**Doctor of Pharmacy**

**Pharmacy Skills Laboratory (PHAR321)**

**Lab 6 : The Compounding and Dispensing of Emulsions and Liniments**

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| Exp. Name | **Emulsions and Liniments**  | **Exp. NO.** | **6** |

**Experiment 6.1A : Mineral Oil Emulsion**

**Product Formula:-**

**Table 1 : PF 1**

| NO. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | **Mineral Oil-Parrafin oil-** | **50ml** | **Muhammad** | **Dana** |
| 2 | **Acacia-Arabic gum-** | **12.53g** | **Muhammad** | **Dana** |
| 3 | **Simple syrup** | **10ml** | **Dana** | **Muhammad** |
| 4 | **Vanillin** | **4mg** | **Dana** | **Muhammad** |
| 5 | **Ethyl Alcohol** | **5ml** | **Muhammad** |  |
| 6 | **Purified Water qs ad** | **100ml** | **Dana** | **Muhammad** |

**Pharmaceutical Drug in Pharmacy:-**

**Trade name: Mineral Oil-Lubricant Laxative-**

**Company: TopCare**

**Active Pharmaceutical Ingredient: Mineral Oil**

**About Product:-**

**Product name: Mineral Oil Emulsion**

**Product’s components and their roles:**

**Table 1 : Roles of components 1**

| NO. | Ingredients | Role |
| --- | --- | --- |
| 1 | **Mineral Oil** | **Laxative** |
| 2 | **Acacia-Arabic gum-** | **Natural emulsifier** |
| 3 | **Simple syrup** | **Sweetening agent** |
| 4 | **Vanillin** | **Flavor** |
| 5 | **Ethyl Alcohol** | **Help in dissolve vanillin** |
| 6 | **Purified Water** | **Vehicle** |

**Counseling:-**

1. **Indication (Why the medicine is given ) :**

This emulsion is a laxative , used to treat constipation , as the paraffin oil ( mineral oil) acts as a lubricant – keeps water in the intestines - and so it keeps the stool soft and makes the passing of stool easier in chronic constipation –especially hemorrhoids - .

1. **Administration (How to use it ) :**

Preferable to use it in the evening and within 30 minutes of meal times ( it is also preferable to use it on an empty stomach ) , the amount measures should be precise so use a measuring device . Do not lie down after taking it so it shouldn’t be taken immediately before bed .

The doses from 6 yeas to adults is 1 to 3 tbsp. ( 15 to 45 ml) in 24 hours and DO NOT GIVE to children under 6 years old or to elderly above 65 as the side effects may worsen and more side effects can be seen and there is a risk of aspiration(lipid pneumonitis ) .

Don't take this laxative more than a week unless the doctor approves it .

Also this laxative may take 6-8 hours to make bowel movement and if it does not work in this amount of time or your situation worsens , call a doctor .

 **3- Adverse effects**:

* Very bad dizziness or passing out
* Very bad belly pain and upset stomach or throwing up
* Severe diarrhea
* bleeding from rectum
* Allergic reaction

The side effects listed above are dangerous and if they happen the doctor should be seen immediately , and other less dangerous side effects include ;

* Belly pain.
* Stomach cramps.
* [Bloating](https://www.drugs.com/cg/gas-and-bloating.html).
* Gas.
* Upset stomach or throwing up.
* Diarrhea.
* Irritation of rectum/anus

**4-Storage Conditions:**

* Store at room temperature
* Away from light
* Store in a tight closed container
* Away from children
* Do not freeze

Expires in 1 month

**5-Precautions and extra Notes :**

* Do not use other laxatives with it
* Avoid prolonged use ( shouldn’t take more than a week unless the doctor says so ) as it interferes with the absorption of fat soluble vitamins .
* There should be 2 hours between taking this laxative and other drugs as it may interfere with the other drugs’ absorption and tell your doctor about any drugs you are taking before using this laxative .
* Do not take in pregnancy ( unless it is needed) as it can harm the unborn baby and there also can be risks if taken during breastfeeding.
* If you are allergic to t or any of its components do not use it .
* Do not take extra doses or two doses at the same time
* You have to tell your doctor before using this laxative if you have any of those conditions : appendicitis or any of its symptoms , stomach problems , bleeding from rectum , change in bowel habits in the last 2 weeks ,difficulty swallowing
* This drug interacts with warfarin , vitamin d , beta carotene , digoxin ,docusate (stool softener) .
* Do not use if you suffer from inflammatory bowel disease as it can cause colonic perforation (ruptured bowel) or if you have abdominal pain with no known cause or acute surgical abdomen because if used in these conditions you may need an emergency surgery.
* If you overdose , drink a lot of water .

