SHREE H. N. SHUKLA INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH

B.PHRAM

(SEMESTER –I)

SUBJECT NAME: PHARMACEUTICS -I

CHAPTER 2: DOSAGE FORMS

SUBJECT CODE: BP103TP

SYLLABUS:
Introduction to dosage forms, Classification and Definitions.

Syllabus Topic: Introduction to dosage forms

Introduction:

- Dosage forms are a transformation of a pure chemical compound into predetermined form by admixing drug component with different kinds of non drug components collectively known as adjuvant (additives). Each has specific function.
- Dosage form must have a specified quantity which gives a specified type of action pattern.
- Therapeutic efficacy of dosage form depends not only on pharmacological activity of pure chemical compound, but also on the properties of the dosage form in which they are to be administered.
- For formulating the dosage form, attention is given to total composition and processing technique.
- A dosage form should be:
  - Safe to patient
  - Efficacious against a disease
  - Reproducible in giving the desired therapeutic activity
  - Convenient for administration to the patient

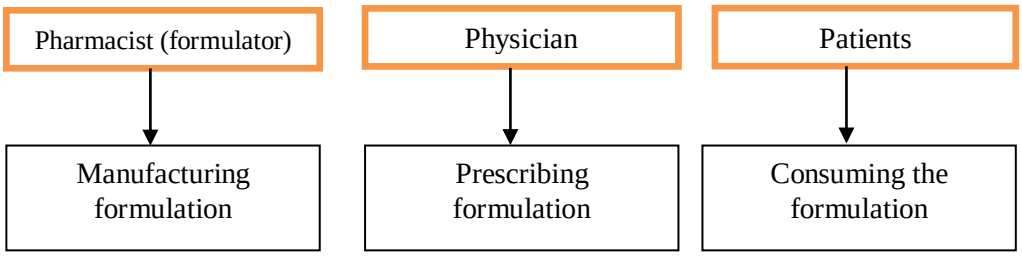
Need of dosage forms:

- Drugs are rarely administered to the patients in their native form. They are always converted to suitable dosage forms before administration.
- Benefit of formation of dosage forms are as follows:
  - It protects the drug from oxidation, reduction and hydrolysis. E.g. coated tablets.
  - It protects the drug from the destructive nature of gastric fluid. E.g. enteric coated tablets.
  - It provides a safe and convenient delivery of accurate dose. Usually the potent drug have low dose in milligrams, which make it very difficult to be weighed accurately prior to administration.
  - It masks the bitter and obnoxious taste and odour of drug. E.g. flavoured syrups
  - It convenient for giving multiple drugs in single dosage form. E.g. Vitamin B complex.
  - It provides specific site of action according to dosage form. E.g. suppositories, skin preparations, buccal tablets.
  - It provides sustained release action of drug. E.g. sustained release tablets/capsules.

Steps involved in dosage form design:

❖ **Deciding the type of dosage form to developed:**

- Formulated drugs dosage for a person should be considered by three types of categories and each has different view regarding formulation.



- So before fabricating any formulations, formulator should consider the views of the three.
  - Physician view point
  - Pharmacist view point
  - Patient view point

❖ **Physician's view point:**

Physician is always interested in following qualities of dosage form.

- Its pharmacological effect.
- Its onset, intensity and duration of action.
- To facilitate the administration of dosage forms to the patient.
- Bioavailability of drugs from its dosage form.

❖ **Pharmacist's view point:**

Pharmacist is interested in

- Quality of product
- Chemical composition and physical structure should remain constant throughout shelf-life.
- Interaction of drug with other drug, drug with adjuvants and drug with container components.
- Stability regarding microbial spoilage.
- Other degradation routes- hydrolysis, oxidation, photo degradation.
- Economical factor.

❖ **Patient's view point:**

Pharmacist has to understand patient's requirement as he is a lay-person. So pharmacist has to try to understand human psychology. Following points should be considered for patients.

- Dosage form- nature and character should be acceptable to a patient and his sense.
- It should have an agreeable appearance and desirable sensual characteristics such as likeable taste-sweet, good flavour and attractive colour.
- Patient wishes convenient dosage form which requires minimum effort and difficulty in use. E.g. ointment can be easily removed from body (water washable), a greasy ointment will not be accepted by patient.
- Sustained action product may appear to be more convenient than conventional tablets.

