Program	B. Pharmacy
Semester	1st semester
Subject /Course	General Pharmacy (Theory)
Subject/Course ID	BP 102T
Module No.	05
Module Title	Semisolid Dosage Forms
Course coordinator	Dr. Gurjeet Singh

Learning Outcome of Module

LO	Learning Outcome (LO)	Course Outcome Code
LO1	Classify semisolids into ointments, pastes, creams, and gels, and describe their specific methods of preparation.	BP102.5
LO2	Select appropriate ointment bases based on the desired penetration and physical properties of the formulation.	BP102.5
LO3	Formulate and evaluate suppositories and pessaries using various types of suppository bases.	BP102.5
LO4	Calculate the displacement value for medicaments in suppository bases to ensure accurate dosing.	BP102.5
LO5	Discuss the ideal properties of suppository bases and the general methods for their large-scale and small-scale preparation.	BP102.5

Module Content Table

No.	Topic
1.	Definitions, classification, advantages and disadvantages, ointment bases and other excipients used in semisolid dosage forms; general methods of preparation of ointments, pastes, creams and gels.
2.	Suppositories / Pessaries: Definition, types of suppositories, advantages and disadvantages, formulation excipients used in suppositories, properties of ideal suppository bases, types of suppository bases, displacement value and general method of preparation.

SEMISOLID DOSAGE FORMS

Semisolid dosage forms are pharmaceutical preparations having a consistency between solid and liquid, intended mainly for external application to the skin or mucous membranes. These formulations are designed to deliver drugs for local action at the site of application or, in some cases, for systemic absorption through the skin. They provide prolonged contact with the skin, thereby enhancing therapeutic effectiveness.

Classification of Semisolid Dosage Forms

Semisolid dosage forms are classified based on their composition and pharmaceutical use:

1. ***Ointments***
   - Greasy, semisolid preparations intended for external application.
   - Bases may be oleaginous, absorption, water-removable, or water-soluble.
   - Used for emollient, protective, or medicated purposes.
2. ***Creams***
   - Semisolid emulsions (O/W or W/O).
   - Less greasy than ointments and more cosmetically acceptable.
   - Suitable for inflamed and moist skin conditions.
3. ***Gels***
   - Semisolid systems consisting of solid particles dispersed in a liquid.
   - Non-greasy and easily washable.
   - Provide rapid drug release.

Pastes

- Thick semisolid preparations containing a high proportion of finely

powdered solids.

- Provide protective and soothing action.
- Less penetrating than ointments.

4. ***Poultices (Cataplasms)***

- Soft, moist masses applied warm to the skin.
- Used to relieve pain or inflammation.
- Rarely used in modern therapy.

MECHANISM OF DERMAL PENETRATION OF DRUGS

Dermal penetration refers to the movement of drug molecules from the surface of the skin into the deeper layers or systemic circulation.

Routes of Drug Penetration

1. Transepidermal Route
    - Most common pathway.
    - Drug passes through the stratum corneum.
    - Includes:
        - Intercellular pathway (between cells)
        - Transcellular pathway (through cells)
2. *Transappendageal Route*
    - Drug enters through hair follicles, sweat glands, and sebaceous glands.
    - Contributes minimally but useful for certain drugs.

Steps Involved in Dermal Penetration

1. Drug release from the semisolid base

2. Partitioning into the stratum corneum
3. Diffusion through epidermis and dermis
4. Absorption into systemic circulation (if intended)

FACTORS INFLUENCING DERMAL PENETRATION OF DRUGS

A. *Drug-Related Factors*

1. Molecular Size
    - Smaller molecules penetrate the skin more easily.
2. *Lipid Solubility*
    - Drugs with moderate lipid solubility show better penetration through the stratum corneum.
3. *Drug Concentration*
    - Higher concentration increases the penetration rate.
4. *Ionization*
    - Unionized drugs penetrate the skin more readily than ionized forms.

B. *Formulation-Related Factors*

1. *Type of Base*
    - Ointment bases enhance penetration more than creams or gels.
2. *Presence of Penetration Enhancers*
    - Substances like DMSO, alcohol, or surfactants increase skin permeability.
3. *Viscosity of Preparation*
    - Lower viscosity allows better drug diffusion.
4. *pH of Formulation*
    - Influences drug ionization and skin compatibility.

C. ***Skin-Related Factors***

1. Condition of Skin
    - Damaged or diseased skin shows increased penetration.
2. *Thickness of Skin*
    - Thinner skin areas absorb drugs faster.
3. *Hydration of Skin*
    - Hydrated skin allows greater penetration.
4. *Age*
    - Infants and elderly may show altered absorption.

D. ***Environmental Factors***

1. Temperature
    - Increased temperature enhances drug absorption.
2. *Duration of Contact*
    - Longer contact time increases penetration.
3. *Occlusion*
    - Covering the application site enhances hydration and absorption.

Semisolid dosage forms play a vital role in topical drug delivery by providing sustained contact with the skin and improved patient compliance. Understanding their classification, mechanisms of drug penetration, and influencing factors is essential for designing effective dermatological formulations and ensuring optimal therapeutic outcomes.

OINTMENTS

Ointments are semisolid preparations intended for external application on the skin or mucous membranes. The method of preparation depends on the nature of the

drug, type of ointment base, and intended therapeutic use. Proper preparation ensures uniform drug distribution, stability, and effective therapeutic action.

