CHAPTER 13
SEMI-SOLID PREPARATIONS: CREAMS, OINTMENTS AND GELS

Mrs. Deepika
Assistant Professor, School of Pharmaceutical Sciences, Faculty of Pharmacy, IFTM University, Moradabad

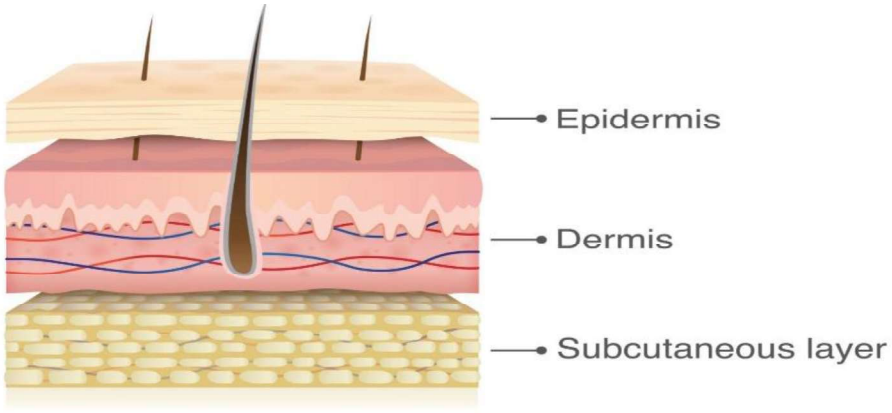
13.1 Introduction

Semi-solid preparations represent a significant category of pharmaceutical dosage forms designed primarily for topical application to the skin and mucous membranes. These systems possess a consistency that allows them to remain at the site of application for extended periods, thereby providing sustained therapeutic action. Unlike oral dosage forms, semi-solids bypass the gastrointestinal tract and first-pass metabolism, offering advantages in localized therapy and reduced systemic side effects.

The therapeutic effectiveness of semi-solid formulations depends not only on the pharmacological activity of the drug but also on the characteristics of the base and excipients used. The base determines spreadability, occlusiveness, hydration effect, and rate of drug release. The rheological behavior of the formulation influences ease of application and patient acceptance.

In modern pharmaceutics, semi-solid systems are also used in transdermal therapy to deliver drugs systemically through the skin. Advances in polymer science, nanotechnology, and permeation enhancement have expanded the potential of semi-solid dosage forms beyond traditional dermatological uses.

13.2 Skin Structure and Drug Penetration



The skin functions as a complex protective barrier and consists of three major layers: epidermis, dermis, and subcutaneous tissue. The outermost part of the

epidermis, the stratum corneum, is composed of dead keratinized cells embedded in a lipid matrix. This structure is often described as a “brick and mortar” arrangement, where corneocytes represent bricks and lipids serve as mortar.

The stratum corneum is the principal barrier to drug penetration. Only molecules with appropriate physicochemical properties, such as moderate lipophilicity and low molecular weight, can effectively penetrate this barrier. The dermis contains capillaries and nerve endings, and drugs reaching this layer may enter systemic circulation.

Drug penetration occurs through transcellular, intercellular, and appendageal pathways. Hydration of the stratum corneum enhances permeability by loosening lipid structures. Occlusive ointments increase hydration and thus enhance drug absorption.

Formulation strategies such as inclusion of permeation enhancers, use of nanoparticles, and optimization of drug concentration gradients are employed to improve penetration efficiency. Understanding these mechanisms is fundamental in designing effective semi-solid formulations.

13.3 Ointments

13.3.1 Definition and Characteristics

Ointments are viscous, greasy, semi-solid preparations intended for application to skin or mucous membranes. They contain little or no water and are typically based on hydrocarbon materials. Due to their occlusive nature, ointments reduce moisture loss and create a protective barrier over the skin.

The occlusive effect increases hydration of the stratum corneum, enhancing drug penetration. Ointments are particularly beneficial in chronic dry skin conditions such as psoriasis or eczema. Their hydrophobic nature also protects them from environmental irritants.

However, ointments may feel heavy and sticky, which can limit patient acceptance, especially in hot climates or when applied to visible areas.

