Chapter 10 - OINTMENTS, CREAMS, GELS

INTRODUCTION
Ointments, Creams, and Gels – TOPICAL APPLICATION

- to the skin
- place on the surface of the eye
- vaginally, nasally, rectally

TOPICAL DERMATOLOGICAL designed to deliver drug into the skin – dermal disorders (SKIN AS TARGET ORGAN)

TRANSDERMAL designed to deliver drug through skin (percutaneous absorption) – general circulation – SKIN NOT BEING THE TARGET ORGAN

NOTE: SYSTEMIC ABSORPTION – always considered

OINTMENTS

- Unguent are semisolid preparations for external application of such consistency that they maybe readily applied to the skin with or without inunction (rubbing)
- Ointments should be of such composition that they soften but not necessarily melt when applied to the body.

General Uses Of Ointments
1. Acts as protective or protectant - serve as physical barrier to environment
2. Acts as emollient - softens skin and makes it pliable
3. Carrier of medicament - vehicle

Types Of Ointments
1. Medicated - those with medicaments for treatments of cutaneous (skin diseases).
   Examples: Sulfur Ointment, Zinc Oxide Ointment and Compound Resorcinol
2. Non-medicated - also referred to as “ointment bases” and use as such for their emollient or lubricating effect or use as vehicles in medicated ointments.
   Example: White Ointment

The USP and NF Classify Ointment Bases Into Four General Groups
a. Hydrocarbon bases or Oleaginous bases
b. Absorption bases
c. Water removable bases or Emulsion Ointment bases
d. Water soluble bases

Factors of selecting ointment bases
a. Physicochemical properties of the medicaments as stability in the base or influence on consistency
b. Patient’s conditions – as to the desired release rate of the drug from the base
c. Intended site of application – ability of occlusion of moisture from the skin by the base
d. Characteristics of the various vehicles available – use the one which provided the majority of essential attributes

Types of bases
1. HYDROCARBON BASES
   - are water-free, and aqueous preparations may only be incorporated into them in small amounts and then with difficulty
   - USES: HC are use mainly for their emollient effect and not intended for penetration into the skin. They are difficult to wash off. They do not “dry out” or change noticeably upon aging.
   - Characteristics
     a. Retained on the skin for prolong period of time
     b. Do not permit the escape of moisture to the skin to the atmosphere
     c. Difficult to wash as such they acts as occlusive dressing

2. OFFICIAL ABSORPTION BASES
   - 2 TYPES
     - Those that permit the incorporation of aqueous solutions resulting in the

- Sources Of Hydrocarbon Bases
  a. Vegetable Oil - Mineral oil
  b. Animal Fat - Oleic oil
  c. HC from Petrolatum

- 3 Forms of HC
  a. Liquid hydrocarbon - Mineral oil
  b. Semi-solid HC petrolatum – Vaseline
  c. Solid HC - Paraffin

- Examples
  a. White Petrolatum
  b. White Ointment
  c. Vegetable shortening
  d. Vaseline

- Examples Of Hydrocarbon Bases
  > Petrolatum, NF - mixture of semisolid HC obtained from petroleum
    Properties: An unctous mass, color yellowish to light amber, melts between 38°C - 60°C
    Synonym: Yellow petrolatum, Petroleum jelly
    Commercial Product: Vaseline
  > White Petroleum Jelly, USP - petrolatum that has been decolorized
    Uses: diaper rash, dry skin
    Synonym: White Petroleum Jelly
    Commercial Product: White Vaseline
  > Yellow Ointment - Each 100 g contains 5 g yellow wax and 95 g of petroleum. Yellow wax is purified wax obtained from honeycomb of the bee (Apis mellifera)
    Synonym: Simple Ointment
  > White Ointment, USP - 100 g contains 5% of white wax (bleached purified beeswax) and 95% white petrolatum
  > Paraffin, NF - is a purified mixture of solid HC obtained from petroleum
    Characteristics: colorless or white, more or less translucent mass that may be used to harden or stiffen oleaginous semisolid ointment bases.
    > Mineral Oil, USP - is a mixture of liquid HC obtained from petroleum. Useful in levigating of substances insoluble in it in the preparation of ointment base e.g. Salicylic acid, Zinc oxide
    Synonym: Liquid Petroleum
  > Olive Oil, USP - from crushed olives- also called sweet oil

- 2 TYPES
  > Those that permit the incorporation of aqueous solutions resulting in the
formation of water-in-oil emulsion.

