

# Semisolid Dosage Forms- Ointments, Pastes & Jellies

Mr. Ravikumar R Patil

Dr. Shivajirao Kadam College of  
Pharmacy, K.Digraj, Sangli

# Introduction

- **DEFINITION:**

**Semi solids are the topical dosage form used for the therapeutic, protective or cosmetic function. They may be applied to the skin, or used nasally, vaginally, or rectally...**

- **Pharmaceutical semisolid dosage preparations include :ointments, pastes, cream, plasters, gels etc..**
- They contain one or more active ingredients dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agents, anti microbial agents, antioxidants, or stabilizing agents etc..

# Advantage of semi-solid dosage form

- It is used **externally**
- Probability of side effect **can be reduce**
- **First pass** gut and hepatic **metabolism** is avoided.
- **Local action** and **Site specific action** of drug on affected area.
- Convenient for **unconscious patient** or patient having **difficulty** on oral administration.
- Suitable dosage form for **bitter drugs**.
- More **stable** than liquid dosage form

# Disadvantages of semi-solid dosage form

- There is **no dosage accuracy** in this type of dosage form
- The base which is used in the semi-solid dosage form can be **easily oxidized**.
- May cause **staining**.
- They are **bulky** to handle.
- Application with finger may cause **contamination**.
- Physico-chemically **less stable** than solid dosage form.
- May cause **irritation or allergy** to some patients

# IDEAL PROPERTIES OF SEMISOLIDS

## PHYSICAL PROPERTIES:

- Smooth texture
- Elegant in appearance
- Non dehydrating
- Non gritty
- Non greasy and non staining
- Non hygroscopic

## **PHYSIOLOGICAL PROPERTIES**

- Non irritating
- Do not alter membrane / skin functioning
- Miscible with skin secretion

## **APPLICATION PROPERTIES**

- Easily applicable with efficient drug release.
- High aqueous wash ability.

# PREPARATION OF SEMISOLIDS DOSAGE FORMS

## **INGREDIENTS USED IN PREPARATION:**

- Bases
- Preservative
- Humectants
- Antioxidants
- Emulsifier
- Gelling agent
- Permeation enhancer
- Buffers



# BASES

- It is one of the most important ingredient used in formulation of semisolid dosage form. Ointment bases do not merely act as the carriers of the medicaments, but they also control the extent of absorption of medicaments incorporated in them.

# IDEAL PROPERTIES OF A BASE

They should be:

- Inert, non-irritating and non-sensitizing.
- Compatible with skin pH and the drug.
- Good solvent and/or emulsifying agent.
- Emollient, protective, non-greasy and easily removable.
- Release medicament readily at the site of application.
- Pharmaceutically elegant and possess good stability.

# ANTIOXIDANTS

**Oxygen** is a highly reactive atom that is capable of becoming part of potentially damaging molecules commonly called “**free radicals.**”

**Free radicals** are capable of attacking the healthy cells of the body, causing them to **lose their structure and function.** To prevent this an antioxidants are added.

E.g. **Butylated hydroxy anisole, Butylated hydroxy toluene**

# PERMEATION ENHANCERS

- Skin can act as a barrier. With the introduction of various penetration enhancers, penetration of the drug through the skin can be improved.
- E.g. Oleic Acid

# EMULSIFIER

- An emulsifier (emulgent) is a substance that stabilizes an emulsion by increasing its kinetic stability.
  - Must reduce surface tension for proper emulsification.
  - Prevents coalescence.
  - Ability to increase the viscosity at low concentration.

# HUMECTANT

A humectant is a hygroscopic substance,  
Humectants are used to :

- increase the solubility of the active ingredient
- to elevate its skin penetration.
- elevate the hydration of the skin.

# BUFFERS

Buffers are added for various purpose such as :

- Compatibility with skin.
- Drug solubility.
- Drug stability.
- E.g. **sodium acetate, sodium citrate, potassium metaphosphate.**

# Ointments

- Ointments are homogenous, translucent, viscous semi-solid preparations, most commonly a greasy, thick oil (oil 80% - water 20%) intended for external application to the skin or mucous membrane.
- Drug ingredients can be dissolved, emulsified or suspended in the ointment base.



