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Diploma in Pharmacy 1st Year
Pharmaceutics
Important Questions
Chapter 5 : Pharmaceutical Dosage Forms

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Chapter 5
Pharmaceutical Dosage Forms
IMPORTANT Questions

Q1. Define tablet write the types merits and demerits.

Ans.

→ Tablets are solid unit dosage forms of medicaments with or without suitable diluents and prepared either by mouldingor compression.

→ They are solid, flat, or biconvex discs in shape.

The ideal properties of a tablet are:

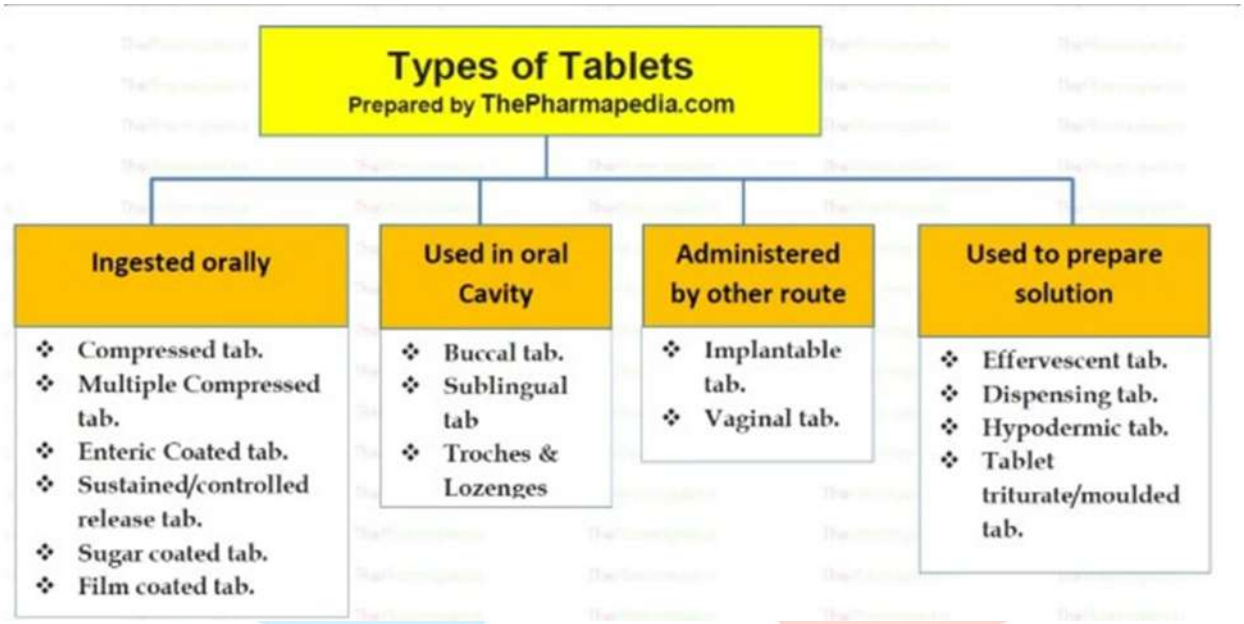
I. It should be attractive having its own identity and free from defects such as cracks, chips, contamination, discolouration, etc.
II. It should have chemical and physical stability to maintain its physical integrity over timey
III. It should prevent any alteration in chemical and physical properties of medicinal agent (s).
IV. It should withstand the rigours of mechanical shocks encountered during its production, packaging, shipping, and dispensing.
V. It should release the medicament(s) in the body in a predictable and reproducible manner.

Merits

- They are unit dosage forms that provide an accurate, stable dose with greatest precision and least content variability.
- They are easy to use, handle, and carry by the patient.
- They are attractive and pleasing in appearance
- They are the most stable dosage form with respect to their physical, chemical, and microbiological attributes
- Their packaging and shipping are comparativeiy easy and cheap
- They are more suitable for large scale production than other oral dosage forms.
- Their identification is probably the easiest because or variety of shapes and colours.
- They are economical as their cost is lowest as compared to other oral dosage forms

Demerits

- Drugs which are amorphous in nature or have low density character are difficult to compress into a tablet.
- Drugs having a bitter taste and objection able odour require special treatment like coating or encapsulation which may increase their production cost.
- Drugs sensitive to oxygen may require certain treatment like special coating as well as packaging which may increase the overall manufacturing cost.
- High dose drugs are difficult to formulate as tablets
- Liquid drugs are difficult to formulate as a tablet.
- Swallowing of tablets, especially by children and critically ill patients is very difficult.



Production of Tablet

Tablets are manufactured by granulation technique which can be carried out by the following three methods:

- Direct compression,
- Wet granulation, and
- Dry granulation.

Q2. Write about the direct compressor, wet granulation, dry granulation, with merits and demerits.

Ans.

Direct compression

→ Crystalline substances (e.g., sodium chloride, sodium bromide, and potassium chloride) are directly Compressible.

→ Most of the medicinal agents cannot be easily formulated into tablets; however, compressing single substance can form tablets which do not disintegrate.

The materials to be directly compressed should have the following properties:

1. Good flowability,
2. Compressibility
3. Inert,
4. Tasteless,
5. Able to disintegrate, and
6. Economical.

Merits

a. This method results in increased output,
b. It is of low cost,
c. It requires less machinery,
d. It increases the stability of drug
e. It involves rapid drug dissolution,
f. It experiences less wear and tear of punches, and
g. It involves simplified validation.

