INTRODUCTION TO DOSAGE FORMS

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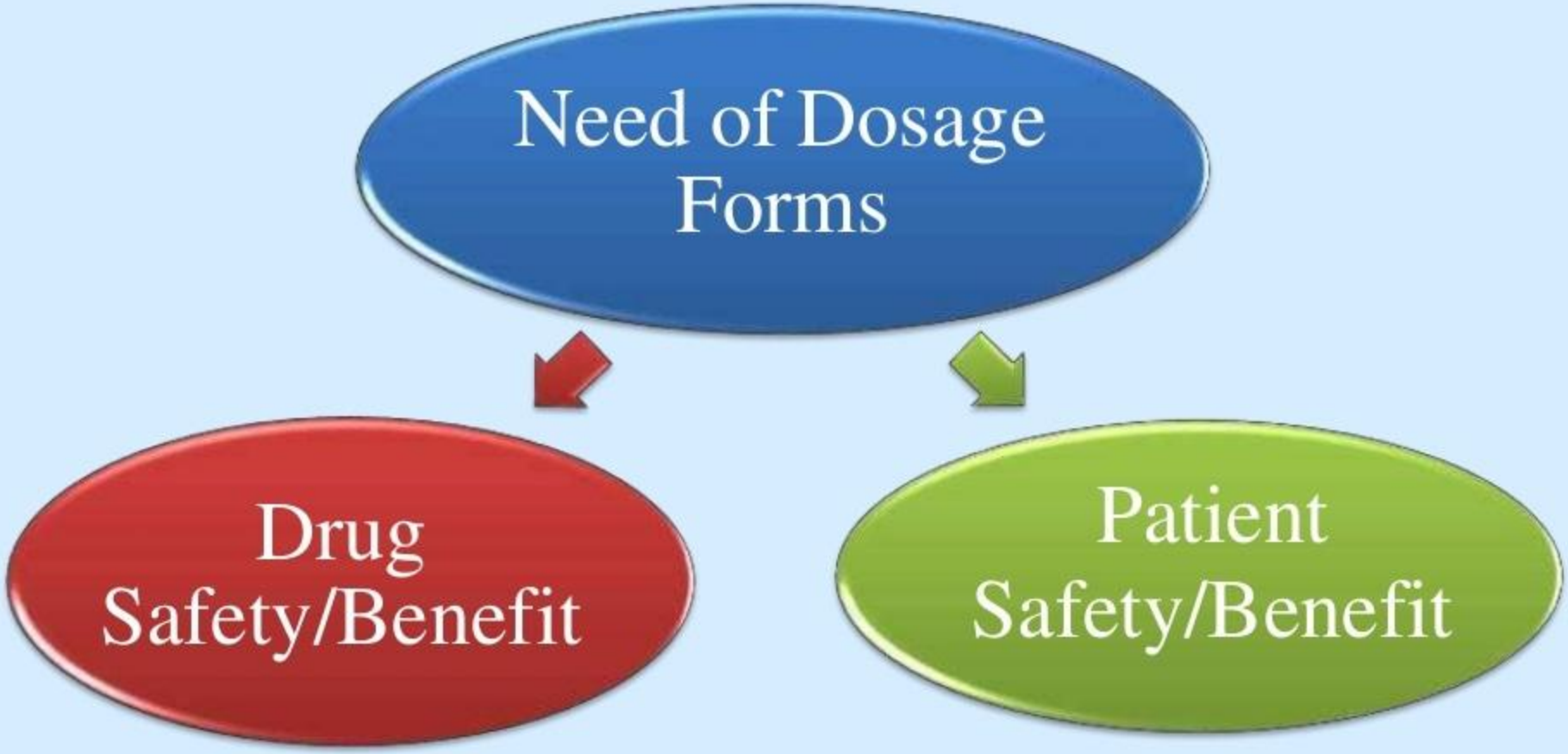
Contents

1. Introduction
2. Classification of dosage forms
   - Solid dosage forms
   - Liquid dosage forms
   - Semi solid dosage forms
3. New drug delivery system

DOSAGE FORM OF DRUGS

Dosage forms are the means by which drug molecules/APIs are delivered to sites of action within the body to produce optimum desired effects and minimum adverse effect.



Introduction

➢**Dosage form (Medicines) = API + Excipients**

The means (or the form) by which drug molecules are delivered to sites ofaction within the body.

➢**Drug (Active pharmaceutical ingredients)**

Chemical compound intended for used in diagnosis, treatment prevention, of disease.

OR

The Active Pharmaceutical Ingredient (API) is the part of any drug that produces its effects.

➢**Excipients**

- Do not increase or affect the therapeutic action of the active ingredient.
- Inactive ingredients may also be referred to as inert ingredients or excipients, and generally have no pharmacological effect.
- Examples of inactive ingredients include binding materials, dyes, preservatives, and flavoring agents,sweetening agents,coloring agents etc.

Direct clinical use of the active drug substances is rare: Why??

- API handling and Accurate dosing can be difficult or impossible (e.g., potent drugs: low mg and µg doses).
- API administration can be impractical/unfeasible because of size, shape, smell/odour, taste and low activity.
- Some API are chemically unstable in light, moisture, O2
- API can be degraded at the site of administration (e.g., low pH in stomach).
- API may cause local irritations or injury when they are present at high concentrations at the site of administration.
- Administration of active substance would mean to have no chance for modification (improvement) of its PK profile.

