- *Experiment 9 :Solid Dosage forms: Suppositories*

ملاحظة: هذا السلايدات تحتوي نفس المعلومات في ال manual ولكن تم اضافة صور للتوضيح

- ***Suppositories***
- are solid dosage form of various sizes, shapes, and weights intended for insertion into body cavities where they melt or dissolve to exert their effect, they are employed rectally, vaginally and urethrally, their size and shape must be such that is capable of being easily inserted into the intended orifice without causing distention.

- The suppositories is usually composed of a medication incorporated in a suppositories base, the medicament may be intended for local drug effect or to be absorbed for systemic effect:
  - For example **rectal localized action** include relief of constipation, pain, itching, and inflammation associated with hemorrhoid conditions.
  - suppositories for **systemic action** include drugs that relief nausea, vomiting, and non-steroidal anti-inflammatory analgesics.

1

- **Classification of suppositories:**
- Classified by composition and physical properties of the **suppository base**:
- (1) **Oleaginous (fatty) bases** *(2)* **Water soluble/water miscible bases**:

- (1) **Oleaginous (fatty) bases**
- Could be called ***natural base like Cocoa butter (Theobroma oil)*** which is a mixture of glyceryl ester of stearic, palmitic, oleic, and other fatty acids or synthetic ones like Witepsols®, which is a mixture of mono, di, and triglyceride of saturated fatty acid (e.g. hydrogenated coccunt oil).
- Cocoa butter is the most commonly used base because of is melting point is in the range of 30-36ºC which is solid at room temperature but melts at body temperature, and is miscible with many ingredients.
- Cocoa butter however has the disadvantages of polymorphism and adherence to the mold, and soluble ingredient such like phenol and chloral hydrate **reduce** its melting point.

2

- *(2)* **Water soluble/water miscible bases**: *are those containing glycerinated gelatin or the polyethylene glycol (PEG) polymers.*
- Glycerinated gelatin bases are mixtures of glycerol and water made into stiff jelly by adding gelatin, mostly used in vaginal suppositories, where localized prolong action moisture.
- In addition to extended their shelf life preservatives should be used such as methyl paraben and propyl paraben.

استعمالاتها Laxative، تمام، استعمالاتها Laxative وممكن نستعملها مثلاً لـ Vaginal، بكون الـ Action لها Localized prolonged action.
طيب ممكن أحياناً إنه نضيف بعض الـ Ingredients علشان نخلي الـ Release أطول، إن نضيف بعض الـ Substances تخلي الـ Release أطول فبتعطيني

glycerinated gelatin

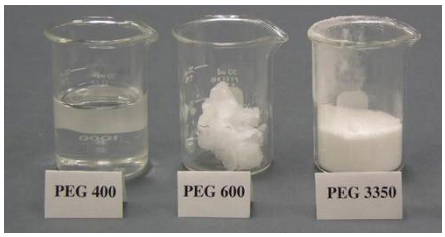
polyethylene glycol (PEG).

3

3

طيب أحياناً بعض أنواع الـ Suppositories، خاصة إذا كان مثلاً زي الـ Glycerol، الجليسرول Hygroscopic بمتص الرطوبة، فممكن إن نعمل ترطيب Moistening للـ Suppository before insertion. وكمان أحياناً نعمل Moistening للـ Suppository before insertion الـ Administration تمام، علشان نسهل دخولها وكمان نقلل من الـ Irritation اللي ممكن تعمله إذا كان واحد من الـ Constituents هاي Hygroscopic ممكن يمتص الرطوبة من الـ Rectum أو من الـ Vagina.

- To facilitate their administration they should be moisten with water prior for insertion.
- **polyethylene glycol (PEG) or macrogol:**
- are usually mixtures of different molecular weights polymers to achieve a base of desired consistency and characteristics, they have a melting point higher body temperature (42ºC) so cool storage is not required, satisfactory for hot climates, and their administration is easy because they are not slippery to handle.
- They are chemically stable, non-irritating, and miscible with water and mucous secretions.