Demerits

i. In this method, segregation problems occur in weight variation and content uniformity,
ii. Since the directly compressible excipients are expensive, the tablet cost also rises.
iii. The active material is 30-40% as the requirement of excipient, thus the tablet is swallowed by the patients with much difficulty.
iv. The method is not suitable for drugs with poor flowability or low bulk density.

Dry Granulation

→ In dry granulation process, the powder mixture is compressed without the use of heat and solvent.
→ The two basic procedures are to form a compact of the material by compression and to mill the compact to obtain granules.

Some of the dry granulation methods

a) Pressing
b) Extruding
c) Tumbling
d) Fluidising
e) Slugging Process
f) Roller Compaction

Merits of Dry Granulation Technique

1. It uses less equipment and space.
2. It does not require binder solution and heavy mixing equipment.
3. The costly and time consuming drying step required for wet granulation is also avoided.
4. It is suitable for moisture- and heat-sensitive materials.
5. Tablets with improved disintegration are produced as powder particles are not bonded together by a binder.
6. Solubility of the drug is also improved.

Demerits of Dry Granulation Technique

i. It requires a specialised heavy duty tablet press to form the slug.
ii. It does not permit uniform colour distribution.
iii. It creates more dust than wet granulation thus increasing the potential contamination.

Wet Granulation

→ The most widely used process of agglomeration in pharmaceutical industry is wet granulation.

→ This process simply involves wet massing of the powder blend with a granulating liquid, followed by wet sizing and drying

Important steps involved in the Wet granulation are :

- Mixing the drug(s) and excipients,
- Preparing the binder solution,
- Mixing the binder solution with powder mixture to form a wet mass,
- Coarse screening the wet mass using a suitable sieve (sieve no. 6-12),
- Drying the moist granules,
- Screening the dry granules through a suitable sieve (sieve no. 14-20),
- Mixing the Screened granules with disintegrant, glidant, and lubricant, and
- Compressing the mixture into tablet

Special Wet granulation Processes are :

- High Shear Mixture Granulation
- Fluid Bed Granulation
- Extrusion and Spheronisation
- Spray Drying Granulation

Merits of Wet Granulation Technique

- High dose drugs having a poor flow or compressibility properties can be prepared.
- The soluble low dosage or potent drugs can attain uniform distribution and content.
- Colour distribution also occurs evenly.
- It prevents the segregation or separation of components of a homogenous powder mix.
- The dissolution rate of hydrophobic drugs is improved.

Demerits of Wet Granulation Technique

- It is an expensive process because of the labour, time, equipment, energy, and space requirements.
- Loss of material occurs during various stages of processing.
- Heat-sensitive drugs also cannot be processed as it involves drying steps.
- Multiple processing steps add complexity and make validation and control difficult

Q3. Write the difference between coated tablet and uncoated tablet.

Ans.

Coated Tablet

→ Tablet coating is the process where coating material is applied to the surface of the tablet to achieve the desired properties of dosage form over the uncoated variety. The advantages of coating are listed below.

I. Improving taste, odor, and color of the drug
II. Improving ease of swallowing by the patient
III. Improving product stability
IV. To protect against the gastric environment
V. To improve mechanical resistance of the dosage form

Uncoated Tablet

→ Uncoated tablets are generally single-layer tablets prepared by a single compression of granules or multi-layer tablets consisting of parallel layers prepared by compression of granules of different compositions. No treatment is given to such tablets after compression.

Difference

→ Tablets can be either coated with a sugar or film coating, or uncoated. Uncoated tablets are rougher, may be more difficult to swallow, and often leave a bad taste in the mouth when swallowed. A coated tablet generally goes down easier and with less aftertaste.

Q4. Write the brief note on various modified tablets

- **sustained release,**
- **extended release,**
- **fast dissolving,**
- **doubleLayered.**

Ans.

Sustained Release Tablets

→ The drug delivery system that is intended to attain a prolonged therapeutic effect by releasing the medication continuously over an extended period of time once a single dose is administered, is termed as sustained release.

Manufacturing

- Wet Granulation
- Dry Granulation
- Direct Compression

Advantages

a. Minimum drug is used.
b. The efficacy in the treatment gets improved
c. It avoids patient compliance problems
d. 4)The local, systemic side effects are minimised.
e. Less fluctuation occurs in the concentration of drug

Disadvantages

a) Therapy can not be terminated in case of any side effects.
b) Expensive
c) Dose dumping
d) Poor systemic availability

Extended Release Tablets

→ Extended-release medications are gradually released into the body over a period of time (12 or 24 hours).
→ Usually they are available in the form of an oral tablet or an oral capsule.
→ These medications do not release the content immediately.

Extended-release medications offer several advantages which include, but are not limited to, the following:

i. They are not taken frequently.
ii. They cause fewer side effects.
iii. They cause less fluctuation in blood levels.
iv. They are completely absorbed.

Fast Dissolving Tablets

→ After coming in contact with saliva, they disintegrate and dissolve to release the drug, thus, eliminating the need of water during drug administration
→ Tablets dissolving completely with in a few seconds are true fast-dissolving tablets.
→ Fast-disintegrating tablets may take about a minute to disintegrate completely.