NEED OF DOSAGE FORMS

- Provide safe and convenient delivery of accurate dosage. **Example – Tablets, capsules, syrups**
- Protection of a drug substances from atmospheric oxygen or moisture. **Example – Coated capsules, sealed ampules**
- Protection of a drug substances from gastric acid after oral administration. **Example – Enteric coated tablets**
- Conceal bitter taste, or odor of a drug substances. **Example – Capsules, coated tablets, flavored syrups**
- Provide liquid preparation of drug that insoluble or unstable in the desired vehicle. **Example – Suspension**
- Provide liquid dosage forms of substances soluble in desired vehicle. **Example – Solution.**

- Provide optional drug action from topical administration sites. **Example – Ointment, cream, ear and nasal preparations.**
- Provide for insertion of a drug into one of the body's orifices. **Example – Rectal and vaginal suppositories.**
- Provide extended drug action through controlled release mechanisms. **Example – Controlled release tablets, capsules, suspensions.**
- Provide for the placement of drugs within body tissues. **Example – Implants.**
- Provide for the optimal drug action through inhalation therapy. **Example – Inhalants.**

CLASSIFICATION OF DOSAGE FORMS

Based on Route of Administration

- Oral
- Parenteral
- Topical
- Transdermal
- Respiratory/Inhaled
- Ophthalmic
- Rectal
- Veginal
- Otic

Based on Physical Form

- Solid
- Semi-solid
- Liquid
- Gases

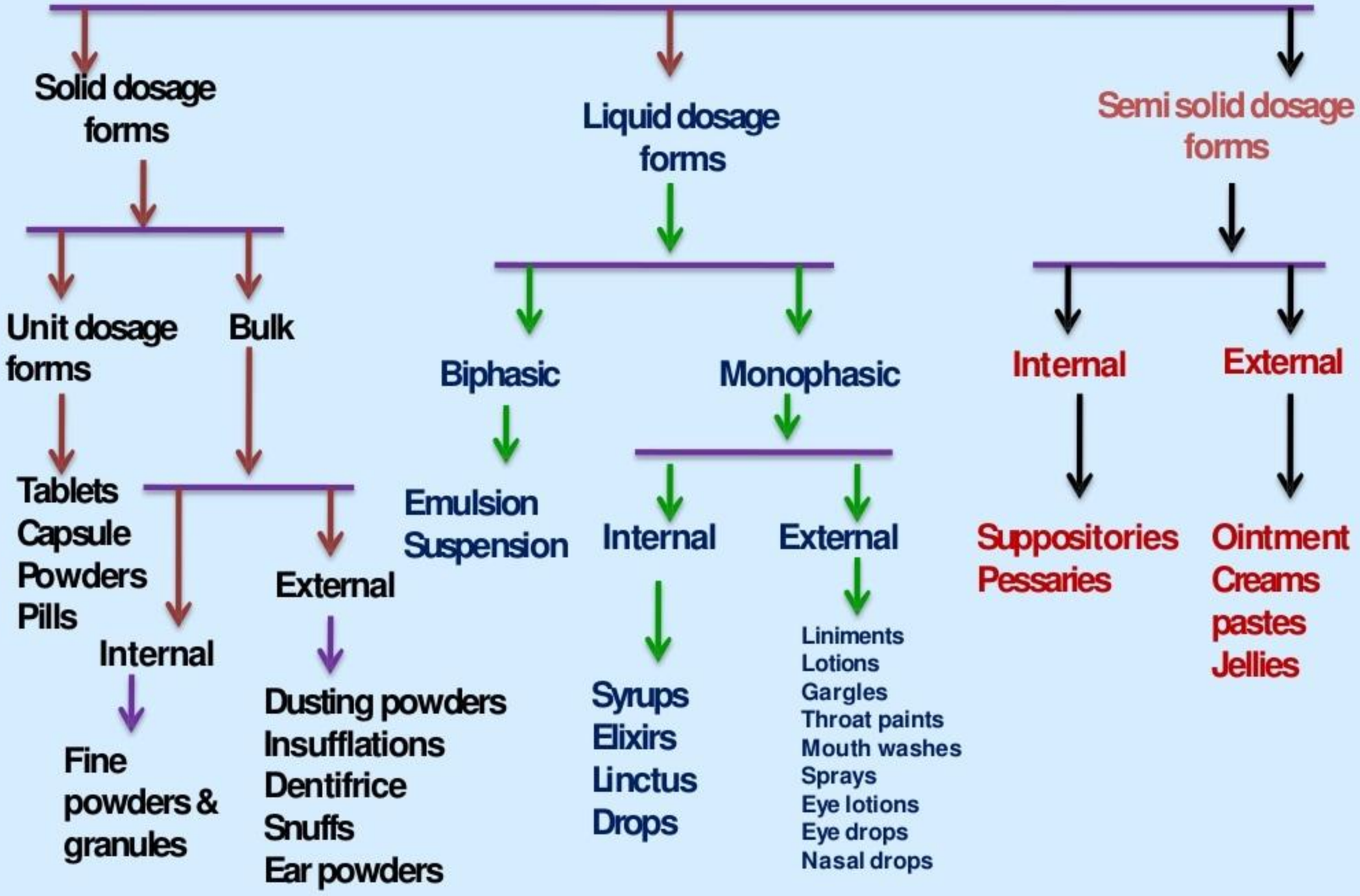
Based on Route of Administration

Enteral Route	
Oral	Tablets, Capsules, Syrups, Suspension, Emulsion etc. Dry Powder Inhaler (DPI), pressurized Metered Dose Inhaler (pMDI) – Nebulizer, Vaporizer
Sub-lingual & Buccal	Orally Disintegrating Tablet (ODT), Lozenges , Chewing tablets, Mouthwash, Toothpaste, Ointment, Oral spray
Rectal & Vaginal	Ointment, Suppository, Enema, Nutrient enema
Parenteral (injections & infusions)	
Intravenous, Intramuscular, Intracardiac, Intraosseous, Intraperitoneal, Intracerebral, Intrathecal, Intradermal, Subcutaneous	
Topical Route	
Dermal	Ointment, Liniment, Paste, Cream, Lotion, Lip balm, Medicated shampoo, Dermal patch
Mucosal	Ear drops, Eye drops, Nasal spray, Ointment, Hydrogel, Nanosphere suspension, Mucoadhesive microdisc (microsphere tablet)
Percutaneous	Transdermal patch etc

