California Northstate University

College of Pharmacy

**PHARMACEUTICS LABORATORY**

For the laboratory, you are required to provide the following:

**White lab coat :** The coat must be long-sleeved.  Please come to the lab session with a white lab coat. No exceptions.

**Professional dress**: To maintain professionalism in the laboratoryprofessional dress must be worn at all times in the laboratory.  No jeans are allowed.  Close-toed shoes must be worn for your safety.  No high-heeled sandals or shoes are allowed.  For your safety jewelry must not be worn in any laboratory session.  Students will lose points for not being dressed appropriately.

Cell phones must be turned off in the laboratory.

Absolutely NO food or drink is allowed at ANY time in the laboratory.

Please advise course coordinator/instructor of any allergies you may have.

**Bring a calculator to the lab session.**

**Bring the lab handout with you to the lab session including the grading sheet.**

**Labeling your product**

Please indicate the following information on the label of any product that you submit:

1. Your name
2. Your ID
3. The date
4. The active ingredient, and its concentration. (the amount of active ingredient *per dosage unit* should be specified). e.g. ZnO 300 mg/suppository.
5. The dosage form (e.g. ointment, suppositories) and the amount of medication or the number of units (e.g. 5 tablets, 6 capsules, or 120 mL).
6. Clear directions for the medication use.

**Always use pen (blue or black )when writing a label.**

**A prescription label format:**

**Name of Pharmacy**

**Rx No. : Date:**

**Patient’s (your) Name: Your ID:**

**Active ingredient and its concentration No. of units: Auxilliary Label**

**Direction for medication use**

**Expiration Date:**

**Auxiliary labels may also be needed.**

It is sometimes necessary to use auxiliary labels to provide supplementary information regarding proper and safe administration, use, or storage of the product.

Abbreviations:

M= mix

Ft= make

Div= divide

Dis= dispense

d.t.d= give such doses

ung=ointment

ud = as directed

**Rx 1. Sulfur Ointment:**

Rx

Sulfur 3g

Mineral oil qs

Plastibase (White ointment) 27 g

M. Ft ung 30g

Sig: Apply to affected area u.d

**Equipment needed:**

Balance, 2 spatulas, glass rod, ointment slab/tile, container, label, measuring boats, measuring paper, dropper if needed.

**Procedure:**

1. Place the sulfur on an ointment tile.
2. Levigate the sulfur with the mineral oil on an ointment tile, and continue until a smooth paste is obtained.
3. Using geometric dilution, combine the paste from step 2 into the ointment base.
4. Package into an ointment jar in a pharmaceutically elegant way and label with instructions to apply to affected area u.d.
5. **Please refer to USP to figure out the expiration date of compounded semisolids.**

**Rx 2 : Acetaminophen Suppositories**

Acetaminophen **325** mg

Polyethylene glycol 2000 qs

M. Ft: Rect. supp.; No. VI

**Sig:** 1 supp PR q4-6hr PRN

Label your product: *Acetaminophen 325 mg Rectal Suppository*

Suppository base:

OR

**Rx2: ZnO Suppositories**

ZnO **300** mg

Polyethylene glycol 2000 qs

M. Ft: Rect. supp.; No. VI

**Sig:** 1 supp PR q4-6hr PRN

Label your product: *ZnO mg Rectal Suppository*

**Note:** From Remington: polyethylene glycol base is assumed to have a density factor of 1.3 relative to cocoa butter. Why do you need this information?

If you are using Acetaminophen 60mg for an adult suppository will this affect your calculation?

The density factor of Acetaminophen to cocoa butter is 1.2

The density factor of ZnO to cocoa butter is 4

Density of PEG is 1.1

**Note:** The plastic mold is calibrated based on volume either 1.3, 2, 2.25, 2.8, 3.0ml. You can find that information on the edge of the mold or by calibrating yourself.

**In the lab, we have the 2 ml mold capacity**. So please base your calculations on a 2ml (in the classroom we used 2.2ml as an example).

Have your calculation ready for both Acetaminophen and ZnO. You will only make one of them in the lab subject to availability of the drug.

Please email me if you have any question.

Suppositories Continued:

**Equipment needed:**

Balance, beaker, measuring cylinder, heating device, 2 spatulas, glass rod, suppository molds, container, label, measuring boats, measuring paper, dropper if needed.

**Procedure:**

1. Weigh your active ingredient.
2. Measure the base and place into a beaker.
3. Melt the base material over low heat around the melting point of PEG 2000 ( **please look it up**) .
4. Once dissolved, add the weighed active drug to the melted base material gradually.
5. Mix gently so air will not be entrapped in the mixture of the active ingredient and base added, continue stirring until completely blended.
6. Remove from heat, let stand and then pour mixture into suppository mold.
7. Allow suppository to cool at room temperature for approximately 30 minutes.
8. May place suppository in refrigerator until they are cooled and relatively hardened.
9. Place the completed suppositories in the proper container.
10. Label the container correctly.
11. Suppositories are ready for dispensing to the patient.

Rx 3. Sucrose capsules

1. Powder Filling into capsules using “Stamping/punching”

Rx

Sucrose (drug substitute) 5 g

Corn starch 15 g

M. Ft. div.cap (size ) No. X

Label *Sucrose Y mg Capsules*

Sig: 1 caps po prn

Calculate how much Sucrose you need to fill the prescription. (you need to count for 10% more of the number of capsules you need to fill). Do your calculations and check it with your instructor.

Remember *M et div. means the amount of Sucrose(Drug), is enough for 10 capsules,* calculate the amount needed for 1 capsule then the amount needed for ( 10 capsules + 10% excess).

**Method:**

1. Finely powder the sucrose using a mortar and pestle
2. Dilute the sucrose with corn starch using geometric dilution (imagine this is a potent drug)
3. Spread the mixed powder onto a tile in an even layer
4. “Punch” a capsule and weigh to estimate the weight of the powder fill.
5. Weigh each empty capsule tare and by trial and error fill the required amount in the capsule.
6. Adjust thickness of powder layer, if necessary, to obtain **Y** mg sucrose per capsule
7. Fill only 10 capsules
8. *Be sure to calculate amount of Sucrose(Y mg) in each capsule.*

Grading sheet: Have the instructor check you out, and then submit this form with your products.

**To be completed by student:**

Name: Student ID #: Date:

Where appropriate or necessary include auxiliary labels. Show all calculations.

|  |  |  |
| --- | --- | --- |
| Rx 1 **Ointment** | Rx 2 **Suppositories** | Rx 3 **Capsules** |
|  |  |  |
| Find the percentage w/w of Sulfur in the ointment | calculate the amount of PEG in blank (disposable/plastic) suppository. | Calculate the weight of sucrose per capsule |

**To be completed by Instructor:**

Student on time for lab: YES NO Comments:

Student appropriately dressed: YES NO Comments:

Exercise completed in time: YES NO Comments:

Bench and sink areas clean when finished: YES NO Comments:

**To be completed by grader:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Rx 1 | Rx 2 | Rx 3 |
| Student followed lab procedures  (0-10 points) |  |  |  |
| Dosage form pharmaceutically elegant  (0-20 points) |  |  |  |
| Label on container correct  (0-10 points) |  |  |  |
| Calculations/auxiliary labels correct  (0-10 points) |  |  |  |
| Total points  (0-50 points) |  |  |  |