**Anhydrous absorption bases**

i. Insoluble in water
ii. Not water washable
iii. Anhydrous
iv. Can absorb water
v. Emollient
vi. Occlusive
vii. Greasy

*Examples:* Hydrophilic Petrolatum and Anhydrous Lanolin

>Those that are already **water-in-oil emulsion** (emulsion base) that permits the incorporation of small additional quantities of aqueous solution

- **Characteristics**
  a. Insoluble in water
  b. Not water washable
  c. Contains water (limited)
  d. Emollient
  e. Occlusive
  f. Greasy

*Examples:* Lanolin and Cold cream; water soluble drugs: Gentamycin Sulfate

- **Characteristics**
  a. Not easily removed from skin with water washing
  b. May possess some power of penetration into the deepest layers of the skin
  c. Used for *“endodermic”* ointment

- **USES**
  >As emollient but do not provide the degree of occlusion
  >Incorporates aqueous solutions into oleaginous bases

- **EXAMPLES OF ABSORPTION BASES**
  a. **Hydrophilic Petrolatum, USP** - composed of cholesterol, stearyl alcohol, white wax and white petrolatum
     *Example:* Aquaphor
  b. **Anhydrous Lanolin, USP** - may contain NMT 0.25% water.
     *Characteristics:* It is insoluble in water but mixes without separation with about 2x its weight in water. The incorporation of water results in the formation of a W/O emulsion
     *Synonym:* Refined Wool Fat
  c. **Lanolin, USP** - is a semisolid fat like substance obtained from the wool of sheep (Ovis aries)
     *Characteristics:* It is a W/O emulsion that contains between 25 to 30% water. Additional water may be incorporated into lanolin by mixing
     *Synonym:* Hydrous Wool Fat
  d. **Cold Cream, USP** - is a semi solid white W/O emulsion prepared with cetyl esters

- **USES**
  >As emollient but do not provide the degree of occlusion
  >Incorporates aqueous solutions into oleaginous bases

- **EXAMPLES OF ABSORPTION BASES**
  a. **Hydrophilic Petrolatum, USP** - is **“water loving”**. It contains sodium lauryl sulfate as the emulsifying agent, with stearyl alcohol and white petrolatum representing the oleaginous phase of emulsion and propylene glycol and water representing the aqueous phase. Methyl and Propyl parabens are used as preservatives
    a. Hydrophilic Ointment
    b. Vanishing Cream
    c. Dermabase
    d. Velvachol
    e. Unibase
  - **USE:** employed as water removable vehicle for medicinal substances

4. **WATER SOLUBLE BASE**

Unlike water-removable bases, which contains both water soluble and water insoluble components. Like water-removable bases, however, water soluble bases are water washable and are commonly referred to as *“greaseless”* because of the absence of any oleaginous materials

- **Characteristics**
  a. Because they soften greatly with the addition of water, aqueous solutions are not effectively incorporated into these bases. Rather, they are better used for the incorporation of non-aqueous or solid substance.
  b. These penetrated the skin and better used for absorption of medicament and therefore used for *“diadermic ointment”.*
  c. Water soluble

3. **WATER REMOVABLE BASE**

Are oil-in-water emulsion that are capable of being washed from skin or clothing with water. For this reason, they are frequently referred to as *“water-washable”* ointment base.

