

आईएफटीएम विश्वविद्यालय, मुरादाबाद, उत्तर प्रदेश

IFTM University, Moradabad, Uttar Pradesh NAAC ACCREDITED

# **E-Content**

# IFTM University, Moradabad

# INTRODUCTION TO DIFFERENT DOSAGE FORMS

By, Mr. Aditya Sharma School of Pharmaceutical Sciences IFTM University, Moradabad



# CONTENTS

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

# Introduction

Dosage form (Medicines) = Active Pharmaceutical Ingredient (API) + Excipients

#### **Drug or Active Pharmaceutical Ingredient (API)**

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

The API is the part of any drug that produces the therapeutic effects. Example: Paracetamol, Aceclofenac, Cefixime, Diclofenac etc.

#### **Excipients or Additives or Inactive Ingredients**

- > 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.
- These includes: binding agents, dyes, preservatives, flavoring agents, sweetening agents, coloring agents etc.
- So the Dosage form is a transformation of pure chemical compound into predetermined form by admixing drug compound with different kinds of non drug components collectively known as adjuvants each having specific function. Examples: Tablet , Capsules, Syrups, Paste, Suppositories, Creams etc.

# **Importance of Dosage Forms**

- 1. Provide safe and convenient delivery of accurate dosage.
- 2. Protect the drug substances from atmospheric oxygen or moisture. Example: Coated Capsules, Sealed Ampules.
- 3. Protect the drug substances from gastric acid after oral administration. Example: Enteric Coated Tablets
- 4. Mask the bitter taste, or odor of a drug substances. Example: Capsules, Coated Tablets, Flavored Syrups
- 5. Provide liquid preparation of drug that are insoluble or unstable in the desired vehicle. Example: **Suspension**
- 6. Provide maximum drug action from topical administration sites. Example: **Ointment**, **Cream, Ear and Nasal Preparations.**
- 7. Provide for insertion of a drug into one of the body's cavities. Example: **Rectal and Vaginal Suppositories.**
- 8. Provide extended drug action through controlled release mechanisms. Example: Controlled Release Tablets, Capsules, Suspensions.
- 9. Provide for the placement of drugs within body tissues. Example: Implants.
- 10. Provide for the optimal drug action through inhalation therapy. Example: Inhalants.

# **Classification of Dosage Forms**

Dosage forms may be classified on the basis of physical form of the final product which are as under:

1.Solid Dosage Forms2.Liquid Dosage Forms3.Semi-solid Dosage Forms



# **SOLID DOSAGE FORMS**

The solid dosage forms are mostly available in the unit dosage form, such as **Tablets, Capsules, Pills, Lozenges**. When drugs are administer orally in dry state **Tablets** and **Capsules** are more convenient form. They are effective and patients have no problem in their handling, identification and administration. The bulk forms meant for internal use are supplied either as **Granules** or **Fine powder**. The bulk powders meant for external use are **Dusting powders, Insufflations, Snuffs and Tooth Powders**.

The powders are generally used in the following forms:

- 1. Bulk powder for internal use e.g. Fine Powders or Granules
- 2. Bulk powder for external use e.g. Snuffs, Dusting Powders and Tooth Powders.
- 3. Simple and compound powders for internal use.
- 4. Powders in the form of compressed tablets and tablet triturates.
- 5. Powders enclosed in cachets and capsules



### **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.

Hence, dusting powders should be passed through a number 80 sieve to enhance their effectiveness.

Dusting powders are of two types:

- 1. Medical
- 2. Surgical



**"Medical Dusting Powders"** are used mainly for superficial skin conditions. **"Surgical Dusting Powders"** are used in body cavities and also on major wounds as a result of burns and umbilical cords of infants.

Surgical dusting powders must be sterilized before their use, whereas medical dusting powders must be free from dangerous pathogenic microorganisms.

Dusting powders are 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.

The dusting powders are mainly used for their antiseptic, astringent, absorbent, antiperspirant and antipruritic (anti-itching) action.

