هي أشكال صيدلانية صلبة بأحجام وأشكال وأوزان مختلفة، مصممة للإدخال في تجاويف الجسم حيث تذوب أو تتحلل لإحداث تأثيرها. تُستخدم عن طريق المستقيم والمهبل والإحليل، ويجب أن يكون حجمها وشكلها مناسبين لإدخالها بسهولة في الفتحة المقصودة دون التسبب في انتفاخ.

شوفو ، حطيت الكم شرح لل calculations of يلي درسته بشابتر ال suppositories عند د. سجى حامد وهو باللون الاسود اما الباقي من الفيديو suppositories

- *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.

• تتكون التحاميل عادةً من دواء مدمج في قاعدة التحميلة. قد يكون الدواء مخصصًا لتأثير موضعي أو ليتم امتصاصه لتأثير جهازي:
• - على سبيل المثال، يشمل التأثير الموضعي في المستقيم تخفيف الإمساك والألم والحكة والالتهاب المرتبط بالبواسير.

تشمل التحاميل ذات التأثير الجهازي الأدوية التي تُخفف الغثيان والقيء ومسكنات الألم غير الستيرويدية المضادة للالتهابات.

1

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

• ثُصنف حسب تركيب وخواص قاعدة التحميلة الفيزيائية:
• (1) قواعد زيتية (دهنية)
(2) قواعد قابلة للذوبان في الماء/قابلة للامتزاج بالماء:

- (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.

يمكن تسميتها قاعدة طبيعية مثل زبدة الكاكاو (زيت ثيوبروما) وهي خليط من إستر الجلسريل لحمض الستياريك، وحمض البالميتيك، وحمض الأوليك، وأحماض دهنية أخرى أو قواعد صناعية مثل وايتيبسولز®، وهو خليط من أحادي وثنائي وثلاثي جليسريد الأحماض الدهنية المشبعة (مثل زيت جوز الهند المهدرج). زبدة الكاكاو هي القاعدة الأكثر استخدامًا نظرًا لأن درجة انصهارها تتراوح بين 30 و36 درجة مئوية، وهي صلبة في درجة حرارة الغرفة ولكنها تنصهر في درجة حرارة الجسم، وقابلة للامتزاج مع العديد من المكونات.

• مع ذلك، يعاني زبدة الكاكاو من عيوبٍ تتمثل في تعدد أشكالها والتصاقها بالعفن، كما أن المكونات القابلة للذوبان مثل الفينول وهيدرات الكلورال تُقلل من درجة انصهارها.

2

• (2) القواعد القابلة للذوبان في الماء/القابلة للامتزاج بالماء: هي تلك التي تحتوي على الجيلاتين الفجلسرين أو بوليمرات بولي إيثيلين جلايكول (PEG).

• قواعد الجيلاتين الفجلسرين هي مخاليط من الجلسرين والماء تُصنع على شكل هلام صلب بإضافة الجيلاتين، وتُستخدم في القالب في التحاميل المهبلية، حيث يُطيل مفعولها الموضعي.

• بالإضافة إلى ذلك، يجب استخدام مواد حافظة مثل ميثيل بارابين وبروبيل بارابين لإطالة مدة صلاحيتها.

- *(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.

glycerinated gelatin

polyethylene glycol (PEG).

3

3

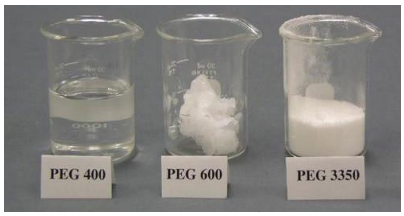
• لتسهيل استخدامها، يجب ترطيبها بالماء قبل الإدخال.

• بولي إيثيلين جلايكول (PEG) أو ماكروغول:

- 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.

• عادةً ما تكون مخاليط من بوليمرات ذات أوزان جزيئية مختلفة لتحقيق قاعدة ذات قوام وخصائص مرغوبة، ولها نقطة انصهار أعلى من درجة حرارة الجسم (42 درجة مئوية) لذلك لا يلزم التخزين البارد، وهي مناسبة للمناخات الحارة، واستخدامها سهل لأنها ليست زلقة عند التعامل معها.