**Calculations:-**

**Product strength = (API Mass / Total volume) \* 100%**

**Strength=( 50ml /100 ml) \*100%**

 = 50 % v/v

**Experiment 6.1B: Basic Emulsion**

**Product Formula:-**

**Table 3 : PF 2**

| NO. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | **Liquid Parrafin** | **35 g** | **Dana** | **Muhammad** |
| 2 | **Wool fat** | **1g** | **Muhammad** | **Dana** |
| 3 | **Cetyl alcohol** | **1g** | **Muhammad** | **Dana** |
| 4 | **Emulgent(Span 20 + Polysorbate 80)** | **7g(3.3g+3.7g)** | **Dana** | **Muhammad** |
| 5 | **Water qs**  | **100g** | **Dana** | **Muhammad** |

**Pharmaceutical Drug in Pharmacy:-**

**Trade name: N/A**

**Company: N/A**

**Active Pharmaceutical Ingredient: Liquid Parrafin**

**About Product:-**

**Product name: Basic Emulsion**

**Product’s components and their roles:**

**Table 4 : Roles of components 2**

| NO. | Ingredients | Role |
| --- | --- | --- |
| 1 | **Liquid Parrafin** | **Emollient** |
| 2 | **Wool fat** | **Water absorbing agent** |
| 3 | **Cetyl alcohol** | **Thickening agent** |
| 4 | **Emulgent** | **Emulsifying agnet** |

**Counseling :-**

1. **Indication (Why the medicine is given) :**

This is a basic emulsion preparation but mainly the liquid paraffin in it is used to treat constipation ( also liqud paraffin ca be used to treat skin conditions ) .

1. **Administration (How to use it ) : // Basic preparation**
2. **Adverse Effects :// Basic preparation**
3. **Storage Conditions : // Basic preparation**

**Calculations:-**

The Required HLB values of the first three ingredients liquid paraffin , wool fat and cetyl alcohol are 12, 10, and 15.

Amount in perecentage : the percentage (in manual)/ total

1. Liquid Paraffin: = 35/37 \*100% = 94.55%

2. Wool fat: 1/37 \*100% = 2.7 %

3.Cetyl alcohol = 1/37 \*100% = 2.7 %

Estimated HLB = (94.5% \* 12) + (2.7%\*10) + (2.7%\*15) = 40.5

% of emulsifier: 100 (x -100) / HLB 1 – HLB 2

RHLB= O1\*R1=35/37\*12+1/37\*10+1/37\*15

 =12.02

12=X1\*8.6+ (1-X1)\*15

X1=45%, 45%\*7= 3.15g this is for span

 X2=55%, 55%\*7=3.85g this is for polysorbate

**Experiment 6.2 : Methyl Salicylate Liniment BP**

**Product Formula:-**

**Table 5 : PF 3**

| NO. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | **Methyl Salicylate** | **-** | **-** | **-** |
| 2 | **Arachis oil** | **-** | **-** | **-** |

**Pharmaceutical Drug in Pharmacy:-**

**Trade name: Methyl Salicylate Liniment APF**

**Company: Gold R Cross**

**Active Pharmaceutical Ingredient: Methyl Salicylate**

**About Product:-**

**Product name: Methyl Salicylate Liniment BP**

**Product’s components and their roles:**

**Table 6 : Roles of components 3**

| NO. | Ingredients | Role |
| --- | --- | --- |
| 1 | **Methyl Salicylate** | **Relieves muscular** |
| 2 | **Arachis oil** | **Vehicle** |

**Counseling:-**

1. **Indication (Why the medicine is given):**

This medication is given for the relief of rheumatic pain , muscle stiffness , joint pains caused by sprains , arthritis , bruising or backaches , also for lumbago, fibrositis and strains of ligaments and tendons. This medication is absorbed by our skin. And works by causing the skin to feel cool and then warm and these feelings distract from feeling pain. This feeling should lessen overtime . and If the burning sensation is painful causes significant discomfort, wash the treated skin area with soap and cool water

1. **Administration (How to use it ) :**

Rub in gently at the area of pain as required and apply 2 times a day for 2 weeks , after you finish rubbing wash your hands and if the affected area is the hands put it on hands for 30 minutes and then wash them

1. **Adverse Effects :**
* Redness or stinging at appliance site
* Can rarely cause allergy , but if this happens stop it immediately and seek doctor’s help . .
* swelling ,severe redness , unusual pain at application site or ringing ears . Stop it immediately if any of those happen .
* Urticaria and angioedema have been reported in aspirin-sensitive patients.