1 word Question Answer

Sr. No.	Question	Answer
1.	Transformation of a pure chemical compound into predetermined form by admixing drug component with different kinds of non drug components is known as……	**Dosage form**
2.	Which type of dosage form is used to protect the drug from oxidation, reduction and hydrolysis?	**Coated Tablet**
3.	Which type of dosage form is used to protect the drug from the destructive nature of gastric fluid?	**Enteric coated tablet**
4.	Give the example of giving multiple drugs in single dosage form.	**Vitamin B complex tablet**
5.	Which type of dosage form is used to mask the bitter and obnoxious taste and odour of drug?	**Flavoured Syrups**
6.	Which type of dosage form is used to provide specific site of action according to dosage form?	**Suppositories, skin preparations, Buccal tablets**
7.	Which type of dosage form is used to provide sustained release action of drug?	**Sustained release tablets/capsules**
8.	The person who manufacturing the formulations is known as.	**Pharmacist**
9.	The person who prescribing the formulations is known as.	**Physician**
10.	The person who consuming the formulations is known as.	**Patients**
11.	The person who is interested in quality of dosage form like onset, intensity and duration of action, bioavailability, easy to administer is known as.	**Physician**
12.	The person who is interested in quality of dosage form like Quality of product, no change in chemical or physical structure during self life, economical factor is known as	**Pharmacist**

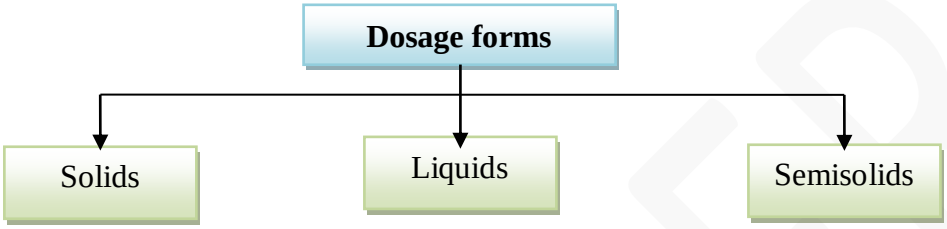
Syllabus Topic: Classification of Dosage forms

Classification of Dosage forms:

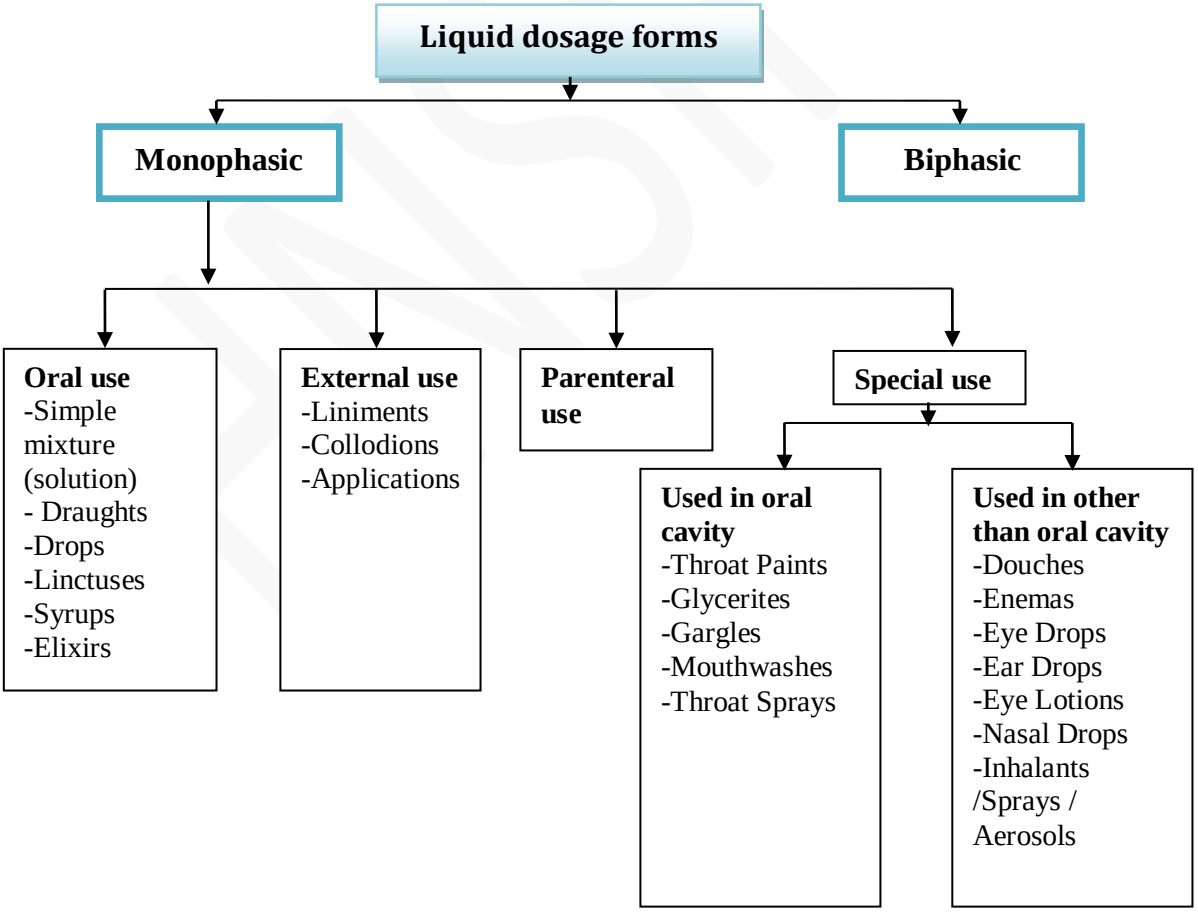
- Dosage form can be classified in several different forms based on their nature of formulation, mode of action, route of administration, drug release pattern, designing of formulation etc.

