

# Experiment 6

## Semisolid dosage forms: Dispersed Systems Creams

Creams: *Are semi-solid or highly viscous liquid emulsions intended for application to the skin.*

- Creams can be used as:
  - Emollients
  - Cleansers
  - Skin protectant
  - And to deliver drugs to the skin (acting as vehicles into which the drug is incorporated) or other body sites
- They are divided into two types:
  - (1) Oil-in-water (O/W) creams which are composed of small droplets of oil dispersed in a continuous aqueous phase e.g. **Vanishing creams**.
  - (2) Water-in-oil (W/O) creams which are composed of small droplets of water dispersed in a continuous oily phase e.g. **Cold cream**.

### Oil-in-water creams: e.g. Vanishing creams.

1. More comfortable and cosmetically acceptable as they are less greasy and more easily washed off using water.
2. Non-occlusive

### Water-in-oil creams: e.g. Cold cream

1. Drugs which are incorporated into w/o creams are hydrophobic and will be released more readily from a water-in-oil cream than an oil-in-water cream.
2. More effective in skin cleansing
3. Have the advantage of being more occlusive since, having oil as the external phase reduce water evaporation from the skin thus increasing its hydration. Those creams are useful in conditions involving dry skin.
4. Increased skin hydration may raise the permeability of the skin and enhance drug penetration.

**Formula (1):**

Rx 20 gm cold cream USP

Ingredients	Master formula	Scaled formula
Spermaceti (Cetyl esters wax)	125gm	
White wax (Bees Wax)	120gm	
Mineral oil	560gm	
Sodium borate	5gm	
Purified water to make	q.s. 1000gm (add 190 ml)	q.s. 20gm (add ---ml)

**Cold cream:** is W/O type of emulsion

- It is an oily and greasy type of creams to which both the cleansing and lubricating creams belong to. *(تتميز بكونها دهنية)*
- In cold cream the emulsifying agent is formed by reaction between the alkaline sodium borate and the free fatty acids in Bees wax.
- Why is it called cold cream?

Procedure:

1. Weight the solid ingredients.
2. If necessary, reduce the size of cetyl esters wax and the white wax in the beaker to small pieces by using glass rod. *صحن انقص اذا احتاج*
3. Melt the cetyl esters wax and the white wax in the beaker using hot plate.
4. Add the mineral oil and continue heating the mixture until it reaches 70°C.
5. Dissolve the sodium borate in the calculated amount of purified water and warm the mixture to 75°C using hot plate.
6. Add the warm aqueous mixture to the melted oleaginous mixture. Stir rapidly and continuously until the mixture has congealed. *اصرف على حرارة الغرفة وجماد*
7. Package in a jar. Provide a professional finish.
8. Perform dilution test using drops of oil and drops of water *درد بردة*

Use of Ingredients:

- (1) **Spermaceti:** Emollient, stiffening agent.
- (2) **Mineral oil:** Emollient, Oleogenous vehicle.
- (3) **Sodium borate:** part of emulsifying agent.
- (4) **White wax (Bees wax):** part of emulsifying agent.

Description of Finished Product:

Uniform, luminescent white cream with no visible particles; spreads easily without a gritty texture.

Quality Control Procedures:

- Observations for uniform consistency
- Weight of final product.

Beyond-Use Date Assignment:

Thirtydays or intended duration of therapy, whichever is less.

Labeling:

- Main Label:
- Auxiliary label:  
*For external use only.*

Storage:

*Store at room temperature.*

*Thirty days use*

*Store in appropriate size plastic with wide-mouthed jar or in proper tube.*

Use of preparation:

Skin Moisturizer and face cleanser.

## Formula 2:

### Rx 20 gm Vanishing Cream B.P.C.

Ingredients	Master formula	Scaled formula
Stearic acid	150gm	
White wax	20gm	
White petrolatum	80gm	
Triethanolamine	15ml	0.3ml (7drops)
Propylene glycol	80gm	
Purified water to make	q.s. 1000gm (655gm)	q.s. 20gm (13.1 gm)

#### Vanishing cream

Is semisolid emulsion of o/w type that is used topically.