Methods of Preparation of Ointments

Ointments are generally prepared by the following two main methods:

1. Incorporation Method
2. Fusion Method

1. Incorporation Method

Definition

In the incorporation method, the drug is physically mixed with the ointment base without applying heat. This method is commonly used when the drug is stable at room temperature and present in solid or liquid form.

Procedure

- Finely powder the solid drug to avoid grittiness.
- Take a small quantity of the ointment base on an ointment slab.
- Incorporate the drug gradually using spatulation or trituration.
- Add the remaining base in portions until a uniform ointment is obtained.
- Transfer the prepared ointment into a suitable container.

Incorporation of Liquids

- If the liquid drug is miscible with the base, it is mixed directly.
- If immiscible, an absorption base or suitable emulsifying agent is used.

Advantages

- Simple and economical method
- Suitable for heat-sensitive drugs
- Minimal risk of drug degradation

Limitations

- Not suitable for waxy or hard bases
- Uniform mixing is difficult for large quantities

2. *Fusion Method Definition*

In the fusion method, the ointment base ingredients are melted together, and the drug is incorporated into the molten mass. This method is used when the base contains solid or waxy components.

Procedure

1. Ingredients of the base are melted in descending order of their melting points.
2. The molten mixture is stirred gently to ensure uniformity.
3. The drug, if heat-stable, is dissolved or dispersed in the molten base.
4. The mixture is cooled slowly with continuous stirring.
5. Perfumes or volatile substances are added near the end of cooling.
6. The final ointment is packed into suitable containers.

Advantages

- Produces uniform and smooth ointments
- Suitable for large-scale preparation
- Ideal for oleaginous and absorption bases

Limitations

- Not suitable for heat-sensitive drugs
- Risk of air entrapment if not stirred properly

Special Considerations During Ointment Preparation

- Particle Size: Solid drugs must be finely powdered to avoid irritation.

- Uniformity: Proper mixing ensures even drug distribution.
- Temperature Control: Excessive heat may degrade drugs or bases.
- Order of Mixing: Ingredients should be added systematically.
- Packaging: Ointments should be stored in airtight containers to prevent contamination.

The preparation of ointments requires careful selection of method based on the nature of the drug and base. The incorporation method is preferred for heat-sensitive substances, while the fusion method is suitable for waxy and solid bases. Proper preparation ensures patient safety, stability, and therapeutic effectiveness, making ointments an important dosage form in pharmaceutical practice.

PASTES

Pastes are thick semisolid pharmaceutical preparations intended for external application on the skin. They contain a high proportion of finely powdered insoluble s-olids (usually 25–50%) dispersed uniformly in a suitable base. Because of their stiff consistency, pastes remain in place after application and provide a protective as well as therapeutic effect on the skin.

Characteristics of Pastes

- High solid content
- Stiff and less greasy consistency
- Less penetrating than ointments
- Provide prolonged contact with the skin
- Form a protective barrier

Types of Pastes

1. ***Fatty Pastes***

- Prepared using oleaginous bases such as soft paraffin.
- Highly occlusive and protective.

Example:

- Zinc oxide paste

2. ***Aqueous Pastes***

- Prepared using water-soluble or water-miscible bases.
- Easily washable and less greasy.

Example:

- Starch paste

Advantages of Pastes

1. Protective Action
    - Form a thick protective layer on the skin.
2. *Reduced Skin Irritation*
    - Absorb secretions and reduce moisture.
3. *Localized Effect*
    - Minimal systemic absorption due to limited penetration.
4. *Prolonged Contact*

- Remain at the site of application for longer duration.

5. *Suitable for Inflamed Skin*
    - Preferred in weeping or oozing skin conditions.

Disadvantages of Pastes

1. Poor Cosmetic Appearance
    - Thick and difficult to spread.
2. *Limited Drug Penetration*
    - Not suitable when deep penetration is required.
3. *Difficult Removal*
    - Fatty pastes are not easily washable.
4. *Unsuitable for Hairy Areas*
    - Adhere strongly and are difficult to remove.

Method of Preparation of Pastes

Incorporation Method

- Finely powder the solid ingredients.
- Mix the powders uniformly.
- Gradually incorporate the base using spatulation.
- Mix until a smooth, homogeneous paste is obtained.

Note: Fusion method is generally not used because high solid content may lead to uneven distribution.

Uses of Pastes

- Protective applications
- Treatment of diaper rash
- Management of eczema and dermatitis
- Absorption of skin exudates

Examples of Official Pastes

- Zinc oxide paste
- Lassar's paste (zinc oxide + salicylic acid)

Pastes are valuable semisolid dosage forms designed mainly for protective and localized therapy. Their high solid content and stiff consistency make them particularly suitable for inflamed and oozing skin conditions, although their limited penetration and poor cosmetic elegance restrict their use in certain cases.

CREAMS

Creams are semisolid pharmaceutical preparations intended for external application to the skin or mucous membranes. They are emulsion-based systems consisting of an oil phase and an aqueous phase, stabilized by suitable emulsifying agents. Creams are softer, less greasy, and more cosmetically acceptable than ointments, making them widely used in dermatological therapy.

