacist**. He was a Arab Muslim who was born in Seville (capital of southern Spain) he got his early education in **Spain** and done his research work also in Spain.

His scientific work include

- He was the first person who describe experimental surgery so he was consider to be the father of experimental surgery.
- He firstly describe the procedure for dissection and autopsy.
- Ibn-Zuhar was that first person who describe the use of inhaled anesthetics So, he was consider to be the pioneer of modern anesthesiology
- He done remarkable work and contribution to subject neuro-phamacology (Clinical , Neuro, Cardio ,Cancer, Reproduction ,Medical ,Toxicology)
- Ibn-Zuhar wrote an early pharmacopoeia which was printed out in 1491.

4. Abu Ali Sina (980-1037AD)

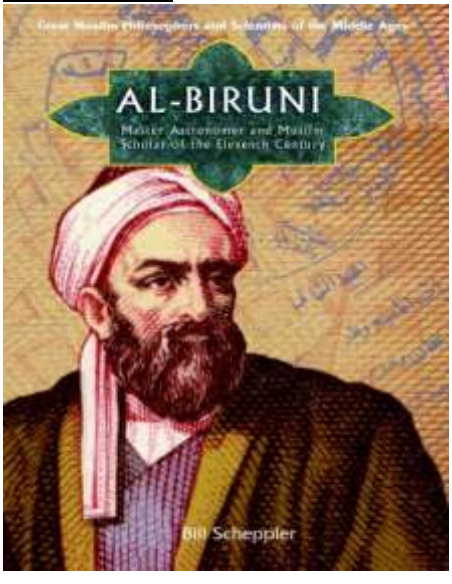
Abu Ali Sina was a great **physician, chemist** and astronomer of his time. He wrote almost 450 treaties on different scientific subjects among them 40 treaties are on medicine .His book " The canon of medicine" was used a text book of medicine for many years Abu Ali Sina was born in Afshana ,Bukhara, **Uzbekistan**.

His most famous scientific work include

- He firstly describe the procedure of diagnosis
- He was the person who describe the different psychiatric diseases e.g Depression, Mania, Insomnia, Dementia etc. in detail
- He was the first person who describes the paralysis in detail.
- He describes the risk factors of clinical trails
- He was the person who firstly describe steam distillation

5. Al Biruni (973-1050)

Al-Biruni was a great **pharmacist**, physician and Geologist. He was born in **Khwarizm**.



His famous scientific works include :

- He works in the development and progress of pharmacy field.
- He wrote a book Al-Saddana fil tibb which has description of more than 720 herbal drugs and these are arranged alphabetically
- He has wrote many other treaties on herbal medicine
- He also describe about the active constituents of drugs

6. Jaber Bin Hayan (721-815)

Jabir Bin Hayan was one of the greatest scientist, **chemist** and Geologist of his time. He was born in **Iran .** He was the first scientist who introduced experimentation in chemistry.

His greatest scientific works include:

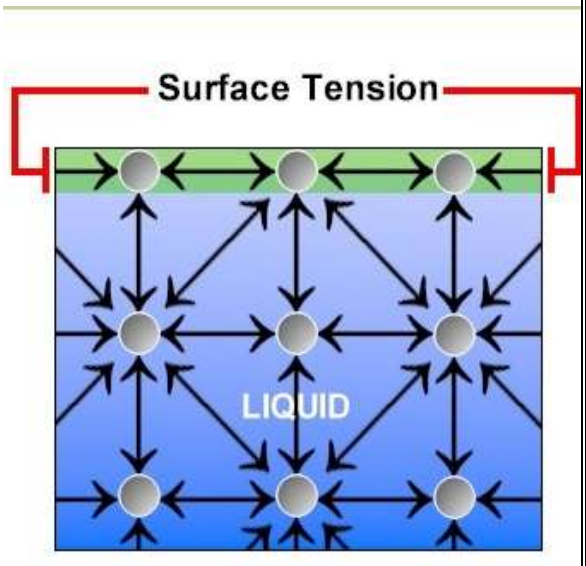
- He invented the practice essence of chemistry which then lead to the era of industrialization
- He invented more than 20 laboratory equipment.
- He firstly describe distillation and crystallization
- He discover many chemical substance e.g. Nitric acid, hydrochloric acid, Sulphuric acid, Acetic acid and oxalic acid. He invented Aqua-regia the only solvent that can dissolve gold.
- He describe the purification process of gold.

Chapter 5

Surface Tension

The boundary between two phases is generally described as an interface. When one of the phases is a gas or a vapour and the other a liquid or solid the term surface is commonly used.

- Surface tension is defined as the force acting over the surface of the liquid per unit length of the surface.



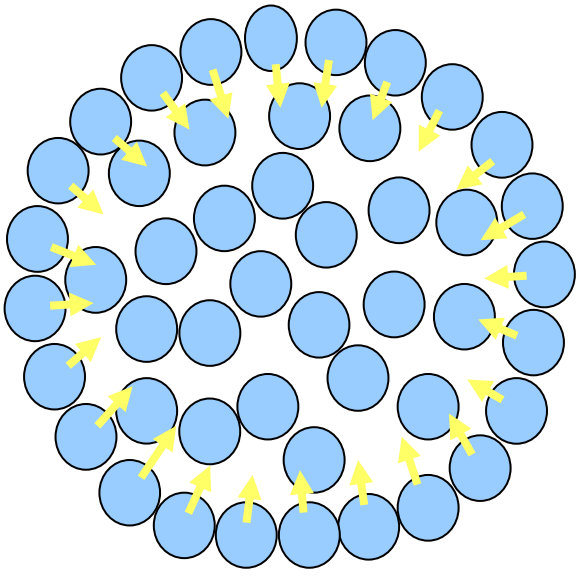
Force per unit area (F/A) on surface of liquid.
Its unit is newton per meter (N/m^2)

EXPLANATION:

The molecule inside the liquid interacts equally with other molecule from all sides, whereas the molecule at the surface is affected only by the molecule below it. The molecules exposed to air behave differently.

Surface molecules are compressed more tightly together; forming a sort of skin on the surface, with less distance between them compared to the molecules below. The molecules on the surface of a liquid are attracted only sideways and towards the interior so, surface molecules are being pulled inward the liquid. Liquid surface is therefore under tension and surface area of the surface molecules is reduced. Water in particular has a very high surface tension.

This explains the characteristic rounded shape that liquids form when dropping through the air: The molecules are all being pulled toward the center.



Factors affecting Surface Tension

Intermolecular forces
Surface tension increases with the increase in intermolecular forces and decreases with the decrease in intermolecular forces.
Hydrogen bonding
Surface tension increases with the increase in hydrogen bonding and decreases with the decrease in hydrogen bonding.
Temperature
Surface tension decreases with the increase in temperature and increases with the decrease in temperature.

Applications

- Emulsifying agents reduce the surface tension of oil and water phase which results in stabilization of emulsion.
- Bile salts reduce the surface tension of fats in duodenum which results in solubilization of lipids which help in the digestion of lipids.

Viscosity

Viscosity can be described as " It is the internal resistance of the molecules of any liquid to flow called viscosity".
Viscosity is the fundamental tool to check the internal friction of any liquid, like water is thin so it has lower viscosity and on the other hand honey is thick so it has higher viscosity.

Viscometers

These are the specialized equipment and apparatus used for the determination of viscosity of different liquids.

Types of viscometers

There are various types of viscometers the most famous are:

1) Ostwald viscometer or U-Tube viscometer
2) Rotational viscometer
3) Falling ball viscometer

Factors affecting the viscosity

Temperature
Viscosity decreases with the increases in temperature

Size of the molecule
Viscosity increases with the increases in size of the molecule

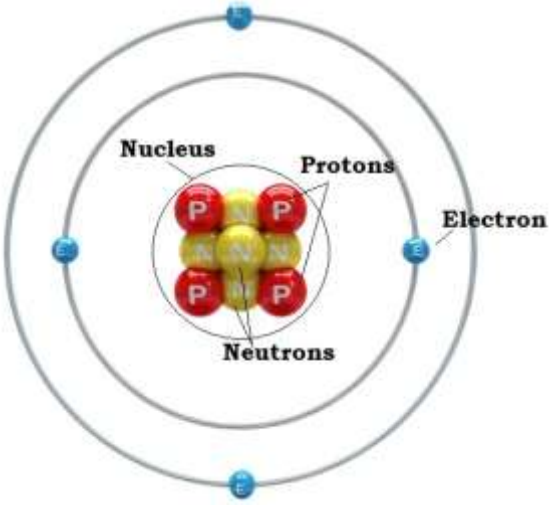
Molecular shape
More irregular the liquid's molecular shape greater would be the viscosity of the liquid. More regular shape of liquid's molecule lesser would be the viscosity.

Adhesive forces
Stronger the adhesive forces greater would be the viscosity of the liquid.

Cohesive forces
Stronger the cohesive forces lesser would be the viscosity of the liquid.

Application of Viscosity measurement

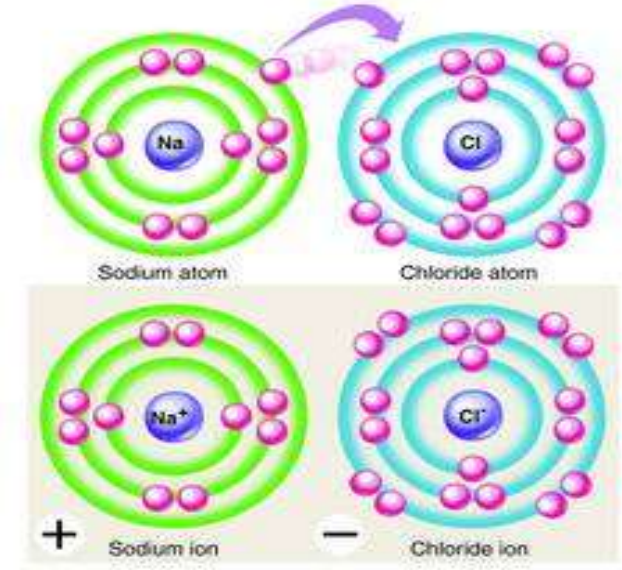
1) Viscosity determination is the fundamental quality control test for syrups, suspension thickness and consistency.
2) Viscosity is also given us the indication regarding quality and purity of liquid raw material
3) Viscosity tell us about the thickness of liquid substances
4) Viscosity determination is also a key quality control test for oil base injections and suspension.
5) Viscosity enhancers (e.g. Methylcellulose, Hydroxyethylcellulose) are used in ophthalmic solutions to increase their viscosity. This enables the formulation to remain in the eye longer and gives more time for the drug to exert its therapeutic activity or undergo absorption.