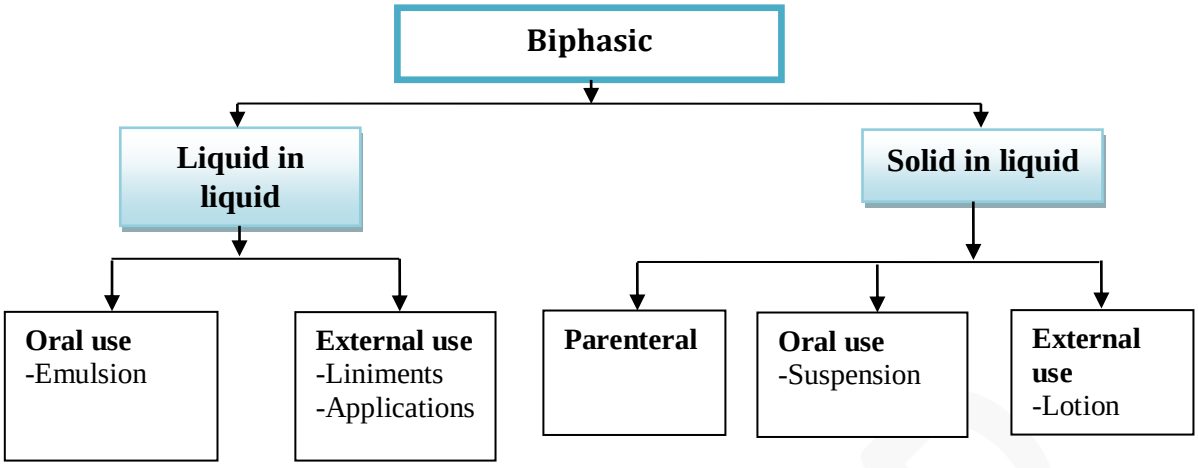
Classification based on physical state:

- Dosage forms are classified according to their physical state as follows.



I. Liquid dosage forms:





Liquid dosage forms are the preferred choice for the following reasons:

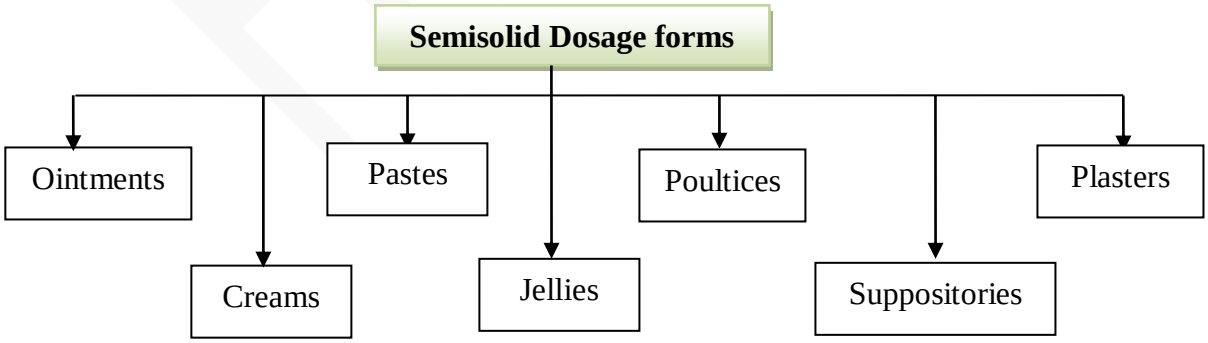
- Unlike solid dosage forms, liquid dosage forms do not undergo dissolution after administration and hence are more effective.
- As they can be easily swallowed so preferred choice for pediatrics and geriatric patients.
- Some drugs are known to cause pain or irritation when administered in solid form so liquid dosage form is preferred.

Liquid dosage forms have the following disadvantages:

- Liquid dosage forms tend to lose potency and deteriorate much faster than solid dosage forms.
- Interaction between dissolved substances gives rise to incompatibilities.
- It required preservatives else they tend to be excellent media for microbial growth.
- Oral liquid dosage forms are bulkier to carry than solid dosage forms.
- The change in solubility produced by solvent alteration lead to many interactions.

II. Semi solid dosage forms:(only for external use)

Semisolid dosage forms are products of semisolid consistency and applied to skin or mucous membranes for therapeutic or protective action or cosmetic function.