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- (3) **Miscellaneous bases:**
- Those are mixtures of the oleaginous and water-soluble or water miscible materials.
- These materials may be chemical or physical mixtures. Some are performed emulsions, usually of w/o type.
- **Method of preparation:**
- (1) Hand rolling and shaping.
- (2) Molding from a melt.
- (3) Compression.

الأولى اللي هي الطريقة الأقدم اللي هي بتكون بالـ Hand rolling and shaping. يعني بنشكلها على شكل مثلاً زي الأسطوانة وبعدين بعمل لها يعني عملية Rolling شيء وبعدين بنقطع الـ Suppository. النوع الثاني اللي هو الشائع اللي هو الـ Molding، Molding يعني استعمل قالب. طيب كيف بدي أحضر المواد؟ بدي أعمل Pouring للمواد، كيف أعمل Pouring؟ بدي أحضر Melt. Melt ممكن بالتسخين وبعدين أعمل لها Pouring أصبهم، بصير لهم Congealing بالـ Suppository mold وبعدين I will remove it وبعدين بوزنهم بحطهم بالباك.
الطريقة الثالثة اللي هي عملية الـ Compression، اللي هي بهاي الحالة بتتحضر بطريقة ماكنة زي ماكنة الكبس اللي رح نركز عليه اللي هي عملية الـ Molding.

5

5

- **Molding:**
- The most commonly used method for producing suppositories on both small and large scale.
- **The steps in molding include:**
- 1. Melting the base
- 2. Incorporating required medicaments (i.e. dispersing or dissolving the drug in the melted base).
- 3. Pouring the melt into moulds
- 4. Allowing the melt to cool down and congeal into suppositories and removing the formed suppositories from the mold

- The molds in common use today are made from stainless steel, aluminum, and plastic.
- Care must be taken while cleaning the molds, as scratches may affect the desired smoothness of the final product.

6

6

طريقة الـ Lubrication بتعتمد على طبيعة الـ Base اللي راح أستعمله وهل الـ Suppository راح يصير لها Contraction أو لا. يعني بعد ما نصبها نحن رح يصير لها Shaping وبعد ما تجمد بعض الـ Bases بصير لها انكماش. إذا انكمشت الـ Suppository معناته فصلت عن المولد، فسهل إزالتها وما بتحتاج Lubrication. إذا الـ Suppository ما صار لها انكماش No contraction، معناتها بهاي الحالة ما فصلت وبالتالي راح أحتاج عملية Lubrication before الـ Pouring. يعني توضيح: Cocoa butter and PEG bases don't contract. شو معنى هذا الحكي؟ لما أجي أصب الكوكو بتر والـ PEG، أولاً Don't contract ما راح ينكمشوا فما راح يفصلوا فـ Adhesion. يبقى Lubrication is needed.

- **Lubrication of the mold:**
- ✓ required for the preparation of clean and easy removal of suppositories
- ✓ a thin coating of mineral oil is applied to the molding surface for lubrication
- ✓ Cocoa butter and polyethylene glycol bases require lubrication as they do not sufficiently contract on cooling within the mold to separate from the inner surfaces and allow their easy removal.
- *Lubrication is not necessary when glycerinated gelatin suppositories are prepared.*

الفكرة اللي بدي أحكيها إنه عملية الـ Lubrication يكن بكون عكس طبيعة، المفروض طبيعة الـ Base عكس طبيعة الـ Base. يعني إذا كان الـ Base Water soluble بكون بـ Mineral oil. إذا كانت بـ مثلاً Oleaginous بتكون بـ مثلاً Soap بمادة Hydrophilic

شو مبدأها؟ مبدأها إنه لو أنا حطيت المولد في فقط Base فهو راح يأخذ يستوعب وزن معين من الـ Base لو كانت فقط Base. لكن أنا راح أضيف Drug وممكن أضيف مثلاً Preservative ففرح يصير في عملية Displacement. شو Displacement؟ الـ Drug والـ Medicament راح تأخذ جزء من هذا الـ Base وتزيحه، Displace. يبقى لو عندي أنا الدراج زائد البيز، Drug displace part of the base ليتكون عندي Suppository.
طيب كيف بدي أعرف؟ يعني كيف راح أحدد كمية البيز اللي راح ينضاف؟ ثابت الـ Drug عيار الدواء ثابت، لكن كم بدي Base؟