Ionization

ATOM

"ATOM" is derived from Greek word means "undividable". it is the smallest particle of an element which cannot be further divided.It consist of central nucleus containing protons and neutrons and outer shells in which electrons are revolving. **Protons** carry positive charge **neutrons** are neutral particles having no change and **electrons** carry negative charge on them. These are called fundamental particles of atoms.



ION

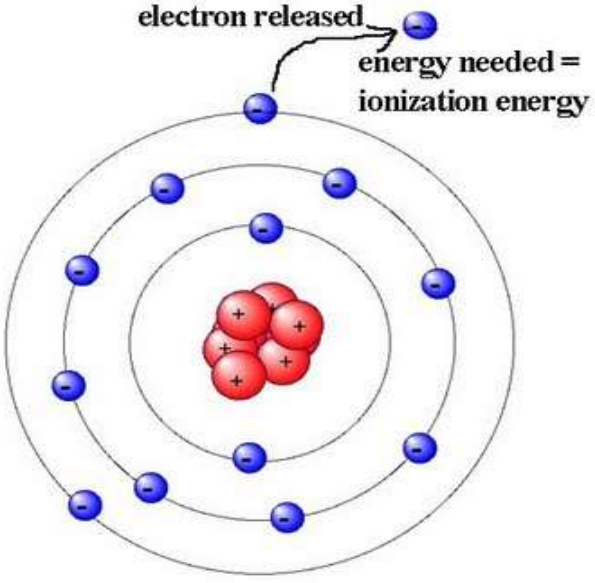
Any charged particle is called ion. It may be positive(+) or may be (-).

Cation(+)

When a atom loses an electron from the outer most shell, cation (positively charge atom) is produced.

Anion(-)

when a atom gains an electron from the other atom, anion(negative charge atom) is produced.



Ionization

Process by which electrically neutral atoms or molecules by the removal or addition of electrons . In this process of atom acquires net positive charge on it

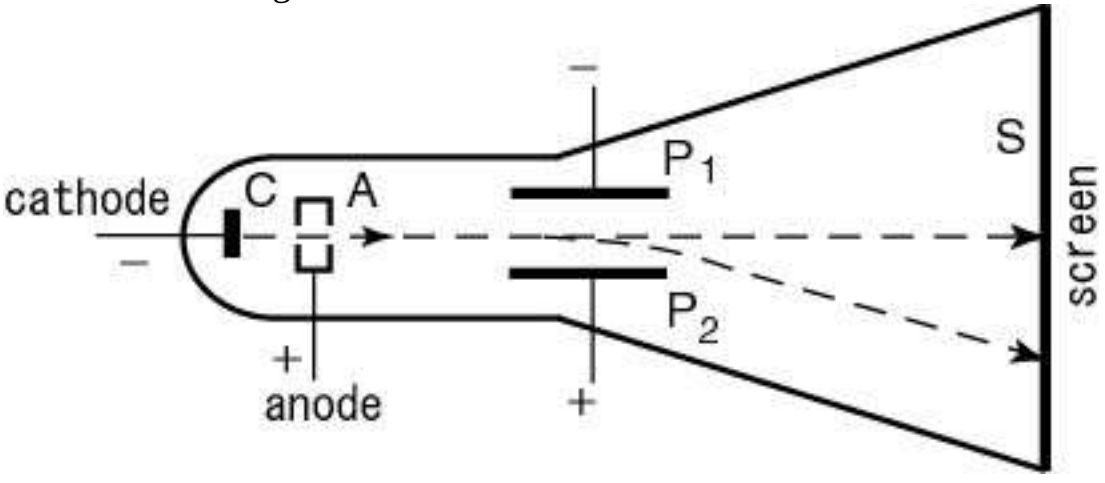
Ionization energy

Amount of energy required to remove an electron from an atom.

Ionization experiment

In 1897,J.J. Thomson conducted the famous discharge tube experiment, by passing electricity at high voltage a gas at very low pressure.

The pressure of air in the discharge tube is reduced to 0.001mm of mercury and a high voltage is applied to the electrodes.When electric current passes through the discharge tube ion of given gas produce some ion carry negative charge and some are neutral creating a condition of ionization.



Applications

Many drugs are either weak organic acids e.g. Acetylsalicylic acid (aspirin) or weak organic bases e.g. procaine, or their salts. The degree of ionization of a drug has an important effect on its absorption, distribution and elimination. So ionization is an important factor which is considered during the manufacturing process of medicines.

1. Ionization radiations are used in medicines and medical radiography to make image inside the body.
2. In biology and agriculture radiation is used to induced mutation to produce new or improved species.
3. Radiation are used in sterilization of tools and equipment used in surgery.

pH

pH involve taking negative log of hydrogen ions concentration.
$pH = -\log [H^+]$
This hydrogen ion concentration is usually expressed in moles per liter.

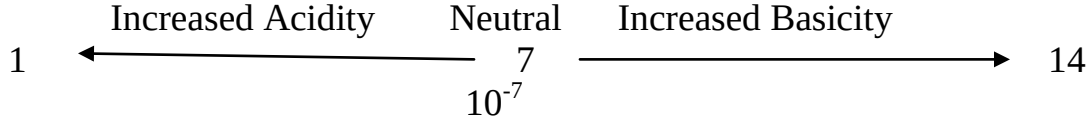
Calculation of $_pH$

Following formula can be use to determine the value of pH of different solution

For acid
pH $= -\log [H^+]$
For base (it is the negative log of hydroxyl ion (OH^-) concentration).
pOH $= -\log [OH^-]$
Where as
pH + pOH = 14

Explanation

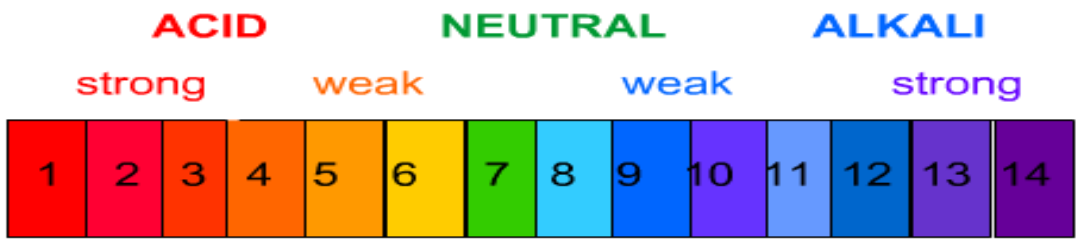
pH of H_2O is 7 and it is consider to be neutral If pH is falls down from 7 then the compound will called acid.
If the pH rises from 7 then the compound is called basic.



Determination of pH

pH of a solution is measured by following methods:

1. By using pH paper
2. By using pH meter
3. By using indicators



pH value as shown by different colour in universal indicator

pH Indicators

pH indicators are organic substance which have tendency to change their color with change of pH of the solution in which they are present.

The aim to use pH indicators are:

- To determine the type of compound
- To determine the pH of different sample
- To verify the presence of any chemical substance

Types of pH Indicators

There are three fundamental types of indicators

i. Acid base Indicators
ii. Redox indicators
ii. Precipitation Indicators

i. Acid base indicators

There are the indicator that change their color as we change the pH of the solution.

Example :Methyl orange , Phenolphthalein

ii. Redox Indicator

These are the compounds that changing their colors during oxidation and Reduction reaction e.g.$KMnO_4$

iii. Precipitation Indicators

Those indicators that change their color during precipitation reaction are called precipitation indicators e.g.

K_2CrO_4 (potassium chromium oxide)

pH Meter

it is an electronic instrument used for measuring the pH of a liquid or semi-solid. A typical pH meter consists of a glass electrode connected to an electronic meter that measures and displays the pH reading.

Applications

- pH measurements are important in medicine, biology, food science and many other applications.
- Enzymes work at specific pH, so their preparations must be maintained at that pH.
- Blood has a specific pH of 7.3-7.4
- pH indicators are used in titrations in analytical chemistry and biology to determine the pH of different substances.

  (A titration is a technique in which a solution of known concentration is used to determine the concentration of an unknown solution.)

Buffer

Buffer is the compound or mixture of compounds that resist to changing pH of any solution on slight addition of acidic or basics solution or compound.

Useful Buffer Mixtures

S.No	Buffer Mixtures	pH Range
1	HCl –Sodium Citrate	1_____5
2	Sodium hydroxide and borax	9.2____11
3	Citric acid /Sodium citrate	2.5_____5.6
4	H_2CO_3 / $NaHCO_3$	

Theory of buffers

Addition of acid

Hcl is strong acid and it will change H+ concentration when added to a solutionbut buffer system (H2CO3/ NaHCO3) tends to maintain the pH of solution and following reaction takes place.

$HCl + NaHCO_3 \longrightarrow H_2CO_3 + NaCl$

$NaOH + H_2CO_3 \longrightarrow NaHCO_3 + H_2O$

i. If we add H+ ions to the above mentioned reaction the reaction will shift to the left side $H3O^+ + H^+$

ii. If we add OH- ions to the reaction the reaction will shift to right side

Applications

i. Buffers are most widely used in biological industry to preserve the pH of biological compounds and fluids
ii. In injection manufacturing buffer are used to maintain their pH.
iii. Buffer are used in fermentation process
iv. Buffers are used to preserved an restored the action of enzymes
v. Buffer are used to maintain the pH of drugs.

Isotonic Solution (Isotonicity)

- If a solution is placed behind a membrane that is permeable only to solvent molecules and not to solute molecules(semipermeable membrane) osmosis occurs as the molecules of solvent passes through the membrane. If a solution filled membrane is placed in a solution of a higher solute concentrationthan its own the solvent can pass in any direction, passes into the more concentrated solution until equilibrium is established on both sides of the membrane. The pressure responsible to prevent osmosis is termed as osmotic pressure.

- Body fluids including blood and tears have an osmotic pressure equal to

that of a 0.9% Nacl solution. Or it can be said that 0.9% Nacl solution is isotonic to body fluids. Isotonic solution can also be defined as "if two solutions on comparison have same osmotic pressure and ions concentration are termed as isotonic solution"

- The solutions which have less ions and it have less osmotic pressure then its comparative solution. OR
- Solutions with a lower osmotic pressure than body fluids or a 0.9% sodium chloride solution are commonly called "**hypotonic solutions**".