Semisolid dosage forms are the preferred choice for the following reasons:

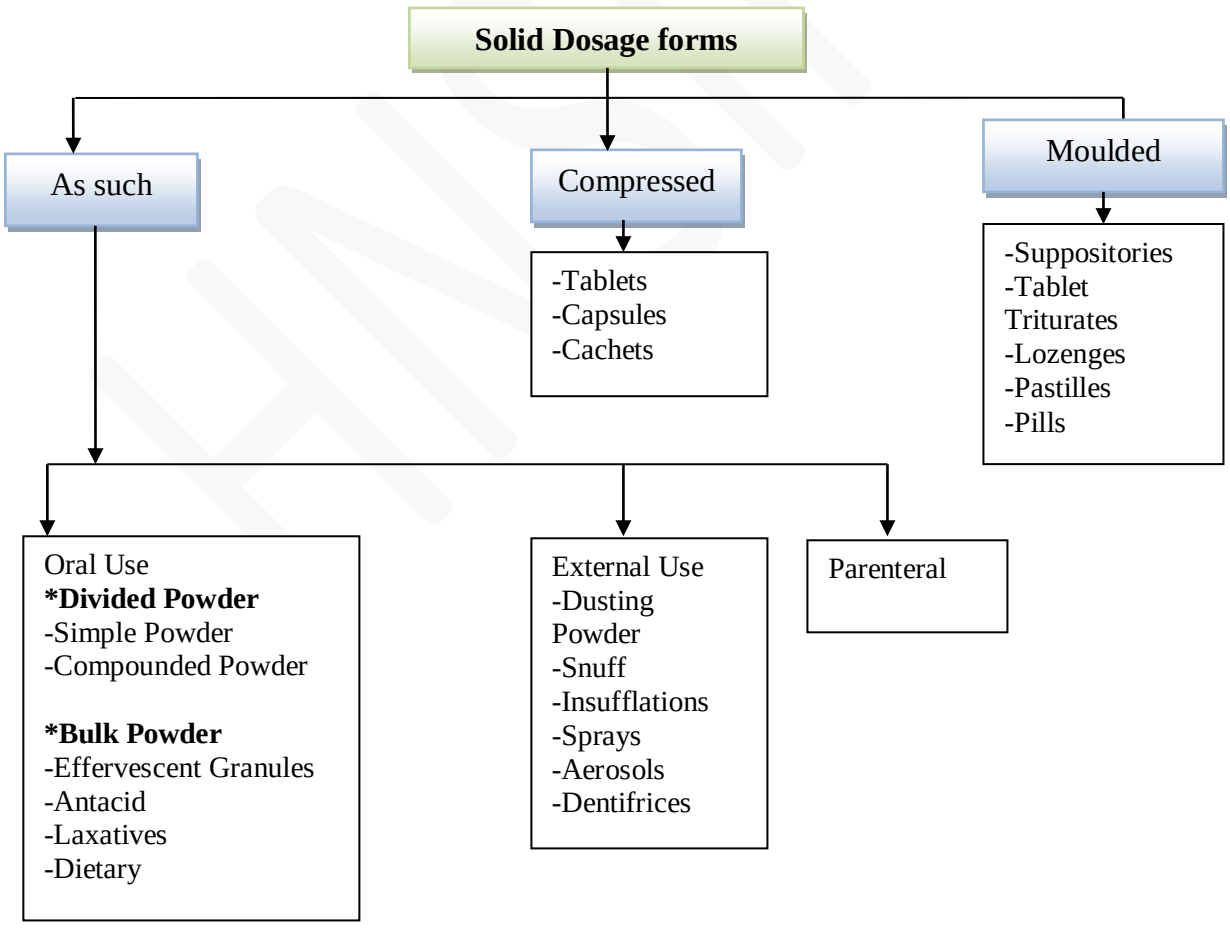
- Semisolid dosage forms are most preferred form for the topical use. A high drug load can be applied on the actual site where the drug is required, with a reduced risk of unwanted side effect.
- It has smooth texture, are elegant in appearance, non greasy, non-dehydrating, non-staining and non hygroscopic.
- Semisolid dosage forms are non-irritating, do not alter membrane or skin functioning, miscible with skin secretion and have low sensitization effect.

Semisolid dosage forms have the following disadvantages:

- Semisolid dosage forms lack dosage accuracy.
- The base of semisolid dosage forms can be easily oxidized.
- Problems may occur if the area is exposed to sunlight after application of semisolid dosage form.

III. Solid dosage forms:

Solid dosage forms are one of the most common ways to deliver a drug substance to a patient.



Solid dosage forms are the preferred choice for the following reasons:

- Solid dosage forms increase the chemical and physical stability of the drug product.
- It provides convenience of handling and ease of transportation. There is less product spoilage during transportation.
- It consumes less space for storage.
- It allows less microbial contamination.
- It facilitates controlled release options.