- **Calculation of replacement factor or displacement value:**
- **(1) Replacement factor (the American method)**

- Which is the amount of base that is replaced by the active ingredients in the suppository formulation (F); given by the following formula:
- **F= 100 *** (weight of pure base suppositories- weight of medicated suppositories)
- (weight of medicated suppositories * % active ingredient)
- **F=[100(E-G)/G(X)]+1**
- E= is the weight of pure base suppositories
- G= is the weight of medicated suppositories
- X =% active ingredient.
- Most drug is tabulated by replacement factor, using cocoa butter arbitrarily assigned the value 1 as the standard base.
- ***Replacement factors of some medicaments for cocoa butter***

Replacement factors of some medicaments for cocoa butter su

Boric acid	0.67
Chloral hydrate	0.67
Bismuth subgallate	2.7
Theophylline sodium acetate	0.6
Zinc oxide	0.15-0.25

- 0.67 of the base is replaced by 1 g of zinc oxide .

Displacement value (the British system)

- Which is the number of parts by weight of the medicament that displaces on part by weight of the base.
- The amount of the **drug** that displaces suppository **base** by unit value.

Drug + Base → Suppository

1g mold

Calculation of displacement value

$$\text{Displacement value} = \frac{d}{(a-c)}$$

d: is the weight of the drug

a: is the weight of pure base suppository

c: is the weight of the weight of the base in the medicated suppository.

In our example:

$$\text{Displacement value} = \frac{3}{(6-5)} = 3$$

Example 1:

Calculate the displacement value of a drug if a prescription requires 200 mg of drug per suppository weighting 1g. The weight of 6 suppositories with required drug weight 6.9 g.

$d = 200\ mg \times 6 = 1200\ mg = 1.2\ g$

$a = 1\ g \times 6 = 6\ g$

$c = 6.9\ g - 1.2\ g = 5.7\ g$

$$Displacement\ value = \frac{1.2}{(6 - 5.7)} = \frac{1.2}{0.3} = 4$$

Thus 4 g of drug displace 1 g of the base

Example 2:

Suppose the weight of six unmediated suppositories (cocoa butter base) is 6 g and the weight of six medicated suppositories containing 40% zinc oxide is 8.8 g. what is the displacement value and the ~~replacement factor~~?

$$d = \frac{40}{100} \times 8.8 = 3.52\ g$$

$a = 6\ g$

$$C = \frac{60}{100} \times 8.8 = 5.28\ g$$

$$Displacement\ value = \frac{3.52}{(6 - 5.28)} = \frac{3.52}{0.72} = 5$$

Thus 5 g of zinc oxide displace 1 g of the base.

- **Calculation of replacement factor or displacement value:**
- **(1) Replacement factor (the American method)**

- Which is the amount of base that is replaced by the active ingredients in the suppository formulation (F); given by the following formula:
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9

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- **Calculation of replacement factor or displacement value:**
- **(1) Replacement factor (the American method)**

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10

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- **F=[100(E-G)/G(X)]+1**
- E= is the weight of pure base suppositories
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- Most drug is tabulated by replacement factor, using cocoa butter arbitrarily assigned the value 1 as the standard base.
- ***Replacement factors of some medicaments for cocoa butter suppositories***

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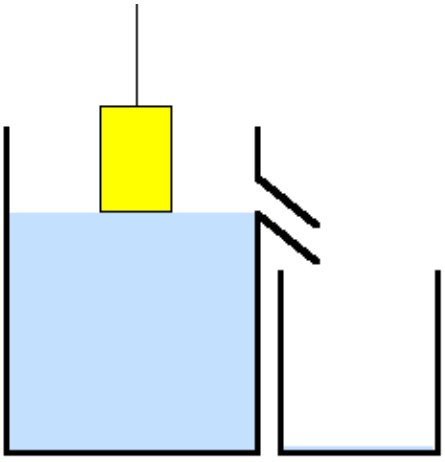