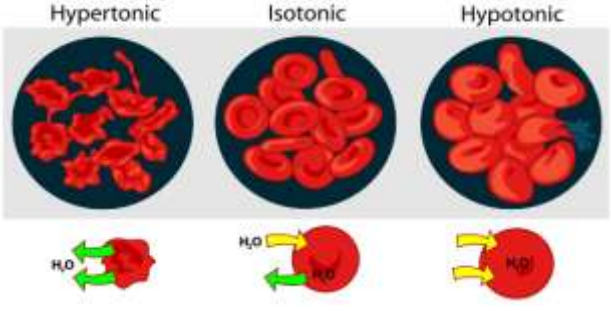
- Those are the solution in which the conc. of the ions and osmotic pressure is greater than its comparative solution . OR
- Solutions having greater osmotic pressure than body fluids or a 0.9% sodium chloride solution are termed as" **hypertonic solutions".**

- A hypotonic solution added to body`s system will lose water and this water will be absorbed by body tissues. It may induce hemolysis of red blood cells.
- A hypertonic solution added to body`s system will have a tendency to draw water from body tissue . so it can cause shrinkage of body tissues and cause complications.

Solutions for injection, for application to mucous membranes and solutions for ophthalmic use must be made isotonic with tissue fluid to avoid pain and irritation. The most widely used isotonicity modifiers are dextrose and sodium chloride.

Applications of Isotonic Solution in Pharmacy

- Isotonic solutions are used in physiological experiments and tissue culture
- Isotonic solutions are used to balance the electrolytes
- Isotonic solutions are used to maintain the physiological conditions
- For medical purpose isotonic solution (normal saline) is used to flush wounds
- Normal saline is also used I.V for patients who cannot take fluids orally
- Saline is also used for nasal washes to relieve some of the symptoms of the common cold.



Chapter 6

DOSAGE FORM

Pharmaceutics

Pharmaceutics is the branch of pharmacy that deals with the conversion of (new chemical entity) NCE to proper dosage form (drug delivery system).
It is also called the science of dosage form design.

- ♣ Pharmaceutics converts a drug into a medicine.

Drug Delivery System.

It is the administration of drug or medicine to the living system for their desired action in body(cure, management or prophylaxis of disease).
Medicines are drug delivery systems, they are means of administering drugs to the body in a safe, efficient and convenient manner.

Dosage form

Dosage form is the physical form of a dose of drug. Any Pharmaceutical product which is ready for the use of patient is known as dosage form

(OR)

Any pharmaceutical product which has defined shape and have prescribed amount of APIs (Active pharmaceutical ingredient) called a dosage form.

Dosage forms are essentially pharmaceutical products, typically involving a mixture of active drug components and nondrug components.

Drug/Active ingredient/Medicament/Medicinal agent

This is a pharmacologically active ingredient in a medicine (Which has pharmacological action). e.g. Aspirin, Insulin, Digoxin

Additives/ Excipients

Additives are the substances other than the active medicaments in the formulation (dosage form), which don't have any pharmacological action.
They are used for many purposes as:

- ✓ To give a particular shape to the formulation.
- ✓ To increase the stability of the product
- ✓ To increase the palatability and elegance of the preparation.

Additives may include: Surfactants, diluents, vehicles, bases, stabilizers, preservatives, coloring agents, flavoring agents, sweetening agents.

Vehicles

It may be described as a medium in which the ingredients of a formulation are dissolved, suspended or dispersed.
The vehicle is a general word may be used for liquids, semisolids or solids. When a liquid is used to dissolve or suspend the medicament the liquid is known as **vehicle**. . Water , Aromatic waters, water for injection, glycerine, propylene glycol, Oils.
When a semi-solid or solid is used; it is known as **base**. In which the drug is incorporated either to increase the bulk or to give a particular shape to the formulation. Generally these are used for the preparation of ointments and suppositories. Commonly used ointment bases are soft paraffin, liquid paraffin, wool fat, wool alcohol, bees wax.
Suppository bases: theobroma oil, glycerogelatin, polyethylene glycols.

Diluents

Diluents are the inert substances which are specially added to increase the bulk of a drug or to decrease the concentration. The liquids which are used as vehicles may be specifically used as diluents but for oral preparations water is the most suitable diluents.
Solid diluents are included in the formulation of powders, granules, tablets, capsules where they are used to increase the bulk of other materials for easy conversion into proper dosage form. In potent drugs diluents are incorporated to increase the bulk so that they can be weighed easily.e.g. Kaolin, lactose, starch, sorbitol, powdered cellulose.

Binders

Substances used to cause adhesion of powder particles in tablet granulations e.g. Acacia, sodium carboxymethyl cellulose, gelatin, liquid glucose.

Tablet Disintegrants

To promote tablet break up into smaller particles after administration. e.g. Starch, microcrystalline cellulose, carboxymethyl ellulose, sodium alginate, alginic acid.

Lubricants/Anti-adherents

Prevent tablet ingredients from sticking to punches and dies during production and assist smooth tablet formation. e.g. magnesium stearate, talc.

Glidants

Used in tablet and capsule formulations to improve flow properties of powder mixture. e.g colloidal silica, corn starch, talc

Surfactants/Surface active agents

Surfactants may be defined as the substances which when added to a liquid, lower the interfacial tension between two phases, thus make them miscible.

This phenomenon is commonly used to make two immiscible liquids miscible with each other and to dissolve the drugs.

The molecules of a surfactant consist of two part i.e. a polar part and non-polar part When such molecules are placed in two phases of different polarities the polar part moves towards high polarity phase while non-polar part moves toward low polarity phase and they are absorbed at the interphase.

Classification of surfactants
- 1. Anionic surfactants
- 2. Cationic surfactants
- 3. Non-ionic surfactants

1. Sulphated compounds like sodium lauryl sulphate, sodium cetyl sulphate, dioctyl sodium sulfosuccinate.
2. Benzylkonium chloride
3.Glyceryl monostearate, spans and tweens.

Hydrocolloids/ Suspending agents

These are high molecular weight solid substances which when added to water produce high viscous solutions, suspensions or gels. Viscosity increasing agents used to reduce sedimentation rate of particles in a vehicle. They are also known as gums and consist of polysaccharides and proteins.

Classification
- Natural
- Semi-synthetic
- Synthetic

Natural: Acacia, Tragacanth, Agar (plant) Gelatin and Casein(animal) Silica, colloidal alumina, bentonite and veegum (mineral).
Semi-synthetic: Modification of cellulose Methyl cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose.
Synthetic: Only a few are used .e.g. carbopols and polyox.

Stabilizers

Stability: the capability of a formulation in a specific container to remain within the physical, chemical, microbiological, therapeutic and toxicological specifications.
The substances used to control these stabilities are known as stabilizers. The most important are:

1. **Antioxidants** Prevent deterioration of preparations by oxidation. E.g. Ascorbic acid. Sodium ascorbate, sodium bisulfite, tocopherols.
2. **Chelating agents:** substances that form stable water soluble complexes (chelate) with metals. These metals might promote instability e.g. Edetate disodium

3.Buffering agents: used to resist change in PH upon dilution or addition of acid or alkali. e.g sodium citrate, sodium acetate, potassium phosphate.

4. Antimicrobial preservative: used in liquid and semi-solid preparations to prevent or inhibit the growth of microorganisms. e.g. emulsions and suspension must be suitably preserved because water and carbohydrates provide very good medium for the multiplication of bacteria and molds.

Parenteral preparations packed in multi-dose containers must contain a preservative.

Flavouring agents

Impart a pleasant flavor and often odor to a preparation and to mask specific type of taste of the preparation, thus make them more palatable. e.g. cherry, banana, pine-apple, peppermint, lemon, orange, rose, vanilla, menthol.

Sweetening agents: Used to impart sweetness to a preparation, and mask the objectionable taste of the drug e.g. sucrose is most widely used. Lactose, mannitol, honey, glycerin, sorbitol, aspartate.

Coloring agents

Substances used to impart color to liquid and solid preparations.
e.g. Caramel, Ferric oxide, chlorophyll, carotenoids, FD&C colors.

Types of dosage forms

On the Basis of Formulation/ Preparation/Physical form

1. **Liquid Dosage Forms**

- Solutions
- Syrups
- Elixirs
- Spirits
- Tinctures
- Liniments(liquid or semi-liquid)
- Lotions
- Sprays
- Aerosols (solutions of gases in liquids)

- Inhalations
- Disperse Systems → Suspensions, Emulsions, Magmas
- Parenteral preparations

2. **Solid Dosage Forms**

- Powders and Granules
- Tablets
- Capsules
- Suppositories

3. **Semisolid Dosage Forms**
   - Ointments
   - Creams
   - Pastes
   - Gels

On the Basis of Route of Administration

1.Oral

Oral Solutions
Syrups
Elixirs
Oral Suspensions
Emulsions
Magmas
Powders
Granules → Effervescent granules

Tablets
Capsules

2.Parental

- ✓ Intracutaneous or intradermal (Beneath the epidermis) **0.1 to 0.2ml**
- ✓ Subcutaneous(Beneath the surface of the skin) **1ml or less**
- ✓ Intravenous(drug directly injected into blood stream) **1ml to 500ml or more**
- ✓ Intramuscular(into the skeletal muscles) **upto 2ml**

Less commonly used are: Intrathecal, intra-articular, intra-cardiac

3.Transdermal (through skin) / Topical

- ❖ Lotions
- ❖ Liniments
- ❖ Ointments
- ❖ Creams
- ❖ Pastes
- ❖ Topical Powders(Dusting powders)
- ❖ Transdermal Patches
- ❖ Gels
- ❖ Ear drops
- ❖ Eye drops

Inhalational route

Nasal Decongestant solutions
Inhalers
Sprays
Nebulizer

Pharmaceutical Inserts

Suppositories ⟹ Rectal
Vaginal
Urethral

Ophthalmic inserts

LIQUID DOGAGE FORMS

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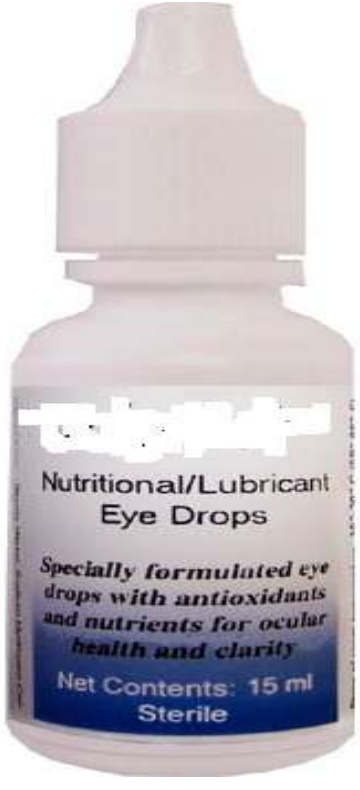


SOLUTIONS

Solution may be defined as a mixture of two or more components that form a single phase which is homogenous and clear.

solutions may be prepared from any combination of solid, liquid, and gas, the three states of matter. In pharmacy most of the solutions are prepared by dissolving a solid , liquid or gas in another liquid

It has two components:

Solvent

Solvent is the liquid portion of a solution in which another substance (e.g. salt) is dissolved to form a solution is called solvent.