Manufacturing

- Freeze-Drying or Lyophilisation
- Tablet Moulding
- Solvent Method
- Heat Moulding

Advantages

- They can be easily administered to patients who cannot swallow (elderly, stroke victims, and bedridden patients), who should not swallow (renal to swallow fa failure patients), and who refuse (paediatric, geriatric, and psychiatric patients).
- They show patient compliance for disabled bedridden patients, for travellers, and busy people who do not have ready access to water.
- They can be administered conveniently with accurate dosing in comparison to liquid formulations.
- They provide advantages of liquid medication in the form of solid preparations.

Double Layered Tablets

→ Bilayer tablets can be a primary option for avoiding tabletting chemical incompatibilities between API by physical separation, and to allow the development of different drug release profiles (immediate release with extended release).

Manufacturing

- OROS Push Pull Technology
- L-OROS tm Technology
- EN SO TROL Technology

Advantages

1. They are unit dosage forms and deliver the utmost capabilities of all oral dosage forms for the maximum dose accuracy and the minimum content variability.
2. Not expensive in comparison to all other oral dosage forms.
3. Lighter and compact.
4. Easiest and cheapest in packing and striping.
5. Can be swallowed easily with least tendency for hanging-up.
6. Coating can be done to cover the objection able odour and bitter taste of the drug

Disadvantages

A. Children and unconscious patients may face difficulties in swallowing.
B. Some drugs resist Compression into dense Compacts, due to amorphous nature and low density character.
C. It can be difficult to formulate drugs having poor wetting, slow dissolution properties, optimum absorption and high in GIT as a tablet because they can deliver adequate or full drug bioavailability.
D. Encapsulation or coating is required for the drugs which have bitter taste, objectionable odour and are sensitive to oxygen.

Q5. Define the capsule and write the difference between hard and soft gelatin capsules.

Ans.

Capsules

→ Capsules are solid dosage forms in which one or more medicinal and inert ingredients are enclosed in a small shell usually made up of gelatin.
→ They are of various shapes and sizes, and contain a single dose of one or more active pharmaceutical ingredients
→ Capsules are also defined as "gelatin or methylcellulose shell designed to hold solids and liquids for oral administration'
→ There are two types of capsules, hard and soft.

HARD GELATIN CAPSULES

- Hard capsules have a rigid shell in two separate pieces fitted together, hence are also called two-piece capsules.
- There was a time when two-piece capsules could be filled the time, only with dry powders; but over the time, the manufacturers began filling capsules with pellets, granules, pastes, and liquids.
- Since hard capsules can be With substances in a variety of forms, they are believed to be more versatile than soft gels.

The material types which can be filled into hard gelatin capsules are:

- Dry Solids: Powders, pellets, granules, or tablets.
- Semi-Solids: Suspensions or pastes.
- Liquids: Non-aqueous liquids

The large-scale or Small-Scale preparation of filled hard gelatin capsules is divided into the following general steps:

i. Formulation development and selection of capsule size,
ii. Manufacturing of hard gelatin capsule shells,
iii. Filling of hard gelatin capsule shells,
iv. Sealing of hard gelatin capsules, and
v. Cleaning and polishing of filled

Merits

a. They have a greater bioavailability in comparison to tablets.
b. Their drug releasing rate is much faster because of high solubility of gelatin shell.
c. They provide high degree of flexibility for formulations.
d. Their manufacturing is simple.
e. They involve less production steps.
f. They undergo less analytical tests

Demerits

a) It is very difficult to ingest hard gelatin capsules containing very large doses of drug.
b) Drugs prone to dissolve the capsule shell cannot be dispensed in these capsules.
c) These capsules are also not suitable to dispense highly soluble salts (iodides, bromides, and chlorides).
d) These capsules involve rapid release of medicaments, thus, may result in gastric irritation due to high drug concentration in localised areas.
e)

SOFT GELATIN CAPSULES

→ Soft capsules or liquid gel caps are formed from liquid gelatin which is later hardened in a humid environment
→ Soft gel capsules are one continuous piece of gelatin
→ Soft capsules have thicker shells than hard capsules, and contain antimicrobial preservatives,
→ The shells are available in various shapes and sizes.
→ The contents of soft capsules are usually solutions or Suspensions of the API(s) in non-aqueous liquid

Merits

1. They can be used for dispensing solids, liquids suspension, emulsions, volatile oils, semisolids, etc.
2. Their disintegration is faster than that of hard gelatin capsules and tablets.
3. They are available in various sizes and shapes.
4. They can be easily swallowed as compared to hard gelatin capsules.

Demerits

a. They cannot be used for dispensing hygroscopic, effervescent, and deliquescent drugs.
b. They cannot be used for dispensing acidic drugs ketones, and aqueous products.
c. They cannot be used for dispensing drugs that cause stomach irritation.

Q6. Write the short note on liquid oral preparation with classification.

Ans.

Liquid Oral Preparations

→ Solutions, syrups, suspensions, elixirs, and concentrates are oral liquid dosage forms.
→ These dosage forms offer exclusive advantages to numerous patients.
→ For example, in patients facing problems in swallowing oral solid dosage forms, liquids offer better compliance for the patients and also provide enhanced dosage control against a fixed dose of tablet.