#### 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 known as "Insufflator".

#### **Snuffs**

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

#### **Dentifrices (Tooth powders)**

- ➤ These are applied with the help of a tooth brush for cleaning the surface of the teeth.
- They contain a suitable detergent or soap, some abrasive substance and a suitable flavour.
- ➤ The abrasive agents such as calcium sulphate, magnesium carbonate, sodium carbonate and sodium chloride are used in fine powder.

#### Granules

- ➤ The bitter, nauseous and unpleasant powders cannot be given in tablet form or in a capsule because a large number of them are required to be taken as a single dose.
- These powders are not given in liquid form because of stability problem.
  Such medicaments are given in the form of granules.
- The drug is mixed with sugar, a flavouring agent and a granulating agent to prepare a coherent mass which is passed through a sieve to convert it into granules and then dried.
- ➤ The dried granules are supplied in single-dose sachets which are dissolved in water before taking.

#### **Effervescent Granules**

They contain a medicament mixed with citric acid, tartaric acid and sodium bicarbonate. Saccharin or sucrose may be added as a sweetening agent. The desired quantity is dissolved in water, the acid and bicarbonate react together and producing effervescence. Example: ENO

#### **Tablets**

- These are solid unit dosage forms of medicament or medicaments which are prepared by moulding or by compression.
- Certain excipients are also added to the medicaments in the formulation of tablets.

(Detail study is given in Chapter "Processing of Tablets", which will be studied later)





### Capsules

The capsules are solid unit dosage form in which one or more medicaments and inert substances are enclosed within a gelatin shell. These are of 2 types:

- 1. Hard gelatin capsules
- 2. Soft gelatin capsules

(Detail study is given in Chapter "Processing of Tablets", which will be studied later)





#### **Pills**

- Pills are small, rounded solid dosage forms containing medicament and are intended to be administered orally..
- 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.



# **LIQUID DOSAGE FORMS**

Liquid dosage forms are meant for internal, parenteral or external use. They are available in:

- 1. Monophasic Liquid Dosage Forms
- 2. Biphasic Liquid Dosage Forms

### **Monophasic Liquid Dosage Forms**

- The component of the solution which is present in a large quantity is known as "Solvent", whereas the component present in a small quantity is termed as "Solute".
- ➤ Water is mainly used as solvent for majority of monophasic liquid dosage forms.
- Monophasic liquid dosage forms are available as:
  - i. Liquids for internal use e.g. Syrups, Eiixirs, Linctus, Drops and Draughts.
  - ii. Liquids for external use, which are of two types:
    - a) Liquids to be applied to the skin e.g. Liniments and Lotions etc.
    - b) Liquids meant for body cavities e.g. Gargles, Throat Paints, Mouth Washes, Eye Drops, Eye Lotions, Ear Drops, Nasal Drops, Sprays and Inhalations.

# Syrups

- Simple syrups are the saturated solution of sucrose in purified water.
- The concentration of sugar is 66% w/w.
- The syrups are sweet viscous preparations.
- The syrups containing medicinal substances are called **"Medicated syrups".**
- Those containing aromatic or flavoured substances are known as **''Flavoured syrups''.**

Example: Syrup I.P., Ginger syrup I.P.

# **Elixirs**

- Elixir are sweet aromatic preparations and are usually coloured.
- Elixirs are ethyl alcohol (4-40%), water, glycerin or propylene glycol, flavouring agents ,syrup and preservatives.
- The medicated elixirs usually containing very potent drug such, antibiotics, antihistamines or sedatives.

Example: Syrup Elixir I.P., Piperazine Citrate Elixir I.P.







#### Linctuses

- Linctuses are viscous liquid and oral preparations that are generally prescribed for the relief of cough. They contain medicaments which have demulcent, sedative or expectorant action.
- Simple syrup is generally used as a vehicle for most of the linctuses.

Example: Codeine Linctus B.P.C.