13.3.2 Types of Ointment Bases

Types of Ointment Bases

Type of Ointment Base	Characteristics	Applications	Examples
Hydrocarbon / Oleaginous	•Anhydrous • Water insoluble • Not water washable • Form occlusive film on skin	• Incorporation of hydrophobic drugs	• Petrolatum • Wax • Synthetic esters (e.g., glycerol monostearate)
Absorption	• w/o emulsions or oleaginous bases that allow incorporation of aqueous solution to form w/o emulsions • Not easily water washable	• Emollients	• Anhydrous: hydrophilic petrolatum and anhydrous lanolin • w/o emulsion: lanolin and cold cream
Emulsion	• o/w emulsions • Leave a hydrophobic film on the surface of the	• Drug carriers • Foundation for makeup	• Hydrophilic ointment • Vanishing cream

	skin when water evaporates		
Water Soluble	• Hydrophilic polymer (e.g., PEG) mixture	• Drug carriers	• PEG 400 + PEG 4000 in 40:60 ratio • Propylene glycol + ethanol with 2% w/w HPC

- Hydrocarbon bases, such as white petrolatum, are chemically inert and highly occlusive. They do not absorb water and provide maximum emollient effect.
- Absorption bases can incorporate small amounts of aqueous solutions and are useful when hydrophilic drugs need to be included in an oleaginous system.
- Water-removable bases are oil-in-water emulsions that can be washed off with water. They combine the advantages of ointments and creams.
- Water-soluble bases contain polyethylene glycol and are completely washable. They are non-greasy and suitable for water-soluble drugs.
- The selection of the base directly influences drug release rate, stability, and patient compliance.
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13.3.3 Preparation of Ointments

Ointments are prepared either by incorporation or fusion methods. In the incorporation method, the finely powdered drug is blended with the base using geometric dilution. Levelling agents may be used to improve smoothness.

In the fusion method, components are melted in descending order of melting point and mixed thoroughly. The mixture is stirred during cooling to ensure uniformity. Industrial production involves mechanical mixers, ointment mills, and vacuum homogenizers to achieve a smooth texture and eliminate air entrapment

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13.3.4 Evaluation of Ointments

Evaluation includes examination of homogeneity, absence of grittiness, consistency, spreadability, drug content uniformity, and microbial limits. Rheological studies determine flow behavior, which influences ease of application.

In vitro drug release testing assesses the rate at which the drug diffuses from the base. Stability testing under various temperature conditions ensures long-term quality.

13.3.5 Advantages and Limitations

Ointments provide prolonged contact with the skin and enhanced drug penetration. They protect the skin from moisture loss. However, they may cause discomfort due to greasiness and may stain clothing.

13.4 Creams

13.4.1 Definition and Characteristics

Creams are semi-solid emulsions containing both oil and water phases. They are lighter in consistency compared to ointments and are more cosmetically acceptable. Creams spread easily and are suitable for application on large areas.

Because they contain water, creams may provide a cooling sensation upon application. They are suitable for both dry and moist lesions, depending on the formulation type.

13.4.2 Types of Creams

Oil-in-water creams contain oil dispersed in water and are easily washable. They are suitable for inflamed or exudative conditions. Water-in-oil creams contain water dispersed in oil and provide better emollient and occlusive properties.

Choice of cream type depends on therapeutic needs and patient preference.

13.4.3 Preparation of Creams

Creams are prepared by separately heating oil and aqueous phases and then mixing them at equal temperatures. Emulsifying agents stabilize the system by forming a protective film around droplets.

High-shear mixing and homogenization improve uniformity and stability. Cooling under continuous agitation prevents phase separation.

13.4.4 Evaluation of Creams

Evaluation parameters include pH measurement, viscosity determination, globule size analysis, spreadability, drug content uniformity, and stability studies. Microbial testing is essential due to the aqueous content.

Rheological studies assess consistency and flow behavior, which influence application properties.

13.4.5 Advantages and Disadvantages

Creams are aesthetically pleasing and easy to apply. However, the presence of water may lead to microbial growth and shorter shelf life if not properly preserved.

13.5 Gels

Gels are versatile semi-solid systems in which a liquid phase is immobilized within a three-dimensional polymeric network. This network structure traps large amounts of solvent, usually water, producing a formulation that appears solid-like but flows under applied stress. Because of their high water content and non-greasy nature, gels are among the most cosmetically elegant topical dosage forms and are widely used in dermatology, cosmetology, ophthalmology, and even for transdermal drug delivery.

The unique structural arrangement of gels allows rapid drug release and uniform application. Their clarity or translucency enhances patient acceptability, particularly for facial or exposed skin areas. In addition, gels provide a cooling sensation upon application due to evaporation of water, which makes them suitable for inflammatory and painful conditions.

13.5.1 Definition and Structural Characteristics

A gel can be defined as a semi-solid system consisting of either small inorganic particles or large organic molecules interpenetrated by a liquid. The rigidity of a gel is attributed to the interconnected network of polymer chains that restricts the movement of the solvent.

