Name: _____ Date: _____

Lab Day: Mon Tues Wed Thurs Friday Time: AM PM

Compounded Non-Sterile Preparation - Suppository

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
    - Suppositories In-Class Procedure video
    - Suppositories Lecture podcast
  - Practice Compounding Prescriptions
    - Aspirin 100 mg Rectal Suppositories
  - 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 - Suppository

QA and Check-Out Form

Compound #1 Dry Lab - Indomethacin/Ondansetron Rectal Suppositories (CB Substitute Base)

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

Compound #2 Wet Lab - Zinc Oxide Suppositories (PEG Base)

_____ 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/3 months) and storage requirements (room temperature)

_____ Label Drug Name and Auxiliary Labels

- Complete, accurate and appropriate
- MUST include Vaginal Use Only, Do not refrigerate

_____ Final Product/Quality Control

- Suppositories are opaque and uniform in color
- Surfaces are smooth with no evidence of air pockets, contraction divots, streaking or capping
- Correct number dispensed, unbroken, properly trimmed
- Average weight of a suppository = _____ g
- Completed DDF worksheet, DDF = _____

Compound #3 Errors and Omissions Prescription Compound

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

Total Points = _____

Instructor comments:

Date: X/XX/XXXX Patient Name: Georgia Elder R_X Indomethacin 25 mg Ondansetron 4 mg Fattibase qs M and Ft. Rectal Suppository Dispense #6 SIG: insert 1 pr bid Refills: 2 Dr. Norman Keyes	**Suppository Rx - Dry** Additional Information: • Use the Digital Balance • Least Weighable Quantity = 40 mg • Calculate for 4 extra suppositories. • Use Plastic Suppository Shells • Plastic Shell Calibration with Fattibase = 1.9 grams • DDF for Indomethacin in Fattibase = 1.2 • DDF for Ondansetron in Fattibase = 0.9 • DDF for all Excipients in Fattibase = 1 • Source of Indomethacin = Indomethacin 50 mg caps • Source of Ondansetron = Ondansetron 8 mg tabs

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Indomethacin	25 mg	anti-inflammatory	active
Ondansetron	4 mg	anti-emetic	active
Fattibase	q.s.	diluent	vehicle

Compounding Calculations:

1. # of suppositories to prepare

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2. Required amount of indomethacin = _____ mg = _____ g

3. Required # of indomethacin 50 mg capsules = _____ caps

4. Weight of indomethacin capsule powder from required # of caps _____ g

5. Weight of excipient in indomethacin capsule powder = _____ g

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6. Required amount of ondansetron = _____ mg = _____ g

7. Required # of ondansetron 8 mg tablets = _____ tabs

8. Weight of required # of ondansetron tabs _____ g

9. Weight of excipients in ondansetron tablets = _____ g

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10. Total weight of excipient from both APIs (indo and ond) = _____ g

11. **Density Displacement Factor (DDF) Calculations**

Weight of Fattibase base displaced by indomethacin (DDF = 1.2) = _____ g

Weight of Fattibase displaced by ondansetron (DDF = 0.9) = _____ g

Weight of Fattibase displaced by excipients (DDF = 1) = _____ g

12. Total weight of Fattibase displaced by all ingredients (APIs and excipients) = _____ g

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13. Weight of Fattibase to prepare required # of blank supps based on mold calibration (1.9 g/supp) = _____ g

14. Final weight of Fattibase needed to prepare required # of supps = _____ g

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Indomethacin 50 mg capsules	Mylan/87234HN	2/2023		
Ondansetron 8 mg tablets	UDL/ZCX8993	4/2024		
Fattibase	PCCA/76222	8/2022		

QA Documentation

Product Weights(s) or Volume:

Visual Inspection & Testing:

Formulation Record #:
MFR-905646

Compounding Record #:
CMPD-406876

Date & Time Prepared:

Beyond-use Date:

Reference Source for BUD:
USP 795

Container-Closure System:

Storage Requirements:

Final Product Name, Strength, and Dosage Form:

Auxiliary Label(s):

Required Equipment & Procedure (step-by-step):

REQUIRED EQUIPMENT - Wood suppository rack, plastic suppository molds, 50 or 100 mL glass beaker, small metal spatula, stainless steel 40 mesh sieve, glass stirring rod, hot plate with magnetic stirrer, stir bar, small and medium weigh boats, suppository box

1. Prepare plastic suppository shells by positioning them upright in a wooden suppository rack. Be sure to inspect the shells for any deformities.
2. Weigh 5 ondansetron 8 mg tablets and the capsule powder from 5 indomethacin 50 mg capsules. Calculate the amount of fattibase needed.
3. Weigh the required amount of grated fattibase in a 100 mL beaker.
4. Place 5 ondansetron 8mg tablets in mortar and triturate to a fine powder. Geometrically add the indomethacin capsule powder and triturate to a fine homogenous powder. Place the indomethacin/ondansetron powder into a sieve that is in a medium weigh boat.
5. Place the glass beaker containing the fattibase on a hot plate and begin melting it using a low setting of 4 or 60°C. Once melted, turn off the heat, add a stir bar and begin stirring the base using a medium rate.
6. Sift the indomethacin/ondansetron powder into the molten base with continuous stirring until all the mixture has been added.
7. Carefully remove the beaker and product from the heat source, place it on the countertop and begin stirring it continuously with a glass rod allowing the mixture to cool for 3-4 minutes at room temperature. Must be able to hold comfortably in your hand.
8. Carefully, yet quickly, pour the mixture into the center of each suppository shell cavity filling to the top. Allow the poured suppositories to congeal at room temperature for a minimum of 25 minutes.
9. Once the suppositories have set, remove the plastic suppository shell from the suppository and trim using a razor blade.
10. Transfer 6 suppositories to a suppository box. Appropriately discard excess. Label and dispense.