# Classification of ointments

- On the basis of penetration
- On the basis of therapeutic use

# On the basis of penetration

## A- Epidermic ointments

- These ointments are intended to produce their action **on the surface of the skin** and produce local effect, they are not absorbed.
- They acts as protectives, antiseptics and parasiticides.

## B- Endodermic ointments

- These ointments are intended to release the medicaments that **penetrate into the skin**. They are partially absorbed and acts as emollients, stimulants and local irritants.

## C- Diadermic ointments

- These ointments are intended to release the medicaments that pass through the skin and produce **systemic effects**.

# On the basis of therapeutic use

- Antibiotic Ointments e.g bacitracin
- Antifungal Ointments e.g Benzoic acid
- Anti-inflammatory Ointments e.g fluocinolone acetonide
- Antipruritic Ointments e.g benzocaine
- Counter-irritant Ointments e.g Methyl salicylate
- Antidandruff Ointments e.g. Salicylic acid

# OINTMENTS BASES

- Oleaginous bases or Hydrocarbon bases
- Absorption bases
- Water-miscible bases/removable bases/Emulsifying bases
- Water-soluble bases

# Oleaginous bases (Hydrocarbon bases)

- Oleaginous bases are non-aqueous formulations which provides emollient & protective properties.
- It is difficult to remove hydrocarbon bases from skin due to their oily nature.
- E.g. Hard Paraffin, White or Yellow soft paraffin, Liquid paraffin, Mineral oil etc..

- **Petrolatum (Soft Paraffin):** It is purified mixture of semi-solid hydrocarbons obtained from petroleum. There are two types of soft paraffin one is yellow & other is white soft paraffin. White soft paraffin prepared by bleaching the yellow soft paraffin. The melting point of soft paraffin is 38 to 56<sup>0</sup>C. White soft paraffin not be used in ophthalmic ointment preparations because small amt of bleaching agents involved in that & they causes irritation in the eye.
- **Hard Paraffin:** It is purified mixture of solid hydrocarbons & obtained from petrolatum. It is colourless or white translucent, odorless, tasteless wax like substance. It is used to harden or soften the ointment base.

- **Liquid Paraffin:** It consist of mixture of liquid hydrocarbons & obtained from petroleum by distillation. It is also called white mineral oil or liquid petroleum. It is colourless, odourless, tasteless it is soluble in ether & chloroform but its insoluble in water & alcohol.
- **Now a days oleaginous bases are not used commonly bec..**
- **They are greasy, so its difficult to remove from skin & clothing.**
- **They retain body heat which may produce an uncomfortable feeling of warmth.**
- **They do not help in the absorption of medicaments.**

# Absorption bases

- In the absorption bases contains small amt. of water & they provide relatively less emollient properties than hydrocarbon bases.
- These bases are generally anhydrous substances which have the property of absorbing considerable qty. of water but still retaining their ointment like consistency.
- They have 2 types : **1. Non-emulsified bases**  
**2. Water in oil emulsion bases**



- Non-emulsified bases:

Those bases absorb water & aqueous solution producing W/O emulsion.

e.g. Wool fat, Wool alcohol, Bees Wax etc..

- Water in oil emulsion bases:

Those bases have the capability of absorbing more water & have the properties of non-emulsified bases.

e.g. Hydrous wool fat (Lanolin)

- **Wool Fat:** It is also known as anhydrous lanoline & It is the purified fat-like substance obtained from wool of sheep. It can be absorb about 50% of its weight of water. So it is used in ointments where the proportion of water or aqueous liquids too large. It is mainly used in eye ointment base & in simple ointment base.
- **Wool Alcohol:** It is obtained from wool fat by treating with alkali & separate out cholesterol & other alcohols. It contains not less than 30% of cholesterol. It is used as an emulsifying agent for the preparation of w/o emulsion. It is also used for improving the texture, stability & emollient properties of o/w emulsion.