Classification of Creams

Creams are classified based on the type of emulsion they form:

1. ***Oil-in-Water (O/W) Creams***
   - Oil droplets are dispersed in a continuous aqueous phase.
   - Non-greasy and easily washable.
   - Suitable for weeping and moist skin conditions.

Examples:

- Vanishing cream
- Hydrocortisone cream

2. ***Water-in-Oil (W/O) Creams***
   - Water droplets are dispersed in a continuous oil phase.
   - Greasy and occlusive.

- Suitable for dry and scaly skin conditions.

Examples:

- Cold cream
- Emollient creams

Advantages of Creams

1. Good Patient Acceptability
   - Pleasant appearance and feel.
2. Easy Application and Spreadability
   - Smooth texture allows uniform application.
3. *Washable (O/W creams)*
   - Easily removed with water.
4. *Suitable for Inflamed Skin*
   - Less occlusive than ointments, reducing irritation.
5. *Flexible Use*
   - Can provide both local and mild systemic effects.

Disadvantages of Creams

1. Less Occlusive Than Ointments
   - Not suitable when deep penetration is required.
2. *Microbial Growth Risk*
   - Aqueous phase supports microbial growth, requiring preservatives.
3. *Lower Stability*
   - Risk of emulsion breakdown on storage.
4. *Shorter Shelf Life*
   - Compared to ointments.

Method of Preparation of Creams

Emulsification Method

Steps:

1. Heat the oil phase and aqueous phase separately to the same temperature.
2. Add the aqueous phase to the oil phase (or vice versa depending on type).
3. Stir continuously until emulsification occurs.
4. Cool the mixture with gentle stirring.
5. Add heat-sensitive ingredients during cooling.
6. Transfer into suitable containers.

Uses of Creams

- Treatment of fungal and bacterial infections
- Anti-inflammatory and antipruritic therapy
- Cosmetic applications
- Moisturizing and emollient action

Examples of Official Creams

- Zinc oxide cream
- Betamethasone cream
- Clotrimazole cream

Creams are versatile semisolid dosage forms offering a balance between effectiveness and cosmetic acceptability. Their emulsion nature allows easy application, patient comfort, and wide therapeutic use, especially in dermatological conditions requiring mild to moderate occlusion.

GELS

Gels are semisolid pharmaceutical dosage forms in which a liquid phase is immobilized within a three-dimensional network of a gelling agent. This structure

provides a jelly-like consistency. Gels are mainly intended for topical application but may also be formulated for ophthalmic, nasal, rectal, or oral use. They are valued for their non-greasy nature, ease of application, and rapid drug release.

Classification of Gels

Gels can be classified based on the nature of the dispersion medium and type of gelling system:

1. ***Single-Phase Gels***
    - Drug and gelling agent are dissolved in the liquid phase.
    - Transparent and uniform.
    - Prepared using polymers like carbomers or cellulose derivatives.

Examples:

- Carbopol gel
- Methyl cellulose gel

2. ***Two-Phase Gels (Magmas)***
    - Solid particles dispersed in a liquid medium.
    - Appear cloudy or opaque.
    - Require shaking before use.

Examples:

- Aluminum hydroxide gel
- Bentonite magma

3. ***Hydrogels***
    - Water is the dispersion medium.
    - Commonly used for dermatological and wound care.

Examples:

- Aloe vera gel

- Lidocaine hydrogel

4. ***Organogels***

- Non-aqueous liquid (oil) is the dispersion medium.
- Used for lipophilic drugs.

Examples:

- Lecithin organogel

Advantages of Gels

1. *Non-Greasy and Easily Washable*
    - Provide good cosmetic acceptability.
2. *Rapid Drug Release*
    - High water content allows quick diffusion of the drug.
3. *Cooling and Soothing Effect*
    - Beneficial for inflamed or burned skin.
4. *Ease of Application*
    - Spread smoothly without excessive rubbing.
5. *Good Patient Compliance*
    - Preferred over oily preparations.

Disadvantages of Gels

1. *Drying Effect*
    - High alcohol or water content may cause skin dryness.
2. *Limited Drug Compatibility*
    - Not suitable for highly lipophilic drugs without modification.
3. *Microbial Contamination*
    - Aqueous gels require preservatives.

4. *Lower Occlusiveness*
    - Less effective for very dry skin conditions.

Method of Preparation of Gels

General Procedure

1. Disperse the gelling agent in water with continuous stirring.
2. Allow sufficient time for hydration and swelling.
3. Add the drug dissolved in a suitable solvent.
4. Adjust pH if required to achieve gel formation.
5. Add preservatives, humectants, or penetration enhancers.
6. Remove entrapped air and pack in suitable containers.

Uses of Gels

- Anti-inflammatory and analgesic therapy
- Antifungal and antibacterial treatments
- Ophthalmic and nasal drug delivery
- Cosmetic and dermatological applications

Examples of Gels

- Diclofenac gel
- Metronidazole gel
- Benzoyl peroxide gel

Gels are important semisolid dosage forms that offer rapid drug release, excellent cosmetic properties, and patient comfort. Their versatility and ease of application make them especially suitable for modern topical therapy, though formulation stability and microbial protection must be carefully controlled.

EXCIPIENTS USED IN SEMISOLID DOSAGE FORMS

Excipients are inactive pharmaceutical ingredients added to semisolid dosage

forms to provide structure, stability, appearance, and therapeutic effectiveness. In topical preparations such as ointments, creams, gels, and pastes, excipients play a crucial role in drug release, skin penetration, stability, and patient acceptability.