Based on Physical Form

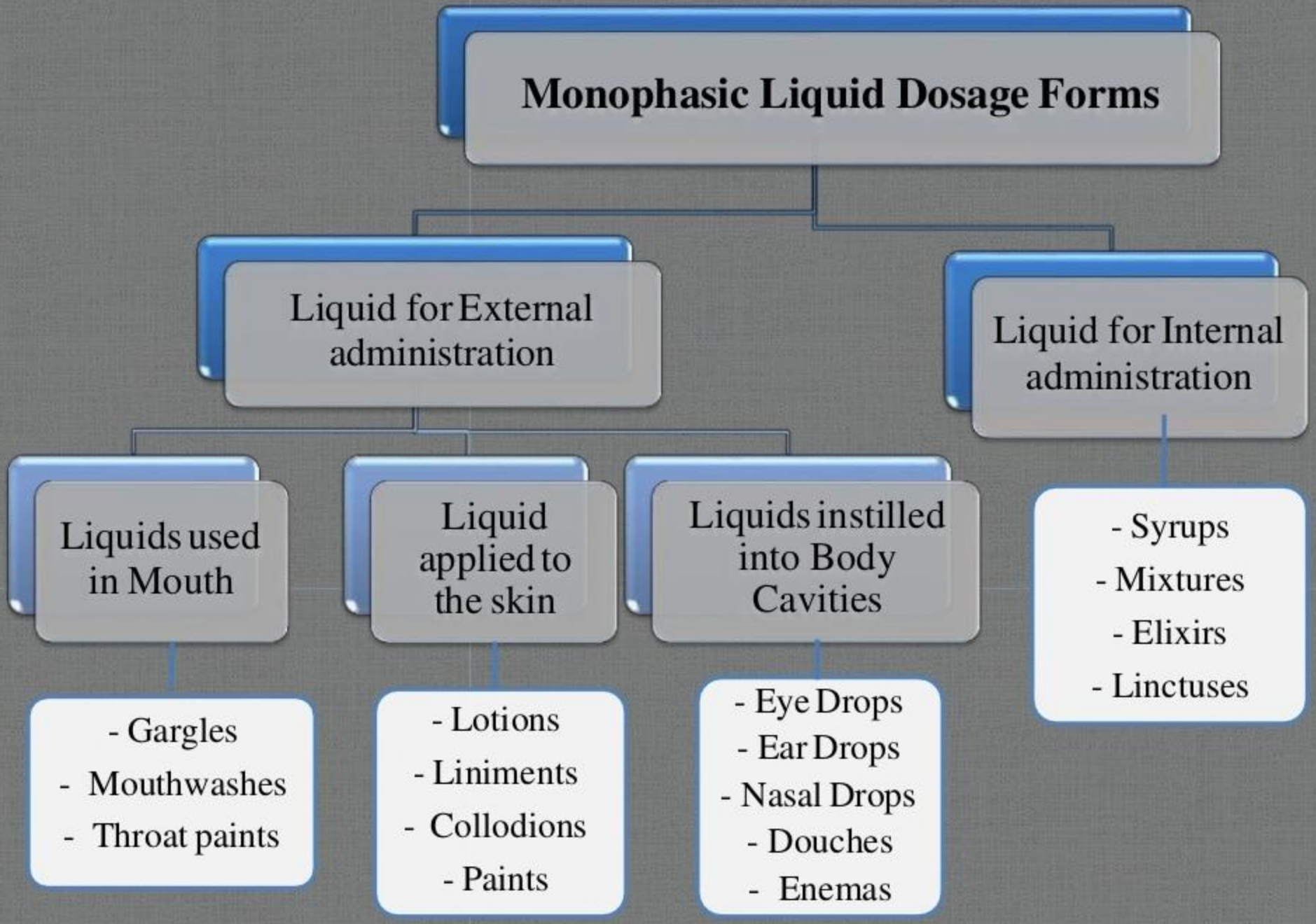
Solid Dosage Forms	
Shaped	Tablets, Capsules, Implants, Transdermal patches
Unshaped	Powders for external/internal use
Semi-solid Dosage Forms	
Shaped	Suppositories (for rectal administration) Pessaries (vaginal suppositories)
Unshaped	Gels, Creams, Ointments, Pastes
Liquid Dosage Forms	
Monophasic	Solutions (syrups, spirits, elixirs, tinctures)
Biphasic	Emulsions, Suspension
External Solutions	Lotions, Liniments, Collodions etc
Gaseous Dosage Forms	
Medicinal Gases	Aerosols: Inhalation/volatile anesthetics
Aerodispersions	Antiasthmatics sprays