- **Bees Wax:** It is purified wax obtained from honey comb of bees. It is available in yellow & white form. White bees wax prepared by bleaching treatment. It is used for stiffening agent in paste & ointments.

# Water-miscible bases/removable bases/ Emulsifying bases

- These are anhydrous, hydrophilic, absorbs water with low thermal conductivity.
- It is easy to remove these bases from the skin due to their hydrophilic nature. These are used to form oil in water emulsion for topical applications.
- They have the same properties as the absorption bases.
- They are used as emollients, cleansing creams, vehicle for solid, liquid drugs.
- e.g. cold cream type, hydrous lanoline, rose water ointment etc.

# Water soluble bases

- In that bases does not contain oily substances & are called greaseless bases & completely soluble in water.
- Those are prepared using mixtures of different molecular weights of polyethylene glycol (Macrogols).
- PEG are mixture of polycondensation product of ethylene oxide & water.
- Lower M.W of this polymers (200,400 & 600g/mol) are liquids & the average M.W increases of this polymers changes from liq. To a waxy solid but not greater than 1000g/mol.
- Tragacanth, gelatin, pectin, cellulose derivatives, bentonite , sodium alginate are also used as water soluble bases.

# Selection of Dermatological Vehicle

- Following are the factors which govern the selection of an ideal bases for ointments:-