#### Drops

- These are liquid preparations meant for oral administrations.
- The oil soluble vitamins, such as, vitamin A and D concentrates in fish-liver oil are presented as drops for administration.
- Since these preparations contain potent medicaments, the dose must be measured accurately.







### Liniments

- Liniments are liquid and semi-liquid preparations meant for application to the skin.
- Liniments are usually applied to the skin with friction and rubbing.
- They may be alcoholic or oily solutions or emulsion. Alcohol helps in the penetration of medicaments into the skin and also increases its counter-irritant or rubefecient action.
- A liniment should not be applied to broken skin because excessive irritation.

#### Example: Camphor Liniment, Turpentine Liniment

### Lotions

- Lotions are liquid preparations meant for external application without friction.
- They are applied direct to the skin with the help of some absorbent material, such as, cotton wool or gauze soaked in it.
- Lotions may be used for local action as cooling, soothing or protective purposes.
- They are generally prescribed for antiseptic action. Example: **Calamine lotion**







#### Gargles

Gargles are aqueous solutions used to prevent or treat throat infections. They are usually available in concentrated form with direction for dilution with warm water before use.

Used to relieve soreness in mild throat infection.

Potassium chlorate is also included in gargles for its weak astringent effect to tone up a relaxed throat. It also stimulates secretion of saliva which relieves dryness. Example: Potassium Chlorate and Phenol Gargles B.P.C., Betadine Gargles etc.

#### **Mouth Washes**

These are aqueous solutions with a pleasant taste and odour used to make clean and deodorise the buccal cavity. Generally, they contain antibacterial agents, alcohol, glycerin, sweetening agents, flavouring agents and colouring agents.

### **Throat Paints**

Throat paints are viscous liquid preparations used for mouth and throat infections. Glygerin is commonly used as a base because, it is viscous and adheres to mucous membrane for a long period. Example: **Iodine Paint (Mandl's Paint) B.P.C.** 







# **Sprays**

Sprays are preparations of drugs in media which may be aqueous, alcoholic or glycerin. They are applied to the mucous membrane of nose or throat with an atomiser.

The throat-sprays must be sprayed from a special type of atomizer known as **'Nebuliser'**, which removes large droplets by a baffling system. Only fine droplets are required so that they may reach the lungs.

Example: Adrenaline and Atropine Spray Compound B.P.C.

#### Inhalations

These are liquid preparations containing volatile substances and are used to relieve congestion and inflammation of the respiratory tract.

# **Nasal Drops**

These are solutions of drugs that are instilled into the nose with a dropper.

Example: Ephedrine Nasal Drops B.P.C.



These are sterile solutions or suspensions of drugs that are instilled into the eye with the help of dropper.

- The eye drops are usually made in aqueous vehicle. It should be sterile, isotonic with lachrymal secretions, buffered and free from foreign particles to avoid irritation to the eye.
- Eye drops usually contain substances having antiseptic, antiinflammatory, anaesthetic and miotic properties.

### **Eye Lotions**

These are the aqueous solutions used for washing the eyes. The eye lotions are supplied in concentrated form and are required to be diluted with warm water immediately before use. Eye lotions should be isotonic and free from foreign particles to avoid irritation to the eye.

Example: Sodium Chloride Eye Lotion,

Sodium Bicarbonate Eye Lotion

#### **Ear Drops**

These are solutions of drugs that are instilled into the ear with a dropper. These are generally used for cleaning the ear, softening the wax and for treating the mild infections. The solution is generally prepared in water, glycerin, propylene glycol or dilute alcohol.

Example: Sodium Bicarbonate Ear-drops B.P.C., Phenol Ear-drops B.P.C.

### Eye Drops

led be om







# **Biphasic Liquid Dosage Forms**

The liquids which consist of two phases are known as biphasic liquids. Examples: *Emulsions* and *Suspensions*.

# EMULSIONS

- ➤ An emulsion is a biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other.
- The liquid which is converted into minute globule is called the 'dispersed phase' and the liquid in which the globules are dispersed is called the 'continuous phase'.
- Normally, two immiscible liquids cannot be dispersed for a long period. So, an emulsifying agent is added to the system.