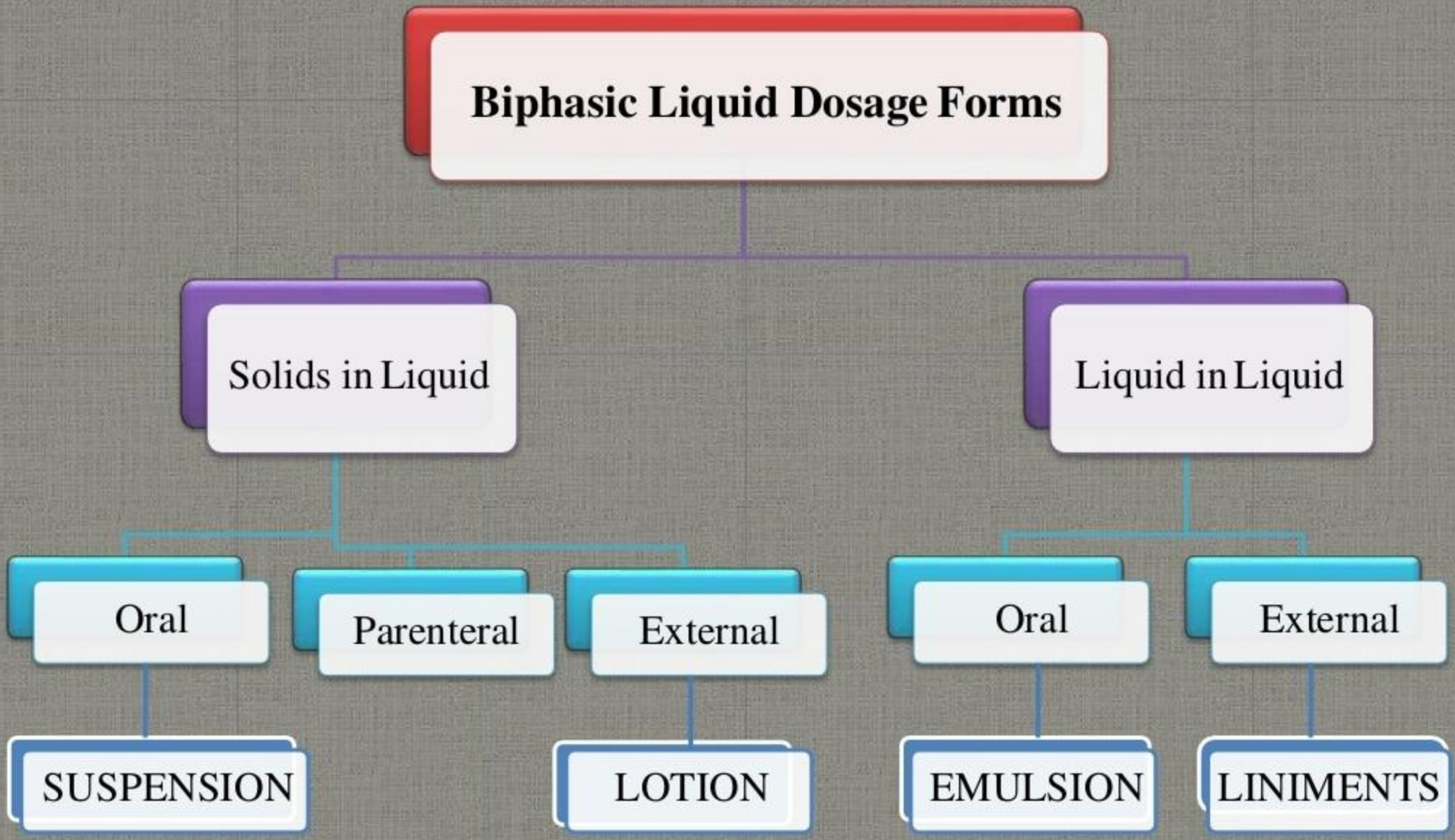
Classification



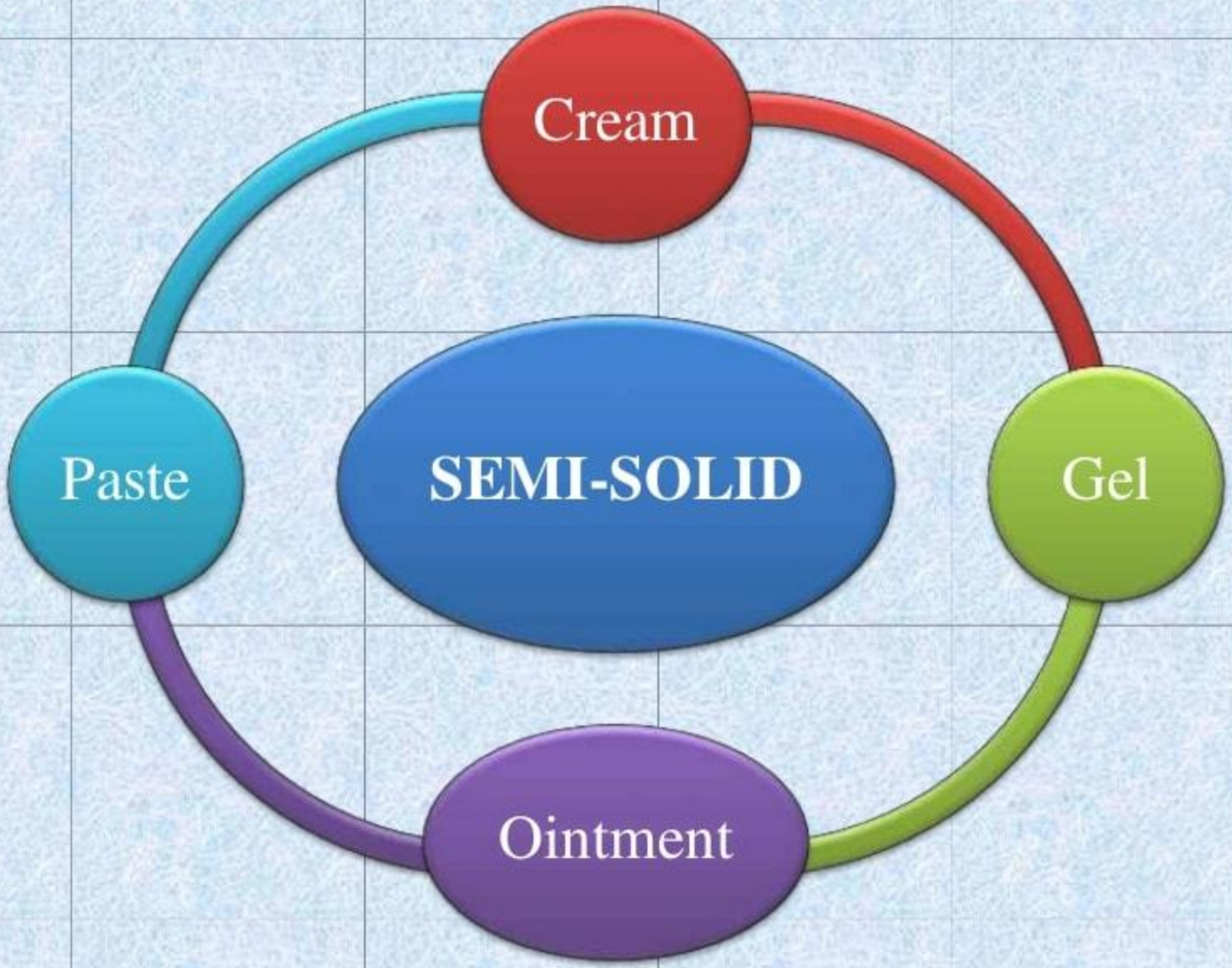
CLASSIFICATION OF SOLIDS

CLASSIFICATION OF LIQUIDS