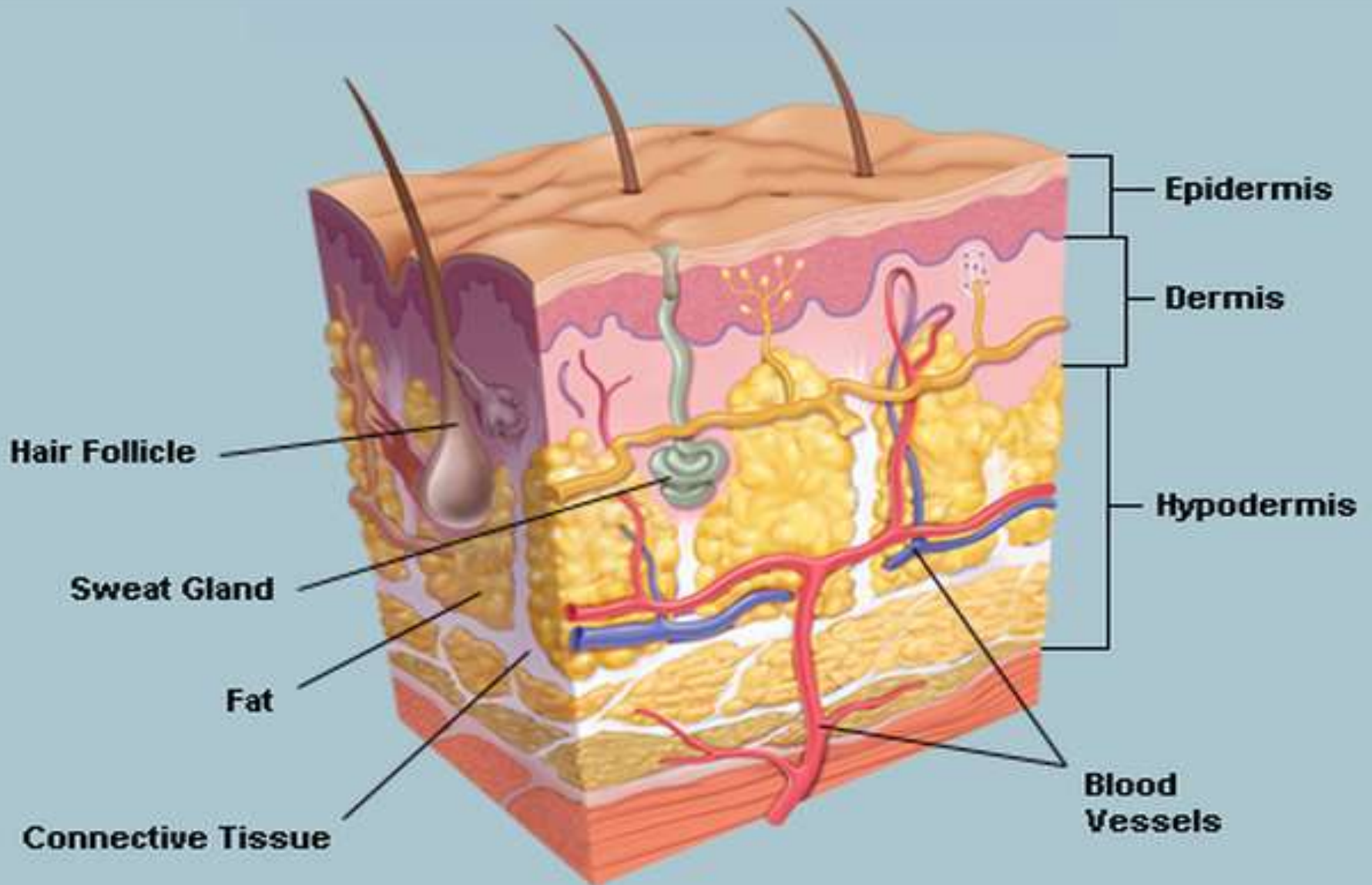
1. Dermatological factors

1. Pharmaceutical factors

# Dermatological Factors

1. Absorption & penetration
2. Effect on skin function
3. Miscibility with skin secretions & serum
4. Compatibility with skin secretions
5. Freedom from irritant effect
6. Emollient properties
7. Ease of application & removal

# STRUCTURE OF SKIN





# 1. Absorption & penetration:

- Absorption means actual entry into the blood stream & penetration means passes through the skin.
- The skin has **3** main layers **epidermis, dermis & hypodermis**.
- Scientifically proved that the **animal fats** like wool fat & fixed oils penetrate **more readily** through the skin in comparison to **mineral oils (paraffin)**.
- The substance which are **soluble in both oil & water** are **most readily absorbed**.
- The **o/w** emulsion bases **release medicaments more readily** than oleaginous bases means **w/o** emulsion bases.

## 2. Effect on skin function:

- **Greasy bases** may interfere with skin function like **heat radiation & sweat excretion** & also they **irritant** to the skin.
- The **o/w** bases means water soluble bases gives **cooling effect with healing effect** & also they readily mix with skin secretions.

## 3. Miscibility with skin secretions & serum:

- **Emulsion bases** are more **readily miscible** with skin secretion compared to **greasy material**. For that reason **small amt of drug is needed** when emulsion bases are used.
- **o/w type of emulsion** bases are readily miscible with serum & are **very useful for ointment base for weeping eczema**.

#### **4. Compatibility with skin secretion:**

- **Neutral pH ointments** are compatible with majority of the medicaments & also they do not cause discomfort in use.
- The ointment **bases should have a pH around 5.5** which is the average pH of the skin secretions.

#### **5. Freedom from irritant effect:**

- Ointment bases should be non-irritant.
- Greasy bases causes irritation & may cause oedema.
- The ointment used for eye ointments should be non-irritant & free from foreign particles.
- Also all ointment bases should be high standards of purity.

**6. Emollient properties:** The ointment bases should be emollient properties that should be able to keep the skin moist. The humectants like glycerin & propylene glycol keep the skin surface moist & soft & wool fat, paraffin used for the skin soft & preventing the loss of moisture from the skin.

**7. Ease of application & removal:** Ointment bases should be remove easily from the skin so, stiff & sticky ointment bases are not suitable. Also ointment bases should be easily applicable & should be spread on the skin surface.

# Pharmaceutical Factors

1. Stability
2. Solvent properties
3. Emulsifying properties
4. Consistency

# 1. Stability:

- The fats & oil obtained from animal & vegetable source have to undergo oxidation so antioxidants are used.
- O/W type of emulsion ointment bases are liable to microbial growth so need to a preservatives.
- Emulsified bases are liable to phase separation due to improper formulation or under influence of temperature so required to store in suitable temperature.