• إنها مستقرة كيميائيًا، وغير مهيجة، وقابلة للامتزاج بالماء والإفرازات المخاطية.



4

4

• (3) قواعد متنوعة:
وهي عبارة عن مخاليط من المواد الزيتية والمواد القابلة للذوبان في الماء أو المواد القابلة للامتزاج بالماء.
قد تكون هذه المواد مخاليط كيميائية أو فيزيائية. بعضها مستحلبات، وعادة ما تكون من النوع المائي. • طريقة التحضير: • (1) الدرفلة والتشكيل اليدوي. • (2) التشكيل من المصهور. • (3) الضغط.

- (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.

5

5

• الطريقة الأكثر شيوعًا لإنتاج التحاميل على نطاق صغير وكبير. تشمل خطوات التشكيل ما يلي:
• 1. صهر القاعدة
2. دمج الأدوية المطلوبة (أي تشتيت الدواء أو إذابته في القاعدة المذابة).
• 3. صب المصهور في القوالب
• 4. ترك المصهور ليبرد ويتجمد في شكل تحاميل وإزالة التحاميل المشكلة من القالب

- **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

القوالب الشائعة الاستخدام اليوم مصنوعة من الفولاذ المقاوم للصدأ والألومنيوم والبلاستيك.

- 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

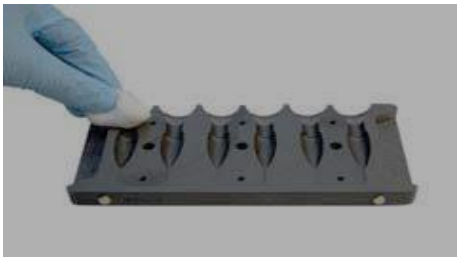
• يجب توخي الحذر أثناء تنظيف القوالب، حيث قد تؤثر الخدوش على النعومة المطلوبة للمنتج النهائي.

6

• تزييت القالب:

مطلوب لتحضير تحاميل نظيفة وسهلة الإزالة
يتم وضع طبقة رقيقة من الزيت المعدني على سطح القالب للتزييت.،
تتطلب قواعد زبدة الكاكاو وبولي إيثيلين جلايكول التزييت لأنها لا تنكمش بشكل كافٍ عند التبريد داخل القالب
للانفصال عن الأسطح الداخلية والسماح بإزالتها بسهولة.
التزييت غير ضروري عند تحضير تحاميل الجيلاتين المجلسرين.

- **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.*


7

7

- **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 .

8

8

• ما هي كمية القاعدة التي يتم استبدالها بالمكونات الفعالة في تركيبة التحاميل (F)؟ يتم حسابها بالصيغة التالية: F = 100 * (وزن التحاميل الأساسية النقية - وزن التحاميل المعالجة) / (وزن التحاميل المعالجة * نسبة المكون الفعال) • f = 100(e - g) / g(x) + 1

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9

9

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إعادة

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10

10

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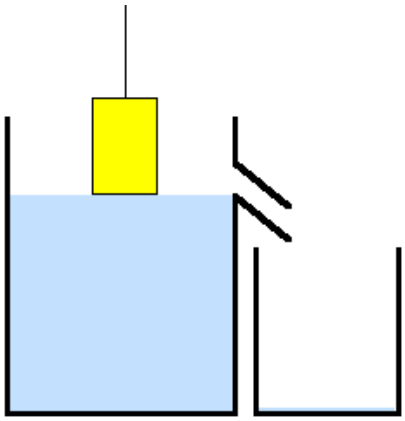
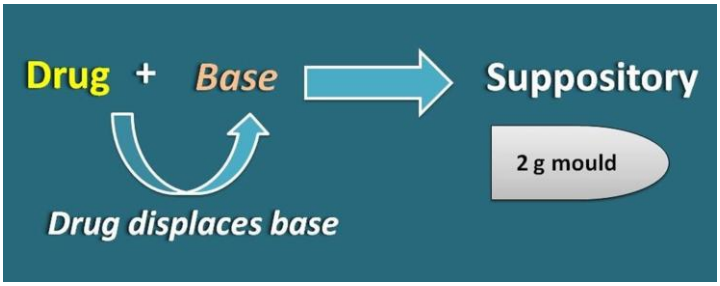
- ***Replacement factors of some medicaments for cocoa butter suppositories***

11



احنا لما نحط ال drug رح نطلع شوي من ال Base عشان نحطه مكانها



12

• وهي عدد أجزاء الدواء بالوزن التي تزيح جزءا من وزن القاعدة, وتُعطى بالصيغة التالية:

• قيمة الإزاحة = وزن الدواء

- **(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.