- **USES**
  a. Resemble creams in their appearance
  b. May be diluted with water or with aqueous solution
  c. From therapeutic viewpoint, no ability to absorb serous discharge in dermatologic conditions
  d. Certain medicinal agents may be better absorbed in the skin
  e. Insoluble in water
  f. Water washable
  g. Contains water
  h. Can absorb water
  i. Non-occlusive
  j. Non-greasy

- **Example:**
  *Hydrophilic Ointment, USP* - is *“water loving”*. It contains sodium lauryl sulfate as the emulsifying agent, with stearyl alcohol and white petrolatum representing the oleaginous phase of emulsion and propylene glycol and water representing the aqueous phase. Methyl and Propyl parabens are used as preservatives
  a. Hydrophilic Ointment
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- **USE:** employed as water removable vehicle for medicinal substances

- **EXAMPLES:**
  - Eucerin cream - is a W/O emulsion of petrolatum, mineral oil, mineral wax, wool wax, alcohol and bronopol. Cold cream - emollient and base.
Preparation of Ointment

SELECTION OF THE APPROPRIATE BASE

1. Water washable
2. May contain water
3. Can absorb water (limited)
4. Non-occlusive
5. Non-greasy
6. Lipid-free

Example: Polyethylene Glycol Ointment, USP is a combination of 400 g of polyethylene glycol 4000 (solid) and 600 g of polyethylene glycol 400 (liquid) to prepare 1000 g of base.

Incorporation Of Liquids

Example: Betamethasone Valerate Ointment – must be absence of Staphylococcus aureus and Pseudomonas aeruginosa

PACKAGING AND STORAGE OF OINTMENTS

Semisolid pharmaceuticals frequently either in jars or in tubes. The jars may be made of glass, uncolored, colored green, amber or blue or opaque and porcelain white. Plastic jars are used in limited extent. The tubes are made of tin or plastic. These are called “collapsible tube”.

TESTS REQUIREMENTS FOR OINTMENTS

1. Microbial Content
   - Meet acceptable standard for microbial
   - Must contain antimicrobial preservatives

   Preservatives: methylparaben, propyl paraben, phenols, benzoic acid, sorbic, quaternary ammonium salts

   Example: Betamethasone Valerate Ointment – must be absence of Staphylococcus aureus and Pseudomonas aeruginosa

2. Minimum Fill Test – net weight and volume
3. Packaging, Storage, and Labeling
   a. metal, plastic tubes, jar
   b. Well close containers, light sensitive, light resistant
   c. Labeling-type of base used (water soluble or insoluble)

4. Additional Standards
   a. Examine the viscosity
   b. Vitro drug release to ensure within lot and lot-to-lot uniformity

Tubes May Be Filled By The Following Steps

1. The prepared ointment is rolled into a cylinder shape of a piece of parchment paper; the diameter is smaller than that of the tube.
2. With cap of the tube off to permit escape of air, the cylinder of ointment with the paper is inserted into the open bottom of the tube
3. The piece of paper covering the ointments is grasped in one hand, the other hand forces a heavy spatula down on the extreme end of the tube, collapsing it and retaining the ointment while the paper is slowly pulled from the tube. About one half (1/2) inch of the bottom is then flattened with the spatula.
4. About 1/8 folds are made from the flattened end of the tube and sealed by pliers or sealing clip on foot operated “crimper” machine.
CREAMS

- Are solid emulsion containing suspensions or solutions of medicinal agents for external application.
- Creams of the O/W type include foundation creams; hand creams; shaving creams; and vanishing creams.
- Creams of W/O type include cold creams; emollient creams.
- Product referred to as creams may not actually conform to the above definition.
- Many products that are creamy in appearance but do not have an emulsion-type base are commonly called creams.
- Example:
  - Bacitracin (Anti-bacterial)
  - Nystatin- Mycostatin cream (Antifungal)
  - Tretinoin- Retin A Cream (Antiacne)
  - Crotamiton- Eurax cream (Scabicides)
  - TIOCONAZOL – TROSYD
  - Luorouracil-Efudex Cream (Antineoplastic)