Solute

A substance that is dissolved in another substance (solvent) to form a solution is called solute. Or

A solute is a substance that creates a solution when dissolved by a solvent. Solute can change its physical state, e.g. salt is solid before getting dissolved in water, and after dissolution it changes from solid to liquid.

Advantages:

- ✓ They are homogenous, therefore the medicament is uniformly distributed.
- ✓ They are more quickly effective than tablets or capsules because they are already in solution form and absorption starts quickly.
- ✓ They can easily colored, flavored and sweetened.
- ✓ Children or patients who cannot swallow tablets or capsules can easily ingest solutions.

Disadvantages:

- ✗ They are less stable as compared to solid dosage forms because deterioration is faster in solutions.
- ✗ In some medicaments their unpleasant taste and flavor is difficult to mask.

Solubility : The amount of substance that passes into solution in order to establish equilibrium at constant temperature and so produce a saturated solution is known as the solubility of the substance.

BP defined the solubility in an approximate manner that 'the no of parts of solvent required to dissolve one part of solute".

TABLE.1 RELATIVE TERMS OF SOLUBILITY

Descriptive Term	**Parts of solvent required For 1 part of solute**
Very soluble	<1
Freely soluble	1–10
Soluble	10–30
Sparingly soluble	30–100
Slightly soluble	100–1000
Very slightly soluble	1000–10000
Practically insoluble or insoluble	>10000

Solubilization: is the process in which the water insoluble substances are dissolved in aqueous solutions in the presence of surfactants.

ORAL SOLUTIONS

According to the British Pharmacopoeia (BP)

Oral solutions are oral liquids containing one or more active ingredients dissolved in a suitable vehicle.

DRY MIXTURES FOR SOLUTION

A number of medicinal agents, particularly certain antibiotics, e.g., penicillin V, have insufficient stability in aqueous solution. Manufacturers of these products provide them to the pharmacist in dry powder or granule form for reconstitution with a prescribed amount of purified water immediately before dispensing to
the patient. The dry powder mixture contains all of the formulative components, including drug, flavorant, colorant, buffers, and others, except for the solvent.

ORAL REHYDRATION SOLUTIONS

Oral rehydration solutions are usually effective in treatment of patients with mild volume depletion, 5% to 10% of body weight. These are available OTC and are relatively inexpensive, and their use has diminished the incidence of complications associated with parenterally administered electrolyte solutions.

SYRUPS

Definition

Syrups are sweet, viscous, concentrated aqueous solutions of a sugar(sucrose) or sugar-substitute in water or any other suitable vehicle. With or without added flavoring agents and medicinal substances.

TYPES:

1. Simple syrup.
2. Medicated syrup
3. Flavoured syrup

1.SIMPLE SYRUP:

:When purified water alone is used in making the solution of sucrose ,the preparation is known as syrup or simple syrup. It is used as flavouring agent and vehicle for drugs. According to BP it is 66.7% (w/w)and USP 85%(W/V).

2.MEDICATED SYRUP:

When aqueous preparation contains some medicinal agent ,the syrup is called as medicated syrup. OR

Solution of medicated substance in which sufficient sucrose is dissolved to produce a syrup liquid .

These are prepared by combining each of the individual components of the syrup. Such as sucrose, purified water, flavors, coloring agents, therapeutic agent and other desirable ingredients. They are employed in therapeutics.

The medicated syrup consist of sucrose mixed with solutions of other substances.

3.FLAVOURED SYRUP/ NON-MEDICATED SYRUP:

Syrups not contain medicinal substances but contains various pleasantly flavored substances are called flavored syrups.

These syrups are added in the preparation of medicated syrup and used for masking the disagreeable taste of medicinal substances.

Examples are: Coca syrup , orange syrup , raspberry syrup etc .

USES AND SIGNIFICANCE:

1.Syrups are used as vehicle for drug substances.
2.Syrups are used as flavouring agents.
3.Syrups are used as sweetening agents.
4.Syrups are used as demulcents.

5.Syrups are used as diluting vehicles for water soluble drugs.
6.As masking agents for nauseous and irritative drugs.

Syrups are significant because:

- ✓ Easy to administer to children and old people.
- ✓ Sucrose retards oxidation because it is partly hydrolyzed into reducing sugars laevulose and dextrose.
- ✓ Strong solution of sucrose prevent decomposition by bacteria , fungi and mold because of strong osmotic pressure which results in dehydration of these organisms.
- ✓ Contain little or no alcohol.

COMPONENTS OF SYRUP

Most syrup contain the following components in addition to the purified water and any medical agent present.

1.Sugar and sugar substitutes
2.Antimicrobial preservatives.
3.Flavourants
4.Colourants
5.Special solvents ,solubilizing agents ,thickness , and stabilizers.

1.Sugar Or Sugar Substitutes

Sucrose is the sugar most frequently employed in syrups. It may be replaced by other sugars or substances such as sorbitol , glycerin, propylene glycol. Artificial sweetening agents: methylcellulose, hydroxyethyl cellulose. These non-sugars are used for syrups of diabetic patients.
Dilute solutions of sucrose support mold, yeast and other microbial growth whereas the growth of such microorganisms is usually retarted when the concentration of sucrose is 65% W/W or more but a saturated solution may lead to crystallization of sucrose. Sucrose and other sugars give proper viscosity to formulation and also sweetness. A syrup contain as much as 60 to 80% sucrose.

2.Anti microbial Preservatives

Sucrose concentration of syrup is itself antimicrobial because it exerts a great osmotic pressure on microbes to draw water out of them thus dehydrating them.

Commonly used preservatives with their effective concentration are

Benzoic acid----------0.1 ---0.2%

Sodium benzoate----------0.1---0.2%

Various combination of methyl, propyl and butyl parabenes totally about----0.1%

3.Flavourants

Most syrups are flavoured with synthetic flavorants or naturally occurring materials to render the syrup pleasant tasting. Such as Volatile oils, Vanillin.

4.Colourants

To enhance the appeal of the syrup ,a colouring agent is generally used. which correlates with the flavorant employed.i.e .green with mint ,brown with chocolate etc .

The colores used should be :

- Water soluble
- Non -reactive with other components
- Colour stable at $_{p}H$ range and under light intensity.

5.Miscellaneous

Special solvents ,solubilizing agent ,thickness and stabilizers are used according to formulation needs.

Methods of preparation of syrups

1. Solution with the aid of Heat
2. Solution by agitation without aid of Heat
3. Addition of sucrose to a medicated liquid
4. Percolation

Storage

Syrups should be stored in a well closed container and at a temperature not exceeding 30^0C.

ELIXIRS

Elixirs are clear, sweetened hydro-alcoholic solutions intended for oral administration and are usually flavoured to enhance their palatability.

The BPC describes elixirs as ' being usually sweet ,aromatic preparations frequently containing alcohol and requiring dilution before use or administration'.

The main ingredients of elixirs are ethanol and water but glycerin, sorbitol, propylene glycol, flavoring agents, sugar and preservatives may be incorporated to the preparation. Elixirs containing agents will low water solubility.

TYPES OF ELIXIRS:

These are of two types

1. Non-Medicated Elixirs.
2. Medicated Elixirs

1. Non Medicated Elixir:-

The elixirs having no medicament are termed as non-medicated elixirs.

Non medicated elixirs are used as:

- . Flavouring agents
- .Vehicles for medicaments (Addition of a therapeutic agent)
- . Diluting agent (Dilution of an existing medicated elixir)

It should have approximately the same alcoholic concentration as the elixir being diluted. Examples are aromatic elixir, orange-spirit elixir.

2.MEDICATED ELIXIRS:-

When medicinal agents are incorporated into hydro-alcoholic vehicles ,called medicated elixers.

- Medicated elixirs are used for the therapeutic effect of the medicinal substances they contain. A medicated elixir may have only a single therapeutic agent or more than one . They usually contain very potent drugs such as antibiotics, anti-histaminic and sedatives.

Elixir having single medical agent are advantageous than those having more than one ,on the behalf of their dosage variability i.e when one medicinal agent is required to be varied in dosage. Most official and commercial elixirs contain a single therapeutic agent.

COMPONENTS OF ELIXIRS

1.Alcohol 2. Water 3.Glycerol
4.Flavoring agent 5. Preservative 6.Sorbitol, propylene glycol syrups etc.

- The proportion of alcohol in elixirs varies widely. These can be low as 5-10% and as high as 30—35%. Elixirs containing more than 10 to 12% of alcohol are usually self-preserving.
- Alcoholic contents on one hand increases the solubility of certain ingredients and at the same time have preservative action.
- Glycerin and syrup may be added to increase the solubility of medicinal agent and for sweetening purposes.
- Propylene glycol may be used as substitute for both alcohol and glycerine.

PREPARATION OF ELIXIRS

Elixirs are usually prepared by:

1.Simple solution with agitation and/or
2.By Admixture of two or more liquid ingredients.

By Admixture of two or more liquid ingredients:

Alcohol soluble and water soluble components are generally dissolved separately in alcohol and in purified water respectively.
Then aqueous sol. is added to the alcoholic solution, rather than the reverse in order to maintain the highest possible alcoholic strength at all times so that minimal separation of the alcohol-soluble components occurs.
When two solutions are completely mixed the mixture is made to volume with specified solvent or vehicles.They are also called as isoalcoholic elixir

PEDIATRIC ELIXIRS:-

In pediatric elixirs alcohol contents are very small. Sometimes syrups do contain alcohol contents up to 10% on the basis of which they are difficult to be differentiated from elixirs. e.g. Ephedrine Syrup USP.

