DOSAGE FORM

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Introduction to Dosage Forms

➢ **Definition of Dosage Form**

Dosage forms are the mechanism by which drug molecules / APIs are administered to areas of action inside the body to generate maximum intended benefits and the lowest unwanted effects.

OR

The Dosage form is the combination of Active Pharmaceutical Ingredients (API) and Excipients in the formulation.

Dosage Forms (Medicines) = API+ Excipients

Active Pharmaceutical Ingredients (API)

Definition of Drug (Active Pharmaceutical Ingredients)

- Drogue is an old French term that means "dry herb" and is sometimes used interchangeably with the word "drug".
- Chemical compounds intended for use in the diagnosis, prevention, treatment, and management of disease(s) in humans and other animals are referred to as "pharmaceutical products" or "pharmaceuticals".
- Chemical/organic synthesis, molecular modification, and biotechnology have all been used to produce medicines in recent years.

OR

- The Active Pharmaceutical Ingredient (API) is the component of a medication that creates its action.

Excipients

- **Do not increase or affect the therapeutic action** of the active components.
- They are also known as inactive components or excipients and have no pharmacological action in general.
- Examples of inactive components are dyes, preservatives, sweetening agents, binding materials, coloring agents and flavoring agents, etc.

Need of Dosage Forms

- Mainly depend on Patient Safety and Drug Safety/ Benefits.
- 1. Deliver precise dosages in a safe and easy manner.

Example – Tablets, capsules, syrups

- 2. Cover bitter taste or odor of drug substances.

Example – Capsules, coated tablets, flavored syrups

- 3. Insoluble or unstable in the selected vehicle, provide a liquid formulation of the insoluble or unstable medication.

Example – Suspension

- 4. Controlled-release methods prolong the duration of medication effect.

Example – Controlled release tablets, capsules, suspensions

- 5. After oral delivery, a drug substance is protected from stomach acid.

Example – Enteric-coated tablets

Need of Dosage Forms

- 6. Provide optional drug action from topical administration sites.

Example – Ointment, cream, ear and nasal preparations

- 7. Drugs can be injected into the body's tissues.

Example – Implants

- 8. Inhalation treatment is the most effective way to get optimum medication activity.

Example – Inhalants

- 9. Liquid dosage forms of chemicals soluble in the vehicle of your choice.

Example – Solution

- 10. Provide for the introduction of medication into the body’s orifice.

Example – Rectal and vaginal suppositories

- 11. Protection of a drug substance from atmospheric oxygen or moisture.

Example – Coated capsules, sealed ampules.