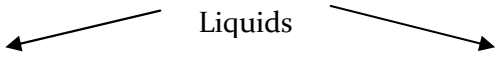
Advantages

a. It is easier to swallow liquids than solids, thus, these dosage forms are more satisfactory and suitable for paediatrics and geriatrics.
b. Solutions get absorbed easily, thus, producing therapeutic response at a faster rate than the solids (which first disintegrates and then getting absorbed from the gastrointestinal fluid).
c. In case a drug precipitates from the solution form under acidic conditions of the stomach, it will become moist and will divide into fine particles, allowing rapid absorption.
d. The drug in solutions is uniformly distributed; whereas in suspensions or emulsions, dose variation may Occur resulting from phase separation during storage.
e. If a drug is administered in a solution form, gastric irritation is reduced as it immediately gets diluted by the contents present in the gastric area.

Disadvantages

i. The transportation and storage of liquids are problematic, as they are bulky.
ii. Growth of microorganisms is supported by liquid media, thus, the preparation needs a preservative to be incorporated within it. .
iii. Dose inaccuracy may occur if a patient takes a dose using household devices, like a teaspoon, etc.
iv. These dosage forms also have flavouring and sweetening properties.
v. The dissolved substances in the liquids may result in incompatible interactions

Classification



Monophasic — Biphasic

Aqueous	Non Aqueous	Emulsions	Suspensions
Internal	External		
Syrups,	Lotions,		
Elixis,	Mouthwash		
Drops	Eye & Ear		

Q7. Explain the solution, syrup, elixis, emulsion, suspension, dry powder for reconstitution.

Ans.

Solution

→ Solution can be defined as a homogeneous system made up or a phase containing two or more components.

The two components of a solution are:

a. Solvent: It is the phase in which dispersion occus
b. Solute: It is the phase which is dispersed in the form of molecules or small ions in the solvent.

Characteristies

1. In any formulation both the phases should be uniformly distributed and clear in composition.
2. The preparation should remain stable before the expiry period.
3. No irritant or toxic effect should be produced by it to the human body.
4. Suitable additives should be present in the product to provide a better patient compliance.
5. During the storage of the solution for a specific period of time, it should not get precipitated or show any type of discolouration

Advantages

i. Drug absorption is rapid.
ii. Being a liquid dosage form they can be swallowed conveniently than the solid dosage form.
iii. They are a homogeneous system as the drug in the solution remains uniformly distributed throughout the formulation.
iv. They do not cause damage and irritation to GIT (often caused by tablets or capsules).

Disadvantages

- Their transportation is not easy because the liquids are bulky in nature.
- Loss of complete preparation occurs if during transportation the container breaks.
- Their shelf-life is shorter than tablets or capsules.
- The stability of drugs in aqueous solution is less than those in solid dosage forms
- Dose accuracy in liquid dosage forms is less than in solid dosage forms.

Syrups

→ A saturated solution of sucrose formed in purified water with the concentration of 66% w/w sugar is known as simple syrup

Classification

A) Simple Syrups: These syrups are made up of simpie solutions or are admixture of solutions. Examples of simple syrup include syrups (I.P.), ginger syrup, orange syrup, and lemon syrup.
B) Preparation: Sucrose is added to the purified water and heated with occasional stirring until the sucrose gets dissolved. The solution is then cooled and sufficient purified water is added to make up the desired weight.
C) Medicated therapeutic agents : Examples of medicated syrups Syrups: These syrups include are chlorpheniramine maleate syrup, ephedrine sulphate syrup, etc.
D) Flavoured Syrups: These syrups comprise of different flavoured or aromatic substances which give a pleasant smell and taste. These are usually added to the preparation for providing a flavour, as a preservative, or as a vehicle. It does not contain any pharmacological activity

Preparation

- Hot Process
- Percolation (cold process)

Elixirs

→ Elixirs are defined as clear, sweetened, aromatic, hydroalcoholic liquids intended for oral use.
→ Elixirs are less sweet and less viscous than syrups and may contain less or no sucrose
→ Elixirs are clear preparation and drugs in liquid from to be administered orally.

Classification

A. Non-Medicated Elixirs: Such elixirs do not contain a medicament and are employed as not flavouring vehicles, e.g., aromatic elixir U.S.P., iso alcoholic elixir NF, compound benzaldehyde elixir as NF, etc.
B. Medicated Elixirs: These elixirs are employed for the therapeutic action of the medicinal substances they contain, e.g., chlorpheniramine maleate elixir U.S.P, diphenhydramine hydrochloride elixir U.S.P., piperazine citrate elixir, terpin hydrate elixir, etc.

Preparation

The preparation method for elixirs is the simple dissolution method involving the following steps:

- In this method, either an admixture of two or more liquid components is used or the components are dissolved by agitation.
- The ingredients are dissolved in the respective Solvents, for example, water is used as a solvent for the water-soluble ingredients, and alcohol is used as a solvent for the alcohol-soluble ingredients.
- Always the aqueous solution is added to the alcoholic solution for maintainingthe ideal alcoholie Strength and preventing the separation of alcohol- soluble ingredients.
- The desired volume is adjuste dusing the vehicle or solvent specified in the formulation.
- At this point, reduction in alcoholic strength is noted which leads to the separation of a few noted flavouring agents, thus, the product may not be found clear.
- In such a case, the elixir preparation is kept aside for some time so that the hydro-alcoholic solvent saturates resultinng the cluster of globules.
- Filtration facilitates the removal of these globules.
- To absorb the excess oil and removing it from the elixir solution, up to 3% of talc is used.
- Filtration yields a bright and clear product

Suspensions

→ Suspensions are biphasic liquid preparations containing finely divided 0.5-5.0u solid drug particles (discontinuous phase)
→ Suspensions are intended for oral administration, external application, or parenteral use
→ A coarse dispersion in which insoluble solids are suspended in a liquid medium is termed as a pharmaceutical suspension
→ In suspensions, water or water-based vehicle are normally used as a liquid medium, in which the insoluble solids (size ranging from 10-1000um) are suspended.