Important Official Elixirs:-

Chloral hydrate Elixir .
Paracetamol Elixir .

Ephedrine Elixir.
Digoxin Elixir (10%alcohol)

Packaging And Storage

- Because of their usual contents of volatile oil and alcohols, elixir should be stored in tight, light resistant containers.
- Should be protected from excessive heat.

COMPARISON BETWEEN ELIXIR AND SYRUPS

ELIXIRS	***SYRUPS***
1. **Alcohol** is necessary component.	Alcohol is not necessary component.
2. **Less sweet** than syrup.	More sweet than elixir
3. **Less viscous** than syrup.	More viscous than elixir.
4. **Low proportion of sugar**.	High concentration of sugar
5. Because of their hydro alcoholic character, elixirs are better able to maintain both water soluble and alcohol soluble components in solution.	This ability of syrup is less than elixirs due to their only aqueous nature.
6. **More stable**	Less stable
7. **Easy to formulate** than syrup.	Difficult to formulate than elixirs.
8. **Less effective** in masking the taste of medicinal agents	More effective in masking the taste of medicinal agents
9.Cannot be used as such for **children and Alcohol prohibited patients.**	NO such disadvantage.
10. Can be used for **diabetic patients** easily	Sucrose syrup can not be used for diabetic patient.
11. These are **clear formulation** .	May not be clear.

TINCTURES

These are alcoholic or hydro-alcoholic solution of non-volatile drug of vegetable and chemical origin.
Tinctures contain 15-80% alcohol. Tinctures contain one part by weight of drug in four parts of product.

These are mostly used → Internally
These are mostly used → Topically

Types of Tinctures

- **Medicated tinctures**

Oral tinctures :
They are taken orally. They are becoming a thing of past, because of bad taste.
Example :Belladonna tincture, digitalis tincture.
Topical tinctures : They prepared by solution. Majority are applied to the skin for the anti-infective activity of their main chemical component. Due to high alcoholic content provide additional antiseptic effect.Example: iodine tincture

- **Non-Medicated tinctures**

Flavouring tinctures : In the flavoring of other types of preparations.

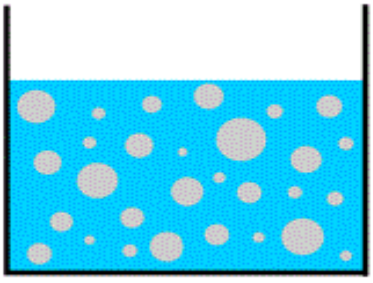
PREPARATION
Tinctures can be prepared by following processes.

- By maceration (latin word *macerare* meaning "to soak").
- By percolation
- By simple solution

Disperse Systems

These are the types of preparations containing undissolved or immiscible drug distributed throughout a vehicle.

- In these preparations, the substance distributed is referred to as the ***dispersed phase***(discontinuous phase), and the vehicle is termed the *dispersing phase or* ***dispersion medium***(continuous phase). Together, they produce a dispersed system.



The particles of the dispersed phase are usually solid materials that are insoluble in the dispersion medium. In the case of **emulsions**, the dispersed phase is a liquid.
In the case of an **aerosol**, the dispersed phase may be small air bubbles. Dispersions also consist of droplets of a liquid in air.

The particles of the dispersed phase vary widely in size.
Colloidal dispersions: the colloidal range,(1.0 nm to 0.5 μm)
Fine dispersions: particles of smaller size (0.5 to 10 μm)e.g magmas & gels
Coarse dispersions; Dispersions containing coarse particles, usually (10 to 50 μm) For example Suspensions ,Emulsions.

Types of disperse systems:

Dispersed phase	Dispersion medium	Name	Example
Liquid	Gas	Liquid aerosol	Mists, aerosols
Solid	Gas	Solid aerosol	Powder aerosols
Liquid	Liquid	Emulsion	Milk
Solid	Liquid	Suspension	$Al(OH)_3$ susp.

SUSPENSIONS

Suspensions may be defined as preparations containing finely divided drug particles (the suspensoid) distributed somewhat uniformly throughout a vehicle in which the drug exhibits a minimum degree of solubility.

These are **biphasic** liquid dosage form. The solid particles constitutes the discontinuous phase whereas the liquid vehicle as continuous phase. Particle size range falls between 10-15µm.

Suspensions are mainly used for:

- Oral administration
- Topical use (Ophthalmic suspensions)
- Parenteral use

Qualities of Good suspension

A well formulated suspension should have the following properties:

- ✓ The dispersed particles should not settle readily and the settled particles should re-disperse immediately on shaking
- ✓ The particles should not form cake on settling
- ✓ The viscosity should be such that the preparation can be easily poured
- ✓ Suspension for internal use must be palatable and for external use must be free from gitty particles.
- ✓ The particle size of the suspensoid should remain fairly constant throughout standing period.

TYPES OF SUSPENSIONS

Extemporaneous suspensions

- Such suspensions are prepared just before dispensing to the patients i.e. infants who are unable to swallow solid dosage forms (tab&cap) and no other liquid dosage form is available.
- When preparing an extemporaneous suspension the contents of the capsule are emptied into mortar, OR the tablet is crushed in a mortar with a pestle. The selected vehicle is then slowly added to and mixed with powder to form a paste and then diluted to desired volume.
- For preparation of such suspensions good quality suspending agents are used which are less liable to microbial attack.
- Extemporaneous suspension cannot be stored for a long time.

Dry powders for oral suspensions OR Reconstituted suspensions

- These are powders or granules which are intended to be suspended in water or some other vehicle prior to oral administration.
- In official title these are designated as "**For oral Suspension".**
- The dry products containing active agent, sweeteners, colorants, stabilizers, suspending agents and preservatives
- The powders should be provided in a slightly oversized container to permit the adequate shaking of the contents after the entire amount of water has been added.

Examples of official drugs for reconstituted suspension are:

- ♣ Antibiotic drugs .e.g. Tetracycline suspension, Amoxicillin, Ampicillin.
- ♣ Barium sulphate for oral suspension

Packaging and storage of suspensions

- ⇨ All suspensions should be packaged in wide mouth containers having adequate airspace above the liquid to permit adequate shaking and ease of pouring.
- ⇨ The label should have statement SHAKE WELL BEFORE USE
- ⇨ For reconstituted suspensions, the bottle should have a clear mark to show the level of water addition.
- ⇨ Suspension should be protected from freezing, excessive heat and light.

EMULSIONS

An emulsion is a dispersion in which the dispersed phase is composed of small globules of a liquid distributed throughout a vehicle in which it is immiscible.

These are biphasic dosage forms. The <u>two immiscible liquids</u> are made miscible by the addition of a third phase an *emulsifying agent*. In emulsion terminology the dispersed phase is *internal phase* and the dispersion medium is the *external* or *continuous phase.*

Emulsions are of two types

Oil in water (o/w) : oil is dispersed in the water.

Water in oil (w/o) : water is dispersed in the oil.

They may be → Liquid — Orally, Parentally, Topically

They may be → Semi-solid — Topically

Two classes of liquid external preparation → Liniments, Lotions } o/w or w/o

Semi-solid emulsions are → Oily creams (w/o) — cold cream

Semi-solid emulsions are → Aqueous creams (o/w) — vanishing cream

Choice of Emulsifying agents

To get an emulsion of required properties, the selected emulsifying agent have the following qualities

- Should be capable of reducing interfacial tension between two immiscible liquids
- Should be capable of keeping the dispersed liquid globules distributed indefinitely throughout the dispersion medium
- It should be non-toxic.
- Chemically compatible with other ingredients of the preparation
- Able to produce and maintain the required consistency of the preparation.

PREPARATION OF EMULSIONS

- **Continental or Dry gum method**
- **English or Wet gum method**
- **Bottle or forbes bottle method**

Dry gum method

The emulsifying agent (usually acacia) is mixed with the oil before the addition of water, that is, dry gum. The continental method is also referred to as the **4:2:1 method** because for every 4 parts by volume of oil, 2 parts of water and 1 part of gum are added in preparing the initial or primary emulsion. Other formulative ingredients that are soluble in or miscible with the external phase may then be mixed into the primary emulsion. When all necessary agents have been added, the emulsion is transferred to a graduate and made to volume with water.

Wet gum method

The emulsifying agent is added to the water (in which it is soluble) to form a mucilage, and then the oil is slowly incorporated to form the primary emulsion, that is wet gum. Should the mixture become too thick, additional water may be blended into the mixture before another portion of oil is added, the other formulative materials are added, and the emulsion is transferred to a graduate and brought to volume with water.