- Earned its name due to rapid water evaporation leading to rapid vanishment of the cream after application. *→ O/W*
- Drugs can easily be incorporated into it as aqueous solutions.
- Vanishing creams sometimes called stearic acid creams and contain only 15% internal phase volume.
- Stearate/Vanishing creams were known for their smooth, dry feel on the skin and their pearly sheen. Chemically they are oil-in-water emulsions consisting of stearic acid, an alkali, a polyol and water. The alkali reacts with some of the stearic acid to form the emulsifier. *propylen glycol*

#### Procedure

1. Melt the first 3 ingredients (oily phase) in a beaker using hotplate.
2. Mix triethanolamine, propylene glycol and water and heat the mixture to 75°C.
3. Pour the aqueous phase (step 2) into the oily phase (Step1) while they are both hot with mixing
4. Mix constantly till congealed
5. Place in a jar

#### Use of ingredients.

- (1) **Stearic acid:** part of the emulsifying agent.
- (2) **White wax:** stiffening agent.
- (3) **White petrolatum:** emollient.
- (4) **Propylene glycol:** Humectant, moisturizing agent.
- (5) **Triethanolamine:** part of the emulsifying agent

#### Labeling:

- Main Label:
- Auxiliary label:  
*For external use only.*

#### Storage:

*Store in a cool place.  
Store in a wide-mouthed jar.*

بعد التكون ←

اصحاب الادوية ← Cream base ← قبل التكون

# Addition of ingredient to cream base (W/O)

- Depending on the mount to be added:

## A- If it is >10% of the total weight of the cream:

- This should be done before cream formation Add the water-soluble to the aqueous part and oil-soluble to the oily part and mix and continue mixing to get the cream

## B- If < 10% of the total weight of the cream, add after cream formation in portions with contiguous stirring for 5 minutes to allow emulsification

Water-soluble (mix with smallest volume of water)   
 ادوية الدواء هي و اجنبة بالترتيب مع الماء

Oil-soluble mix with the smallest volume of castor oil/ or propylene glycol   
 بنوع

**Congealing:** solidify while cooling to room temperature

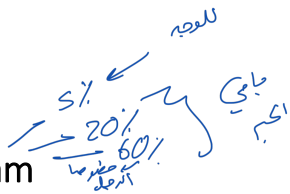
**Stiffing agent:** Give firm and solid texture

## Urea cream

Urea cream helps soften dry, rough or thick skin as a result of eczema, psoriasis (صدفية) or other skin conditions.

This cream works best if you apply it to your skin while your skin is damp, like after a bath or shower.

**Strength** 5 % for face  
10-50% for body and foot

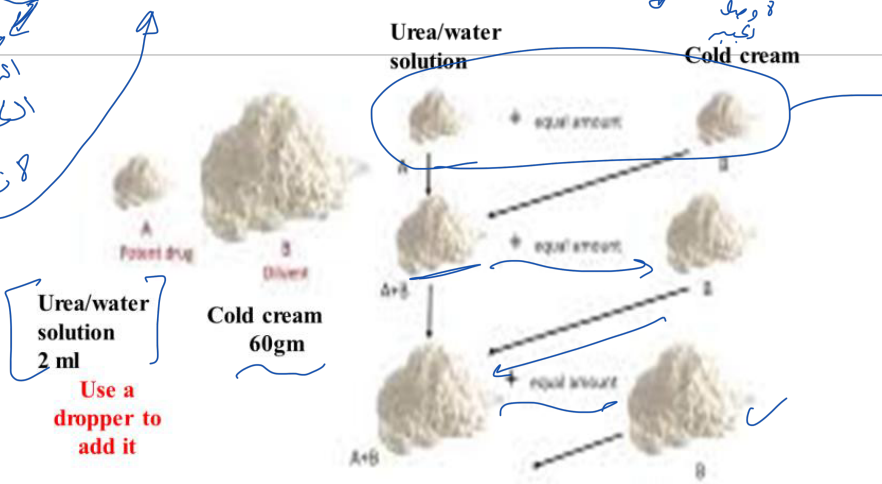


### Preparation of Urea cream for foot (Strength 10% urea Cold cream)

#### Geometric mixing (Geometric dilution)

حاجت به احتیاج  
الروا على  
الكثير على طول  
8 زرع العمل

جزء صغير  
3 و 3  
لكن



Urea/water solution 2 ml  
Use a dropper to add it

Cold cream 60gm



Put in a jar and continue mixing for minutes

The process is repeated until all of the diluent B is incorporated.