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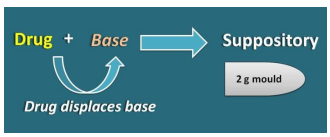
- **Example:** Zinc oxide suppositories 40% zinc oxide. Each is 1gm weight
- Suppose the weight of six unmedicated suppositories (cocoa butter base) is 6 g
- the weight of six medicated suppositories containing 40% zinc oxide is 8.8 g.
- what is the displacement value and the replacement factor?
- (1) 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)

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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

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- **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)

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- ***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

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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

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- **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

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- ***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.

20

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- ***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.

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- **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

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- **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.

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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.

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- **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).**

- *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 =*

- ***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***

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Density Factors

* بسبب ال density ل drug رح يأدي إلى إخراج جزء من ال suppository base عشان يحصلها.

* اذا كانت $d_{drug} = d_{base}$ فرح يطلع نفس الكمية من ال base

* اذا كانت $d_{drug} > d_{base}$ فرح يطلع smaller weight من ال base.

* Density factor = $\frac{\text{weight drug}}{\text{weight displaced base}}$ = $\frac{\text{وزن الدواء}}{\text{وزن القاعدة اللي طلعناها}}$

ex: Aspirin density = 1.3 g

If a suppository has 0.3 g of aspirin

(A) How much cocoa butter (base) will be displased

sol: $d = \frac{W_{drug}}{W_{displased}}$

$1.3 = \frac{0.3}{W_{displased}}$

$W_{displased} = 0.23$ g

(b) If blank suppository weighed 2 g how much cocoa butter we will need for each suppository ??

sol: يعني لو بزبط كمية ال butter اللي لازم نحطها أو اللازمة بعد ما دخلنا ال drug وطلع ال butter

$2 - 0.23 = 1.77$ g of cocoa butter

(c) suppositry weight after putting drug inside with cocoa butter

sol: هذا أهم فرع لأنه ممكن بس يجيلك ياه وانت بتضطر إنك تحسب فرع a + b عشان تطلع المطلوب

$1.77 + 0.3 = 2.07$ g

(d) How much cocoa butter will be needed for 12 suppository ??

sol: $1.77 \times 12 = 21.24$ g

(e) How much Aspirin will be needed for 12 suppository?

$0.3 \times 12 = 3.6$ g

ex: mold with PEG base weighed 2.24 g
mold with cocoa butter weighed 1.87 g

(A) The ratio is ??

sol: $\frac{W_{PEG}}{W_{butter}} = \frac{2.24}{1.87} = 1.2$

(B) If 200 mg of aspirin is incorporated with PEG

* ~~PEG = 1.0~~ $d_{cocoa\ butter} = 1.3$

calculate How much PEG will be displaced?

sol: يعني بقلك انه أنا ماعندي ال d لل PEG عشان هيك ما بقدر استخدم نفس القانون البسيط فكديل رحت حسبت ال ratio بين الكمية يلي معي و cocoa butter و رح استخدمها كالآتي

200 mg = 0.2 g

$\frac{0.2\ g}{1.3\ g} * 1.2 = 0.18\ g$ of PEG base

هذا نفس القانون القديم بس غيرتناه بالنسبة يلي معنا

(C) How much PEG base will be needed for each suppository ??

Sol: 2.24 كلها PEG هو اعطاني بنص السؤال انه ال
واحنا حسبنا كم رح يطلع من ال PEG بسبب ال drug
باي وظناه بداله فبنطرحهم من بعض

$$2.24\,g - 0.18\,g = 2.06\,g$$

ex: using a particular mold.