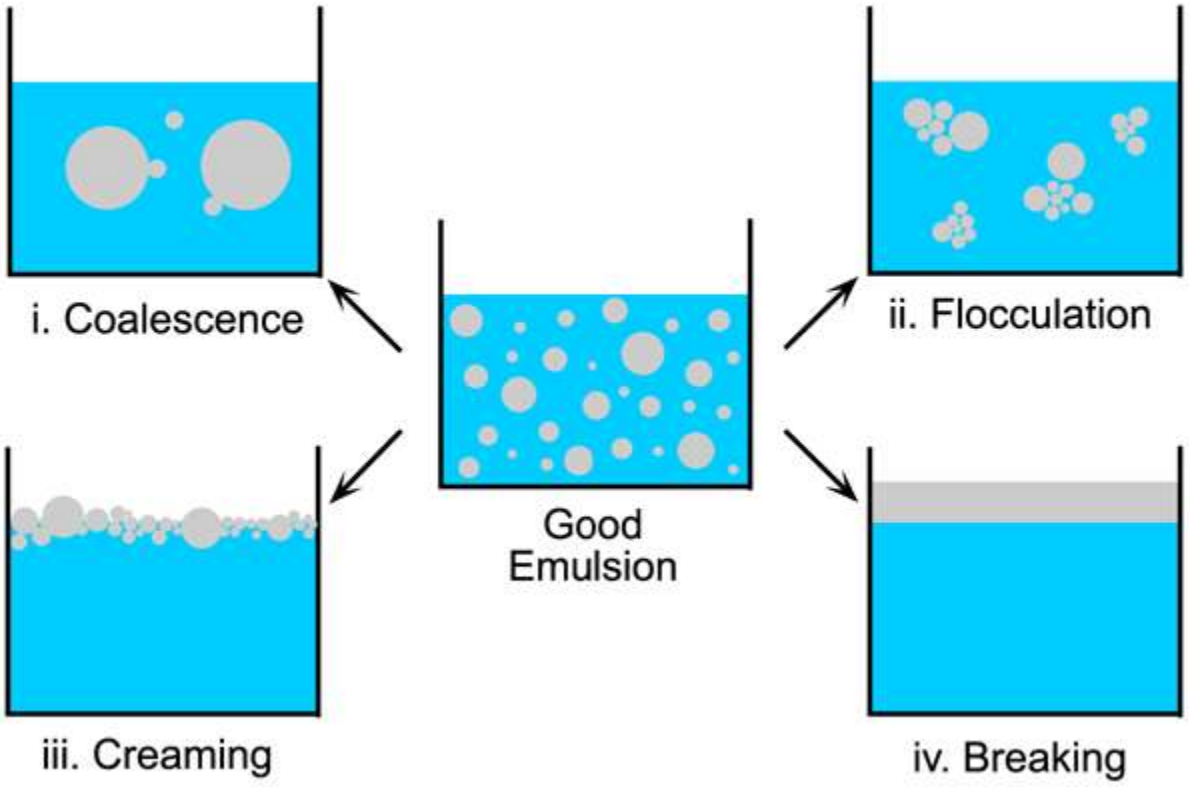
Bottle method

The bottle method is used for the preparation of emulsions of volatile oils or less viscous oils and is a variation of the dry gum method. Because of low viscosity the volatile oils require greater amount of gum for emulsification therefore the proportion for oil, water and gum for primary emulsion are 4:4:2.

Oil and powdered dry gum are shaken vigorously in a large bottle until mixed thoroughly. Then water is added to form primary emulsion. More water is added in small portions with constant agitation to produce final volume.

STABILITY OF EMULSION

Stability of emulsion means that a formulated emulsion should retain its original characters i.e. as the size of globules and their uniform distribution throughout the continuous phase.



1.Coalescence

Coalescence means to grow together, to fuse. The dispersed phase fuse to form large globules.

2.Creaming and sedimentation

Upward (creaming) or downward (sedimentation) movement of dispersed globules in the continuous phase. In creaming they form a thick layer at the surface of emulsion.

3.Cracking/Breaking

Separation of the internal phase from the emulsion is called breaking. The coalescence of the dispersed globules take place and the two separate layers of the dispersed phase and continuous phase are formed which are difficult to re-disperse by shaking or stirring to get the original product.

4.Flocculation

The individual particles of dispersed phase come in contact with each other to form loose aggregates and create a network like structure.

- Many molds, yeasts, and bacteria can decompose the emulsifying agent, disrupting the system.

LOTIONS

Lotions are liquid aqueous preparations intended for external application to the skin without rubbing with the help of some absorbent material such as cotton wool or gauze soaked in the lotion, applied to the affected part.

Lotions contain finely powdered substances that are insoluble in dispersion medium and are suspended by the use of suspending agents. If liquids are used as dispersed phase then they dispersed by emulsifying agents.

Lotions may be employed for:

- Protective action
- Local cooling and soothing action: The inclusion of alcohol in a lotion hastens its drying and produces cooling effect. Whereas the addition of glycerin keeps the skin moist for sufficiently long time and have soothing effect.
- Therapeutic action of their constituents from sun burn, skin disorders, insect bite, acne etc.

Examples

Calamine lotion
Salicylic acid lotion
Zinc sulphate lotion

Precautions

- Bacteria and molds grow in certain lotions if no preservative is added to the preparation.
- On long standing the lotions have a tendency to separate out. So container must be labeled “Shake before Use”.
- The container should be labeled “For External Use Only”.

LINIMENTS

These are alcoholic or oleaginous preparations of various medicinal substances intended for external application to the skin generally with friction and rubbing.
These are liquid or semi-liquid preparations and can be solution, suspension or emulsion.

Uses

- They are used for their **rubefacient** action: Produce congestion or redness to the area to which they are applied.
- **Irritant**: not directly affect the tissues but cause inflammation of area to which applied.
- **Counter-irritant**: Irritate intact skin thus reducing or relieving another irritation or deep seated pain.
- Penetrating action

Two types of vehicles

1. **Alcoholic or hydro-alcoholic vehicle** is useful when rubefacient, counter-irritant or penetrating action is desired.
2. **Oleaginous vehicles** are employed when massage is desired. They are less irritating than alcoholic liniments

Precautions

- ♣ Liniments are not to be applied to the broken skin because they may produce excessive irritation.

Storage and Labeling

- ⇨ The bottle should be labeled: ”For external use only”.
- ⇨ They should be stored in tightly closed containers
- ⇨ The container must bear a label “Shake the bottle well before use”

Aerosols

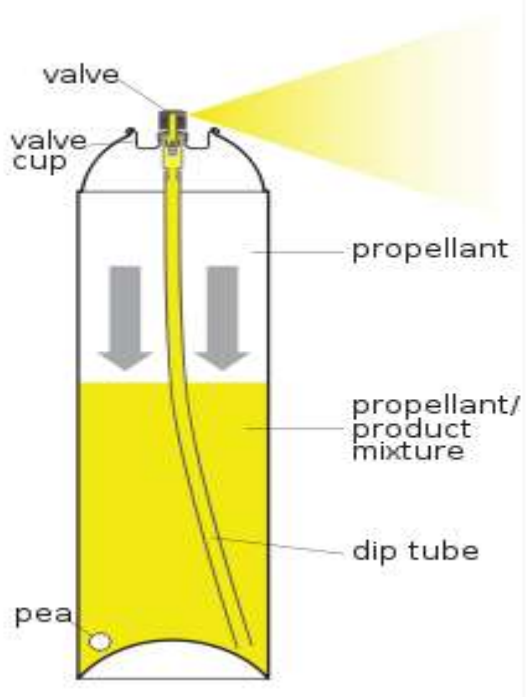
Aerosols are pressurized dosage forms containing one or more than one active ingredients which upon actuation emit a fine dispersion of solid and liquid in gaseous form.
The liquid or solid drug particles are dissolved or suspended in gas. The gas used for this purpose is known as propellant.

Components of Aerosols are:

1. Propellant 2.Container
3.Valve assembly and actuator
4. Product concentrate

1.Propellants

These are chemical substances which are responsible for developing pressure within a container and expel the product when valve is open.
Commonly used propellants
Butane, isobutane, Chlorofluorocarbons(difluoroethane, dichlorotetrafluoroethane)



2.Containers

Containers are available in tin plate, aluminum, stainless steel and glass material.

3.Valve Assembly

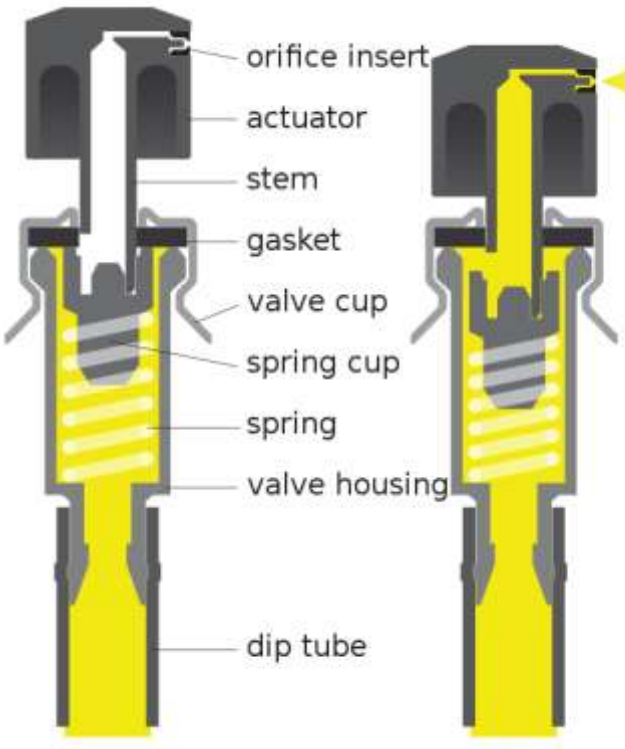
Function of valve assembly is to permit the expulsion of contents of containers:

- ⇨ In desired form
- ⇨ In proper amount or dose

It has following parts

1. Mounting cup

Used to attach the valve properly to the container, made of tin. Aluminum can also be used.



2. Housing

It contains an opening at the point of attachment of dip tube. It is made of nylon.

3. Stem

It supports actuator and delivers the product in proper form. Made of nylon, brass and steel.

4. Gas kat

It is used to prevent leakage of formulation from container. Made of rubber.

5. Spring

Used to hold gas kat in plate. When actuator is depressed and released it returns the valve to its close position again.

6. Dip tube

It is used to bring formulation from container.
Its diameter vary from formulation to formulation.

7. Actuator

Its function is to deliver the aerosol product in proper and desired form.

- Spray actuator (Dispersing product into relatively small particles)
- Foam actuator (Large orifice)
- Solid actuator (Relatively large orifice used for semi-solid products)
- Specially designed actuator (For appropriate site as nasal, throat, eye)

Metered Valve

These are valves which allow specific amount of product to come out and then stop automatically. Such valves contain reservoir of specific volume which on actuation empties all the contents present in it on single push of actuator.
e.g. metered dose inhaler (MDI)

4.Product Concentrate

It consist of: Active ingredient, Solvent system, Preservative/ Anti-oxidant, surfactants.