Classification of Dosage Forms

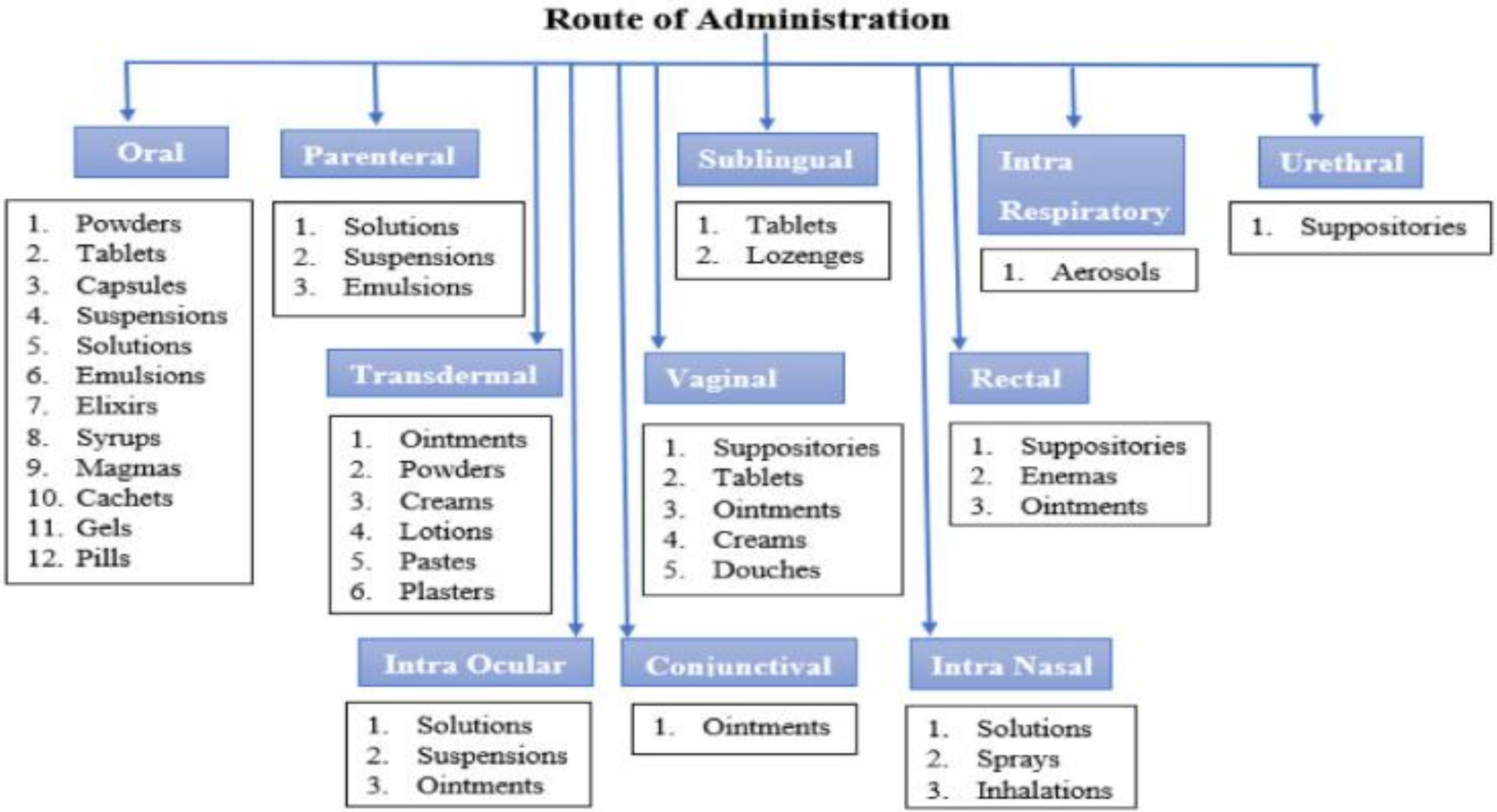
Dosage Forms

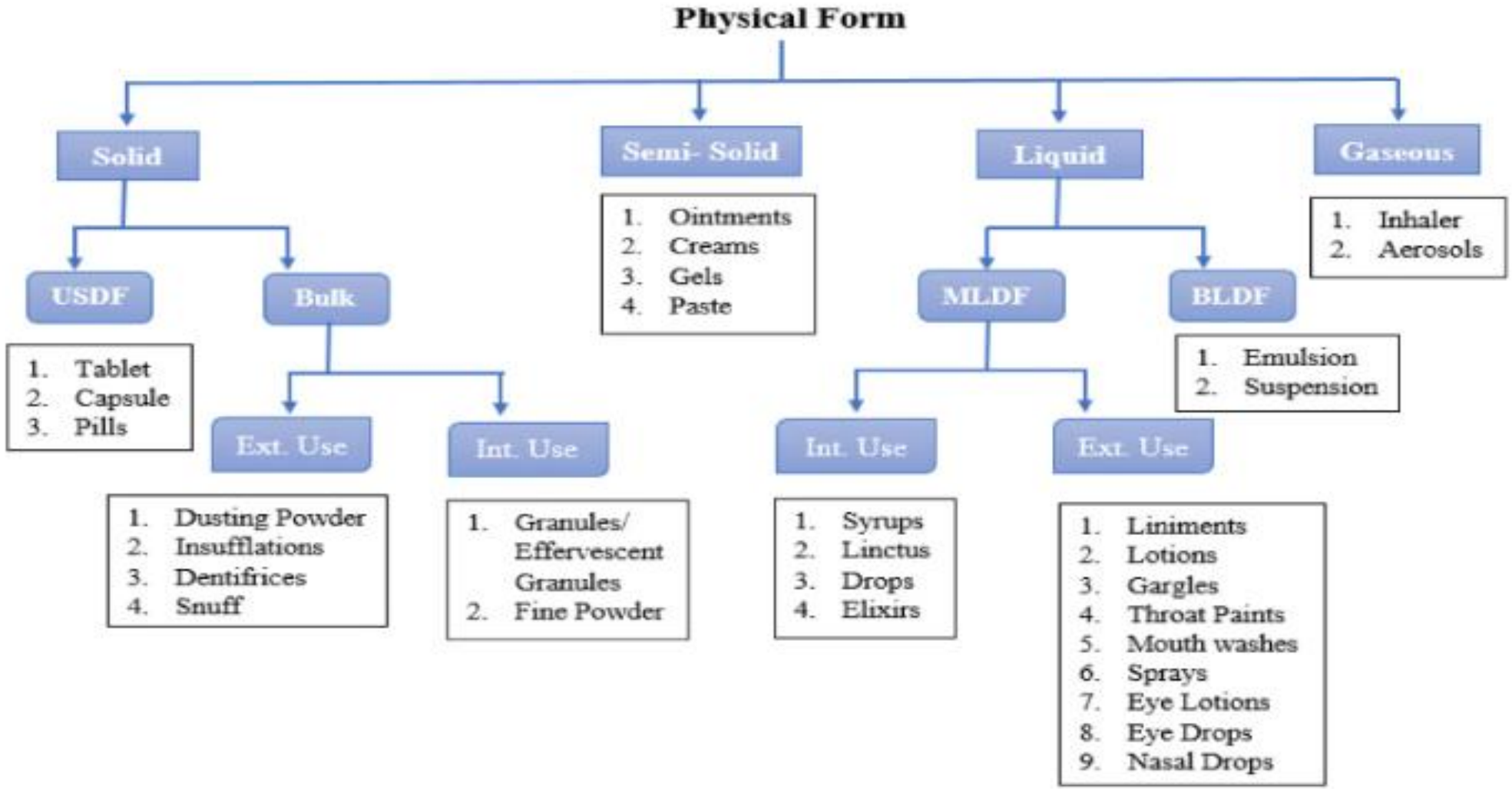
Routes of Administration

Site of Applications

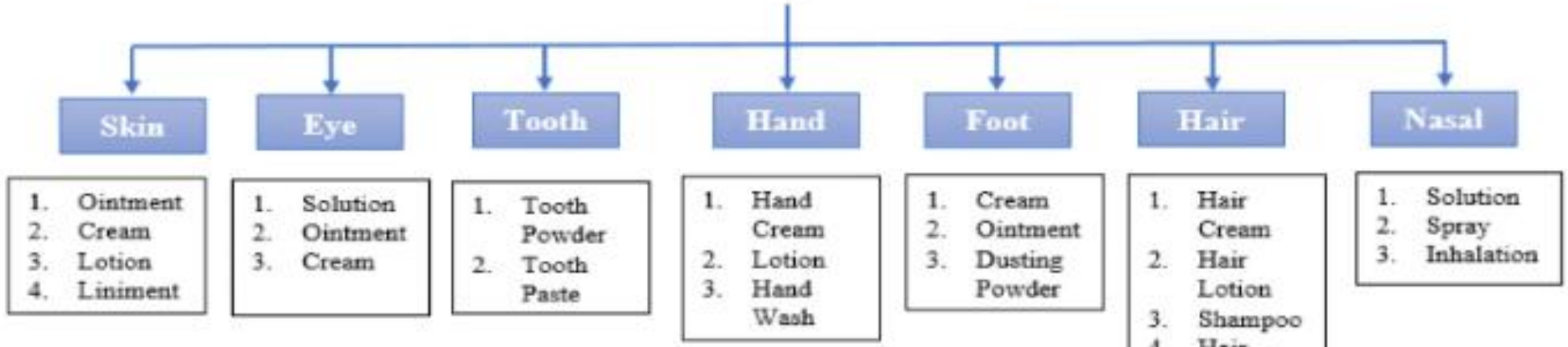
Physical State

Uses


Route of Administration
Oral
1. Powders
2. Tablets
3. Capsules
4. Suspensions
5. Solutions
6. Emulsions
7. Elixirs
8. Syrups
9. Magmas
10. Cachets
11. Gels
12. Pills
Parenteral
1. Solutions
2. Suspensions
3. Emulsions
Transdermal
1. Ointments
2. Powders
3. Creams
4. Lotions
5. Pastes
6. Plasters
Intra Ocular
1. Solutions
2. Suspensions
3. Ointments
Sublingual
1. Tablets
2. Lozenges
Vaginal
1. Suppositories
2. Tablets
3. Ointments
4. Creams
5. Douches
Conjunctival
1. Ointments
Intra Respiratory
1. Aerosols
Rectal
1. Suppositories
2. Enemas
3. Ointments
Intra Nasal
1. Solutions
2. Sprays
3. Inhalations
Urethral
1. Suppositories