Advantages

- Stability
- Choice of Solvent
- Taste Masking
- Prolonged Action Dosage Forms
- Bioavailability

Disadvantages

- An accurate dose can be attained only if the suspensions are packed in unit dosage forms. Thus, the potent drugs are not administered as suspension.
- Problems related to physical stability, sedimentation, and compaction of sediment can occur. These problems cannot be solved easily.
- Oxidation and hydrolysis may affect the chemical stability of suspension.
- Suspensions are liquid dosage forms, therefore, are need to be protected against microbial attack.

Types of Suspensions

On the basis of their general classes: -

I. Oral Suspensions: These are meant for oral administration in which one or more insoluble medicaments are dispersed in the liquid vehicle.
II. Externally Applied Suspensions: These are meant for topical application.
III. Parenteral Suspensions: These are heterogeneous systems in which the solid phase dispersed within a liquid phase.

Pharmaceutical Applications

The applications of suspensions are as follows:

a. They are used either for avoiding drug damage or for improving drug stability, e.g, oxytetracycline suspensions.
b. They are required to conceal the obnoxious taste of certain drugs, e.g., chloramphenicol palmitate suspensions.
c. They can be modified to control the drug absorption rate for parenteral administration, e.g., penicilin procaine suspensions.
d. Some of the vaccines containing immunising agents are prepared as suspensions, e.g., cholera vaccine.
e. They can be formulated with drugs intended for topical use, e.g., calamine lotion

Emulsions

→ A biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other, is termed as a pharmaceutical emulsion.
→ The liquid in the form of minute globules is the dispersed phase, while the liquid containing the dispersed globules is the continuous phase

Advantages

- The inedible oils can easily be administered as edible emulsions.
- The obnoxious taste of oils can be concealed.
- The flavouring of aqueous phase of emulsion is possible.
- They are more rapidly absorbed than the solid dosage forms.
- Two incompatible ingredients can incorporated, with one in each phase.

Disadvantages

1) The manufacturing process of stable emulsions requires technical experts and calculations of primary emulsion formulae.
2) A measuring device is employed for administering emulsions
3) In case they are not shaken well before use, dose accuracy decreases in comparison to solutions.
4) The dispersion system may get affected if the emulsions are improperly stored.

Types of Emulsions

Depending on dispersed phase, emulsions can be categorised into:

1) Water-in-Oil (w/o) Emulsions:
2) Oil-in-Water (o/w) Emulsions :

Pharmaceutical Applications

- ➲ The o/w type emulsions are known to enhance the drug absorption through GIT.
- ➲ The nutrient oils that are difficult to swallow can be injected intravenously as emulsions.
- ➲ Certain o/w emulsions like per-fluorinated hydrocarbons are used for oxygen replacement therapy.
- ➲ Many water-soluble antigens and certain drugs are prepared as w/o type emulsions to be given as depot injection (sustain and release).
- ➲ Certain emulsions comprising different radio opaque elements can be used for diagnosis.

Dry Powder for Reconstitution

→ Powders for oral suspension are preparations that include solid, loose, dry particles of different degrees of fine particle size.

→ They are prepared as powder mixtures of typical ingredients required for an aqueous suspension

Types of powder for Oral Suspension

- Unit Dose / Single Dose Powders For Oral Suspension:
- Multidose Powders for Oral Suspension:

Q8. Write the note on ointments, cream, paste, gels, liniments, and lotions, Suppositories, and pessaries.

Ans.

Ointments

→ Ointments are semisolid formulations carrying medicaments and are designed for topical application.

→ The ointment should be of such consistency that it can be easily rubbed on the skin

→ The ointment base contains the medicament in solution suspension, or emulsion form The vehicles used act as skin protective and emollient

Advantages

1. They are easy to handle than the bulky liquid dosage
2. They are chemically more stable than the liquid dosage forms.
3. They are directly applied to the target area avoiding the other body parts.
4. Patients sensitive to parenteral and oral routes prefer ointments.
5. The contact time between the medicament and the applied area is enhanced by ointments.
6. Drugs undergoing first-pass metabolism on oral administration are given as ointments.

Disadvantages

- ➲ They are bulkier than the solid dosage forms.
- ➲ They are less stable than the solid dosage forms.

Types of Ointments

- Hydrophobic / Lipophilic
- Water-Emulsifying Ointments
- Hydrophilic Ointments

Preparation of Ointments

- Trituration
- Fusion
- Chemical Reaction
- Emulsification

Pastes

→ Pastes are one of the types of semisolid preparations intended to be used externally on the surface of the skin, in order to provide a protective covering

Preparation of pastes

- Trituration method
- Fusion Method

Suppositories and Pessaries

→ Suppositories are defined as medicated solid or semisolid dosage forms meant for insertion into the body cavities like rectum, vagina, or urethral tract.

→ When inserted into the body these dosage forms melt, disintegrate, or dissolve at the body temperature.