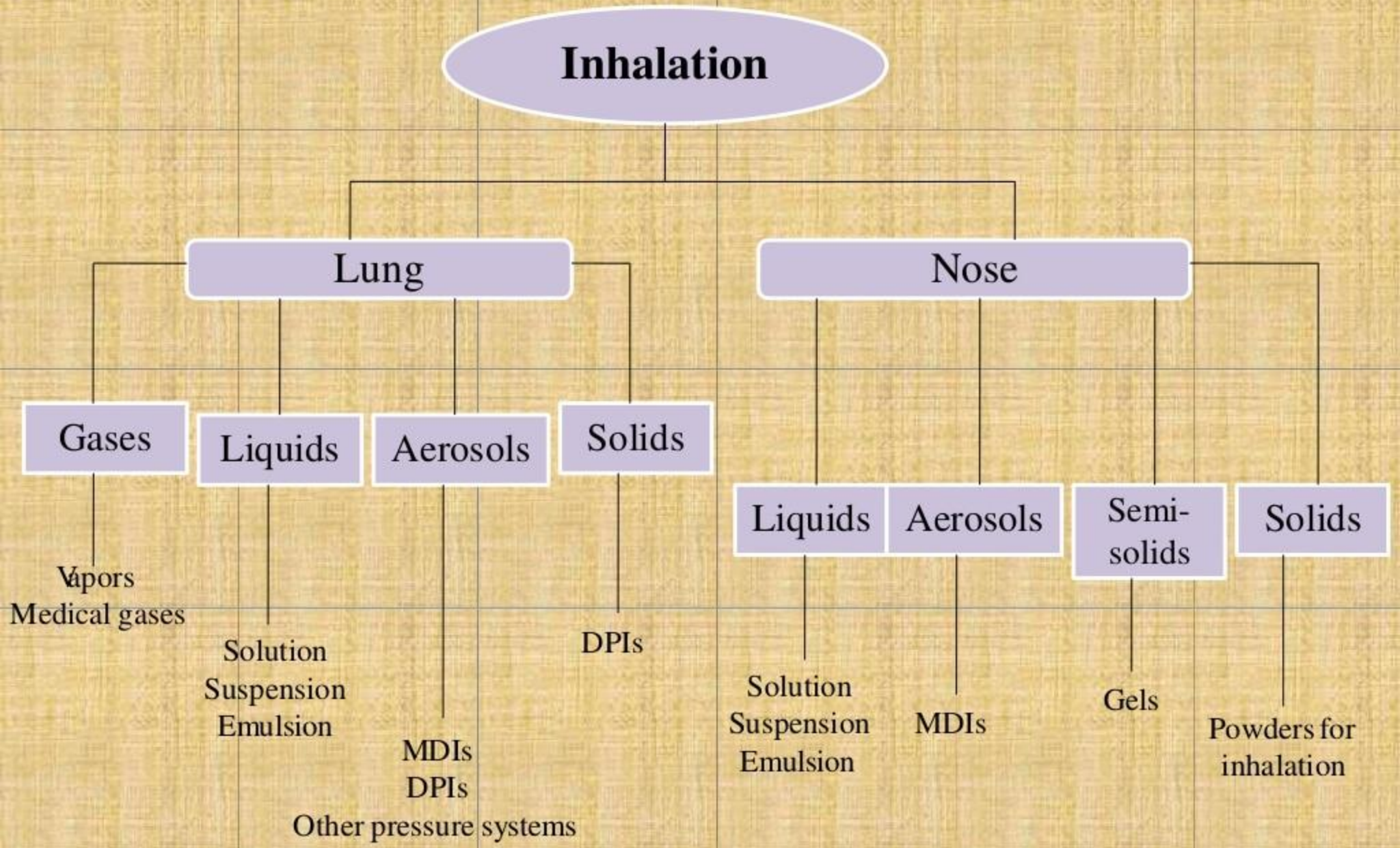



Biphasic Liquid Dosage Forms
Solids in Liquid
Liquid in Liquid
Oral
Parenteral
External
Oral
External
SUSPENSION
LOTION
EMULSION
LINIMENTS