1. ***Bases Role***

- Form the main body of the semisolid preparation.
- Control drug release and skin hydration.

Types and Examples

- Oleaginous bases: White soft paraffin, yellow soft paraffin
- Absorption bases: Wool fat, hydrophilic petrolatum
- Water-removable bases: Emulsifying ointment
- Water-soluble bases: Polyethylene glycol (PEG)

2. ***Emulsifying Agents Role***

- Stabilize emulsions in creams.
- Prevent phase separation.

Examples

- Natural: Acacia, gelatin
- Semi-synthetic: Cetostearyl alcohol
- Synthetic: Sodium lauryl sulfate, polysorbates (Tween)

3. ***Gelling Agents Role***

- Provide gel structure and viscosity.

Examples

- Carbopol (carbomers)
- Hydroxypropyl methylcellulose (HPMC)
- Sodium alginate
- Xanthan gum

4. ***Humectants Role***
    - Retain moisture and prevent drying.
    - Improve skin hydration.

Examples

- Glycerin
- Propylene glycol
- Sorbitol

5. ***Preservatives Role***
    - Prevent microbial growth, especially in aqueous formulations.

Examples

- Methyl paraben
- Propyl paraben
- Benzyl alcohol
- Chlorocresol

6. ***Antioxidants Role***
    - Prevent oxidation of drugs and bases.

Examples

- Butylated hydroxyanisole (BHA)
- Butylated hydroxytoluene (BHT)
- Ascorbic acid
- Sodium metabisulfite

7. ***Penetration Enhancers Role***
    - Improve drug permeation through skin.

Examples

- Dimethyl sulfoxide (DMSO)

- Oleic acid
- Urea
- Isopropyl myristate

8. ***Thickening Agents Role***
    - Increase viscosity and stability.

Examples

- Cetyl alcohol
- Stearyl alcohol
- Beeswax

9. ***Buffers and pH Adjusters Role***
    - Maintain optimal pH for stability and skin compatibility.

Examples

- Citric acid
- Sodium citrate
- Phosphate buffer

10. ***Solvents and Co-solvents Role***
    - Dissolve drug and other excipients.

Examples

- Purified water
- Ethanol
- Propylene glycol

11. ***Perfumes and Coloring Agents Role***
    - Improve patient acceptability and product appearance.

Examples

- Lavender oil
- Menthol (also provides cooling effect)

Excipients used in semisolid dosage forms are essential for ensuring stability, effective drug delivery, patient comfort, and product quality. Proper selection and combination of excipients help achieve the desired therapeutic outcome while maintaining safety and acceptability of topical formulations.

EVALUATION OF SEMISOLID DOSAGE FORMS

Evaluation of semisolid dosage forms is carried out to ensure that the formulation is safe, stable, effective, and acceptable to the patient. Semisolid preparations such as ointments, creams, gels, and pastes must meet quality standards related to physical appearance, drug content, consistency, and performance before being used clinically.

1. Physical Appearance and Homogeneity

- The product should be smooth, uniform, and free from grittiness.
- There should be no phase separation, air entrapment, or lump formation.
- Color, odor, and texture should be consistent throughout the preparation.

2. pH Determination

- pH is measured using a digital pH meter.
- The pH should be compatible with skin pH (approximately 5.5–7).
- Incorrect pH may cause skin irritation or drug instability.

3. Viscosity Measurement

- Viscosity determines the thickness and flow properties of semisolid preparations.

- Measured using Brookfield viscometer.
- Proper viscosity ensures easy application, retention at site, and uniform drug distribution.

4. Spreadability Test

- Measures the ease with which the formulation spreads on the skin.
- Determined by placing a fixed amount of sample between two glass slides and measuring spread under applied weight.
- Good spreadability improves patient compliance.

5. Extrudability Test

- Evaluates the ease of removal of the formulation from collapsible tubes.
- A formulation should be easily extrudable without excessive force.

6. Drug Content Uniformity

- Ensures uniform distribution of drug throughout the formulation.
- A fixed quantity of sample is analyzed chemically.
- Results should fall within pharmacopeial limits.

7. In Vitro Drug Release Study

- Determines the rate and extent of drug release from the formulation.
- Usually performed using diffusion cells.
- Helps predict in vivo performance.

8. Skin Irritation Test

- Conducted to ensure safety for topical use.
- Evaluates redness, swelling, or allergic reaction after application.
- May be performed on animals or using in vitro skin models.

9. Stability Studies

- Assess changes in physical appearance, pH, viscosity, and drug content over time.
- Conducted under different temperature and humidity conditions.
- Ensures adequate shelf life.

10. Microbial Limit Test

- Ensures the formulation is free from harmful microorganisms.
- Especially important for aqueous and multi-dose formulations.

Evaluation of semisolid dosage forms is a critical step in pharmaceutical formulation and quality control. These tests ensure that the product is physically stable, therapeutically effective, microbiologically safe, and acceptable to patients, thereby ensuring reliable clinical performance.

SUPPOSITORIES

Suppositories are solid or semi-solid dosage forms intended for insertion into body cavities such as the rectum, vagina, or urethra, where they melt, soften, or dissolve at body temperature to produce local or systemic therapeutic effects.
They are formulated using suitable suppository bases that release the drug after administration.