Physical Form
Solid
Semi- Solid
Liquid
Gaseous
USDF
Bulk
MLDF
BLDF
1. Tablet
2. Capsule
3. Pills
Ext. Use
Int. Use
Int. Use
Ext. Use
1. Ointments
2. Creams
3. Gels
4. Paste
1. Inhaler
2. Aerosols
1. Emulsion
2. Suspension
1. Dusting Powder
2. Insufflations
3. Dentifrices
4. Snuff
1. Granules/ Effervescent Granules
2. Fine Powder
1. Syrups
2. Linctus
3. Drops
4. Elixirs
1. Liniments
2. Lotions
3. Gargles
4. Throat Paints
5. Mouth washes
6. Sprays
7. Eye Lotions
8. Eye Drops
9. Nasal Drops

Site of Application



Uses

Common Types of Solid Dosage Forms

1.Tablets

- ✓ Tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents.
- ✓ May have coatings **(e.g., film-coated, enteric-coated)** to modify release patterns or protect the drug from degradation.
- ✓ Variants include chewable tablets, effervescent tablets, and sustained-release tablets.

2.Capsules

- ✓ Capsules are solid unit dosage forms in which drug and/or inert substances are enclosed in a small gelatin shell **OR**
- ✓ Gelatin or hydroxypropyl methylcellulose (HPMC) shells filled with powder, granules, or liquid.
- ✓ Two main types: hard capsules (solid or granular drugs) and soft capsules (liquid or semi-liquid drugs).

Common Types of Solid Dosage Forms

3.Lozenges

- ✓ Lozenges are solid dosage forms that are intended to be dissolved or disintegrated slowly in the mouth.
- ✓ They contain one or more active ingredients and are flavored and sweetened so as to be pleasant tasting.

4.Pills

- ✓ A medicinal substance in a small round or oval mass meant to be swallowed.
- ✓ Pills often contain a filler and a plastic substance such as lactose that permits the pill to be rolled by hand or machine into the desired form.
- ✓ The pill may then be coated with a varnish like substance.

Dusting Powders:

- These are meant for external application to the skin and are generally applied in a very fine state of subdivision to avoid local irritation.
- It should be passed through a **80 sieve** to enhance their effectiveness.
- Generally prepared by mixing two or more ingredients one of which must be either starch, Kaolin or talc as one of the ingredients of the formulation.
- It must be sterilized dry heat method (160°C for 2hrs) before use.

Dusting powders are of two types:

- **Medical**: used mainly for superficial skin conditions
  : must be free from dangerous pathogenic microorganisms

- **Surgical**: used in body cavities and also on major wounds as a result of burns and umbilical cord of infants
  :must be sterilized before their use

Insufflations:

- These are medicated dusting powders meant for introduction into the body cavities such as nose, throat, ears and vagina with the help of an apparatus "Insufflator".
- It sprays the powder into a stream of finely divided particles all over the site of application.
- Insufflations are available in the form of pressure aerosols.

Snuffs:

- These are finely divided solid dosage forms of medicament which are inhaled into nostrils for its antiseptic, bronchiodilator and decongestion action.

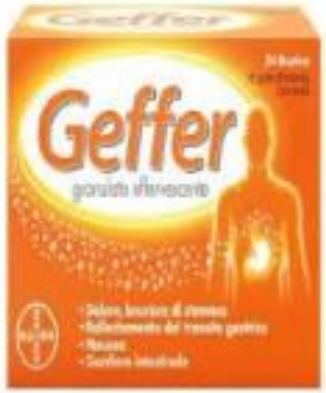
Dentrifices (Tooth Powders):

- These are applied with the help of tooth brush for cleaning the surface of teeth.
- They contain suitable detergent or soap, some abrasive substances like calcium sulphate, magnesium carbonate, sodium carbonate and sodium chloride and a suitable flavor.
- They are available in many forms, including toothpastes, gels, powders, dental creams, and dental foams.

Granules:

- Granules are the multiparticle entity in which primary powder particles are made to adhere to form larger particles.
- Granules size range- between 0.2 to 4mm.
- In tablets and capsules granules are the intermediate product and having size of 0.2 to 0.5mm .

- **Effervescent granules:**
- Effervescent granules are uncoated granules generally containing acid substances and carbonates or hydrogen carbonates which react rapidly in the presence of water to release carbon dioxide.
- They are intended to be dissolved or dispersed in water before administration.
- They contain a medicament mixed with citric acid, tartaric acid and sodium bicarbonate.