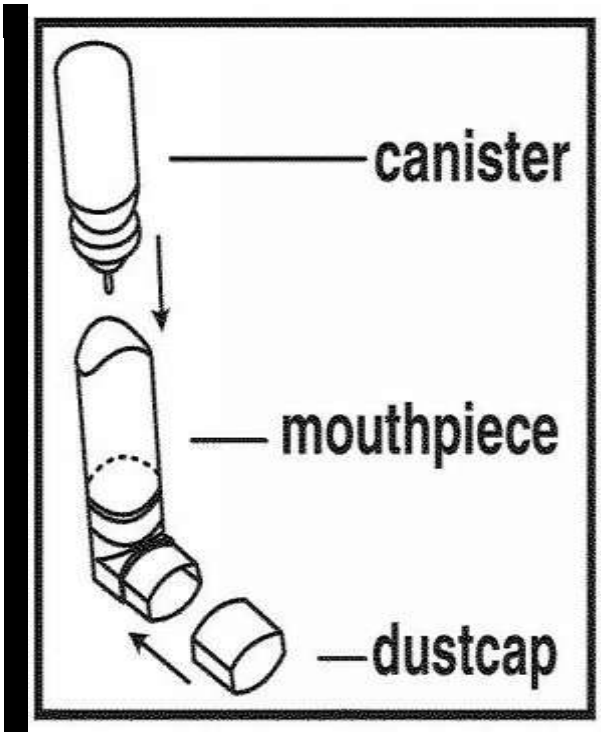
INHALATIONS

Inhalations are drugs or solutions of drugs administered by the nasal or oral respiratory route. OR

Inhalations are liquid preparations containing volatile ingredients and are used for local or systemic action (Absorption from the lungs) on the nasal or respiratory tract.

Inhalations are used to relieve nasal congestion and inflammation of the respiratory tract. Inhalations are used in various ways:

- If the ingredients are volatile at room temperature, they may be placed on an absorbent pad and inhaled thereof.
- In other cases they may be added to warm water, the vapours are inhaled for five to ten minutes.
- Another group of products known as **inhalants** are drugs or combination of drugs that carried into nasal passages by their high vapour pressure. The device in which drug is contained and by which inhalants are administered is known as inhaler.



In order for the inhaled drug substance or solution to reach the bronchial tree, the inhaled particles must be just a few microns in size. A widely used instrument capable of producing fine particles for inhalation is **nebulizer**.

This apparatus consists of:

1.An atomizing unit

2.A rubber bulb

Inhalation Aerosols

1.Humidifier: To provide a cool mist to the air in room, it may be ultrasonic.

2.Vaporizer: A device producing a fine mist of steam to humidify the room.

Uses

Inhalations are used to relieve nasal congestion and inflammation of the respiratory tract.

SPRAYS

These are aqueous or oleaginous solutions in the form of coarse droplets or as finely divided solids to be applied topically usually to nasal pharyngeal tract or to the skin.
They are sprayed into mouth for their laryngitis, pharyngitis and tonsillitis action. But mainly they are used to produce their action on the lungs for which they are sprayed with a special type of atomizer known as **nebulizer**.

Powder blowers or **Insufflators** may be employed to produce a spray powder. This divides the powder into a stream of finely divided particles.

INJECTIONS/ PARENTERAL PREPARATIONS

Parenteral preparations or injectable are the sterile, pyrogen free solutions or suspensions of drugs in aqueous or oily vehicles meant for introduction into the body by means of an injection (parentally).
Since they are introduced into internal body parts they must be:

- ⇨ Sterile, free from all types of microorganisms and microbial products such as toxins, pyrogens etc.
- ⇨ Must be free from particles like dust, fibers.
- ⇨ Should be isotonic with body fluids.
- ⇨ Multi-dose injections must contain preservatives

Advantages

- ✓ Rapid onset of action in emergency situations (IV route)
- ✓ Most suitable route for non-cooperative and unconscious patients
- ✓ Prolonged action of a drug can be produced by this route (IM route)
- ✓ The route is preferred when the drug is not absorbed or inactivated in the GIT.
- ✓ Solutions in volumes from mililitres to 4 litres can be introduced by parenteral route

Disadvantages

- × The administration of drug through wrong route may prove fatal.
- × Mode of treatment is expensive as expertise is required

Formulation of parenteral products

Vehicles: The most suitable vehicle for dissolving or suspending the medicament is water.

Oily vehicles are used when medicament is insoluble in water, prolong the duration of action of drug. Cotton seed oil, peanut oil, sesame oil, olive oil.

Added substances

1. Solubilizing agents
2. Stabilizers
3. Buffers
4. Antibacterial agents
5. Isotonicity adjusters
6. Wetting, suspending and emulsifying agents

The use of coloring agents is strictly prohibited.

Manufacturing of parenteral preparations

- ➢ Washing and cleaning of containers, closures and equipment
- ➢ Collection of materials
- ➢ Compounding the preparation
- ➢ Filteration
- ➢ Distributing the preparation in final containers

- Sealing the containers
- Sterilization
- Labelling and packaging
- Evaluation of parenteral preparations

Packaging and storage of injections

Single-dose container or ampoule
The container holding a quantity of sterile drug intended for parenteral administration as a single dose and which when opened can not be re-sealed.

Multi-dose container or Vial
The container permits withdrawal of successive portions of the drug without changing the strength, quality or purity of the remaining portion.

Intravenous fluids (Large volume parenteral) / IV Infusions

1. Dextrose injection
2. Dextrose and sodium chloride injection
3. Mannitol injection
4. Ringer`s injection
5. Lactated Ringer`s injection
6. Sodium chloride injection

SOLID DOSAGE FORMS

POWDERS

Powders are the solid dosage form of medicament that is homogenous, finally divided, dry materials.

Medicated powders intended to be as:

- Internal use
- External use

According to mode of dispensing powders are of two types:

1. **Bulk powders**

Generally less-potent drugs are supplied in the form of bulk powders. These are packed in bulk containers. These are used internally and externally

Internal use: They are supplied in wide-mouthed containers in which a teaspoon is entered for easy removal of the contents.e.g. Antacids, laxatives

External use (Dusting powders): these are meant for external application to the skin for their antiseptic, protective and lubricant purposes. These are dispensed in sifter type containers or pressure aerosols.

2. **Divided powders**

Powder is divided into individual dosing units based upon the dose to be administered at a single time. These are simple (one ingredient) or compound (two or more ingredient) powders for internal use. Divided portion of powder is placed on a small piece of paper which is then folded.

e.g.Analgesics, ORS.

GRANULES

Granules are prepared from powdered substances, the particles of which are made to aggregate by additions of solvents or binding agents or by some other means.

They are generally irregular shaped but may be prepared to be spherical.They are used in the manufacturing of tablets.

Effervescent Granules

They contain a medicinal agent in a dry mixture usually composed of sodium bicarbonate, citric acid and tartaric acid. When added to water the acids and base react to liberate carbon dioxide resulting in effervescence.

Citric acid + sod. Bicarbonate $\longrightarrow$ sod. Citrate + CO_2

Resulting carbonated solution masks the saline or undesirable taste of medicinal agent present.

TABLETS

Tablets are the solids dosage forms of medicinal substances usually prepared with the aid of pharmaceutical adjuncts (excipients). Intended for oral, buccal, vaginal or rectal route of administration.

Advantage of tablets

- ✓ Ease of administration (easy to swallow)
- ✓ Surety of accurate dose
- ✓ Unpleasant taste can be masked by coatings.
- ✓ They are dry so more stable than liquid preparations
- ✓ The deterioration of medicaments due to environmental factors (oxygen and light) is less in tablet form

Disadvantage of tablets

- × Children and elderly people cannot swallow the tablets
- × The manufacturing cost is high.

DIFFERENT TYPES OF TABLETS

1. **Compressed tablets**

These are the tablets that are made up of single compression and in addition to medicinal agent contain lubricant, binder disintegrant, diluents colorant and flavorant.

Example

i. Paracetamol tablet

ii. Aspirin Tablets

2.Multiple Compressed Tablets

These are the tablets that are manufactured by multiple compression resulting in

I. A multiple layered tablet

ii. A Tablet within a tablet

3.**Film Coated Tablets**

To mask the unpleasant taste of drug and to prevent the tablets from external conditions, a coating of polymer is applied. This coat ruptures in GIT. e.g. Maxit

4.Sugar coated tablets

These are the tablets that are coated by colored or uncolored sugar solution intended to make the bitter taste of tablets e.g. Brufen

5.Enteric coated tablets

These are the tablets which are required to be disintegrated in the intestines and not in the stomach. They are coated which makes the tablet to pass the stomach as such and breaks in alkaline medium of intestines.e.g Loprin

6.Buccal/Sublingual Tablets

These tablets are required to be placed below the tongue (sublingual) or in the side of the cheek (buccal) e.g. Angised (nitroglycerine)
Generally these types of tablets contain those drugs which are destroyed, inactivated or not absorbed in the GIT.

7.Effervescent Tablets

These tablets along with active medicament contain other ingredients like sodium bicarbonate, citric acid and tartaric acid which react in the presence of water and liberate carbon dioxide, producing effervescence leading to disintegration. e.g. Disprin, Cac 1000.

8.Chewable tablets

These are the tablets which are required to be broken and chewed in between the teeth before ingestion. These are given to children and adults who have difficulty in swallowing. E.g antacids, multivitamin tablets

8.Sustained Release Tablets

These are the tablets which after oral administration have prolong action duration of drug e.g. Dicloran or Voltral

Formulation of tablets

Compressed tablets usually consists of active medicaments mixed with a number of inert substances known as excipients or additives

According to the functions which these additives play in the preparation of tablets may be classified as follows:

1. Diluents
2. Binders
3. Disintegrating agents
4. Lubricants
5. Coloring agents
6. Flavoring agent
7. Sweetening agents

Methods of preparation of tablets

- Direct compression
- Dry granulation/ Slugging
- Wet granulation

TABLETS COATING

Deposition of any desired material on tablets to impart characteristics properties to tablets.

OBJECTS OF TABLETS COATING :-

1. For pharmaceutical elegance by improving their appearance, taste and stability.
2. Protection against environmental factors (air, humidity)
3. To mask the taste of drug

Most recently coating has been used:
To control the site of drug release (enteric coating)
Delay or prolong the release of drug from dosage form (sustained release)

Coating pan

TYPES OF TABLET COATING

1.Sugar Coating

Sugar coating is used to mask the unpleasant taste and odor, to improve the appearance and to protect the ingredients

The various stages involved in sugar coating are:

1.**Water Proofing and Sealing Coat**: is applied for tablets that may absorb moisture and are adversely affected on contact with moisture. i.e. shellac

2.**Sub -coating** :- 3-5 coats using sugar based (heavy syrup)containing gelatin /acacia.

3.**Smoothing and final rounding**:- 5-10 coats using thick simple syrup

4.**Finishing and coloring** :-several coats of a thin syrup containing the desired colour are applied to attain final rounding smoothness and colour.

5.**Polishing**:- with fabrics / carnauba wax.