- weight of cocoa butter suppository was 2g
- weight of cocoa butter suppository, each containing 300mg of drug A were 2.1 g

calculate

300mg = 0.3g

(a) weight of base

sol:

هو طلب وزن ال base يلي موجود جوا ال suppository يعني بعد ما دخلنا ال drug

$$2.1 - 0.3g = 1.8g$$

هو وزن التحميلة موجود فيها ال drug + base

0.3g ↓ وزن ال drug

(b) weight of displaced ??

sol:

المطلوب هون كمية ال base يلي طلعت

$$2g - 1.8 = 0.2g$$

2g ← وزن ال base الكلي

1.8 ↓ الوزن الحقيقي داخل ال suppository

(c) density factor of drug A

sol: على القانون مباشرة

$$d = \frac{W_{drug}}{W_{displaced}} = \frac{0.3}{0.2} = 1.5$$

200 mg drug / suppository of 1g

6 suppositories ⟶ 6.9 g
+ drug

calculat displacment Value??

Solu:

0.2 g drug ⟶ 1 supp

x g drug ⟶ 6 supp

d = 1.2 g of drug in each supp

$\frac{d}{a-c}$ = Displacment Value $= \frac{1.2}{(6.9-5.7)}$

$= 4$

a = 1 g × 6 = 6 g

c = 9.6 − 1.2
= 5.7 g

∴ 4 g of drug displace 1 g of base.

6 supp are 6 g.

6 medicated supp are 8.8 g

40% zinc oxide

displacment and ~~replacment~~ ~~value~~ ?

$d = \frac{40}{100} \times 8.8 = 3.52$ g of drug in each supp

$a = 6$ g (base supp)

$c = 8.8 - 3.52 = 5.28$ g or $c = \frac{60}{100} \times 8.8 = 5.28$ g

the same

$$\text{Displacement value} = \frac{d}{a - c} = \frac{3.52}{6 - 5.28} \approx 5$$

Formula (1):

B- Rx 4 Bismuth Subgallate suppositories by molding:

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.

*Mold calibration= 1g.

*DV of Bismuth subgallate=2.7

Firstly, We need to calculate required amount per one suppository (c).

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

$$2.7 = \frac{0.3\ g}{(1\ g - c)} \rightarrow 1 - c = \frac{0.3}{2.7} \rightarrow 1 - c = 0.11\ g \rightarrow c = 0.89\ g$$

Formula (1):

B- Rx 4 Bismuth Subgallate suppositories by molding:

Rx		For 6 suppositories
Bismuth Subgallate	300 mg	1.8 g
Cocoa butter (Theobroma oil)	q.s = 890 mg	5.34 g

Quantities are calculated for an excess of TWO to account for incomplete recovery from the evaporating basin.

*Mold calibration = 1g.

*DV of Bismuth subgallate=2.7

Preparation notes:

1. Base should be gently warm (Temperature should not exceed 36° C).
2. Melted base should be poured into each suppository molds at once.

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:

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

Based on this ratio:

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

Formula (2):

C- prepare 4 macrogol suppositories by molding:

Rx

PEG 6000	47%
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.

Mold size = 1g → suppositories weight = 1.2 g

Amount of PEG 6000 $= \frac{47}{100} \times 1.2 = 0.564\ g$ → for 6 suppositories = 3.384 g

Amount of PEG 4000 $= \frac{33}{100} \times 1.2 = 0.396\ g$ → for 6 suppositories = 2.376 g

Amount of water $= \frac{20}{100} \times 1.2 = 0.24\ g$= 0.24 ml → for 6 suppositories = 1.44 ml

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

Extra example:

Prepare six suppositories each containing 250 mg bismuth subgallate. Quantities are calculated for an excess of two suppositories. Therefore calculate for eight suppositories. (calculate amount of both drug and base need)

DV of bismuth subgallate = 2.7

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

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

d= 0.25 g * 8 = 2 g → amount of drug

a= 0.94 * 8 = 7.52

DV= 2.7

C= ? → amount of base

$$2.7 = \frac{2}{(7.52 - c)}$$

$$7.52 - c = \frac{2}{2.7} = 0.74$$

$$c = 7.52 - 0.741 = 6.78\ \text{g}$$

Extra example 2:

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).

DV of hamamelis dry extract = 1.5, DV of zinc oxide = 4.7.

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= ??

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

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

Since we have more than one drug :

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

Amount of base:

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

$$34.68 - C = 1.7 + 2.026$$

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