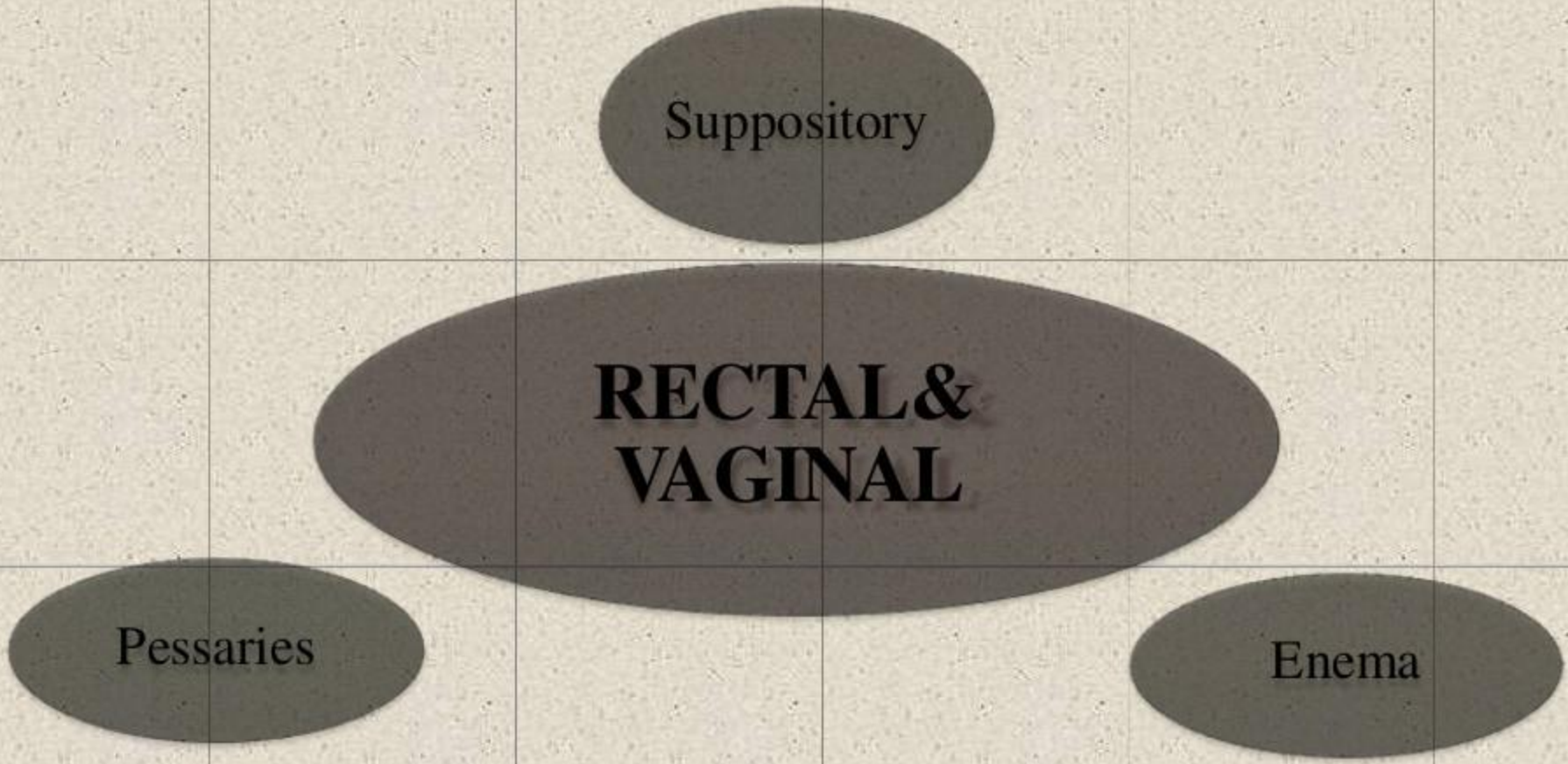
SEMI-SOLID DOSAGE FORMS



INHALED DOSAGE FORMS



RECTAL & VAGINAL DOSAGE FORMS



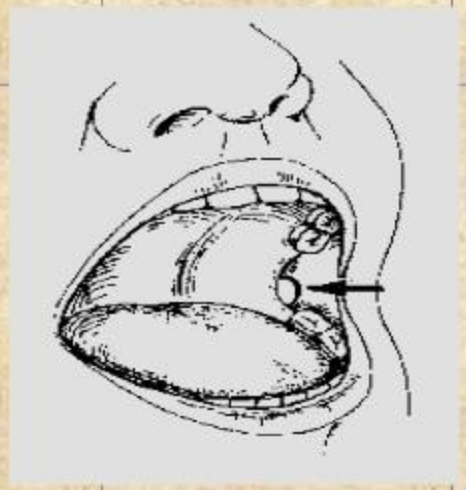
SOLID DOSAGE FORMS

1 -TABLET

- A tablet is unit dose of one or more medicament. Prepare by compression ormould method.
- Common excipients used in tablet are :
  - ✓ **Diluents** – Provide bulkiness of tablet.
  - ✓ **Disintegrants** – To ensure that the tablet breaks up in the digestive tract.
  - ✓ **Binder** – Important for granulation of powder.
  - ✓ **Glidants and Lubricants** – Provide good flow and ensure efficient tabletting.
  - ✓ **Sweeteners and Flavors** – To mask the taste ofAPIs.
  - ✓ **Pigments** – To mask uncoated tablets visually attractive.
- A coating may be applied to mask taste, smooth tablet for easyswallow, expending shelf life, and prevent gastric degradation of drug.

2 - BUCCAL AND SUBLINGUAL TABLET

- **Buccal tablets** placing between the gum and the cheek.
- **Sublingual tablets** placing under the tongue.
- Medicaments of both systems rapidly dissolve in mouth and absorbed through the mucous membrane of mouth.
- Drug reaches in systemic circulation without affecting by gastric juices and metabolizing enzymes of the liver.
- Examples – **Vasodilators, Steroidal hormones.**



3 - EFFERVESCENT TABLET

- **Effervescent tablets** are uncoated and generally contain acid substances (citric and tartaric acids) and carbonates or bicarbonates , which react rapidly in presence of water and release carbon dioxide.
- They are intended to be dissolved or dispersed in water before use, it provide :
- ✓ Tablet immediately dissolve or dispersed
- ✓ Pleasant taste of carbonated drink

4 - CHEWABLE TABLET

- They are tablets that chewed prior to swallowing.
- They are designed for administration to children e.g. vitamin products.

5 - CAPSULES

- Solid unit dosage form that contain a solid, semi-solid, and liquid fill and a gelatin shell.
- Common excipients used in capsules are :
  - ✓ **Gelatin** – Commonly used as gelling agent.
  - ✓ **Plasticizers** – To ensure elasticity or mechanical stability.
  - ✓ **Additional Additives** – Preservative, coloring and opacifying agents .
- They are mainly two types are :
  - ✓ **Hard gelatin capsules** used for dry powder ingredients.
  - ✓ **Soft gelatin capsules** used for semi-solid and for active ingredients that are dissolved or suspended in oil.

6 - LOZENGE

- It is a solid preparation that used to medicate the mouth and throat for the slow administration of indigestion or cough remedies.
- It consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge and facilitating slow release of the medicament.

7 - PASTILLES

- It is a solid medicated pill or candy preparation that design to dissolve slowly in the mouth.
- They are softer than lozenge and their base are glycerol, gelatin, acacia and sugar.

8 - DENTAL CONES