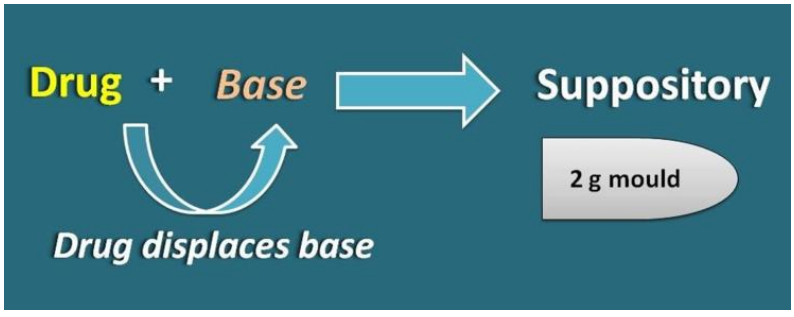

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12

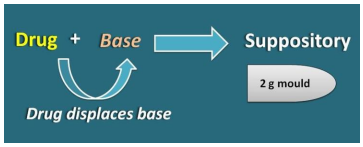
- **(2) displacement value (the British system)**
- Which is the number of parts by weight of the medicament that displaces on part by weight of the base, given by the following formula:
- **Displacement value = the weight of the drug**

  (the weight of pure base suppositories -weight of the base in the medicated suppositories)

- **Displacement value=d/(a-c)**
- d: is the weight of the drug
- a :is the weight of pure base suppository
- c :is the weight of the base in the medicated suppository.

- **Example:** Zinc oxide suppositories 40% zinc oxide. Each is 1gm weight
- Suppose the weight of six unmedicated suppositories (cocoa butter base) is 6 g
- the weight of six medicated suppositories containing 40% zinc oxide is 8.8 g.
- what is the displacement value and the replacement factor?
- (1) the weight of cocoa butter base in the medicated suppositories =60/100*8.8 =5.28g
- (2) the weight of zinc oxide in the medicated suppositories =40/100*8.8=3.52g
- (3) the weight of cocoa butter base displaced by 3.52 g of zinc oxide
- = 6 -5.28=0.72g

40% zinc oxide
60% coco butter base



- **Displacement value = the weight of the drug**

  (the weight of pure base suppositories -weight of the base in the medicated suppositories)

- =3.52/0.72= 5 (approximately)

40% zinc oxide
60% coco butter base

- **the replacement factor F(the American system)**

the weight of six unmedicated suppositories (cocoa butter base) is 6 g

- the weight of six medicated suppositories containing 40% zinc oxide is 8.8 g.
- the weight the weight of cocoa butter base in the medicated suppositories =60/100*8.8 =5.28g
- (2) the weight of zinc oxide in the medicated suppositories =40/100*8.8=3.52g
- (3) the weight of cocoa butter base displaced by 3.52 g of zinc oxide
  - **F= 100 * (**weight of pure base suppositories- weight of medicated suppositories)
  - (weight of medicated suppositories * % active ingredient)
- =[100/(6-8.8)/(8.8*40)]+1=0.2
- (6) Thus 0.2 of the base is replaced by 1 g of zinc oxide .or 5 g of zinc oxide displace 1 g of the base.

15

15

- **Practical part:**
- **A- Calculation of the replacement value:**
- 1. Melt cocoa butter, pour in the molds 4 suppositories, allow cooling, and then finding out the average weight of the suppositories(**pure unmedicated).**
- 2. Melt an amount of cocoa butter equal to half the quantity needed for 4 suppositories.
- 3. Mix with amount of **drug** equal to the dose for 4 suppositories.
- 4. Pour in each mold an amount of the mixture that contain the dose of the drug. (**pure medicated).**
- 5. Fill the mold with melted cocoa butter, and then allow to cool.
- 6. Weight the suppositories and calculate the displacement value of the drug.