Solid dosage forms have the following disadvantages:

- Compressed and moulded oral dosage forms are not suitable when rapid action is required.
- Some drugs resist compression into dense compacts owning to their amorphous nature.
- Some patients mainly children and unconscious have difficulty to take solid dosage form orally.

Classification according to the Route of administration:

- The various route of administration of dosage forms are classified as follows:
  I. Systemic route
  II. Local or Topical route

I. <u>Systemic route:</u>

In the systemic route the drug uses the systemic circulation of the body (blood) to reach the desired area. The systemic route is further classified as:

Enteral route	Parenteral route
oral route	Intravascular route
Sublingual or Buccal route	Intramuscular route
Rectal route	Subcutaneous route
-	Inhalation

A. Enteral route:

In this route the drug is passed through G.I. tract and then absorbed in blood.

This route is further classified into:

I. Oral route:

The drug is consumed by swallowing through mouth. This route is also called per oral (p.o.)

Examples:

- Tablets
- Capsules
- Syrups

II. Sublingual or Buccal route:

- In sublingual route drug is placed under the tongue and the patient keeps it there till it totally disintegrate and absorption occurs in mouth.

- The sublingual gland is under the tongue and because there is more saliva the pill disintegrate and results is faster administration of thyroid hormone in the blood via capillaries.
- In the Buccal route of administration the drug is kept in the buccal cavity of the mouth where the drug disintegrates and absorption occurs in the mouth.
- The Buccal gland is located in the mucous membrane which lines the cheeks and because there is less saliva it produce a slightly slower administration of drug.

III. Rectum route:

- There are many orally administered drugs that can also be administered rectally. Rectum form is preferred by the people who have nausea, cannot swallow or have restrictions on eating.
- The vaginal route is based on the same principle of rectum route.
- This route of administering drugs, such as solutions, tablets, creams, gels or suppository, can be used on women. This route is preferred as the drug is slowly absorbed through the vaginal walls.

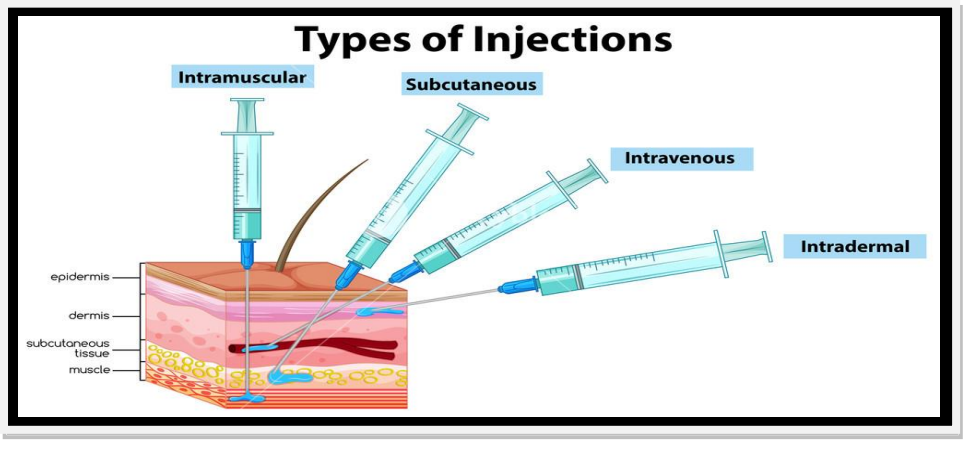
B. Parenteral route:

- In the Parenteral route of administration the drug does not pass through the G.I. tract i.e. drug is directly deliver to the systemic circulation (blood).

This route is further classified into:

I. Administration with injections: In this class the drugs are administered through injections.

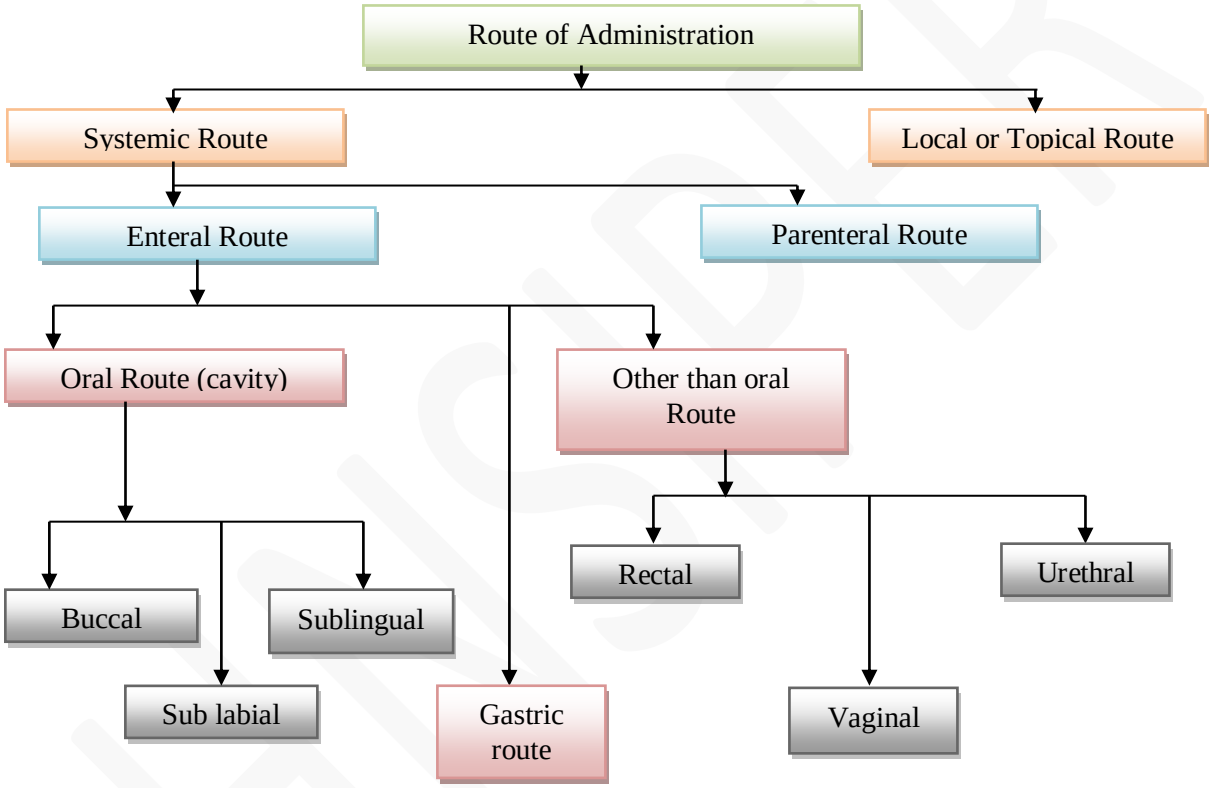
- Intraderamal – into the skin
- Subcutaneous – into subcutaneous tissue of skin
- Intramuscular – into muscle
- Intravenous – into veins
- Intra arterial – into arteries
- Intrathecal – into cerebrospinal fluid
- Intra articular – into synovial fluids
- Intraperitoneal – into the peritoneal cavity