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

They are of the following three types:

1. Moulded Pessaries: These are cone-shaped and prepared in a similar way to moulded suppositories.
2. Compressed Pessaries: These are of various shapes and are prepared by compression similar to oral tablets.
3. Vaginal Capsules: These are similar to soft gelation oral capsules differing only in size and shape.

Merits

- Improved Enzymatic Drug Stability
- Avoidance of Hepatic First Pass Metabolism
- Higher Drug Load
- Lymphatic Delivery
- Constant and Static Environment
- Patients with Swallowing Difficulty

Demerits

★ Patient Acceptance and Compliance
★ Potential for Non-Specific Drug Loss
★ Limited Fluid in Rectum
★ Formulation
★ Expensive

Types of Suppositories

- ♠ Rectal Suppositories
- ♠ Vaginal Suppositories (Pessaries)
- ♠ Nasal Bougies
- ♠ Ear Cones (Aurinaries)

Preparation of Suppositories

Suppositories can be prepared by any of the three methods:

i. Hand rolling and moulding,
ii. Compression moulding, and
iii. Fusion moulding (hot process).

Liniments

→ Liniments are the liquid or semisolid dosage forms applied with friction over unbroken skin.
→ They can also be applied on lint or any other suitable material which is then placed should be scratch-free, or else uneven surfaced on the affected area.
→ Liniments are either soap solutions or emulsions.
→ Use of oil or soap base in the formulation facilitates the ease of application and massage.

Preparation

- ➢ The nature of individual ingredients present in the formulation determines the method employed for preparing liniments.
- ➢ Therefore, the methods used to prepare solutions, suspensions, or emulsions, can be employed for preparing liniments also.

Lotions

→ Lotions are liquid preparations intended to be applied externally on broken skin without friction.
→ They possess low to medium viscosity.
→ They, are formulated as oil-in- water or water-in-oil emulsions.
→ Absorbent material like gauze or a cotton wool is Soaked in lotions and then directly applied over the affected skin.
→ Lotions provide local cooling, soothing. actions as they are incorporated with or protective alcohol.
→ Some lotions provide antiseptic action, e.g., calamine lotion
→ Lotions are either applied directly on the skin or are applied on a dressing which is further covered with a waterproof dressing, thus, reducing evaporation.

Preparation

The following methods are used to prepare lotions:

- ➲ High-speed mixers or homogenisers are used to triturate the ingredients and form a smooth paste to which the leftover liquid phase is carefully added.
- ➲ For example, in calamine lotion the finely divided insoluble solids are held in somewhat permanent Suspension, in the presence of suspending agents or surface active agents.
- ➲ Through chemical interactions in the liquid. For example, freshly prepared white lotion without any Suspending agent

Gels or Jellies

→ Jellies are semisolid gels, having suspensions containing either small inorganic particles or large organic molecules interpenetrated by a liquid

Types of Jellies

Jellies are transparent or translucent, non-greasy, and semisolid gels meant for external application. They are of the following types:

- ➲ Medicated Jellies
- ➲ Lubricants
- ➲ Miscellaneous Jellies

Cold Cream

→ Cold creams are water-in-oil or oil-in-water type mulsions added with certain fats (generally beeswax) and perfuming agents.

→ These are applied on skin to provide smoothness and remove makeup.

→ Cold creams are named so due to the cooling effect they impart on application.

An ideal cold cream should have the following properties :

I. It should have a low sensitisation index.
II. It should be elegant in appearance.
III. It should be non-dehydrating.
IV. It should provide a smooth texture.
V. It should be non-greasy and non-staining.
VI. It should not cause irritation to the skin.
VII. It should not alter the membrane or skin functioning.
VIII. It should be miscible with skin secretion.

Q9.Write this short note on powder and granules.

Ans.

POWDERS AND GRANULES

→ Powder is defined as a uniform and dry mixture of one or more finely divided particulate material.

→ In the current scenario, powder is rarely used as a dosage form but it is being employed as the starting material in the manufacture of many dosage forms.

→ The significance of particle size is well-known in powder dosage forms.

→ Powder is one of the oldest dosage forms which are meant for internal as well as external application

Types of Powders

Based on Usage: Depending on their use, powders their use, powders are divided into:

i) Internal Use: The powders meant for internal for internal meant use are

a) Simple powders,
b) Compound powders, and
c) Bulk powders, e.g., effervescent powders or granules, laxatives, and dietary powders. c) non-effervescent antacids, snuffs,

ii) External Use: Dusting powders, snuffs, insufflations, sprays, aerosols, dentifrices, and dentifrices, and tooth powders.

Advantages

Powdered dosage forms exhibit the following advantages,

I. These are the oldest dosage form, used both internally and externally.
II. As compared to liquid dosage forms, they are more stable.
III. Specific amount of drug can be prescribed by the physician depending on the patient's need.
IV. They easily dissolve in body fluids due to greater surface area, thus, the blood concentration of drug increases in a very short time span
V. They are portable.
VI. By dissolving or mixing the powdered drugs in an appropriate liquid, large quantity of the drug can be administered easily.

Disadvantages

i. Powdered drugs possessing bitter, nauseous, and unpleasant taste cannot be dispensed.
ii. Powdered drugs which are deliquescent and hygroscopic in nature cannot be dispensed.
iii. Drugs affected by atmospheric conditions are inappropriate for dispensing in powdered dosage form.
iv. Preparation of powdered drugs is a time-consuming process.