**4- Storage Conditions:**

* Store in a cool and dark place , Under 25 C
* Keep away from heat and light
* Store in a tightly closed container
* external use only
* Away from children

Expires I 1 month

**5- Precaution and Exra Notes ;**

* Do not use if you are allergic to methyl salicylate or aspirin or any other salicylates
* Since this medicine contains peanut oil (arachis oil) , you should not use it if you are allergic to peanuts . Also if you are allergic to soya as there is a relation between soya and peanut
* Consult with your doctor before using it if you have asthma or abnormal growths in your nose .
* It should not be used pregnancy ( 1st 6 months) unless needed and absolutely should not be used in the last 3 months because it can harm the unborn baby and can induce labour .
* Do not use this medication in children under 2 years old
* Heat increases side effects so do not apply It during, before or after activities that cause the skin’s temperature to increase or in hot weather and do not use tanning beds or apply heat packs either before using it , you should wait until the skin is cool and then use it .
* Do not apply to wounds , irritated skin and avoid getting it in contact with contact lenses , dentures and other items that come into contact with sensitive areas of our body .
* Do not put I mouth as it is harmful if swallowed or in nose or eyes , and if it gets in any of those places , flush them with a lot of water .
* Do not wrap the affected area after applying the medicine as it can increase side effects.
* If swallowed and cause overdose (for adults 50-500 mg/ kg this dose is dangerous ) , induce emesis followed by supportive therapy and then gastric lavage , also charcoal haemoperfusion has been used in the treatment of poisoning with methyl salicylate. As little as 4 ml has caused death in infants.
* Medication interacts with warfarin

**Questions(1):-**

1. **What are the quantities of surfactants that were used explain?**

**Quantities of surfactants used- Span 20, Polysorbate 80- are calculated** according to their HLB values and the required HLB:

Wet fraction= %of ingredient/Sum of ingredient percentage

Wet fraction of liquid paraffin (W1)= 35/ (35+1+1) = 0.95

Wet fraction of wool fat (W2) =1/(35+1+1)= 0.027

Wet fraction of cetyl alcohol (W3)= 1/(35+1+1)= 0.027

Required HLB= (W1 \* HLB1) + (W2 \* HLB2) + (W3 \* HLB3)

 = (0.95 \* 12) +(0.027 \* 10) + (0.027 \* 15) = 12.075

%Span 20 = 100 \* (RHLB – HLBPoly80) / (HLBSpan20- HLBPoly80)

 = 100 \*(12.075-15) / (8.6-15) = 45.7%

7g of emulgent will be used in the experiment

Weight of Span 20 = 45.7% \* 7 = 3.2g

Weight of Polysorbate 80= 7 - 3.2= 3.8g

1. **What are the breaking processes for an emulsion?**

An emulsion breaks in two steps: coagulation which removes the emulsifying properties of the emulsifying agent, and flocculation which agglomerates the formed, separated droplets into large, separable globules.

Emulsion breaking involves two processes: gravity separation of the non-emulsified oil droplets, and chemical treatment to separate emulsified oil by addition of an emulsifier agent which can separate the phases using a number of mechanisms according to the agent used.

1. **How can you predict the HLB for a surfactant experimentally?**

HLB values of surfactant can be predicted to be within certain ranges according to water dispersibility:-

| Dispersiblity | HLB Range |
| --- | --- |
| No dispersiblity | 1-4 |
| Poor | 3-6 |
| Milky dispersion | 6-8 |
| Stable milky dispersion | 8-10 |
| Translucent to clear | 10-13 |
| Clear solution | +13 |

A titration method for determination of HLB experimentally uses an aqueous and an oily phase, and another surfactant of known HLB.