## 2. Solvent properties:

- Most of the medicaments incorporated with ointment bases are insoluble with it so, necessary to mix finely powdered drug in ointment bases.
- If phenol used in solid form with ointment bases it causes blisters. So, chose the suitable ointment base which should keep phenol in solution form.
- Mixture of hard & soft paraffin, beeswax ointment bases are used for phenol.
- Similarly, in the preparation of compound mercury ointment, olive oil is used to keep camphor in solution form.

### **3. Emulsifying properties:**

- Hydrocarbon bases absorb less amount of water compared with animal fats, which can absorb a large quantity of water.
- E.g. wool fat can absorb 50 % of water but when it is mixed with other fats can take up several times of water or hydro-alcoholic liquids. So, wool fat is included as base in the eye ointment preparation.



## 4. Consistency:

- The consistency of ointments should neither be too hard or nor too soft.
- The consistency of an ointments can be adjusted in a such way that, in soft ointments included have the high melting point substance like hard paraffin, bees wax. So, soft ointments must be stable in summer season.
- In hard ointments included the lower melting point substance like liquid paraffin. so, hard ointments must be stable in winter season.

# Preparation of Ointments

- **Incorporation Method / Trituration Method**
- **Fusion Method**
- **Chemical Reaction**
- **Emulsification Method**

# Incorporation Method / Trituration Method

- Powders pass out from mesh no. 250 or 180 or 125.
- Then apply levigation process with small amt. of base.
- Then add remaining qty. of base.
- Finally add liquid ingredients & mix well.
- E.g Whitfield Ointment