Examples of Ophthalmic Ointment

<table>
<thead>
<tr>
<th>Ointment</th>
<th>Commercial Product</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol</td>
<td>Chloromycin Ophthalmic</td>
<td>Antibacterial</td>
</tr>
<tr>
<td>Dexamethasone Na</td>
<td>Decadron Phosphate</td>
<td>Anti-inflammatory</td>
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<tr>
<td>adrenocortical steroid</td>
<td></td>
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<tr>
<td>Gentamicin sulfate</td>
<td>Garamycin</td>
<td>Antibacterial</td>
</tr>
<tr>
<td>Isosulfonate inhibitor</td>
<td>Floropryl Sterile</td>
<td>Cholinesterase</td>
</tr>
<tr>
<td>Polymyxin B-Bacitracin</td>
<td>Polysporin</td>
<td>Antimicrobial</td>
</tr>
<tr>
<td>Polymyxin B –Bacitracin</td>
<td>Neosporin</td>
<td>Antimicrobial neomycin</td>
</tr>
<tr>
<td>Sulfacetamide Na</td>
<td>Sodium sulamyd</td>
<td>Antibacterial</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>Tobrex</td>
<td>Antibacterial</td>
</tr>
<tr>
<td>Vidarabine</td>
<td>Vira A</td>
<td>Antiviral</td>
</tr>
</tbody>
</table>

GELS

- Are semisolid systems consisting of either suspensions made up of small inorganic particles or large organic molecules in an liquid vehicle rendered jelly like by the addition of a GELLING AGENT.
- Sometimes called JELLIES
- Examples of Gelling Agents
  1. Carboxomers 910; 934; 934P; 940; 941;1342
  2. Carboxymethylcellulose; natural gums
     * 0.5 to 2.0% concentration in water
- Classes of Gel
  1. 2 phase systems - separation between the insoluble matter and liquid vehicle is observed. This type contains inorganic materials
     Example: Al(OH)_3, Gel
  2. Single phase gel - consist of organic macromolecules uniformly distributed throughout the liquid where no apparent boundary is seen
     Example: Na CMC and Tragacanth Gel
  3. Continuous phase - commonly aqueous where alcohol and gels may be use as continuous phase
     Example: Mineral oil + polyethylene resin = oleaginous ointment base

Characteristics of Gels

- Gels may be thicken on standing, forming a THIXOTROPE, and must be shaken before use to liquefy the gel and enable pouring – Aluminum Hydroxide Gel
- Because of high degree of attraction between the dispersed phase and water medium, the gels remain fairly uniform upon standing and does not readily settle
- Example of Gel
  1. Clobetasol propionate- Termovate Gel (Dermatologic: Antipruritic)

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Example of Gel
1. Clobetasol propionate- Termovate Gel (Dermatologic: Antipruritic)
2. Acetic acid- Aci-jel (Vaginal; Restoration and maintenance of acidity)
3. Progesterone- Crinone Gel (Vaginal; Bioadhesive gel; Progesterone supplement and replacement)

- Uses of Gels
  1. Lubricant for catheters
  2. Bases for patch testing
  3. NaCl gel for electrocardiography
  4. Floucinonide Gel for anti-inflammatory corticosteroid
  5. Na Fluoride & Phosphoric acid gel – dental care prophylactic
  6. Tretinoin Gel for treatment of acne
  7. Prostaglandin Gel – intravaginal

- Gels and Magmas are considered colloidal dispersion since they contain particles of colloidal dimensions

APPROPRIATE NAMES (COLOIDAL DISPERSION)

SOLS – term to designate a dispersion of solid in either a liquid, solid or gas dispersion medium
a. Prefix HYDRO – water as dispersion medium so called HYDROSOL
b. Prefix ALCO – alcohol as the dispersion medium so called ALCOSOL
c. AEROSOL – dispersion of solid or liquid in gaseous phase

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Proprietary</th>
<th>Gelling agent</th>
<th>Route &amp; Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>Aci-jel</td>
<td>Tragacanth, acacia</td>
<td>Vaginal; restoration &amp; maintenance of acidity</td>
</tr>
<tr>
<td>Becaplermin</td>
<td>Regranex gel</td>
<td>Na CMC</td>
<td>Dermatologic</td>
</tr>
<tr>
<td>Benzoyl peroxide</td>
<td>Desquam-X gel</td>
<td>Carbomer 940</td>
<td>Acne vulgaris</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>Cleocin T gel</td>
<td>Carbomer 934</td>
<td>Antipruritic</td>
</tr>
<tr>
<td>Cyanocobalamin</td>
<td>Nascobal</td>
<td>Methylcellulose</td>
<td>Nasal: hematologic</td>
</tr>
<tr>
<td>Desoximetasone</td>
<td>Topicort gel</td>
<td>Carbomer 940</td>
<td>Anti-inflammatory, antipruritic</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Metro-gel</td>
<td>Carbomer 934P</td>
<td>Vaginal-bacterial</td>
</tr>
<tr>
<td>Progesterone</td>
<td>Crinone gel</td>
<td>Carbomer 934P</td>
<td>Progesterone supplement</td>
</tr>
<tr>
<td>Tretinoin</td>
<td>Retin-A</td>
<td>Hydroxypropyl cellulose</td>
<td>Acne vulgaris</td>
</tr>
</tbody>
</table>