- **Displacement value** = the weight of the drug

(the weight of pure base suppositories -weight of the base in the medicated suppositories)

16

16

- ***Formula (1):***
- **B- Rx 4 Bismuth Subgallate suppositories by molding:**

Rx 4 Bismuth Subgallate suppositories by molding:

Rx	
Bismuth subgallate	300 mg
Cocoa butter (Theobroma oil)	q.s

- Rx
- Bismuth subgallate 300 mg
- Cocoa butter (Theobroma oil) q.s
- Quantities are calculated for an excess of TWO to account for incomplete recovery from the evaporating basin.
- *Mould calibration = 1g.
- *DV of Bismuth subgallate= 2.7
- Calculate for extra 2---→ 6 suppositories

- **Displacement value** = $\frac{\text{the weight of the drug}}{\text{(the weight of pure base suppositories -weight of the base in the medicated suppositories)}}$

- 300 mg *6= 1800mg= 1.8gm
- DV: d/ (a-c)
- 2.7= 1.8/(a-c)
- a-c= 0.666= 6 - c → c= 6-0.666= 5.3 gm

17

17

$dV = \frac{d}{(a-c)}$

$dV = 2.7V$

$d = g$ الدوا

300 mg ⇒ .3g

a = Mold calibration

drug وزنة الـ mold بدون

1g

c = Base??

$C = 0.89g$

0.89 * 6 = 5.34

Rx 4 Bismuth Subgallate suppositories by molding:

Rx	
Bismuth subgallate	300 mg
Cocoa butter (Theobroma oil)	q.s

- **Procedure:**
- 1. Lubricate the mold with mineral oil and invert the mould to allow any excess lubricant to drain off.
- 2. Melt cocoa butter*, pour into 4 suppositories molds and allow to cool. Find out the average weight of the suppository.
- 3. Calculate the weight of one medicated suppository using the above instructions.
- 4. Calculate and weight the amount of base and the amount of drug needed for the preparation of 6 suppositories (allowing extra 2).
- *Warm gently using a water bath. Allow 2/3 of the base to melt and remove from the heat. (Temperature should not exceed 36o C, why?).
- 5. Melt the base* and incorporate the drug.
- 6. Pour into 6 suppository molds.
- 7. Wait until congeal, and then carefully remove suppositories from the molds.
- 8. Keep in wide mouth jar and store in cool place.

18

18

- **Use of ingredients:**
- (1) **Bismuth subgallate:** treatment of Hemorrhoids, astringent
- (2) **Theobroma oil:** suppository base

Rx 4 Bismuth Subgallate suppositories by molding:

Rx

Bismuth subgallate	300 mg
Cocoa butter (Theobroma oil)	q.s

- **Labeling:**
- - Main Label:
- - Auxiliary label:

- *For rectal use only. Do not swallow.*

- *Warm gently using a water bath. Allow 2/3 of the base to melt and remove from the heat. (Temperature should not exceed 36o C, why?).
- **Storage:**
- Store in a cool place, protected from light.
- Should be kept in well-closed container.
- **Use of preparation**
- Mild astringent, soothing preparation. For the treatment of hemorrhoids.

19

19

- ***Formula (2):***
- **C- prepare 4 macrogol suppositories by molding:**

prepare 4 macrogol suppositories by molding:

Rx

PEG 6000	47%
PEG 4000	33%
Water	20%

- Rx
- PEG 6000 47% (high??)
- PEG 4000 33%
- Water 20%
- **Procedure:**
- 1. Calculate the amounts of all components for 6 suppositories.
- 2. Melt and dissolve all the PEG together with water on a water bath.
- 3. Pour into the suppositories molds and allow to cool slowly.
- 4. Wait till congeal, and then remove suppositories from the molds.

How many grams of base needed for each suppositories?