**SIZE REDUCTION**



**LEVIGATION**



**MIXING WITH BASE**



**SPATULATION OR TRITURATION**



**MIXING BASE TO PRODUCE FINAL  
WEIGHT**



**HOMOGENIZATION**

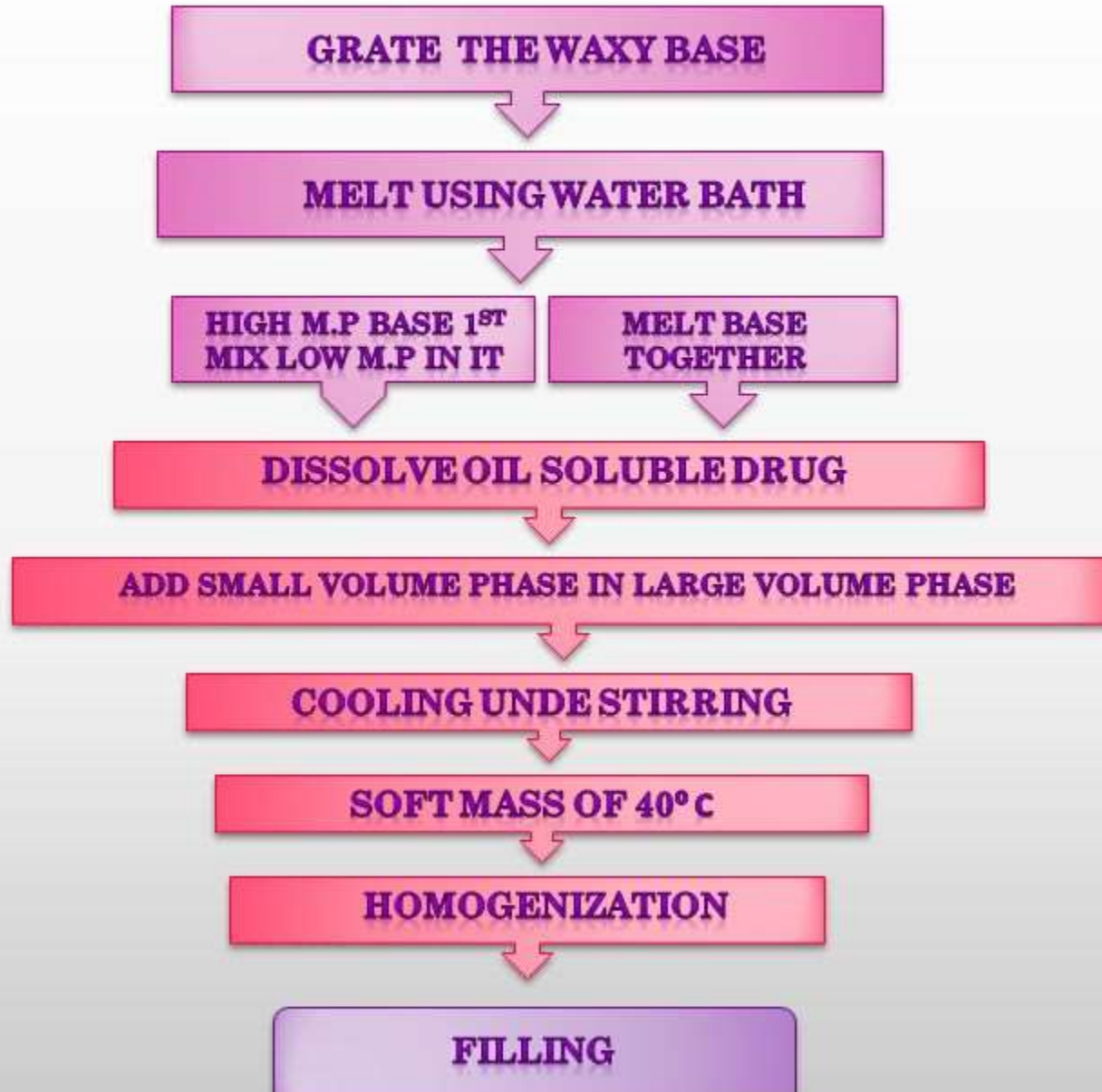


**FILLING**

# Fusion Method

- When an ointment base contains a number of solid ingredients such as white bees wax, cetyl alcohol, stearyl alcohol, hard paraffin etc.
- By the fusion method, **all or some** of the components of an ointment are combined & being **melted together** and cooled with constant stirring until congealed.
- Naturally, heat-labile substances and any volatile components are added last when the temperature of the mixture is low enough not to cause decomposition or volatilization of the components.

# *Fusion method*



# Chemical reaction

- Ointment containing free iodine
- Ointment containing combined iodine

# Ointment containing free iodine

- Iodine is slightly soluble in most of the fats & oil but very readily soluble in conc. Aq. solution of potassium iodide due to formation of molecular complex.
- These polyiodides complex are readily soluble in water, alcohol & glycerin.
- E.g. Strong iodine ointment is used to treat ringworm in cattle. At one time this type of ointment used on humans for counter-irritants but they were not popular bec. they remain stain on skin a deep red colour.



# Ointment containing combined iodine

- Fixed oils & many vegetable & animal fats absorb iodine which combines with the double bonds of the unsaturated constituents.

Oleic acid + iodine = di-iodo stearic acid

- Since free iodine is not available, these ointments are dark, greenish black in colour & it leaves no stain on skin when rubbed so, it is known as non-staining iodine ointment.
- E.g. Non-staining iodine ointment.

# Emulsification Method

- In this method, fats, oils & waxes are melted on water bath at 70°C.
- Then in another beaker take water soluble ingredients with water & heat at same temperature.
- Then, aq. solution are slowly added in melted bases with continuous stirring until product cools down & semi-solid not be formed.

# Paste

- Pastes are homogeneous semisolid dosage form contains high conc. Of insoluble powder substance ( not less than 20%) dispersed in the suitable base.
- The paste are usually less greasy, more absorptive & stiffer than ointments.
- They have good adhesion on skin & they do not melt at ordinary temperature.

# Bases Used for Pastes

- Hydrocarbon Bases : e.g. soft paraffin & liquid paraffin used as a base.
- Water miscible bases : Emulsifying ointment is used as a base. Also glycerin is also used as a base.
- Water soluble bases: combination of high & low M.W PEG are mixed together as a base.