The structure of gels may be classified as either single-phase or two-phase systems. In single-phase gels, the polymer is uniformly distributed throughout the liquid phase at the molecular level. In two-phase systems, the gel consists of a flocculated network of particles dispersed in a continuous liquid phase.

The rheological behavior of gels is typically non-Newtonian and exhibits pseudoplastic or plastic flow. This means that viscosity decreases with increasing shear stress, allowing easy spreading during application while maintaining consistency at rest.

13.5.2 Types of Gels

Gels may be broadly classified into hydrogels and organogels. Hydrogels contain water as the continuous phase and are the most common type used in pharmaceutical preparations. They are suitable for hydrophilic drugs and provide cooling and soothing effects.

Organogels contain organic solvents such as alcohol or oils as the continuous phase. These systems are used when the drug is lipophilic or when enhanced penetration through the skin is required.

Gels may also be categorized as biodegradable gels, thermosensitive gels, and bioadhesive gels depending on their functional characteristics. Thermosensitive gels remain liquid at room temperature and gel at body temperature, making them useful for ophthalmic and nasal delivery systems.

13.5.3 Gelling Agents

The formation of gels depends on gelling agents, which are polymers capable of swelling and forming a network structure. Common gelling agents include carbomers, hydroxypropyl methylcellulose, sodium carboxymethyl cellulose, poloxamers, and natural polymers such as xanthan gum and alginates.

Carbomers are widely used due to their high viscosity at low concentrations and clarity. Cellulose derivatives provide stable and biocompatible gel systems. Poloxamers are thermoreversible polymers used in temperature-sensitive gels.

The choice of gelling agent influences viscosity, clarity, drug release rate, and stability of the final product.

13.5.4 Preparation of Gels

Gel preparation involves dispersing the polymer in the liquid medium and allowing it to hydrate fully. For carbomer-based gels, neutralization with an

alkaline agent such as triethanolamine induces gel formation by ionizing the polymer and causing chain expansion.

Uniform mixing is essential to prevent lump formation. The drug may be dissolved in the solvent before polymer addition or dispersed within the gel matrix, depending on solubility characteristics.

Careful control of pH is crucial because the viscosity and stability of many gels are pH-dependent. Industrial production utilizes high-shear mixers and vacuum systems to remove entrapped air and ensure uniformity.

13.5.5 Evaluation of Gels

Evaluation of gels includes determination of viscosity, pH, drug content uniformity, clarity, spreadability, and in vitro drug release. Rheological studies assess flow properties and thixotropic behavior, which are important for ease of application.

In vitro diffusion studies using synthetic membranes or excised animal skin evaluate drug release and penetration characteristics. Stability studies assess changes in viscosity, color, and drug content under accelerated conditions.

Microbial limit testing is essential because the high water content of hydrogels may support microbial growth.

13.5.6 Advantages and Limitations

Gels offer numerous advantages, including non-greasy texture, ease of removal, rapid drug release, and high patient acceptability. They are especially suitable for acne treatment, anti-inflammatory therapy, and cosmetic formulations.

However, gels may lack occlusive properties and are less suitable for very dry or scaly skin conditions. They may also dry out upon exposure to air if not properly packaged.

13.6 Stability of Semi-Solid Preparations

Stability is a critical aspect of semi-solid formulations. These preparations may undergo both physical and chemical instability during storage. Physical instability includes phase separation in creams, syneresis in gels, and changes in consistency in ointments.

Chemical degradation of active ingredients may occur due to oxidation, hydrolysis, or photodegradation. The presence of water in creams and gels increases susceptibility to hydrolytic degradation. Antioxidants and preservatives are incorporated to enhance stability.

Microbial contamination is a major concern, particularly in aqueous systems. Preservatives such as parabens or benzyl alcohol are added to inhibit microbial growth. Packaging in air-tight, light-resistant containers minimizes exposure to environmental factors.

Accelerated stability testing under controlled temperature and humidity conditions predicts shelf life. Parameters monitored include pH, viscosity, color, odor, drug content, and microbial limits.

13.7 Conclusion

Semi-solid preparations such as gels, creams, and ointments are indispensable in topical and transdermal drug delivery. Their therapeutic effectiveness depends on the proper selection of base, understanding of skin physiology, and optimization of formulation variables.

Gels provide rapid drug release and cosmetic elegance, creams offer balanced hydration and patient comfort, and ointments ensure maximum occlusion and enhanced penetration. Each system has distinct advantages and limitations that must be considered during formulation design.

Comprehensive evaluation and stability testing ensure safety, efficacy, and quality of semi-solid products. With advancements in polymer science and drug delivery technologies, semi-solid preparations continue to evolve, offering innovative solutions for localized and systemic therapy.