- A 1 g mold occupied with 1g theobroma oil.
- If we used different base we should calculate the weight of the base that occupies the same volume as 1g theobroma oil.
- " the ratio of blank suppository of the none cocoa butter base to the blank suppository of the cocoa butter base "
- This information is generally obtained by calibrating the mold first with one base and then the other base

Example:

A mold was calibrated with the PEG base and the average blank suppository weighted 2.24 g. The same mold was calibrated with coca butter and those blank suppository weighed 1.87 g on average. Therefore, the ratio of two weights was:

$$= \frac{weight\ of\ PEG\ suppositories}{weight\ of\ cocoa\ butter\ suppositories} = \frac{2.24g}{1.87} = 1.20\ g$$

Based on this ratio:

The weight of one macrogol suppositories is 1.2 g instead of 1g

20

- ***Formula (3):***
- **D- Rx 4 Glycerinated Gelatin suppositories BP.**

- **Gelatin:**
- Natural compound derived from the partial hydrolysis of collagenous tissue (skin or bone), consists of colorless or pale-yellowish or amber colored translucent sheets, shreds or powder.
- Quantities are calculated for an excess of TWO to account for incomplete recovery from the evaporating basin.

Formula (3):

D- Rx 4 Glycerinated Gelatin suppositories BP.

Rx

Powdered Gelatin	% 14
Glycerol	% 70
Purified water	to 100%

Mold size = 1g → suppositories weight = 1 g

Amount of gelatin = $\frac{14}{100} \times 1 = 0.14\ g$ → for 10 suppositories = 1.4 g

Amount of glycerol = $\frac{70}{100} \times 1 = 0.7\ g$ → for 10 suppositories = 7 g

Glycerol density 1.26 g/ml

1.26 g → 1ml

7 g → ?? = 5.6 ml

Amount of water = $\frac{16}{100} \times 1 = 0.16\ g$ → for 10 suppositories = 1.6 g = 1.6 ml

21

21

- **Procedure:**
- 1. Lubricate the mould with mineral oil.
- 2. Mix glycerol with purified water.
- 3. To the above mixture, add 14 gm of gelatin and mix carefully and slowly to avoid incorporation of air.
- 4. Heat on a steam bath until gelatin dissolves.
- 5. Pour the molten mixture into moulds and allow to congeal.

Rx 4 Glycerinated Gelatin suppositories BP.

Rx

Powdered Gelatin	% 14
Glycerol	% 70
Purified water	to 100%

- **Use of ingredients:**
- (3) **Glycerin:** Lubricant, laxative.
- (4) **Gelatin:** base, gelling agent.

glycerol with purified water

gelatin

22

22

Rx 4 Glycerinated Gelatin suppositories BP.

Rx

Powdered Gelatin	% 14
Glycerol	% 70
Purified water	to 100%

- **Labeling:**
- - Main Label:
- - Auxiliary label:

- *For rectal use only. Do not swallow.*
- **Storage:**
- Store in a cool place
- Should be kept in a well-closed container.
- **Use of preparation:**
- For treatment of constipation (laxative).

23

23

- **Self-reading**
- **Displacement value**
- The displacement value of a drug: *is the number of parts by weight of drug which displaces (occupies the same volume of) 1 part by weight of the base.*
- ✓ Displacement values refer to values for theobroma oil. These values can also be used for other fatty bases.
- ✓ With glycerol-gelatin suppository base approximately 1.2g occupies the same volume as 1g of theobroma oil.

24

24

- **Q1: Prepare six suppositories each containing 250 mg bismuth subgallate**.
- Quantities are calculated for an excess of two suppositories.
- Therefore calculate
- for eight suppositories.
- DV of bismuth subgallate = 2.7
- A l g mould will be used with ***mould calibration y***= 0.94.
- **(calculate amount of both drug and base need)**
- the amount of base required:
- ***Amount of base = (N x y) – (N x D/ DV)***
- N =number of supositorios=8, y =***mould calibration*** = 0.94
- D = **amount of drug** = 250 mg = 0.25 g
- DV = 2.7
- *Amount of base required*
- *= (8 x 0.94) –((8x0.25)/2.7) = 7.52-0.741 = 6.779 9 = 6.78 g*
- *Amount of Drug = 8 x 0.25g = 2g*

A l g mould will be used with ***mould calibration*** = 0.94.