add cream

1. Weight the solid ingredients.
2. If necessary, reduce the size of cetyl esters wax and the white wax in the beaker to small pieces by using glass rod.
3. Melt the cetyl esters wax and the white wax in the beaker using hot plate.
4. Add the mineral oil and continue heating the mixture until it reaches 70°C.
5. Dissolve the sodium borate in the calculated amount of purified water and warm the mixture to 75°C using hot plate.
6. Add the warm aqueous mixture to the melted oleaginous mixture. Stir rapidly and continuously until the mixture has congealed.
7. Package in a jar. Provide a professional finish.
8. Perform dilution test using drops of oil and drops of water

صفت انقصة اذ اصحاب  
اصولت على حدة  
الغرفة وفضلت  
مالتدريج ليوم 70 في جبره  
مالتدريج ليوم 70 في جبره

احكام از permaedi بيكر ولو حست جيات - حبيبه الحرم  
احكام از white wax واكر  
احكام على النار مع خلط الحبي واخلع - لاصه  
اذوب (sodium borate) ? purified water واحكم واحكام على النار ليوم 70  
واخلط الا حست 3:8

اضيف بيبي الحبي على بيكر الحست - droper مع التحريك والتدريج  
تب احكام اخرى بدون نار  
از ايه

المضغوت صابون كريم احكام جبار واخلطه

**Procedure**

1. Melt the first 3 ingredients (oily phase) in a beaker using hotplate.
2. Mix triethanolamine, propylene glycol and water and heat the mixture to 75°C.
3. Pour the aqueous phase (step 2) into the oily phase (Step1) while they are both hot with mixing
4. Mix constantly till congealed
5. Place in a jar

propylene glycol  
في حبات  
وعرض الحست

Vanishing cream

واشبه على  
الاصحاب

احكام مواد احكام انا احست واخلط واحكام لغرامه 20 اصل احكام  
مالتدريج على النار مع تدريج  
احكام مع الwater مالتدريج على النار ليوم 20

**Use of ingredients.**

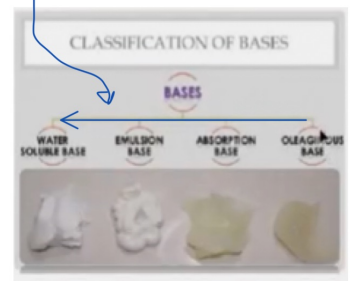
- (1) **Stearic acid:** part of the emulsifying agent.
- (2) **White wax:** stiffening agent.
- (3) **White petrolatum:** emollient.
- (4) **Propylene glycol:** Humectant, moisturizing agent.
- (5) **Triethanolamine:** part of the emulsifying agent

اصل احكام ليوم 20  
احكام في jar واخلطه

صحت لتجرب  
سبت

وزي ما كنا نحكي مثلاً في ال Emulsion، ال Emulsion عبارة عن Oil and Water، الكريمات مثلاً مبنية على مبدأ ال Emulsion، يكون عنا جزء Oil وجزء Water. من ناحية ال Ointment، ال Vehicle فيها اسمه Ointment base. وال Ointment bases أنواع من اليمين لليسار

من ال Most Lipophilic أو الي بسموها  
Oleaginous bases الي هي دهنية جداً  
وغالباً بكون ال Base تبعها زي الفازلين مثلاً، ال  
White petrolatum وال Yellow petrolatum  
بعدين كل ما رحنا باتجاه ال  
Absorption bases وال Emulsion bases  
وال Water soluble bases بنبلش  
ندخل كمية مي وتصير تخف الطبيعة الزيتية  
ويدخل فيها المي



# Experiment 7

## Semisolids dosage forms: Dispersed Systems Ointments and Pastes

Ointments:

Are a homogeneous, viscous, semi-solid intended for external application to the skin or mucous membranes". or *Pectal*

بالفارما متعارف عليه إنه كلمة Ointment طبيعتها دهنية أو زيتية، مثلًا عنا Hydrocortisone Ointment معناه إنه Hydrocortisone incorporated in oil-type semisolid base.

They are used as emollients or for the application of active ingredients to the skin.

- However, pharmaceutical manufacturers use the word ointment more specifically to indicate that a drug is incorporated into an oleaginous ointment base; for example, the name Hydrocortisone Ointment means that hydrocortisone is incorporated into an oil-type semisolid base.

Levigation:

Grinding of Solid in presence of non-solvent liquid to obtain a paste (by mortar and pestle or slab and spatula).