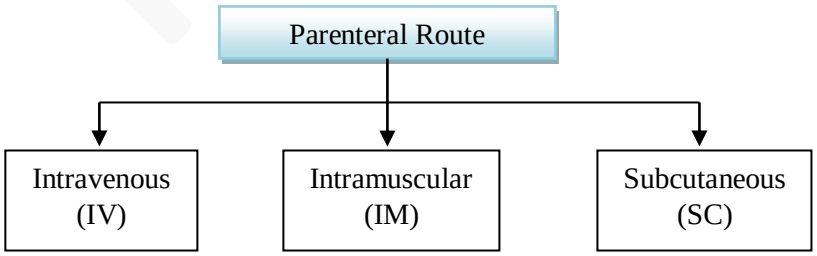


II. Local or Topical route of drug administration:

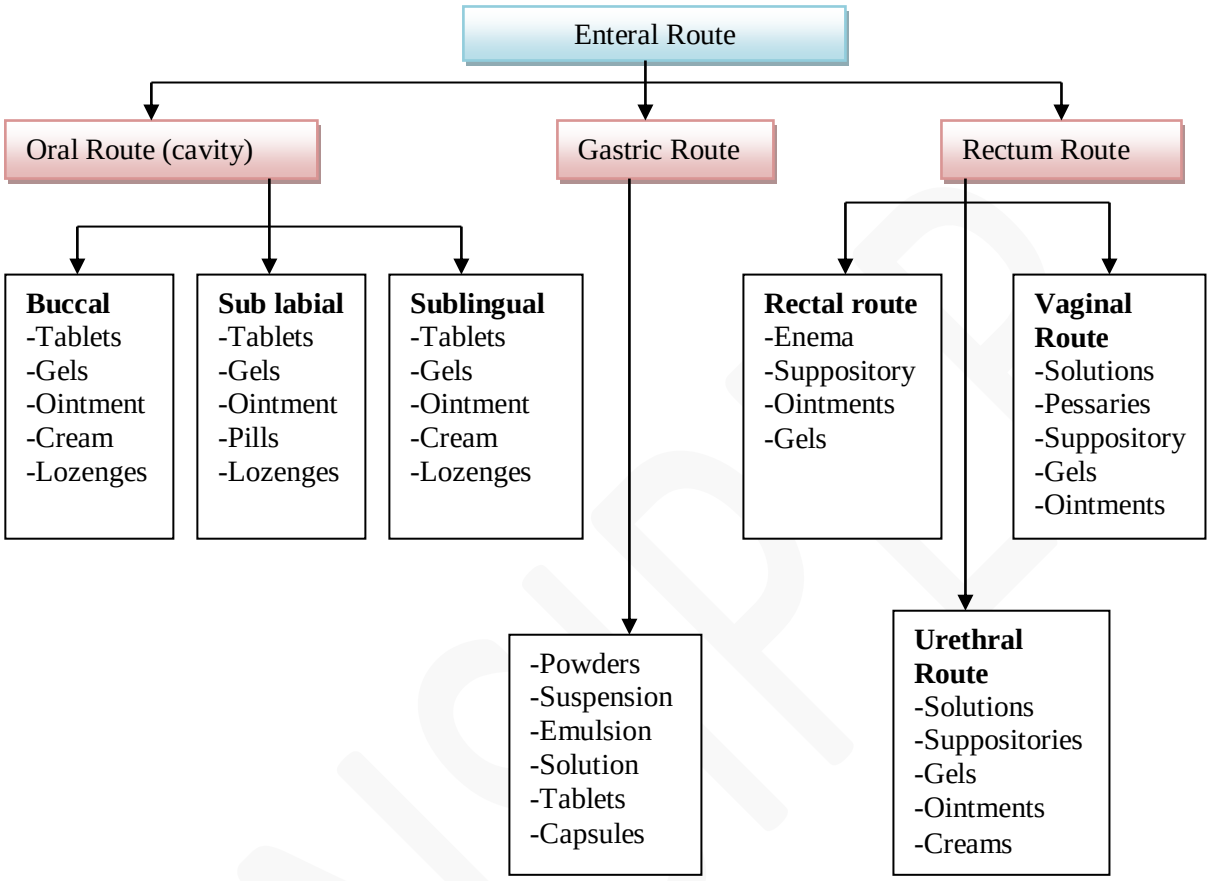
- In this route the drug is applied on the skin and mucous membrane for local or topical action
  - **Mucosal membrane:** Eye drops, antiseptic, sunscreen, nasal drops etc.
  - **Skin:**
    1. Dermal- Rubbing oil or ointment for local action.
    2. Transdermal – Absorption of drug through skin for systemic action.
       E.g. creams, lotions and gels.

Classification of Route administration:

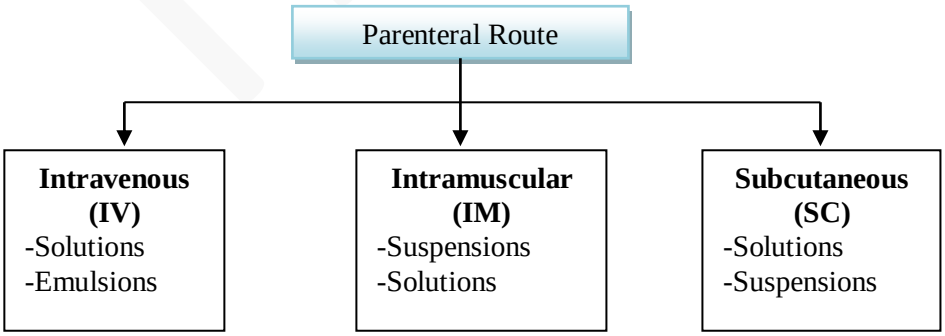




Classification of Enteral route:



Classification of Parenteral route:



1 word Question Answer

Sr. No.	Question	Answer
1.	Give the name of biphasic liquid in liquid type of dosage form.	**Emulsion**
2.	Give the name of biphasic solid in liquid type of dosage form.	**Suspension**
3.	The products of semisolid consistency and applied to skin or mucous membranes for therapeutic or protective action or cosmetic function is known as.	**Semisolid dosage form**
4.	Which route of administration is in that the drug is passed through G.I. tract and then absorbed in blood?	**Enteral route**
5.	The drug is consumed by swallowing through mouth. This route is known as.	**Per oral(p.o.)**
6.	The route of administration in which the drug is kept in the buccal cavity of the mouth where the drug disintegrates and absorption occurs in the mouth is known as .	**Buccal route**
7.	The route in which the drug is placed under the tongue and the patient keeps it there till it totally disintegrate and absorption occurs in mouth is known as.	**Sublingual route**
8.	Dermal and Transdermal route is which type of administration?	**Topical administration**
9.	The route in which the drug is applied on the skin and mucous membrane is known as	**Topical route of administration**
10.	In this route the drug uses the systemic circulation of the body (blood) to reach the desired area is known as.	**Systemic route**
11.	Which route of administration is in that the drug does not pass through the G.I. tract i.e. drug is directly deliver to the systemic circulation (blood)?	**Parenteral route**
12.	I.M. stands for.	**Intramuscular**
13.	I.V. stands for.	**Intravenous**
14.	I.D. stands for.	**Intraderamal**
15.	S.C. stands for.	**Subcutaneous**
16.	The route in which the injection of drug is directly given into the cerebrospinal fluid is known as.	**Intrathecal**
17.	The route in which the drug is given directly into synovial fluid through injection is known as	**Intra articular**

Syllabus Topic: Definitions

1. **Powders :**
   Powders are homogenous mixtures of drugs and chemical in dry, fine state of subdivision.