25

- **Q2: Calculate the quantities required to make 15 suppositories each containing**
- **150 mg hamamelis dry extract and 560 mg of zinc oxide. A 2g mould, with mould calibration of 2.04, will be used. Calculate for 17 suppositories (2 excess).**

d1= Weight of hamamelis dry extract = 17 x 0.15 = 2.55 g.
d2=Weight of zinc oxide = 17 x 0.56 = 9.52 g.
a= 2.04 * 17 = 34.68
DV1= 1.5
DV2= 4.7
c= ??

- *DV of hamamelis dry extract = 1 .5*
- *DV of zinc oxide = 4.7.*
- *Weight of hamamelis dry extract = 17 x 0.15 = 2.55 g.*
- *Weight of zinc oxide = 17 x 0.56 = 9.52 g.*
- *Weight of base =*

$$\text{Displacement value} = \frac{d}{(a-c)}$$

$$(a-c) = \frac{d}{DV}$$

Since we have more than one drug :

Amount of base:

$$(a-c) = \frac{d1}{DV1} + \frac{d2}{DV2} + \ldots\ldots$$

$$34.68 - C = \frac{2.55}{1.5} + \frac{9.52}{4.7}$$

$$34.68 - C = 1.7 + 2.026$$

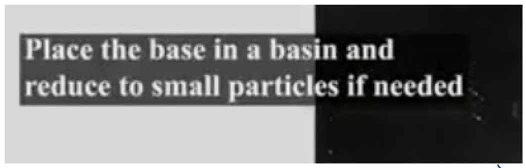
$$C = 34.68 - 1.7 - 2.026 = 30.954$$

- ***Amount of base = (N x y) – (N x D/ DV)***
- *17 x 2.04- (2.55/1.5 + 9.52/4.7) = 34.68- (1.7 + 2.03) = 30.95g.*

hamamelis ***zinc oxide***

26

- **Procedure:**
- 1. Lubricate the mold with mineral oil and invert the mould to allow any excess lubricant to drain off.
- 2. Melt cocoa butter*, pour into 4 suppositories molds and allow to cool. Find out the average weight of the suppository.
- 3. Calculate the weight of one medicated suppository using the above instructions.
- 4. Calculate and weight the amount of base and the amount of drug needed for the preparation of 6 suppositories (allowing extra 2).
- *Warm gently using a water bath. Allow 2/3 of the base to melt and remove from the heat. (Temperature should not exceed 36o C, why?).
- 5. Melt the base* and incorporate the drug.
- 6. Pour into 6 suppository molds.
- 7. Wait until congeal, and then carefully remove suppositories from the molds.
- 8. Keep in wide mouth jar and store in cool place.



اعمل lubricate للـ mold

اعمل لها Melt افليها وامزج بعدين Incorporate the drug

دفع ولاشي تنزلي الزوايا

8 لازم الحرارة تكون واطية ما تتعدى 36°C

خلصت؟ اصب بـ 4 اماكن
استنى ليتماسكو
اتماسكو؟
بال spatula اشيل الزوائد قبل ما افتح
احطهم بشويش

Mineral oil — d.w — PEG 6000 — PEG 4000

Mineral oil: اعمل تشحيم احطه بقطنة وامسح كل جزء بالـ Mold ثم اقفل

PEG 6000 + PEG 4000: سوا مرة وحدة

احط بـ basin واكسر

احطها small particles

اعمل لهم Melt امزج
ثم احطهم بالـ Mold واخليهم ليبردوا
بعدين اطلعهم

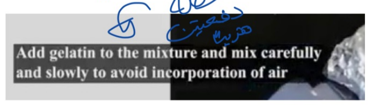
Mineral oil — D.W — Glycerin — Powdered Gelatin

Mineral oil: اعمل له lubricate

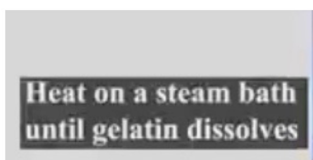
1. Mix (D.W + Glycerin)

احط الـ water بانوب الـ Glycerin اذا احتجت عشان انزل

2. احطها دفعة



3.



4. اصب بالقالب استنى يبرد
اشيل الزوائد واطلع التحاميل لازم يكون زي الكلابش