Types of Suppositories

Suppositories are classified based on the site of administration:

1. ***Rectal Suppositories***

- Inserted into the rectum.
- Used for local effects such as relief from constipation, hemorrhoids, and rectal inflammation.

- Also used for systemic effects when oral administration is not possible.
- Average weight: 1–2 g (adults) and ~1 g (children).
- Shape: Torpedo-shaped for easy insertion.

Examples:

- Glycerin suppositories (laxative)
- Paracetamol suppositories (analgesic)

2. ***Vaginal Suppositories (Pessaries)***

- Inserted into the vagina.
- Mainly intended for local action.
- Used in treatment of infections, inflammation, and contraception.
- Weight: 3–5 g
- *Shape: Ovoid or cone-shaped*

Examples:

- Clotrimazole pessaries
- Metronidazole pessaries

3. ***Urethral Suppositories (Bougies)***

- Inserted into the urethra.
- Rarely used.
- Intended for local anesthetic or antibacterial action.
- Shape: Thin, rod-like
- Weight:
    - Male: ~4 g
    - Female: ~2 g

Examples:

- Local anesthetic bougies

Advantages of Suppositories

1. *Suitable for Patients Unable to Take Oral Medication*
    - Useful for unconscious, vomiting, pediatric, and geriatric patients.
2. Avoids Gastrointestinal Irritation
    - Drugs that cause gastric irritation orally can be administered rectally.
3. *Bypasses First-Pass Metabolism*
    - Partial avoidance of hepatic first-pass effect improves bioavailability.
4. *Local and Systemic Action*
    - Can provide localized treatment or systemic absorption depending on formulation.
5. *Rapid Onset of Action*
    - Rectal mucosa allows quick absorption for some drugs.
6. *Useful in Emergency Conditions*
    - Effective when oral route is not feasible.

Disadvantages of Suppositories

1. Patient Discomfort and Poor Acceptance
    - Some patients feel embarrassment or discomfort, reducing compliance.
2. *Variable Drug Absorption*
    - Absorption can vary due to rectal contents, blood flow, and

placement depth.

3. *Storage Problems*
    - Many suppositories melt at warm temperatures and require cool storage.
4. *Risk of Expulsion*
    - Suppositories may be expelled before complete drug release.
5. *Limited Drug Dose*
    - Not suitable for drugs requiring large doses.
6. *Local Irritation*
    - May cause irritation or inflammation of rectal or vaginal mucosa.

Suppositories are an important alternative dosage form in pharmaceutical practice, especially when oral administration is unsuitable. Their ability to provide both local and systemic effects, combined with avoidance of gastric irritation and partial bypass of first-pass metabolism, makes them valuable in clinical therapy. However, factors such as patient acceptability, absorption variability, and storage requirements must be carefully considered during formulation and use.

Types of Suppository Bases

Suppository bases are inactive substances that carry the drug and release it after insertion. Selection of a suitable base is essential for proper drug release and stability.

A. *Fatty (Oleaginous) Bases*

These bases melt at body temperature and release the drug.

1. Cocoa Butter (Theobroma Oil)
    - Most commonly used base.

- Melting point close to body temperature (~34–36°C).
- Non-toxic and bland.

Advantages:

- Soothing effect
- Good patient acceptance

Disadvantages:

- Polymorphism (changes in melting point)
- Softens easily at high temperature
- Poor water absorption

B. ***Water-Soluble and Water-Miscible Bases***

These bases dissolve in body fluids instead of melting.

1. Glycerinated Gelatin

- Contains gelatin, glycerin, and water.
- Mainly used for vaginal suppositories.

Advantages:

- Prolonged action
- Does not melt at room temperature

Disadvantages:

- Hygroscopic (absorbs moisture)
- May cause irritation
- Requires preservatives

2. Polyethylene Glycol (PEG) Bases

- Synthetic, available in various molecular weights.
- Melting depends on molecular weight.

Advantages:

- Chemically stable
- No need for refrigeration
- Suitable for tropical climates

Disadvantages:

- May cause irritation
- Slow drug release

1. ***Methods of Preparation of Suppositories***

A. **Hand Molding Method**

- Oldest method.
- Base is softened and mixed with drug.
- Molded by hand into suppository shape.

Limitations:

- Non-uniform weight
- Not suitable for large-scale production

B. *Fusion (Molding) Method*

- Most widely used method.

Steps:

1. Base is melted on a water bath.
2. Drug is dissolved or dispersed in molten base.
3. The mixture is poured into lubricated molds.
4. Allowed to cool and solidify.
5. Suppositories are removed and packed.

Advantages:

- Uniform shape and weight
- Suitable for most bases

C. ***Compression Method***

- Used when drug is sensitive to heat.

Steps:

- Drug and base are blended.
- Compressed into suppositories using special machines.

Advantages:

- No heat involved
- Suitable for thermolabile drugs

DISPLACEMENT VALUE

Displacement value (DV) is defined as the number of parts by weight of drug that displace one part by weight of the suppository base.

It helps in calculating the exact quantity of base required when a drug is incorporated.

Importance of Displacement Value

- Ensures uniform weight and dose.
- Prevents over- or under-filling of molds.