The higher HLB solution is added in a graduated cylinder with carbon black, and the aqueous and oily phases, and the mixture is titrated with the lower HLB solution. The end point that suggests emulsification is even division of the black color of carbon black between the two phases. Then using HLB calculations, the HLB of the unknown surfactant can be determined.

**Questions(2):-**

1. **There are methods for preparing emulsions, describe them briefly. Which one you prefer in preparing mineral oil emulsion?**

Dry gum metod: 4 oil: 2 water: 1 emulsifier. 1 part emulsifier is levigated with 4 parts oil until the powder is wetted, then the 2 parts water are added all at once and the mixture is vigorously triturated until the primary emulsion forms.

Wet gum method: 4 oil: 2 water: 1 emulsifier. 1 part emulsifier is triturated with 2 parts water to form a mucilage, then the 4 parts oil are added slowly in portions with trituration.

Forbes bottle method : A variation of the dry gum method for low viscosity substances. The mixing is done by shaking the bottle instead of using a mortar and pestle.

In situ soap method: Only used for calcium soaps and soft soaps. Mineral oil emulsion is preferably prepared with the dry gum method.

1. **What is the method used in preparing mineral oil emulsion?**

Mineral oil is prepared using the dry gum method.

1. **What is an emulsifying wax? And what is the primary emulsion?**

Emulsifying wax is a self-emulsifying material, it’s used to emulsify other products to keep the oil and water phases from separation, it can be used to make thick and thin emulsions depending on the concentration used.

Primary emulsion is an emulsion made from one internal phase and one external phase, they can be O/W or W/O.

1. **Cracking is one of the problems encountered when making primary emulsion, what is this problem?**

When an emulsion cracks it’s separated into its separate ingredients forming layers that cannot be re-emulsified by shaking, it could be due to creaming and coalescence of the emulsion’s particles, addition of an incompatible emulsifying agent, chemical composition of the emulsifying agent, exposure to hear or cold.

1. **What is oil of wintergreen, and what are its uses?**

Wintergreen oil is taken from the *Gaultheria species*, it’s a pale yellow and pinkish fluid that is strongly aromatic with a sweet woody odor, it’s obtained by steam distillation of the leaves of the plant following maceration in warm water, it’s used to treat pain including headache, nerve pain(Particularly sciatica), arthritis, ovarian pain, and menstrual cramps. It is also used for digestion problems including stomach-ache and gas(Flatulence); lung conditions including asthma and pleurisy; pain and swelling(Inflammation); fever, and kidney problems.

1. **What quantities of : fixed oil, aqueous phase, and the gum would be required to produce 100ml of a 20% emulsion of a fixed oil?**

To make 100ml of the 20% emulsion we need to add 4:2:1 parts of the ingredients; 20ml oil, 10ml water and 5ml of gum and after we prepare this emulsion we can adjust the volume to 100ml.

**Exp 6.1**

**Main Label:-**

**Pharmacy name**: MID Pharmacy

**Pharmacist name**: Dana Joza’

**Partner name**: Mohammad Musleh

**Product name:** Mineral Oil Emulsion

**Product strength:** 50 % v/v

**Expiration date:** One month

**Amount prepared:** 100ml

**Use:** Laxatives-Relieves constipation-

**Auxiliary Label:-**

* Shake will before use
* Keep out of the reach of children
* Store at Room Temperature-Approx. 24 Co
* Do not freeze

**Exp 6.2**

**Main Label:-**

**Pharmacy name**: MID Pharmacy

**Pharmacist name**: Dana Joza’

**Partner name**: Mohammad Musleh

**Product name:** Basic emulsion

**Product strength:**   35 % w/v liquid paraffin

**Amount prepared:** 100 ml

**Use:**  basic emulsion

**Exp 6.3**

**Main Label:-**

**Pharmacy name**: MID Pharmacy

**Pharmacist name**: Dana Joza’

**Partner name**: Mohammad Musleh

**Product name:** Methyl Salicylate Liniment BP

**Product strength:**   25 % v/v

**Expiration date:** 1 month

**Amount prepared:** 100 ml

**Use:**  relief of rheumatic , joint and muscular pain .

**Auxiliary Label:-**

* external use only
* Save in a cool and dark place below 25 C
* avoid contact with broken skin
* store away from heat and light
* away from children