**Preparation of Gels**

1. By freshly precipitating the disperse phase upon reacting an inorganic agents, a gelatinous precipitate results
   - Example: Preparation of Al(OH)_3 gel is by reacting
     \[ Al(OH)_3 + Na_2CO_3 \rightarrow NaHCO_3 \]

2. By direct hydrating the inorganic material in water
   \[ Al_2O_3 + H_2O \rightarrow Al(OH)_3 \]

- Examples: Aluminum Hydroxide Gel; Alugel; Amphogel; Ce-Iu-gel; Crema-lin; Hydroxal; Vanogel; Aluminum Phosphate Gel (Phosphagel) – Antacid

- Examples Of Topical Gels
  a. Erythromycin and benzoyl peroxide topical gel - Benzamycin
  b. Clindamycin Topical gel - Cleocin T Topical Gel
  c. Benzoyl Peroxide Gel - Desquam-X 10 Gel - acne vulgaris
  d. Hydroquinone Gel - Solaquin Forte Gel - bleach for hyperpigmented skin
  e. Salicylic Acid Gel - Compound W Gel - keratolytic
  f. Desoximetasone Gel - Topicort - anti-Inflammatory, antipruritic agent

**TRANSDERMAL PREPARATIONS**

- Ointments, creams, gels designed to deliver a drug systematically by addition of PENEtrATION ENHANCERS to the topical vehicle
- Examples of Penetration Enhancers
  o Dimethyl sulfoxide (DMSO), ethanol, propylene glycol, glycerin, polyethylene glycol, urea, dimethyl acetamide, sodium lauryl sulfate, poloxamers, Spans, Tweens, lecithin, and terpenes
  o Example: PLURONIC lecithin organogel (PLO) – Pluronic (Poloxamer) F127 gel (usually 20% to 30% concentration)

**PASTE**

- Dermatologic paste are ointment like preparations employed in practice of dermatology
- Usually stiffer, less greasy and more absorptive than ointments such as starch, ZnO, CaCO_3_, and talc in the base
- Characteristics
  a. Stiffness and impenetrability, not suited for hairy parts of the body
  b. Absorbs serous secretions and are preferred for acute lesions having a tendency to ooze
  c. Are less penetrating than ointment
  d. Are less macerating than ointment

- Types
  a. Dermatologic Paste
  b. Paste for injection

- Examples of Paste
  a. Zinc Oxide Paste with acid - Lassar’s Paste - Salicylic acid 20 g; and ZnO paste q.s. to make 1000g
  b. Zinc Oxide Paste - ZnO 250 g; Starch 250 g; White petrolatum 500 g to make 1000 g
  c. Triamcinolone Acetionide Dental Paste

**PLASTERS**

- Substances intended for external application, made of such materials and consistency as to adhere to the skin and thereby attach as dressing
- Purpose:
  a. To afford protection and mechanical support
b. To furnish an occlusive macerating action

c. To bring medication into close contact with surface of skin

- Example of Plasters

  a. Adhesive plaster – consisting of vinyl resin, plasticizers, and chemical additives
  b. Modern Plasters – are practically all machine made and are available in colors such as flesh, striped, and others
  c. Medicated plasters - Salicylic Acid Plaster, Salonpas
  d. BACK PLASTERS

    i. are made of heavy cotton or wool and cotton backing to provide warmth and support.
    ii. They are usually used for backache, sore shoulders, sore arms, and other muscular aches
    iii. The active constituents of back plaster is OLEORESINS OF CAPSICUM
    iv. EXAMPLES: Chilli Plaster; Hot Salonpas