Calculation of Displacement Value

Formula:

$$\text{Weight of base required} = \text{Weight of blank suppository} - \frac{\text{Weight of drug}}{\text{Displacement value}}$$

EVALUATION OF SUPPOSITORIES

Evaluation ensures quality, safety, and therapeutic efficacy.

1. *Appearance and Shape*
   - Should be smooth, uniform, and free from cracks or air bubbles.
2. *Weight Variation Test*
   - Weigh individual suppositories.
   - Weight variation should be within pharmacopeial limits.
3. *Melting Point / Softening Time*
   - Determines how quickly suppository melts or softens at body temperature.
4. *Disintegration Test*
   - Time taken to disintegrate or dissolve in simulated body fluids.
5. *Drug Content Uniformity*
   - Each suppository should contain uniform drug quantity.
6. *Breaking Strength (Hardness Test)*
   - Measures mechanical strength to withstand handling.
7. *Liquefaction Time*
   - Time taken for suppository to liquefy at 37°C under specified conditions.
8. *Stability Studies*
   - Evaluates effect of temperature, humidity, and storage conditions.

Suppositories are valuable dosage forms offering an alternative route of drug administration. Proper selection of base, accurate calculation of displacement value, suitable preparation method, and thorough evaluation are essential to ensure quality, stability, and therapeutic effectiveness.

Points to be Remembered

- **Ointments & Creams:** Understand the classification of **ointment bases** and the general preparation methods for pastes, creams, and gels.
- **Suppositories/Pessaries:** Memorize the properties of an **ideal suppository base** and the concept of **displacement value**.
- **Formulation:** Focus on why specific excipients are chosen for semisolids to ensure proper consistency and drug release.

Level 1: Remember (Knowledge)

1. **Which semisolid dosage form contains a high percentage (up to 50%) of finely divided solids?**

A) Ointment

B) Paste

C) Cream

D) Gel

Ans: B

2. **The term 'Pessaries' refers to suppositories intended for:**

A) Rectal use

B) Vaginal use

C) Nasal use

D) Aural use

Ans: B

3. **Which of the following is a 'Hydrocarbon' base?**

A) Wool fat

B) Soft paraffin

C) Polyethylene glycol

D) Bentonite

Ans: B

4. **'Cold cream' is an example of which type of emulsion?**

A) o/w

B) w/o

C) Multiple emulsion

D) Micro-emulsion

Ans: B

5. **The most commonly used base for rectal suppositories is:**

A) Glycerogelatin

B) Theobroma oil (Cocoa butter)

C) PEG

D) Beeswax

Ans: B

6. **A 'Gel' is a semisolid system consisting of a network of:**

A) Small molecules

B) Large organic or inorganic molecules interpenetrated by a liquid

C) Pure oil

D) Compressed powder

Ans: B

7. **The process of decreasing the particle size of a drug by grinding it with a small amount of liquid in which it is insoluble is:**

A) Trituration

B) Levigation

C) Maceration

D) Sifting

Ans: B

8. **Which base is also known as 'Adeps Lanae'?**

A) Paraffin

B) Wool fat

C) Lanolin

D) Cetostearyl alcohol

Ans: B

9. **The term used for a base that is easily removed from the skin by washing with water is:**

A) Oleaginous base

B) Water-removable base

C) Absorption base

D) Hydrocarbon base

Ans: B

10. **The solidification of a gel into a rigid mass upon standing is called:**

A) Syneresis

B) Swelling

C) Imbibition

D) Thixotropy

Ans: A (Syneresis is the squeezing out of liquid; Thixotropy is the reversible gel-sol transition).

Level 2: Understand (Comprehension)

11. **What is the primary difference between a Cream and an Ointment?**

A) Creams are always greasy

B) Creams are emulsions (viscous liquids/semisolids); Ointments are usually anhydrous fatty bases

C) Ointments are for internal use

D) There is no difference

Ans: B

12. **Why is Cocoa Butter (Theobroma oil) considered an ideal suppository base?**

A) It is very cheap

B) It melts at body temperature ($30^\circ C$ to $35^\circ C$)

C) It is a liquid at room temperature

D) It is blue in color

Ans: B

13. **What is the purpose of 'Absorption bases'?**

A) To absorb all the medicine into the blood

B) To allow the incorporation of aqueous solutions into oleaginous bases

C) To make the ointment smell better

D) To prevent the skin from breathing

Ans: B

14. **Why are 'Pastes' less greasy than 'Ointments'?**

A) They contain more water

B) They contain a high concentration of insoluble solids that absorb the base

C) They contain alcohol

D) They are used only on hair

Ans: B

15. **What is 'Displacement Value' in suppository formulation?**

A) The speed at which the suppository is inserted

B) The quantity of the drug that displaces one part of the base

C) The time it takes for the base to melt

D) The price of the base

Ans: B

Level 3: Apply (Application)

16. **If a drug is heat-labile (destroyed by heat), which method should be used to prepare an ointment?**

A) Fusion method

B) Trituration method

C) Chemical reaction method

D) Boiling method

Ans: B

17. **A pharmacist needs to incorporate 10 ml of water into White Soft Paraffin. What should be added?**

A) More paraffin

B) An absorption base like Wool fat

C) Alcohol

D) Sand

Ans: B

18. **Which base would you choose for a suppository that needs to provide a prolonged release of a drug?**