Granules

→ Granules are powder agglomerates.
→ The normal size range of granules is 4-12 sieves. Different size of granules can be formed according to the application.

Following are the advantages of granules :

➲ They have good flowability than powders
➲ They also remove or control the dust.
➲ They increase the compressibility.
➲ Their physical and chemical stability is much more than powders because they have a smaller surface area
➲ They give rise to particle size uniformity, which further leads to content uniformity.

Q10. Explain this sterile formulation Injectable, eyedrop and eye ointment.

Ans.

STERILE FORMULATIONS

→ According to I.P. Parenteral are injectable preparations and parenteral products are formulated for administration by the method of injection, infusion or implantation inside the body.
→ Parenterals should be free of physical, chemical and biological contamination.
→ Parenteral preparations should be sterile, pyrogen free liquids (solutions, emulsions, or suspensions) or solid dosage forms packaged in either single-dose or multi dose containers.
→ These preparations can be administered theongh the skin or mucus membranes into internal bdy compartments.
→ These include any method of administration n which passage through the digestive tract is not involved
→ Injectable solutions need to be free from visible particulate matter like reconstituted sterile powders

General Requirements for Injectable

1) Stability
2) Sterility
3) Free from pyrogens
4) Free from foreign particles
5) Isotonicity
6) Specific gravity
7) Chemical purity

Preparation

Filtration
Filling
Sealing
Ampoules
Vials and bottles
Sterilisation

Advantages

- It shows quick onset of action
- The drugs which cannot be administered by oral route can be administered by this route.
- The drug can be administered by this route in case the patients are unconscious or vomiting
- Modification of the formulation can prolong the drug action.
- Transfusion fluids containing nutritives such as glucose and electrolytes (sodium chioride) can be given through this route.

Disadavantages

1) It causes pain at the site of injection.
2) The drug should be administered by the trained persons.
3) The administration of a drug through wrong route of injection can be dangerous.
4) The over dose given to the patient may cause death.
5) Sensitivity or allergic reaction of a drug may occur i an individual, which can be at times life threatening or may cause death.

Eye Drops

→ Eye Drops are sterile aqueous or oily solutions or suspensions of drug that are infused into eye through dropper.

→ The Eye Drops are usually comprised of drugs having antiseptic, anaesthetic, anti inflammatory, etc

Some of the essential characteristics of eye drops are as follows:

1) They should be sterile
2) They should be iso-Osmotic with lachrymal secretion
3) They should be free from the foreign particles. fibres and filaments
4) They should have almost neutral pH.
5) They should be preserved with suitable bacterioside.
6) They should remain stable during their storage.

Formulation

An eye drop formulation comprises of the following:

- Active ingredient(s) to produce the desired therapeutic effect
- Vehicle (aqueous or oily).
- Inert antimicrobial preservatives to prevent microbial contamination and to maintain sterility.
- Inert adjuvants for adjusting tonicity, viscosity or pH to increase the stability of active ingredient(s).
- Suitable container to maintain the preparation in a form and provide protection against stable contamination during preparation, storage, and use.
- The most important requirement of eye drops is that they should be sterile.
- In history, some eye drops were found to be contaminated with Pseudomonas aeruginosa, which is difficult to treat and can cause loss of vision.

Advantages

1) It can be used in replacing the natural moisture in patient's eye, and can be a life saver for anyone with dry eyes.
2) Medication in eye drops can help the eye to recover fast after an injury on the surface of the eye
3) They are compact and easy to administer and much simpler to deal with overall in comparisonto injections or pills.

Disadvantages

1) Usually, eye drops are stored in a bottle that should be handled carefully to prevent contamination
2) At times the eye drops does not work for some patients because of which patient has to apply it repeatedly for several days and gets minimal results in return.
3) In some cases, the use of eye drops can mask minor symptoms that can be tackled from the source and treating the effect is not required as it won't recover the actual cause

Uses

1) Used for treating infection.
2) Used for dilating or contracting pupil.
3) Used for instilling medication before examination or Surgery to eyes.
4) Used for relieving pain, itching, discomfort.
5) Used for lubricating the eyes.
6) Used for staining the cornea for identifying abrasion and scars.

Eye Ointments

→ Ophthalmic ointment vehicle can be used to maintain the stability of the drug in contact with the external ocular surface for the longer time duration.
→ The ointment base is sterilised through heat and filtered properly in liquid phase for removing the foreign particulate matter. (repeat).
→ The ointment base selected for an ophthalmic ointment should be non-irritating to the eye and

→ Eye ointment base can be sterilised by heat and filtered in liquid phase for removing the foreign particulate matter.
→ Then it is placed in a sterile steam jacketed for maintaining the ointment in a molten state and excipients are added.
→ Thus, the entire ointment can be passed through a previously sterilised colloid mill.

Formulation

The following bases can be used for the preparation of eye ointments:

1) Yellow soft paraffin (80gm),
2) Liquid paraffin (10gm), or
3) Wool fat (10gm).