2. Film Coating

Sugar coating makes the tablets bulky and is time consuming. These disadvantages can be overcome by using film coating. Which places a thin, skin tight coating of a plastic like material(polyethylene glycol, carbowax, cellulose polymers) on the compressed tablets. Film coating tablets are far more resistant to destruction by abrasion than are sugar coated tablets.

3. Enteric Coating

It is done when tablets are required to disintegrate in intestine but not in stomach

Among material used in enteric coating are:

>Shellac and shellac derivative >Hydroxypropyl methylcellulose phthalate

>Polyvinyl acetate phthalate >Cellulose acetate phthalate

4. Air Suspension Coating

Hot air is passed into the coating chamber from lower which keep the tablets somewhat suspended. Coating solution also enters the system at bottom; it is rapidly placed on the suspended, rotating tablets.

5.Compression Coating

This method is also known as press coating or dry coating as no water or any solvent is used in the coating. Only the dried granules are compressed around the precompressed tablets.

6.Dip Coating

The tablets to be coated are placed in a basket and then dipped in coating solution.

7.Gelatin Coating

Gelatin coated tablets are called as GELCAPS. Gelcaps are easier to swallow.

8.Electrostatic Coating

An ionic charge is imparted to the substance and an opposite charge to coating solution.To apply films to conductive materials.

9.Laminated Coating

It is marely a coating that provides a second action or layer of medicament for tablet as in :An enteric coated tablet in which on drug may be made available for gastric absorption and another is released in the intestine.

CAPSULES

Capsules are solid unit dosage form in which the medicaments are enclosed in a particularly tasteless, hard or soft gelatin shell and are intended for oral use.
The basic empty capsule shells are made from a mixture of gelatin, sugar and water.

TYPE OF CAPSULES

There are two types of capsules

- Soft Gelatin Capsules
- Hard Gelatin Capsules

Hard Gelatin Capsules

These are the capsules that have hard shell of Gelatin around its medicaments this Gelatin can be prepared by reacting sugar ,water and gelatin .

There are two halves of hard Capsule shells:

- **Cap** (slightly large in diameter but shorter in length)
- **Body** (shorter in diameter and longer in length)

The drug is filled in the longer half (body) and other half is fitted as a cap.
Hard gelatin capsules intended for human medicine are manufactured in eight sizes.

Soft Gelatin Capsule

These are prepared from gelatin and water to which glycerin, sorbitol or propylene glycol are added to make them elastic or plastic like. Soft Gelatin Capsules are found in different shapes e.g.

- Oval
- Tube Shape
- Round

These are used for filling liquids and semi-solids. Vitamin preparations such as vitamin A, D and multivitamins

Advantages of Capsules

- ✓ Capsules may be used for dispensing solid, semi-solid and liquid drugs.
- ✓ Easy to swallow as they are tasteless and odorless.
- ✓ In capsule manufacturing less adjuncts are required as compare to tablets
- ✓ Capsules can be colored to protect from light.
- ✓ They are easy to handle and carry

Disadvantage of Capsule

- × Capsules cannot be used for aqueous and alcoholic preparation as they will attack the shell.
- × Hygroscopic substances are not suitable to capsulate, they absorb moisture and make shell brittle.

SUPPOSITORIES

Suppositories are solid dosage form of medicament intended for insertion into body cavities other than mouth. They may be inserted into rectum, vagina or urethra, where suppositories soften or melt at body temperature which releases the medicament and exert local and systemic actions.

Suppositories vary in shapes, sizes and weights.

- ✓ These are convenient for administration of drugs which irritate GIT, cause vomiting, destroyed by stomach $_{p}$H.
- ✓ Easily administered to children, old people, and unconscious patients.
- ✓ Suppositories are used for local actions(rectal: relieve constipation), (vaginal: antibacterial, local anesthetic, analgesic)

- ✓ For systemic effects, mucous membrane of rectum and vagina permits absorption of many soluble drugs

CLASSIFICATION OF SUPPOSITORIES

1.Rectal suppositories

Shape: They are tapered at one or both ends
Size: 32mm in length
Weight: 2g ----------Adult
1g ----------children

2.Vaginal suppositories or pessaries

Shape: Oval, rod or cone shaped.
Size: They are larger than rectal suppositories.
Weight: is about 5g and varies depending upon the base used and purpose.

3.Urethral suppositories or bougies

Shape: long, thin, pencil shaped rounded from both sides
Size: Male 3-6mm---------- diameter
140mm ----------length
Female 70mm ----------length
Weight: Male 4g
Female 2g

4.Nasal suppositories

Also known as nasal bougies meant for introduction into the nasal cavity
Shape: similar in shape to urethral bougies
Size: 32 mm ----------length
Weight: 1g

5.Aural suppositories (Ear cones)

Shape: These are also pencil shaped like bougies
Size: 32mm ----------length

Type	Shape	Size	Weight
Rectal	Tapered on one or both ends	32mm	Adult: 2g Children: 1g
Vaginal	Oval, rod, cone shaped	Larger than rectal	5g
Urethral	Long, thin, pencil shaped	M: 140mm F: 70mm	M: 4g F: 2g
Nasal	----------	32mm	1g
Aural	----------	--------	

SUPPOSITORY BASES

These play very important role in release of medication. They remain solid at room temperature but melt at body temperature and made drug available. Commonly employed bases are cocoa butter (Theobroma oil), glycerogelatin base, polyethylene glycols.

1. Fatty or oleaginous bases: Cocoa butter

It is a fat obtained from the roasted seed of theobroma cocoa. Its melting point is 30-35^{0}C. it melts at body temperature and release the medicament. It's a very good base for rectal suppositories. It is not suitable for pessaries, urethral or nasal bougies because immiscible with mucous secretions and after melting leaks out of the cavities.

2. Water miscible bases:

1.Glycero-gelatin base

It is a mixture of glycerin and water which is made stiff by addition of gelatin. The base being hydrophilic slowly dissolves in aqueous secretions and slow release of medicament. It may be used to prepare all types of suppositories particularly vaginal suppositories.

2. Polyethylene glycols

These are polymers of ethylene oxide and water. They are commonly known as carbowaxes. They don't melt but dissolve in body fluids and release medicament.

SEMI-SOLID DOSAGE FORMS

OINTMENTS

Ointments are soft and greasy semi-solid preparations intended for application on the skin or mucous membrane.

Types of Ointments

i. **Medicated Ointment**: contains a medicament dissolves, suspended or emulsified in the base.

ii. **Non-Medicated ointment** : are used as vehicles for preparation of medicated ointments or can be used for their emollient and protective action to the skin.

Classification Of Ointment Bases

1. **Oleaginous bases**

These bases consist of water insoluble hydrophobic oils and fats. The most important are hydrocarbons e.g. petrolatum (soft paraffin), liquid paraffin (liquid petrolatum or white mineral oil)

These bases are greasy and difficult to remove from skin. They prevent drainage on oozing areas and evaporation of cutaneous secretions.

2. **Absorption Bases**

The term absorption is used to show the hydrophilic character of the base. They absorb large amount of water but still retain their ointment like consistency.

Wool fat (anhydrous lanolin) obtained from wool of sheep

Hydrous wool fat (lanolin)

Bees wax it obtained from honey comb of bees.

3. **Emulsion bases**

These are semi-solid emulsions. These are of two types: o/w and w/o

The additional amount of water can be incorporated in both the types. These bases

contain both water soluble and water insoluble components. These have emulsifiers and because of their surface active property may facilitate contact between medicament and skin.

Hydrophilic ointment, rose water ointment, vanishing creams.

4. **Water soluble bases**

These contain only the water soluble ingredients but not the greasy substances.so also known as greaseless bases. These are water washable.

Polyethylene glycols (carbowaxes)

Certain other substances that are used as water soluble bases include tragacanth, gelatin, pectin, cellulose derivatives.

Other additives in ointments

Preservatives: bases having high water contents support the microbial growth as compared to that having no water. So preservatives such as methyl parabene or propyl parabene, benzoic acid may be incorporated if they are intended to be stored for a long time.

Antioxidants

Chelating agents

Preparation of ointments

1. Trituration method
2. Fusion method

Packaging

- Should be packed in well closed container
- These are packed in ointment jars and collapsible tubes
- Should be so packed that there are no air spaces in container

Storage

- Store at cool place to avoid softening and liquification of the base.
- They must be protected from air, light and moisture.

Labeling

It should be labeled

"FOR EXTERNAL USE ONLY"

OPTHALMIC OINTMENTS

Ophthalmic ointments are sterile dispersions of medicaments in a base meant for application into the eye. They should be sterile and free from irritation. The base selected for an eye must be non-irritating and permit the diffusion of drug throughout the secretions of the eye and must melt close to the body temperature.

The preparation must be carried out under aseptic

conditions.

CREAMS

Creams are non-greasy viscous liquid or semi-solid preparations (emulsions) intended for the application on skin and mucous membrane.

Creams may be:

i. Medicated creams (for specific action)
ii. Non -Medicated creams (as emollients: to soften the skin)

- Creams contain a water soluble base due to which they can be easily removed from skin.
- They are of softer consistency

TYPES

Water in oil (oily creams)
Oil in water (aqueous creams)

Preservation

The aqueous creams have a tendency to bacterial and mold growth, therefore a preservative must be added.

Containers and storage

- ⇨ Creams should be supplied in well closed containers, which should prevent evaporation and contamination.
- ⇨ They should be stored in a cool place.
- ⇨ The collapsible tubes made of metals or plastic are most suitable for packing the creams.
- ⇨ Aluminum tubes are not suitable for packing creams.

PASTES

Pastes are semi-solid preparations, used for application to the skin. They are dispersions of high concentration of insoluble powdered substances in a fatty or aqueous base.

- ♣ They are less greasy and stiffer than ointments due to high solid concentration.
- ♣ They are more absorptive than ointments
- ♣ As they are stiff so don't melt at ordinary temperatures and forming a protective covering over the areas to which they are applied.
- ♣ They are difficult to remove so not suitable for application to hairy area.

Zinc and salicylic acid paste which is also known as **Lessar`s paste** is the most commonly used paste. It is used as an anti-septic paste.

Storage and labeling

- ❖ They should be stored in air tight containers. So as to prevent evaporation of moisture present in the paste.
- ❖ Pastes which contain water must be suitably preserved by adding anti-microbial preservatives.
- ❖ They must be labeled "FOR EXTERNAL USE ONLY"