عملية ال Levigation هي إننا نحرك ال Powder مع ال Base أو مع Levigating agent باستعمال Tile أو Glass plate مع ال Spatula. وخلال عملية ال Levigation بصير عنا أول شيء Grinding وكمان Mixing. ويمكن تتم بالمورتر والبستل. ال Trituration هو غالباً لل Solid، أما ال Levigation فيكون بوجود جزء Oily. Petrolatum ال.

### Formula (1):

Rx. ---gm Zinc and castor oil ointment, BP

Ingredients	Master formula	Scaled formula
Zinc oxide finely divided	15 gm	
Castor oil	40 ml (d=0.961g/ml)	
Cetosteryl alcohol	25 gm	
White bees Wax	50 gm	
Arachis oil (peanut oil)	35 ml (d= 0.915g/ml)	
Total		

Solid ← Zinc oxide finely divided  
Liquid ← Castor oil  
Solid ← Cetosteryl alcohol  
Solid ← White bees Wax  
Liquid ← Arachis oil (peanut oil)

- This formula is a type of absorption ointment base that is used for the relief of symptoms of nappy rash and as a water resistant emollient barrier for dry skin conditions and nappy rash.

- Absorption bases help absorb water from skin discharge. They consist of a hydrocarbon base combined with water in oil emulsifier such as fatty alcohols.

- Fatty alcohol (Cetosteryl alcohol) are the emulsifier in this form that allow the absorption of water.

Procedure:

- Melt together the beeswax, cetosteryl alcohol, and arachis oil at the lowest possible temperature.
- Warm the castor oil in separate dish
- Using a tile and spatula, lavigate zinc oxide with a suitable quantity of castor oil until smooth
- Transfer the suspension in step 3 to the dish containing the melted ingredients taking care to leave virtually no materials on the tile. Mix well, add the rest of castor oil and stir until cold.

الاصطناعية  
في عاكس الكلدوج  
ويعمل ال emulsification له مواد ال

الاصطناعية  
يحمي عن الحرارة  
كما يتصلب

Recommended doses and dosage schedules:

As required, up to four times daily or at each nappy change. The product is suitable for use by adults, children and the elderly

تعدى زياده  
للطفولة

Use of ingredients:

(1) **ZnO**: astringent, soothing agent.

(2) **Castor oil**: emollient, levigating agent

(3) **Arachis oil**: emollient.

(4) **White bees Wax and Cetosteryl alcohol**: emollient + vehicle for other ointment.

بتشده الجلب

ملطف

مركب  
ذو كوكب  
non solvent

المركبة جدا الطيب  
والخلط منه ما اخلا  
ال levigating agent  
مع ان oil  
تطعم على ساني اللاد  
تصا من معوم

الاماني لا يوجد

Labeling:

- Main Label:

- Auxiliary label:

*For external use only.*

*Keep all medicines out of reach of children.*

*Zinc and Castor Oil Ointment BP contains Arachis Oil (peanut oil) and should not be applied by patients known to be allergic to peanut.*

Storage:

*Store in a cool place.*

*Store in an airtight container, (a wide-mouthed plastic jar or tube).*

*Avoid prolong exposure to temp above 30°C.*

Use of preparation:

For diaper rash, astringent, protective.

ماتى حى

180 days (6 months) from the date of preparation, if no specific stability data exists. The earliest expiration date of any ingredient used.

او صلاحه المواد الداخلة  
↓  
لا تعتبر الصلاحه  
3 شهر

Pastes:

Paste are semi solid preparation for external use. They consist of finely divided powder combined with non- solvent molten base. .

- Contain more solid material than ointments (at least 20%)
- Stiffer than ointments
- The stiffness reduce the percutaneous absorption potential of any drug incorporated in the paste

They are used for their:

- 1) protective action ✓
- 2) and ability to absorb serous discharge from skin lesions and wounds. They also can absorb harmful chemicals such as ammonia that is released by bacterial action on urine and so are often used in nappy products
- 3) and ability to remain in place longer than ointments
- 4) E.g. Zinc Oxide paste USP, Carboxymethylcellulose Sodium Paste USP, Triamcinolone Acetonide Dental Paste USP, Tooth paste.

