

Name: _____

Date: _____

Lab Day: Mon Tues Wed Thurs Friday

Time: AM PM

Compounded Non-Sterile Preparation - Capsule

Required Pre-Lab Preparation

- Review this packet Dry Lab and Wet Lab Prescriptions/Calculations/Procedures
- PSK Lab Website Compounding Area
 - Compounding Lectures and Procedure Videos
 - Capsules In-Class Procedure video
 - Capsules Lecture podcast
 - Practice Compounding Prescriptions
 - Diphenhydramine/Haloperidol/Lorazepam Oral Capsules
 - Complete Errors and Omissions Practice Prescription

INSTRUCTIONS

Prepare the attached wet lab compound prescriptions as outlined in the compounding procedure. Show all necessary calculations and document in detail all required information requested in the compounding record. Upon completion of the compound, generate a prescription label including any pertinent and necessary auxiliary labels. Once completed

1. Thoroughly clean your compounding equipment.
2. Return your cleaned equipment to its proper storage location.
3. Clean the surface of your work station thoroughly.
4. Place your completed lab packet along with your product at your work station.
5. Complete the error and omission prescription.
6. Summon an instructor for final check out.

Please note: Check out will not be performed until your equipment and work station have been thoroughly cleaned and equipment returned to its proper storage location.

LABORATORY SAFETY NOTICE PLEASE READ

1. In the compounding lab various active bulk pharmaceuticals, chemicals and commercial legend pharmaceuticals will be used during each compounding procedure. Should you have or suspect a sensitivity and/or allergy to any of the products being used as part of a particular procedure, including but not limited to sulfur, penicillin, topical anesthetics, etc., do not begin the procedure and notify an instructor.
2. Lab jackets and gloves must be worn at all times while in the compounding lab. Protective eyewear is available for use.
3. Some bulk pharmaceuticals and chemicals that exist as fine powders are easily aerosolized when opened. Use caution against inadvertent inhalation of these types of products. Filter masks are available for your use when working with these types of products.
4. Some compounding procedures require the use of a hot plate to heat certain components. Take your time and use extreme caution when working with heat to minimize the possibility of accidental burns.
5. All compounded products must remain in the compounding laboratory for proper destruction and disposal by an instructor.

Compounded Non-Sterile Preparation - Capsule

QA and Check-Out Form

Compound #1 Dry Lab - Indomethacin Capsules

_____ Completed all dry lab calculations, procedure and compounding record documentation

Compound #2 Wet Lab - Propranolol and Hydrochlorothiazide Capsules

_____ Calculations

- Accurate, all requested information completed, all work shown

_____ Compounding Record/Documentation

- Requested documentation and procedural information completed in its entirety
- Correct beyond-use date (shortest exp. date/6 months) and storage requirements (room temperature, tight container)

_____ Label Drug Name and Auxiliary Labels

- Complete, accurate and appropriate
- Note: there are no required auxiliary labels for capsules as a dosage form

_____ Final Product/Quality Control

- Powder is fine with slight colored tint
- Capsules have aesthetic appearance
- Capsules are full with minimal void space
- Powder content of each capsule is within 5% of specified target weight
 - Capsule Size 2, Target weight = 300 mg. Acceptable Range = 285 mg to 315 mg.
 - Write individual weights below

_____ mg _____ mg _____ mg _____ mg _____ mg _____ mg

Compound #3 Errors and Omissions Prescription Compound

_____ Corrected all calculation, procedure, documentation and label errors/omissions

Total Points = _____

Instructor comments:

<p>Date: X/XX/XXXX</p> <p>Patient Name: Bob Sykes</p> <p>R_x</p> <p>Indomethacin 12.5 mg</p> <p>M and Ft. capsules</p> <p>Dispense 6 (six)</p> <p>SIG: take one cap po qAM with food</p> <p>Refills: 3</p> <p>Dr. Samuel Bernstein</p>	<p>Capsule Rx - Dry</p> <p>Additional Information:</p> <ul style="list-style-type: none"> • Use the Digital Balance • Least Weighable Quantity = 40 mg • Base your calculations on the preparation of 4 extra capsules • Source of active drug is Indomethacin 50 mg capsules • Use food coloring to visualize powder mixing • Use a size 3 capsule and a target weight of 250 mg
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Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Indomethacin	12.5 mg	anti-inflammatory	active
Lactose	q.s.	diluent	vehicle
Food coloring	q.s.	color	vehicle
Gelatin capsule, size 3	1	shell	vehicle

Compounding Calculations:

1. Desired/ amount of Indomethacin = _____ mg

2. Number of Indomethacin 50 mg capsules needed to provide the required weight of Indomethacin = _____ caps

3. Weigh the contents of required number of Indomethacin 50 mg capsules. Weight = _____ mg

4. Weight of Indomethacin Capsule Powder needed to obtain the required amount of Indomethacin = _____ mg

5. Selected Capsule Size = **Size 3**

6. Target weight based on selected capsule size = _____ mg

7. Total weight (# caps * target weight) = _____ mg

8. Required weight of capsule diluent (lactose) needed to complete the prescription = _____ mg

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt	QA Documentation
Indomethacin 50 mg capsule	Mylan/30143	5/2023			Product Weights(s) or Volume:
Indomethacin capsule powder	---	---			
Lactose, USP	PCCA/C874321	12/2024			
Gelatin Capsule, Size 3	Gallipot/88231	6/2023			Visual Inspection & Testing:
Food Coloring, Green	PCCA/76324	8/2023	---		

<p>Formulation Record #: MFR-510425</p> <p>Compounding Record #: CMPD-804804</p> <p>Date & Time Prepared:</p> <p>Beyond-use Date:</p> <p>Reference Source for BUD: USP 795</p> <p>Container-Closure System:</p> <p>Storage Requirements:</p> <p>Final Product Name, Strength, and Dosage Form:</p> <p>Auxiliary Label(s):</p>	<p>Required Equipment & Procedure (step-by-step):</p> <p>REQUIRED EQUIPMENT - mortar, pestle, large and small metal spatulas, rubber spatula, small/medium/large weigh boats, size 3 clear gelatin capsules, 6 dram prescription bottle with child-proof cap</p> <ol style="list-style-type: none"> 1. Open _____ indomethacin 50 mg capsules and weigh the required amounts of indomethacin capsule powder and lactose. <i>**Document exact weights of each ingredient in the compounding record**</i> 2. Place the indomethacin capsule powder into a mortar. Add one drop of green liquid food coloring and <u>triturate</u> until uniform in appearance. 3. Geometrically combine the lactose with the colored indomethacin capsule powder using trituration until the mixture is uniform. 4. Place the mixture onto a piece of ointment paper and <u>block</u> the mixture into a <u>bed of powder</u> using two large metal spatulas. 5. Punch 6 capsules to a target weight of 250 mg using a size 3 capsule. 6. Pinch each capsule closed once it has the correct final weight. 7. Polish each capsule using a soft tissue. 8. Document exact weight of each capsule in QA and transfer finished capsules to a 6 dram prescription bottle. 9. Appropriately discard any excess capsule powder. 10. Label and Dispense.
<p>Compounding Personnel Signature(s):</p>	

<p>Date: X/XX/XXXX</p> <p>Patient Name: Joel Bontrager</p> <p>R_x</p> <p>Propranolol 5 mg</p> <p>Hydrochlorothiazide 6.25 mg</p> <p>M and Ft. capsules</p> <p>Dispense 6 (six)</p> <p>SIG: 1 cap po q8h until seen by the cardiologist</p> <p>Refills: 0</p> <p>Dr. Cynthia McDonald</p>	<p>Capsule Rx - Wet</p> <p>Additional Information:</p> <ul style="list-style-type: none"> • Use the Digital Balance • Least Weighable Quantity = 40 mg • Base your calculations on the preparation of 4 extra capsules • Use a size 2 capsule and a target weight of 300 mg • Do not use additional food coloring
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Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Propranolol	5 mg	antihypertensive	active
Hydrochlorothiazide	6.25 mg	antihypertensive	active
Lactose	q.s.	diluent	vehicle
Gelatin Capsule, Size 2	1	shell	vehicle

Compounding Calculations:

1. Required amount of propranolol = _____ mg

2. Number of propranolol 10 mg tablets to provide the required amount of propranolol = _____ tabs

3. Weight of propranolol tablets (or crushed tablet powder) needed to provide the required amount: _____ mg

4. Required amount of hydrochlorothiazide = _____ mg

5. Number of hydrochlorothiazide 50mg capsules to provide the required weight of hydrochlorothiazide = _____ caps

6. Weight of the contents of the required number of hydrochlorothiazide 50 mg capsules = _____ mg

7. Weight of hydrochlorothiazide capsule powder to provide the required amount in the Rx: _____ g

8. Selected Capsule Size = **Size 2**

9. Target weight based on selected capsule size = _____ mg

10. Total weight (# caps * target weight) = _____ mg

11. Required amount of lactose needed = _____ mg

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt	QA Documentation
					Product Weights(s) or Volume:
					Visual Inspection & Testing:

<p>Formulation Record #: MFR-684460</p> <p>Compounding Record #: CMPD-587155</p> <p>Date & Time Prepared:</p> <p>Beyond-use Date:</p> <p>Reference Source for BUD: USP 795</p> <p>Container-Closure System:</p> <p>Storage Requirements:</p> <p>Final Product Name, Strength, and Dosage Form:</p> <p>Auxiliary Label(s):</p>	<p>Required Equipment & Procedure (step-by-step):</p> <p>REQUIRED EQUIPMENT - mortar, pestle, large and small metal spatulas, rubber spatula small and medium weigh boats, size 2 clear gelatin capsule, 6 dram prescription bottle with child-proof cap</p> <ol style="list-style-type: none"> 1. Open _____ hydrochlorothiazide 50 mg capsules and weigh the required amount of hydrochlorothiazide capsule powder and lactose. 2. Weigh the required amount of lactose powder. 3. Place _____ propranolol tablets into a mortar. Triturate to a fine powder. 4. Add the hydrochlorothiazide capsule powder to the propranolol in the mortar and triturate until uniform in appearance. 5. Geometrically add the lactose to the mortar and triturate after each addition until the mixture is uniform. 6. Place the mixture onto a piece of ointment paper and block the mixture into a bed of powder using large metal spatulas. 7. Punch _____ capsules to a target weight of _____ using a size _____ capsule. <i>**Specify number of capsules to punch, target weight and size of capsules used**</i> 8. Pinch each capsule closed once it has the correct final weight. 9. Polish each capsule using a soft tissue. 10. Document exact weight of each capsule in QA and transfer finished capsules to a 6 dram prescription bottle. 11. Appropriately discard any excess capsule powder. 12. Label and dispense.
<p>Compounding Personnel Signature(s):</p>	

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Ketoprofen 50 mg capsules	URL/87TRG54	12 months	3 caps	3 caps
Ketoprofen capsule powder	---	---	700 mg	710 mg
Caffeine Powder, USP	PCCA/87123412	16 months	600 mg	595 mg
Lactose Powder, USP	Humco/34SSD1	14 months	1,700 mg	1,692 mg
Food Coloring (blue)	PCCA/BL87100LK	4 months	---	1 drop
Clear Gelatin Capsules, Size 2	PCCA/1077654	9 months	6 caps	6 caps

QA Documentation

Product Weights(s) or Volume:
Cap Wts.: 290 mg, 286 mg, 300 mg, 340 mg, 301 mg, 295 mg

Visual Inspection & Testing:
light blue powder in a clear size 2 capsule

<p>Formulation Record #: MFR-346545</p> <p>Compounding Record #: CMPD-179515</p> <p>Date & Time Prepared: 4/1/20XX, 12:56</p> <p>Beyond-use Date: 7/25/20XX</p> <p>Reference Source for BUD: USP 795</p> <p>Container-Closure System: 12 dram prescription bottle</p> <p>Storage Requirements: Room Temperature, Air-tight Container</p> <p>Final Product Name, Strength, and Dosage Form: Ketoprofen 12.5 mg and Caffeine 100 mg Oral Capsule</p> <p>Auxiliary Label(s): See Labels Above</p>	<p>Required Equipment & Procedure (step-by-step):</p> <p>REQUIRED EQUIPMENT - mortar, pestle, large and small metal spatulas, rubber spatula, ointment paper, small and medium weigh boats, 12 dram prescription bottle with child-proof cap</p> <ol style="list-style-type: none"> Open 3 ketoprofen 50mg capsules and weigh the required amount of capsule powder. Discard remaining ketoprofen powder appropriately. Weigh the required amount of lactose and caffeine powders. Place the ketoprofen capsule powder into a mortar. Add one drop of blue liquid food coloring and triturate until uniform in appearance. Add the caffeine powder to the colored ketoprofen capsule powder and triturate until it is uniform. Add the lactose to the mortar with the colored ketoprofen/caffeine mixture and triturate until uniform. Empty the mixture onto ointment paper and block the mixture into a bed of powder using large metal spatulas. Punch capsules to the a target weight of 300 mg using a size 3 capsule. Polish the capsules and transfer to a 12 dram prescription bottle. Appropriately discard any excess product. Label and Dispense.
<p>Compounding Personnel Signature(s): <i>Jaye Hawc, PharmD</i></p>	