- A tablet from intended to be placed in the empty socket following a tooth extraction, for preventing the local multiplication of pathogenic bacteria associated with tooth extractions.
- These tablets contain an excipients like – lactose, sodium bicarbonate, and sodium chloride etc.
- Cones may contain an antibiotic or antiseptic.

9 - PILLS

- It is a solid oral dosage form which consists of spherical masses prepared from one or more APIs with inert excipients.
- Pills are now rarely used.

10 – ORAL GRANULES

- They are consisting of solid, dry aggregates of powder particles with irregular shape often supplied in single-dose sachets.
- Some granules are placed under the tongue and swallowed with water and other are intended to be dissolved in water before taking.
- Effervescent granules evolve carbon dioxide when added to water.

11 – ORAL POWDER

- Bulk Powders are multi dose preparations consisting of solid, loose, dry particles of varying degrees of fineness.
- Contain one or more active ingredients, with or without excipients and, if necessary, coloring matter and flavoring substances.
- Usually contain non-potent medicaments such as antacids since the patient measures a dose by volume using a 5 ml medicine spoon.

LIQUID DOSAGE FORMS

1 – ORALSOLUTION

- Oral solutions are clear Liquid preparations for oral use containing one or more active ingredients dissolved in a suitable vehicle.

2 – ORALEMULSION

- Oral emulsions are stabilized oil-in-water dispersions, either or both phases of which may contain dissolved solids either oil is dispersed in finely divided form in water or vice versa.

3 – ORALSUSPENSION

- Biphasic liquid preparations for oral use containing one or more active ingredients suspended in a suitable vehicle. It sediment which is readily dispersed on shaking to give a uniform suspension which remains sufficiently stable to enable the correct dose to be delivered.

4 – SYRUP

- It is a concentrated aqueous solution of a sugar, usually sucrose to which medicaments are added.
- Flavored syrups are a convenient form of masking disagreeable tastes.

5 – ELIXIR

- It is pleasantly flavored clear liquid oral preparation of potent or nauseous drugs.
- The vehicle may contain a high proportion of ethanol or sucrose together with antimicrobial preservatives which confers the stability of the preparation.

6 – MOUTHWASHES

- These are similar to gargles but are used for oral hygiene and to treat infections of the mouth.

7 – LINCTUSES

- It is viscous, liquid oral preparations that are usually prescribed for the relief of cough. It contain high proportion of syrup and glycerol which have a demulcent effect on the membranes of the throat.
- The dose volume is small (5ml) and, to prolong the demulcent action, they should be taken undiluted.

8 – ORAL DROPS

- Oral drops are liquid preparations for oral use that are intended to be administered in small volumes with the aid of a suitable measuring device.
- They may be solutions, suspensions or emulsions.