2. **Effervescent granules:**
   An effervescent granule formed from acid and bicarbonate, in presence of water, the acid and base react and liberate carbon dioxide and produce effervescence.

3. **Snuff :**
   These are medical powders inhaled into nostrils for their antiseptic, bronchodilator and decongestive action. They are dispensed in flat metal box with hinged lid.

4. **Insufflations:**
   Insufflations are medicated powders which are blown into the regions such as the ear, nose and throat using insufflators.

5. **Syrups:**
   Syrups are concentrated solutions of sucrose or other sugars.

6. **Elixir:**
   Elixirs are hydro alcoholic solutions of medicinal substances which are sweetened and flavored.

7. **Mouthwash:**
   A mouthwash is aqueous solution intended to rinse the oral cavity.

8. **Liniments:**
   Liniments are alcoholic or oily solutions or emulsions containing drugs, intended for external application to the skin with friction.

9. **Lotions:**
   Lotions are liquid or semisolid preparations that contain one or more active ingredients in an appropriate vehicle intended to be applied on the intact skin without friction.

10. **Gargles:**
    Gargles are clear, aqueous solutions used to prevent or treat mild throat infections.

11. **Enema:**
    Enemas are aqueous or oily solutions intended for rectal use.

12. **Throat paints :**
    Throat paints are viscous preparations containing one or more medications for local action in the mouth or throat region.

13. **Suspensions :**
    Suspensions are defined as liquid preparations that consist of insoluble solid drug particles dispersed uniformly throughout liquid phase.

14. Emulsions:

Emulsions are defined as biphasic disperse system, consisting of two immiscible liquids, one of which is distributed throughout the other in minute globules, the system being stabilized by the presence of a third substance, the emulsifying agents.

15. Paste:

Pastes are defined as semisolid dosage forms containing high concentration (25-50%) of solids, in a fatty or aqueous base, intended for topical applications

16. Jellies:

Jellies are transparent or translucent, non-greasy, semisolid preparations generally applied externally or may be introduced into body cavities such as nasal or vaginal.

17. Suppositories:

Suppositories are solid or stiffened semisolid dosage forms of various shapes and weights used for introduced into body cavities like rectal, vaginal and urethral where they melt, soften or dissolve and exert local or systemic action.

1 word Question Answer

Sr. No.	Question	Answer
1.	A homogenous mixture of drugs and chemical in dry, fine state of subdivision is known as.	**Powder**
2.	The medical powders inhaled into nostrils for their antiseptic, bronchodilator and decongestive action is known as.	**Snuff**
3.	The medicated powders which are blown into the regions such as the ear, nose and throat using insufflators are known as.	**Insufflations**
4.	The concentrated solutions of sucrose or other sugars are known as.	**Syrup**
5.	The hydro alcoholic solutions of medicinal substances which are sweetened and flavored are known as.	**Elixir**
6.	The aqueous solution intended to rinse the oral cavity is known as.	**Mouthwash**
7.	The alcoholic or oily solutions or emulsions containing drugs, intended for external application to the skin with friction is known as.	**Liniment**
8.	The clear, aqueous solutions used to prevent or treat mild throat infections are known as.	**Gargles**
9.	The liquid or semisolid preparations that contain one or more active ingredients in an appropriate vehicle intended to be applied on the intact skin without friction is known as.	**Lotion**
10.	The aqueous or oily solutions intended for rectal use is known as.	**Enema**

11.	The viscous preparations like paint containing one or more medications for local action in the mouth or throat region is known as.	**Throat paints**
12.	A biphasic disperse system, consisting of two immiscible liquids, one of which is distributed throughout the other in minute globules, the system being stabilized by the presence of a third substance, the emulsifying agent is known as.	**Emulsion**
13.	The liquid preparations that consist of insoluble solid drug particles dispersed uniformly throughout liquid phase are known as.	**Suspensions**
14.	A semisolid dosage forms containing high concentration (25-50%) of solids, in a fatty or aqueous base, intended for topical application is known as.	**Paste**
15.	A transparent or translucent, a non-greasy, semisolid preparations generally applied externally are known as.	**Jellies**
16.	A solid or stiffened semisolid dosage forms of various shapes and weights used for introduced into body cavities like rectal, vaginal and urethral where they melt, soften or dissolve and exert local or systemic action is known as.	**Suppositories**