Preparation

★ Wool fat and yellow soft paraffin are melted on a heated water bath
★ Liguid paraffin is added to the melted mixture and filtered through a coarse filter Paper (e-g, Whatman 54) placed in a heated funnel.
★ The obtained mixture is sterilised at 160°C temperature for 2 hours
★ The medicament is added with eye ointment base, and the final mixture is packed in a sterile containers

Advantages

i. They have longer contact time and greater storage stability
ii. There is flexibelity in selecting the drug
iii. They improve the stability of the drug

Disadvantages

i. After using it eys lids starts sticking.
ii. Person may experience the blurred vision.
iii. It has poor patient compliance.
iv. They interfere with the attachment of new corneal epithelial cells to their normal base
v. Matting of eyelids occur

Q11. Explain the Immunological products Sera, vaccines, Toxoids, with their manufacturing methods.

Ans. Immunological products

Features of Antisera

a. These are antibodies which are developed in animals (horses especially)
b. They are obtained from the serum of an animal (e.g., rabies antiserum), containing the target antibody for which a specific antigen has been injected.
c. Antitoxins are prepared by injecting toxin or toxoid,

Vaccines

★ To memorialise the work of Edward Jenner (i.e., first successful immunisation against small pox), Louis Pasteur invented the term vaccine derived from the term vacca (means cow), because Jenner prevented smallpox infection using Vaccinia (cowpox virus).
★ A process in which an individual is intentionally exposed to antigen under such conditions where disease should not occur is termed vaccination
★ Vaccine is a live attenuated (weakened) or killed microorganism or parts or products of them containing antigens which induce a specific immune response consisting of protective antibodies and T cell immunity.

Live Attenuated Vaccines

- Live attenuated vaccines are prepared using a non-virulent microorganism that retained its antigenicity.
- These vaccines can provide permanent or lifetime immunity to an individual against a disease.
- Merits
- Multiple booster doses are not always required; most of these vaccines provide lifelong immunity with a single dose.
- Whole microorganisms stimulate immune response to antigens in their natural conformation.
- Orally administered live vaccines induce mucosal immunity and IgA synthesis, which provides more protection at the site of entry.
- Oral preparations of these vaccines are less expensive than the injections.
- These vaccines can even help in eliminating the wild type virus from the community.
- Demerits
- The microorganisms in these vaccines may relapse to their virulent form and cause a disease; however this rarely happens

Inactivated-Killed Vaccines

- Inactivated-killed vaccines are prepared using either killed pathogens using with altered or inactivated inactivated by applying heat or chemical.
- These vaccines are first administered as a primary dose and antigenicity.
- These microorganisms are killed or These then a single or multiple booster doses are required.
- A killed form of the disease-causing microorganism is used for making inactivated vaccines.
- A single dose of inactivated vaccine does not provide immunity as strong as live vaccines; thus booster doses are required after specific time intervals in order to achieve continuous immunity against diseases

Merits

1) These vaccines can be safely used in immunocompromised individuals and pregnant women.
2) These vaccines are less expensive than live attenuated vaccines.
3) These vaccines do not demand storage facilities as critical as live vaccines.

Demerits

1) The microorganisms in these vaccines cannot multiply, thus a large amount is needed to be injected for stimulating immunity.
2) Periodic booster shots are also required for achieving desired immunity
3) These vaccines can be only injected.
4) Presence of some un-inactivated microorganisms can cause some vaccine-associated diseases.

Toxoids

I. Toxoid vaccines are prepared from the toxins secreted by certain bacterial species
II. The preparative method of these vaccines is termed toxoiding
III. Bacterial Cell Component Vaccines
IV. Conjugate Vaccines
V. Viral Subunit Vaccines
VI. DNA Vaccine

Production of Vaccines

Vaccines are used for providing good health to large number of population; thus they should be manufactured on a large-scale, which is a challenging task.

Vaccine production includes:

1. Generation of the Antigen: In the first step, the antigen that will evoke immune response is generated by growing and harvesting the proteinsor DNA of the pathogen using the following mechanisms:
    i. For preparing influenza vaccine, viruses are grown on primary cells (e.g., cells from chicken embryos or fertilised eggs); and for preparing hepatitis A vaccines, viruses are grown on repeatedly reproducing cell lines.
    ii. Bacteria are grown in bioreactors which utilise a particular growth medium to optimise the antigen production.
    iii. Recombinant proteins derived from the pathogen are generated either in yeast, bacteria, or cell cultures.
2. Release and Isolation of the Antigen: In the second step, virus or bacteria are released by separating the antigen from the cells and isolating from the proteins and other parts of the growth medium are still present.
3. Purification Process: In the third step, membrane separation (ultrafiltration) and chromatographic separation (gel filtration and size exclusion) are used for separating the inactivated antigen in group separation mode. Separation of large viruses from the fermentation broth is beneficial,e.g., human influenza viruses which are larger than protein and peptide molecules can be separated. shows a basic purification process after the sample has been prepared by centrifugation and depth filtration.
4. Addition of Other Components: In the fourth step, vaccine is formulated by adding an adjuvant which enhances the immune response the recipient produces against a supplied antigen. stabilisers which modify the shelf-life. and preservatives which allow multi-dose vials to be used safely. Development of combination vaccines challenging incompatibilities and interactions between antigens and other ingredients. All the components constituting the final vaccine are combined and uniformly mixed in a single vial or syringe.
5. Packaging: In the final step, the vial or syringe (recipient vesse) containing the vaccines are sealed with sterile stoppers. After packaging the vaccines are labelled and distributed throughout the world all the above given process should comply with the GMP including the quality control methodds and adequate infrastructure having separate areas for different activities to avoid cross-contamination.