9 – GARGLES

- They are prepared in a concentrated solution with directions for the patient to dilute with warm water before use.
- They are aqueous solutions used in the prevention or treatment of throat infections.

10 – LOTIONS

- It is mono-phasic liquid preparations (aqueous) for external application without friction either dabbed on the skin or applied on a suitable dressing and covered with a water proof dressing to reduce evaporation.

11 – NASAL DROPS & SPRAYS

- Drugs in aqueous solution may be instilled into the nose from a dropper or from a plastic squeeze bottle.
- Used for local effect, e.g. antihistamine, decongestant.

11 – COLLODION

- Collodion is a solution of nitro cellulose in ether or acetone, some times with the addition of alcohols.
- As the solvent evaporates, it dries to a celluloid-like film.
- It is highly flammable.
- **Compound Wart Remover** consists of acetic acid and salicylic acid in an acetone collodion base used in treatment of warts by Keratolysis.

12 – PAINTS

- Paints are mono-phasic liquids for application to the skin or mucous membranes.
- **Skin paints** contain volatile solvent that evaporates quickly to leave a dry resinous

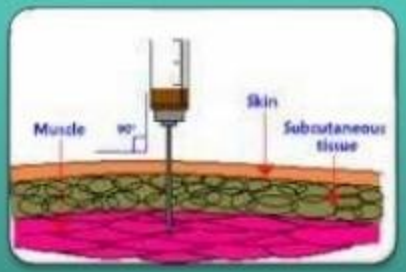
  film of medicament.
- **Throat paints** are more viscous due to a high content of glycerol that designed to prolong contact of the medicament with the affected site.

PARENTERAL DOSAGE FORMS

An injection is an infusion method of putting liquid in to the body, usually with a hollow needle and a syringe which is pierced through the skin.

Intravenous Injection

- It is a liquid administered directly into the bloodstream via a vein.
- It is advantages when a rapid onset of action is needed.



Intramuscular Injection

- It is the injection of aAPIs directly into a muscle.
- Intramuscular injections are often given in the deltoid, vastus lateralis, ventrogluteal and dorsogluteal muscles.

Subcutaneous Injection

- It is injecting into the subcutis, the layer of skin directly below the dermis and epidermis.
- It is highly effective in administering vaccines and insulin.

SEMI-SOLID DOSAGE FORMS

1 – OINTMENTS

- Ointments are semi-solid, greasy preparations for application to the skin, rectum or nasal mucosa.
- Base is usually anhydrous and immiscible with skin secretions.
- Ointments may be used as emollients or dissolved medicaments to the skin.

2 – GELS

- In gel a liquid phase is constrained with in a 3-D polymeric matrix (consisting of natural or synthetic gum) having a high degree of physical or chemical cross-linking.
- It is used for medication, lubrication and some miscellaneous applications like carrier for spermicidal agents to be used intra vaginally.

3 – CREAMS

Oil-in-water (O/W)

- It composed of small droplets of oil dispersed in a continuous aqueous phase.
- Less greasy and more easily washed off using water.

Water-in-oil (W/O)

- It composed of small droplets of water dispersed in a continuous oily phase.
- More difficult to handle but used for hydrophobic drug preparation.
- Reduces water loss from the stratum corneum maintain moisture of skin.

4 – PASTES

- Pastes are basically ointments into which a high percentage of insoluble solid has been added.
- The extra ordinary amount of particulate matter stiffens the system.
- It provide less heating and penetration than ointment.
- It make good protective barrier when placed on the skin, the solid they contain can absorb and thereby neutralize certain noxious chemicals before they ever reach the skin.

Greasy Pastes	Non-greasy Paste
• Leaser's paste	• Bassorin paste

INHALED DOSAGE FORMS

1 – INHALER

- Inhalers are solutions, suspensions or emulsion of drugs in a mixture of inert propellants.
- Release of a dose of the medicament under pressure in an aerosol dispenser in the form of droplets of 50 um diameter or less from the container through a spring loaded valve incorporating a metering device.
- It is commonly used in the treatment of asthma and other respiratory problems.

2 – NEBULIZER OR ATOMIZER

- It is commonly used in treating asthma, and other respiratory diseases.
- It is a device used to administer medication in forms of a liquid mist to the air ways.
- It pumps air or oxygen through a liquid medicine to turn it into a vapor, which is then inhaled by the patient.
- Generally prefer to inhalers for patients, due to advantages such as:

1- Cheaper

2 More portable

3 Less risk of side effects.

- For that reason, are usually reserved only for serious cases of respiratory disease or severe attacks.

RECTAL & VAGINAL DOSAGE FORMS

1 – SUPPOSITORY

- It is a semi solid medicated mass, usually cone shaped, that is inserted either into the rectum, vagina where it melts at body temperature.

2 – ENEMA

- An enema is the procedure of introducing liquids into the rectum and colon via the anus.

Evacuant Enema	Retention Enema
• Used as a bowel stimulant to treat constipation. • Their volume up to 2 liters. • Warmed to body temperature. • Example - soft soap enema & Magnesium sulphate enema	• Their volume does not exceed 100 ml. • No warming needed. • Example – barium enema & nutrient enema.

3 – PESSARY

- Pessaries are solid medicated preparations designed for insertion into the vagina where they melt or dissolve.

Moulded Pessaries

- Cone shape and prepared by molded method.

Compressed Pessaries

- Prepare by compression as similar manner to oral tablets.
- Available in different shape.

Vaginal Capsules

- Prepare same as soft gelatin capsules and various size and shape.

THANK YOU