A) Cocoa Butter

B) Glycerogelatin base

C) Simple Paraffin

D) Water

Ans: B

19. **Calculate the amount of base required for 10 suppositories (each 1g) containing 100mg of drug (Displacement Value = 2):**

A) 9.0 g

B) 9.5 g

C) 10.0 g

D) 8.5 g

Ans: B (Formula: $Total Base - (Total Drug / DV) \rightarrow 10 - (1/2) = 9.5$)

20. **Which levigating agent is most suitable for an ointment containing Sulfur and White Petrolatum?**

A) Water

B) Mineral Oil (Liquid Paraffin)

C) Alcohol

D) Glycerin

Ans: B

Level 4: Analyze (Analysis)

21. **Analyze why 'Fusion Method' is used when an ointment contains high-melting-point solids like beeswax:**

A) To make the ointment harder

B) To ensure a uniform distribution by melting all components together

C) To kill bacteria

D) To make the ointment transparent

Ans: B

22. **Compare 'Vanishing Cream' and 'Cold Cream'. What makes the former "vanish"?**

A) It contains invisible ink

B) It is an o/w emulsion that leaves a thin, non-greasy film as water evaporates

C) It is absorbed instantly into the bone

D) It is a clear gel

Ans: B

23. **Identify the consequence of 'Polymorphism' in Cocoa Butter:**

A) It changes color

B) Overheating causes it to solidify at a much lower temperature, making it useless for suppositories

C) It becomes more expensive

D) It becomes toxic

Ans: B

24. **Why are 'Gels' often preferred for topical delivery of anti-inflammatory drugs?**

A) They are easy to wash off and provide a cooling effect

B) They are very greasy

C) They stay on the skin for 5 days

D) They are only for internal use

Ans: A

25. **What is the role of 'Antioxidants' in ointment bases containing natural fats?**

A) To provide color

B) To prevent rancidity and oxidative degradation

C) To increase the melting point

D) To improve the smell

Ans: B

Level 5: Evaluate (Evaluation)

26. **Evaluate the use of 'Rectal Suppositories' for a patient who is vomiting:**

A) It is a poor choice

B) It is an excellent choice as it avoids the stomach and first-pass metabolism

C) It will make the vomiting worse

D) It is only used for local pain

Ans: B

27. **Why must suppositories be slightly lubricated before insertion (if using certain bases)?**

A) To make them taste better

B) To prevent them from sticking to the mold and to facilitate easy insertion

C) To change the color

D) To prevent the drug from leaking

Ans: B

28. **Assess the importance of 'Storage Conditions' for suppositories:**

A) They can be stored anywhere

B) They must be stored in a cool place (refrigerator) to prevent melting or deformation

C) They should be stored in direct sunlight

D) They should be kept in a hot oven

Ans: B

29. **Which is a more critical evaluation parameter for an ointment?**

A) Color

B) Spreadability and consistency

C) Price

D) The shape of the jar

Ans: B

30. **Judge the suitability of 'Pastes' for treating 'oozing' or 'weeping' skin lesions:**

A) Poor; they will slide off

B) Excellent; the high powder content absorbs the serous secretions

C) Only if they are hot

D) They should never be used on skin

Ans: B

Level 6: Create (Synthesis)

31. **Propose a labeling instruction for a 'Suppository':**

A) "Shake well"

B) "FOR RECTAL USE ONLY - Store in a cool place"

C) "Dilute with water"

D) "Apply with friction"

Ans: B

32. **If a formulation requires a 'Water-soluble' base that does not stain clothes, which would you choose?**

A) Soft Paraffin

B) Macrogols (PEG)

C) Lanolin

D) Beeswax

Ans: B

33. **Develop a plan to incorporate a volatile oil into a fusion-method ointment:**

A) Add it at the beginning with the waxes

B) Add it at the end when the mixture is cooling but still fluid

C) Boil it with the base

D) Do not add it at all

Ans: B

34. **How would you design a 'Mould' for a suppository to ensure uniform weight?**

A) Make it by hand

B) Use a calibrated metal or plastic mold with specific volume

C) Use a spoon

D) Use a syringe

Ans: B

35. **Create a quality control test to check if a suppository will melt inside the body:**

A) Friability test

B) Melting point or liquefaction time test

C) Color test

D) Taste test

Ans: B

Mixed Bloom's Levels (36-50)

36. **'Yellow Soft Paraffin' is also known as:**

A) Petrolatum

B) Vaseline

C) Both A and B

D) Wool fat

Ans: C

37. **'Lanolin' is:**

A) Hydrous wool fat

B) Anhydrous wool fat

C) Liquid paraffin

D) Hard wax

Ans: A

38. **Which of the following is a 'Preservative' used in semisolids?**

A) Methyl paraben

B) Starch

C) Talc

D) Water

Ans: A

39. **The 'fusion temperature' should be:**

A) As high as possible

B) The minimum required to melt the component with the highest melting point

C) $100^\circ C$ always

D) $0^\circ C$

Ans: B

40. **'Glycerogelatin' suppositories are commonly used for:**

A) Cough

B) Laxative effect or as a base for pessaries

C) Eye infections

D) Muscle pain

Ans: B

41. **'Clarity' is a critical requirement for:**

A) Ointments

B) Clear Gels

C) Pastes

D) Suppositories

Ans: B

42. **A 'Poultice' is a:**

A) Hard tablet

B) Soft, moist mass applied to the skin (usually hot)