Monophasic Liquid Dosage Forms

Definition: Monophasic liquid dosage form is **a liquid preparation containing two or more components in one phase system.**

Examples: For Internal Use :

1) Simple mixtures: Liquid preparations containing one or more medicinal substances in dissolved form.
2) Syrup : Concentrated, aqueous preparations of sugar or sugar substitutes with or without added flavoring agents and medicinal substances.
3) Elixirs: Sweetened, clear and colored aromatic hydro-alcoholic liquids of potent or nauseous drugs.
4) Draughts: A draught is a single-dose liquid medicine, typically prepared and consumed immediately or within a short time after preparation. It is often used for specific treatments requiring precise dosing in liquid form.

Monophasic Liquid Dosage Forms

5) Linctuses :Viscous liquids containing high concentration of sucrose usually prescribed for the relief of cough.

6) Drops: Clear, sweetened, and flavoured liquids usually formulated for pediatrics and dispensed in a suitable bottle containing calibrated dropper.

7)Tinctures: Alcoholic or hydro-alcoholic solutions prepared from vegetable materials or from chemical substances.

8)Spirits: Alcoholic or hydro-alcoholic solutions of volatile substances. Spirits are taken internally or sometimes inhaled for their medicinal value. A large number of spirits are used as flavoring agents and provided a readymade means for formulation of aromatic waters.

9) Aromatic Water: Clear, saturated aqueous solutions of volatile oils or other aromatic or volatile substances. Mostly, they are used as flavored or perfumed vehicles in other liquids.

Monophasic Liquid Dosage Forms

Examples:

For External Use : Liquids applied on Skin

1) Liniments: Alcoholic or oily clear solutions intended for application to the skin with friction or massage. Liniments must not be applied to broken skin.
2) Lotion : Clear solutions, may be either aqueous or oily, suspension or emulsions intended for application to skin without friction. Lotions are just dabbed on the skin or applied with the help of suitable dressing material.
3) Collodions: Liquid preparations for external use, usually applied with a brush or rod. The solvent system of collodions is volatile which evaporates.

Monophasic Liquid Dosage Forms

Examples:

For External Use : Liquids for body cavities

1) Eye Drops: Aqueous or oily solutions of drugs intended to be instilled into a conjunctival sac.

2) Nasal Drops : Aqueous solutions of drugs intended to be instilled into the nose with dropper.

3) Ear Drops: Solutions of drugs intended to be instilled into ear with a dropper.

4) Douches: Medicated solutions for rinsing a body cavity. The word "douche" is most often used for rinsing vaginal cavity.

5) Enemas: Aqueous solutions of drug intended for rectal administration.

Monophasic Liquid Dosage Forms

Examples:

For External Use : Liquids for oral cavities

1) Gargles: Aqueous solutions employed for local action in the throat. They are dispensed in concentrated form with directions for dilution with luke-warm water before use.

2) Paints: Solutions in viscous vehicle intended to be applied on the mucosa with some soft device such a brush or cotton. Example: Iodine Throat Paint

3) Mouthwashes: Liquid preparations for treating oral infections and bad breath and providing feeling of freshness. They are usually supplied in concentrated form and diluted before use.

Monophasic Liquid Dosage Forms

Examples:

For Other External Use :

1) Irrigations: Solutions of medicament used to treat infections of the bladder, vagina and less often the nose. They are usually supplied in concentrated form and diluted before use.

2) Sprays: Aqueous, alcoholic or glycerin containing solutions of drugs intended to be applied to the mucosa of nose or throat with an atomizer or nebulizer.

3) Inhalations: Solutions of drugs administered by nasal or oral respiratory route for local or systemic effect.

4) Parenterals: Sterile, pyrogen free preparations containing one or more medicaments intended to be administered parenterally. The word "Parenteral" is derived from the greek words "Para" and "Enteron" mean outside the intestine, and denotes routes of administration other than the oral route.