CERATES

- Are unctuous preparations of such consistency that may be easily spread at ordinary temperature upon muslin cloth or similar material with spatula yet not soft to liquefy and run when applied to the skin

  **Contents:** oil, hard petrolatum and beeswax

  **Examples:** Cantharides cerates; Rosin cerate; Camphor cerate; Cerate of lead acetate; Compound Rosin Cerate

CATAPLASM

- Are viscous preparation intended for warm, external application to a body for purpose of reducing inflammation

- Are soft semisolid, external applications which either stimulate a body surface or alleviate an inflamed area by supplying medication substance in the presence of heat and mixture.

  Example: Numotizine

CEMENTS

- Are dental preparation employed primarily as temporary protective coverings for exposed pulps; also for holding medicinal agents in tooth cavities and re-basing of dentures.

  **Methods of preparation and Ingredients**

  a. Mixing a powder consisting of ZnO, and other metallic salts with a liquid consisting of either eugenol or clove oil mixed with a bland oil.
  b. Zinc acetate and other metallic salts accelerate the settling time
  c. The consistency of the cement may be altered by varying amount of the liquid.

GLYCEROGELATINS

- Are plastic masses intended for topical application and containing gelatin, glycerin, and water and a medicament suitable for application in dermatological practice.

  **ADMINISTRATION OF GLYCEROGELATIN**

  a. Glycerogelatins are melted prior to application, cooled to only slightly above body temperature, and applied to the affected area with a fine brush. After application the glycerogelatins hardens, usually covered with bandage.
  b. Example: Zinc Gelatin Boot
  c. **Zinc Gelatin** is a firm, plastic mass containing 10% zinc oxide in a glycerogelatin base - treatment of varicose ulcers because of its ability to form pressure bandage known as “gelatin boot”.

General information

**Medicinal substance** 100g
**Gelatin** 150g
**Glycerin** 400g
**Purified water** 350g

**to make about** 1000g

DRESSINGS

- Dressings are external application resembling ointments in consistency, but remaining semisolid at body temperature, they liquefy at 50°C and remain pliable in thin films below 28°C.

**Classes Of Dressings**

a. Primary wound dressing or now as wet dressing
b. Absorbents - surgical cotton and gauze
c. Bandages
d. Adhesive tapes

**Examples of Dressings**

a. Paraffin dressing, formerly official in the NF VI, was employed as an air-excluding, soft, pliable, analgesic, splint-like covering for surface denuded by burns
b. Petrolatum Gauze, USP - is absorbent gauze saturated with white petrolatum.
c. Furazone gauze pads-sterile - antibacterial dressings containing nitrofurazone
d. Surgical dressing is any material used as covering, protective, or support for a diseased part

  1. Adhesive bandage, USP
  2. Gauze bandage

**Packaging Semi Solid Preparations**

a. Topical dermatologic – jars or tubes
b. Ophthalmic, nasal, vaginal, rectal – tubes
c. Ointments – ointment jars – opaque glass or plastic; some colored green, amber or blue
d. Ointment jars – about 0.5 ounce to 1 pound
e. Jars and tubes – must be tested for compatibility and stability
f. Ointment tubes – aluminum or plastic
g. Ophthalmic, rectal, vaginal, aural or nasal – packaged with special applicator
h. Aluminum tubes – coated with epoxy resin, vinyl lacquer to eliminate any interaction with the content
i. Plastic tubes – High or low density polyethylene (HDPE or LDPE), polypropylene (PP), polyethylene terephthalate (PET), plastics, foil or paper laminate sometimes 10 layers thick
j. LDPE – soft and resilient, provides good moisture barrier
k. HDPE – less resilient but provides a superior moisture barrier
l. 12. PP – has a high level of heat resistant
m. 13. PET – transparency and high degree of chemical compatibility
n. 14. Multiple dose tubes – continuous thread closures
o. 15. Single dose tubes – “tearaway tip”
p. 16. Tubes – capacities of 1.5, 2, 3.5, 5,15,30,45,60,120g
q. 17. Ophthalmic ointments- collapsible plastic or aluminum