# Fusion method

- Any powder pass through under mesh no.180
- Melt all bases & wax with conti. Stirring.
- Then add powder form ingredient.
- And again continuous or constant stirring until cool.
- E.g zinc & coal tar paste.
- Use : treatment for eczema

# Fusion & Trituration method

- Pass the powders through mesh no. 180.
- Then melt the base
- Take powder in mortar & triturated with melted base.
- Triturate until become cool.
- E.g compound zinc paste BP
- Use: treatment for eczema & also act as a sun protecting.

# JELLIES

## INTRODUCTION

- Jellies are transparent or translucent non-greasy semisolid dosage form.
- They are less greasy compare with gel.
- They are mainly used for mucous membrane for lubricating, antiseptic purpose.
- Jellies are also used for lubricating surgical gloves, catheters & rectal thermometers.
- Vaginal jellies & contraceptive jellies are also commonly used.

## Types of Jellies

- 1. Medicated jellies:** Medicated jellies contains a considerable amount of water therefore those are suitable for water soluble medicaments & used for anesthetics, antiseptics and spermicidal. After evaporation of water they produce cooling sensation to the skin.
- 2. Lubricating jellies:**
- 3. Miscellaneous jellies: Patch testing:** Used for allergens which are applied on skin to check the sensitivity. **Electro-cardiography:**



# Following jelling agents are used...

- Tragacanth
- Sodium alginate
- Pectin
- Starch
- Gelatin
- Cellulose derivatives

# Tragacanth

- It is commonly used for the preparation of lubricating, medicated & contraceptive jellies.
- For lubricating jellies 2 to 3 %
- For dermatological vehicle about 5%
- For medicated jellies 5%



- Tragacanth jellies are also called **bassorin paste.**
- When tragacanth added in water it produce lumpy product.
- So, dispersing agents like alcohol, glycerin or a volatile oil is used to get a homogeneous preparation.



# Sodium Alginate

- Those jellies are used as lubricants & for dermatological vehicles.
- In lubricants 1.5 to 2% & for dermatological vehicle 5 to 10% sodium alginate used.
- In that type of jellies alcohol, propylene glycol or glycerin used as dispersing agents.



# Pectin

- Pectin is a very good gelling agent.
- Pectin used in various preparation of jellies including edible jellies.
- It is mainly used in dermatological jellies.
- Glycerin is used as humectant & dispersing agent.
- Pectin jellies prepared with suitable preservatives.

# Starch

- Starch jellies prepared with combination of gelatin & glycerin.
- Starch glycerin jellies prepared by heating method or fusion method.
- Glycerin in large amounts i.e 50% may be act as preservative & humectant.

# Gelatin

- Gelatin soluble in hot water.
- 2% gelatin produce jelly in a hot solution.
- Very stiff medicated jellies can be prepared by incorporating with 15% gelatin.
- Such jellies melted before use & after cooling to desired temperature it can be applied with brush on affected area.
- Those applied areas are cover with bandage.
- The dressing may be left in place after several weeks.
- Zinc gelatin jellies is also known as Unna's paste.

# Cellulose derivatives

- Methyl cellulose & sodium carboxy methyl cellulose are widely used for preparation of jellies.
- Those substances produce natural & stable jellies.
- Those afford good resistance against bacterial growth.
- Those produce strong film on the skin after drying on skin.



# Preparation of Jellies

- Preparation of jellies using thickening agents such as tragacanth, pectin, CMC etc in aq. Vehicle.
- Then triturate with medicaments until a uniform product is obtained.

# POULTICES (CATAPLASAMS)

- Poultices are viscous, soft wet masses of solid substances applied to skin.
- It is used for relief from pain, reduce inflammation or act as counter-irritant.
- Now a days poultices are out dated.
- In the formulation of the poultices contains heavy kaolin because it acts as a carrier of heat.
- Poultices is applied to the affected part after heating it in a china dish with stirring until the heat is tolerated on the back of the hand.
- The melted poultices is spread as thick film on a dressing material & applied as hot as the patient can bear it to the affected area.

Thank  
you!