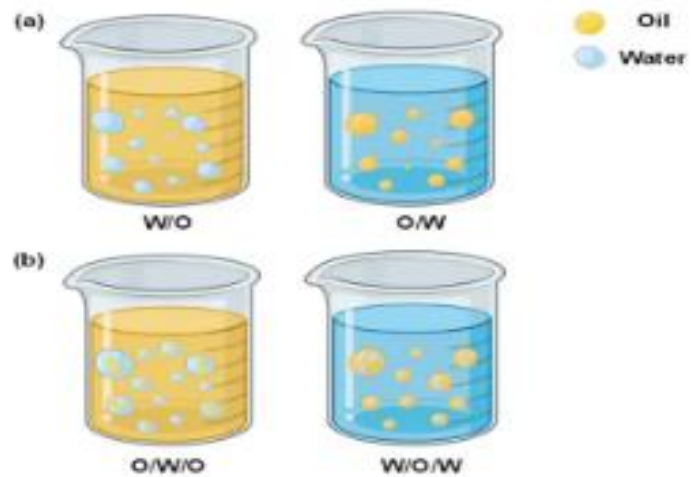
Biphasic Liquid Dosage Forms

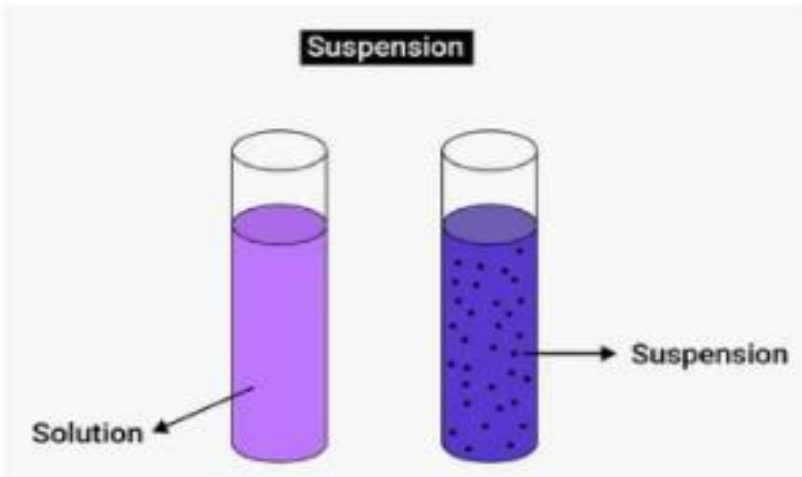
➢ **The liquid which consist of two phases are known as biphasic liquids.**

Examples:

For Oral Use :

1) Emulsion: These are heterogeneous systems in which one liquid phase is dispersed in the form of minutes globules into another immiscible liquid phase. They are also called coarse dispersions of liquid in liquid.
2) Suspension: Aqueous or oily coarse dispersions containing finely divided insoluble drug suspended in a liquid medium.





Biphasic Liquid Dosage Forms

Examples:

For External Use :

1) Applications: Suspensions or emulsions intended to be applied to the skin.

2) Liniments: Emulsions intended for, application to the skin with friction or massage. They are Do not applied to the broken skin.

3) Lotions: Emulsions or suspensions intended to be applied to the skin without friction. They may be applied as such or with the support of suitable dressing material.

Semisolid Dosage Forms

- **Semi-solid dosage (SSD) forms are a type of medication that is neither solid liquid; they are somewhere in between the two states.**

Examples:

1) Ointment: Semisolid dosage forms containing medicinal agents uniformly dispersed in a oleaginous and fatty base intended for external use.

2) Creams: Highly viscous emulsions containing medicinal agent intended for external use.

3) Pastes: Semisolid preparations containing very high proportion of the solid medicament (20%-50%).

4) Jellies: Transparent or translucent, non-greasy, semisolid preparations intended to be used externally.

Semisolid Dosage Forms

Examples:

5) Poultices or cataplasm: Semisolid pastes like preparations used externally by spreading while hot on a dressing and bandaged on to the affected part to reduce inflammation.

6) Suppositories: Suppositories are semisolid dosage form of medicament for insertion into body cavities other than mouth. They may be inserted into rectum, vagina or nasal cavity. The medicament is incorporated into the suppository base and product is formulated in such a way that they will either melt or dissolve in the body cavity fluid to release the medicament.

Gaseous Dosage Form

1. AEROSOLS:

- Suspension of fine solid or liquid particles with gas used to apply drug to respiratory tract having atomizer with in device

2. INHALATIONS:

- Internal liquid preparations containing medicaments dissolved in suitable solvent or if insoluble suspended in the propellant

3. SPRAYS:

- Gaseous preparations of drugs containing alcohol applied to mucous membrane of nose or throat with atomizer or nebulizer