The emulsions are of two types:

- *a) Oil in Water type (O/W) emulsion,* in which oil is in the dispersed phase whereas water is in the continuous phase.
- b) Water in Oil type (W/O) emulsion, in which water is in the dispersed phase whereas oil is in continuous phase.

## **EMULSIONS**

The following tests are done for distinguishing between o/w and w/o emulsions:

- *a) Dilution test* The emulsion is diluted with water. In case the emulsion remains stable after its dilution, it is o/w emulsion. The w/o emulsion breaks on its dilution with water but remains stable when diluted with oil.
- b) Dye test The scarlet red dye is mixed with the emulsion. Place a drop of the emulsion on a microscope slide, cover it with a cover-slip, and examine it under a microscope. If the disperse globules appear red and the "ground" colourless, the emulsion is o/w type. The reverse condition occurs in w/o type emulsion i.e. the disperse globules appear colorless in the red "ground".
- *c) Conductivity test* Water is a good conductor of electricity, whereas oil is nonconductor of electricity. The conductivity test can be performed by dipping a pair of electrodes connected through a low voltage bulb in the emulsion. If the bulb glows on passing the electric current, the emulsion is o/w type, because water is in the continuous phase. In case the bulb does not glow, the emulsion is w/o type, because oil is in the continuous phase.

The emulsions are of three types according to their use. These are:

- A. Emulsions for oral administration (Example: Liquid Paraffin Emulsion I.P.)
- B. Intravenous emulsions (Example: oil soluble hormones, vitamin A, D and K)
- C. Emulsions for external application (Example: both o/w or w/o type)

# **SUSPENSIONS**

The suspensions are the biphasic liquid dosage form of medicament in which finely divided solid particles are dispersed in a liquid or semisolid vehicle.

The solid particles act as disperse phase whereas liquid vehicle acts as the continuous phase. Suspensions are generally taken orally or by parenteral route. They are also used for external applications.

#### An ideal suspension must possess the following properties:

- 1. It should settle slowly and should be readily re-dispersed on gentle shaking of the container.
- 2. The particle size of the suspension remains fairly constant throughout its long period of undisturbed standing.
- 3. The suspension should pour readily and evenly from its container.
- 4. It should be free from large particles which spoil its appearance, give a gritty taste to oral preparations and also cause irritation to sensitive tissues when applied externally.

All suspensions should be packed in containers having adequate airspace above the liquid to permit adequate shaking. The suspensions should be stored in tight containers, protected from freezing, excessive heat and light. The suspension should be shaken before its use to ensure a uniform distribution of solid in the vehicle, thereby giving a uniform and proper dosage.

# **SEMI-SOLID DOSAGE FORMS**

Semi-solid dosage forms are mainly meant for external application. e.g. ointments, creams, pastes, jellies, suppositories etc.

#### Ointments

- Ointments are semi-solid preparations meant for application to the skin or mucous membrane.
- They usually contain a medicament or medicaments dissolved, suspended or emulsified in the ointment base.
- ➤ The ointments are mainly used as protective or emollient for the skin. The medicated ointments are meant for action on epidermis or for action on deeper layers of cutaneous tissues or to penetrate deep and release medicaments to body fluids.
- The ointments which are meant for application to the eye are called 'Ophthalmic Ointments'. These ointments are sterile and free from irritation.





The ointment bases are into:

- 1. Oleaginous bases (consist of water soluble hydrocarbons, vegetable oils, animal fats and waxes.)
- 2. Absorption bases (wool fat (anhydrous lanolin), wool, alcohol, bees wax and cholesterol.)
- **3.** Emulsion bases (consist of either o/w or w/o or both type emulsions)
- 4. Water soluble bases (commonly known as "greaseless ointment bases")

#### Example: Emulsifying Ointment I.P. Compound Benzoic Acid Ointment B.P.C. (Whitfield's Ointment)

#### Creams

- ➤ These are viscous semi-solid emulsions which are meant for external use. The creams are of two types, aqueous and oily creams.
- ➢ In case of aqueous creams, the emulsions are oil-in-water type and in case of oily emulsions are water in oil type.
- The oily creams are generally prepared with emulsifying agents, such as, wool fat, wool alcohols, beeswax and calcium soaps.
- Creams should be stored and supplied in well-closed containers which prevent evaporation and contamination.