C) Liquid drink

D) Type of gas

Ans: B

43. **Which base is most likely to cause 'occlusion' (blocking moisture loss from skin)?**

A) PEG base

B) Hydrocarbon base (Paraffin)

C) Water-soluble base

D) Glycerin

Ans: B

44. **'Stiffness' of a paste is due to:**

A) High solid content

B) High water content

C) Alcohol

D) Being kept in a fridge

Ans: A

45. **Suppositories are often shaped like a:**

A) Square

B) Torpedo or Bullet

C) Flat disc

D) Triangle

Ans: B

46. **'White ointment' contains:**

A) Yellow wax

B) White wax and White petrolatum

C) Only water

D) Zinc oxide

Ans: B

47. **'Nasal bougies' are:**

A) Ear drops

B) Suppositories for the nose

C) Throat sprays

D) Eye washes

Ans: B

48. **'Tallow' is a fat obtained from:**

A) Plants

B) Animals (sheep or cattle)

C) Petroleum

D) Synthetic chemicals

Ans: B

49. **'Urethral bougies' are intended for the:**

A) Ear

B) Urethra

C) Rectum

D) Vagina

Ans: B

50. **'Simple Ointment IP' contains:**

A) Wool fat, Hard paraffin, Cetostearyl alcohol, and White/Yellow soft paraffin

B) Just water and sugar

C) Only soft paraffin

D) Only beeswax

Ans: A

Objective Type (2 Marks - Remember/Understand)

1. Define 'Ointment'.
2. What is a 'Suppository'?
3. Define 'Displacement Value'.
4. Name two types of ointment bases.
5. What is a 'Pessary'?
6. Define 'Paste'.

7. What is a 'Gel'?
8. Mention one ideal characteristic of a suppository base.
9. What is 'Cream'?
10. Name a commonly used suppository base.
11. Define 'Absorption Base'.
12. What is the use of a 'Levigating Agent'?
13. List two advantages of suppositories.
14. Define 'Water-soluble Base'.
15. What is 'Cold Cream'?
16. Define 'Vanishing Cream'.
17. What is a 'Hydrocarbon Base'?
18. Mention one disadvantage of semisolid dosage forms.
19. What is 'Theobroma Oil'?
20. Define 'Fusion Method' in ointment preparation.

Short Answer (5 Marks - Understand/Apply)

1. Classify ointment bases and give examples of each.
2. Explain the method of preparation of ointments by the Trituration method.
3. Describe the different types of suppositories based on the route of administration.
4. Discuss the calculation of displacement value with an example.

5. Compare the properties of pastes, creams, and gels.
6. Explain the preparation of suppositories by the Fusion (Hot) method.
7. Discuss the various excipients used in semisolid dosage forms.
8. Describe the ideal properties of a suppository base.
9. Explain the classification and advantages of jellies.
10. Discuss the storage and packaging of semisolid preparations.

Long Answer (10 Marks - Analyze/Evaluate)

1. Discuss in detail the classification, formulation, and preparation of ointments.
2. Explain the formulation and manufacturing of various types of suppositories and pessaries.
3. Analyze the factors influencing drug penetration through the skin from semisolid dosage forms.
4. Evaluate the different types of suppository bases and their selection criteria.
5. Discuss the formulation and evaluation of cosmetic creams (Cold cream and Vanishing cream).
6. Analyze the importance of displacement value in the accurate dosing of suppositories.
7. Describe the preparation and clinical applications of various types of pastes and gels.
8. Evaluate the stability issues and preservation of semisolid dosage forms.

9. Discuss the Fusion method vs. Cold compression method for suppository preparation.

10. Elaborate on the role of emulsifying agents and humectants in semisolid formulations.

Case-Based Learning (CBL)

1. **Ointment vs. Cream:** A patient with very dry, scaly skin is asking for a "non-greasy" cream.

- **Solution:** For scaly/dry skin (chronic lesions), an **ointment** (oleaginous base) is better as it provides occlusion and hydration. Creams are better for moist/weeping wounds.

2. **Suppository Melting:** A patient complains that their suppositories melted in the car.

- **Solution:** Suppositories are designed to melt at body temperature (). They must be stored in a cool place (refrigerator) and can be hardened by holding the foil under cold water before use.

3. **Paste Application:** Why use a paste instead of an ointment for a diaper rash?

- **Solution: Pastes** contain a high percentage of solids (e.g., Zinc Oxide), making them more porous and better at absorbing secretions while providing a thick protective barrier.

Problem-Based Learning (PBL)

1. **Displacement Value:** You need to make 10 suppositories (1g each) containing 200mg of a drug (D.V. = 2). Calculate the base needed.

- **Solution:** Total drug = 2g. Weight displaced = . Base needed = of cocoa butter.

2. **Base Selection:** Which base would you choose for a water-washable ointment?

- **Solution: Water-removable bases** (e.g., Hydrophilic Ointment) or **Water-soluble bases** (e.g., PEG), which allow easy removal from skin/clothing.

3. **Suppository Base Comparison:** Compare Theobroma Oil (Cocoa Butter) with Synthetic bases.

- **Solution:** Cocoa butter shows polymorphism (melts too easily if overheated), whereas synthetic bases (like Witepsol) are more stable and don't require careful temperature control during melting.