Formula (2):

Rx. 50 gm zinc oxide paste (Lassar's Plain Zinc Paste):

Ingredients	Master formula	Scaled formula	Uses
Zinc oxide	150gm		Protective, slightly astringent, and slightly antiseptic.
Starch	50gm		Filler ⇒ <u>Bulking agent</u>
White soft paraffin	750gm		Ointment <u>base</u>
Total	950 gm	50gm	

- **Zinc oxide paste is a very thick topical ointment**. People use it as a skin protectant and to treat a variety of skin irritations.

Procedure:

1. Melt White soft paraffin with minimum heat (at the lowest possible temperature)
2. sieve zinc oxide and starch powder
3. mix the powders in a mortar using the “doubling-up” technique (Geometric mixing).
4. levigate the mixed powders with a suitable quantity of the semi-molten base on a tile
5. A considerable shearing force should be applied to avoid a gritty product
6. Add the remaining semi-molten base and triturate with the powder/fatty base mixture on the tile until the powder is dispersed in the base.

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The “doubling-up” techniques (Geometric mixing):

1. Weight the powder present in the smallest amount (powder A) and place in the mortar
  2. Weight the powder present in the next largest amount (powder B) and place on labeled weighing paper
  3. Add approximately the same amount of powder B, as powder A in the mortar
  4. Mix well with pestle
  5. Continue adding an amount of powder B that is approximately the same as that in the mortar and mix with the pestle, i.e. doubling the amount of powder in the mortar at each addition
  6. If further powders are to be added, add these in increasing order of volume as in steps 3,4,and 5 above.
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Labeling:

- Main Label:
- Auxiliary label:  
*For external use only.*  
*Keep all medicines out of reach of children.*

Storage:

*Store in a cool place.*  
*Store in an airtight container, (a wide-mouthed plastic jar or tube).*  
*Avoid prolong exposure to temp above 30°C.*

Use of preparation:

Astringent

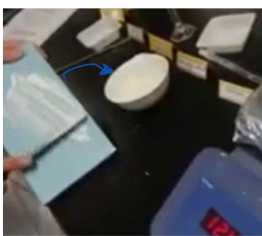
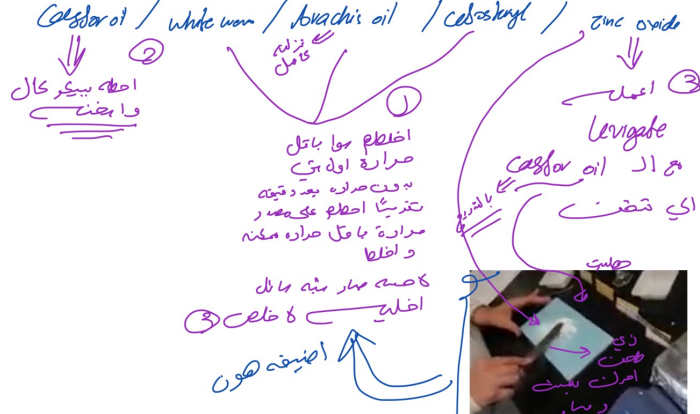
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Procedure:

1. Melt together the beeswax, castor oil, and arachis oil at the lowest possible temperature.
2. Warm the castor oil in separate dish
3. Using a tile and spatula, levigate zinc oxide with a suitable quantity of castor oil until smooth
4. Transfer the suspension in step 3 to the dish containing the melted ingredients taking care to leave virtually no materials on the tile. Mix well, add the rest of castor oil and stir until cold.

انترجيك الحبيبات  
بجانب عت الحبيبات  
كما يحتمل



ارصحه على انوار متوي داظلم شاتج

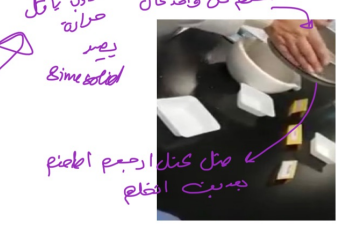
بعد ذوب اظلم بعينه من انوار وامل الزوايا لاصح صرارة صرارة

ليس  
مصحح



عمل Blending  
اجم بين ما يكون منه يعني عنه  
ان اظلمه  
يا لشرطي  
اخذ الكفاية  
ايضا للذوقه اي  
بالفان

white soft / starch / Zinc oxide



عمل Levigate مع  
Levigation  
عمله كمال  
Zinc كمال ثم ال Zinc جابر ذوقه ال doubling up  
داظلم كماله صرارة من ال Zinc واملت رصكنا  
لعم تقريبا 3 دفع