#### Example: Hydrocortisone Cream B.P.C.



#### **Pastes**

- Pastes are semi-solid preparations intended for external application to the skin.
- They different from ointment as they contain a high proportion of finely powdered medicaments, such as zinc oxide, calcium carbonate, starch etc. These substances make the paste very thick and stiff.
- Pastes are less greasy than ointments.
- They are used mainly as antiseptic, protective purposes.



# **Jellies or Gels**

- Jellies or gels are transparent or translucent, non-greasy, semi-solid preparations mainly used for external application to the skin.
- These are also used for lubricating catheters, surgical gloves and rectal thermometers.
- The substances like gelatin, starch, tragacanth, sodium alginate and cellulose derivative are used in the preparation of jellies.





### **Suppository**

- Suppositories are semi-solid dosage forms of medicament for insertion into body cavities other than mouth.
- They may be inserted into rectum, vagina and nasal cavity.
- Medicament incorporated into suppository base.
- Available in different size, shape and weight.
- Used to produce local, systemic and mechanical action.

#### Pessaries

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. Vaginal Capsules Prepare same as soft gelatin capsules and various size and shape.





# **NEW DRUG DELIVERY SYSTEM**

Some of the modern dosage forms are:

- 1. Implants
- 2. Films and strips
- 3. Liposome drug carriers
- 4. Nanoparticles
- 5. Prodrugs.

# Implants

- The hypodermic tablets are placed under the skin by a minor surgery in order to release drugs over prolonged periods of time.
- Now the magnetically controlled implants have been developed which can be opened or closed at will in order to release or stop the drug.
- The implants which are in capsule form, consist of a body and a cap. It can be opened by placing a magnet on the skin and moving it in the desired direction.
- These implants are placed in the upper thigh at a depth of 5 mm. These implants are useful in hormone therapy.





### **Films and Strips**

These are meant for topical application for slow release of drug over predetermined period of time. The films and strips which are becoming popular these days are:

- Laminates (propylene glycol + 1% carbopol resin, mixture neutralized with NaOH solution and then 0.1 % nitroglycerin)
- Buccal strips (Consist of thin adsorbent base of fabrics, filter paper and cotton etc.)
- Spray bandages (Drug + Polymer of lactic acid anhydride)

## **Liposome Drug Carriers**

- There are several carriers in our body which transport bio-chemicals from one part of the body to an other e.g. proteins, enzymes etc.
- Liposomes are phospholipids which can transport both hydrophilic and hydrophobic drugs. Large multilamellar vesicles (LMV), small unilamellar vesicles (SUV) and large unilamellar vesicles (LUV) are some of the liposomes which are known today.
- The small drug molecules get trapped in liposomes, whereas large drug molecules can also Hydrophobic drug make hydrophobic or electrostatic bonding with it.



Hydrophilic head



#### Nanoparticles

- ➢ It is based on colloidal drug delivery system.
- ➤ The particle size of this system is in nanometer range i.e. 200-500 mm. That is why they are called nanoparticles.
- > The system consists of a drug and a carrier to deposit the drug at the target site.



#### **Prodrugs**

- The compounds which undergo biotransformation before showing desired pharmacological activity are called "**prodrugs**" or "**proagents**".
- Prodrugs are generally the esters or amides of parent drugs. The prodrugs are useful in improving the solubility, stability, bioavailability of drugs, masking the unpleasant taste and odour of the parent drug and reducing the drug toxicity.



Book reference: Pharmaceutics-I by R.M. Mehta, Vallabh Prakashan Figures reference: www.google.com