Compounding Personnel Signature(s):

Date: X/XX/XXXX Patient Name: Lily Hanson R_X Zinc Oxide 100 mg Polybase qs M and Ft. Vaginal Suppository Dispense #6 SIG: insert 1 vaginally qHS Refills: 5 Dr. Sandra Jones	**Suppository Rx - Wet** Additional Information: • Use the Digital Balance • Least Weighable Quantity = 40 mg • Calculate for 4 extra suppositories • Use the Aluminum Suppository Mold • Aluminum Mold Calibration with Polybase = 2.3 g • **Use the double casting technique**

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Zinc Oxide	100 mg	astringent/protectant	active
Polybase	qs	diluent	vehicle

Compounding Calculations:

1. # of suppositories to prepare

2. Required amount of Zinc Oxide = _____ mg = _____ g

3. Weight of Polybase to prepare required # of blank supps based on mold calibration (2.3 g/supp) = _____ g

Double Casting Method

Beaker #1 = _____ g of Polybase

Put approximately 50% of the total weight of Polybase required for # of supps into beaker #1. (Round UP)

Beaker #2 = _____ g of Polybase

Beaker #2 is excess plain Polybase. A good estimate is approximately 2.5 times the amount of base in beaker #1.

Use worksheet to calculate the DDF of zinc oxide in Polybase AFTER completing the compounding procedure.

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Zinc Oxide Powder, USP				
Polybase			- - - - -	- - - - -
Beaker #1	- - - - -	- - - - -		
Beaker #2	- - - - -	- - - - -		

QA Documentation

Product Weights(s) or Volume:

Visual Inspection & Testing:

Formulation Record #:
MFR-791647

Compounding Record #:
CMPD-230608

Date & Time Prepared:

Beyond-use Date:

Reference Source for BUD:
USP 795

Container-Closure System:

Storage Requirements:

Final Product Name, Strength, and Dosage Form:

Auxiliary Label(s):

Required Equipment & Procedure (step-by-step):

REQUIRED EQUIPMENT - 50 or 100 mL glass beakers, small metal spatula, stainless steel 40 mesh sieve, glass stirring rod, microwave, hot plate with magnetic stirrer, stir bar, small and medium weigh boats, suppository box

1. Prepare mold by separating and cleaning. Some molds may need to be lubricated. The aluminum molds used in lab do not need to be lubricated.
2. Weigh the required amount of zinc oxide and place in the sieve resting in a medium weigh boat.
3. Weigh 12 g Polybase in a 100 mL beaker (one) and 30g in a 100 mL beaker (two). Place both beakers in a microwave for 30 seconds on high power. Add one drop of red coloring to beaker one. (Color is used in lab only to visualize the drug distribution.)
4. Place beaker one on the center of the hot plate at a setting of 5 or 75°C and add a stir bar to the molten base. Begin stirring the base at a medium rate (5). Place beaker two on one corner of the hot plate to keep warm.
5. Sift the zinc oxide into the molten base with continuous stirring. Carefully remove the beaker, gently swirl beaker to remove any zinc oxide from the stir bar, place it on the counter and remove the stir bar with a metal spatula.
6. Quickly pour some of the mixture into the center of 10 mold cavities. You do not need to be exact at this stage.
7. Pour a SMALL amount of the plain Polybase from beaker two into beaker one and stir with a stir rod. Quickly pour the rinsing into the center of the mold cavities. You do not need to be exact at this stage. Repeat the rinsing process several times with SMALL amounts of plain base. Do not fill any one cavity over the top in this step.
8. Use plain melted Polybase from beaker two and overfill the mold cavities.
9. Turn off the hot plate and allow the poured suppositories to cool at room temperature. Once the suppositories have set, trim the excess from the top of the mold with a heated spatula, fill any divots if necessary, unmold and weigh the 10 suppositories.
    - **Weight of all 10 suppositories =** _____ **g** (needed for DDF calculation)
10. Place the 10 suppositories in a clean beaker and microwave for 20 seconds. Set the melted Polybase/zinc oxide mixture on the counter and stir. When you can comfortably touch the beaker to the palm of your hand, carefully, yet quickly, pour the mixture into the molds overfilling each one.
11. Allow the poured suppositories to cool at room temperature for approximately 20 minutes. Once the suppositories have set, trim the excess from the top of the mold with a heated spatula, fill divots if needed and remove the suppositories from the mold.
12. Place 6 suppositories in a suppository box. Appropriately discard excess. Label and dispense

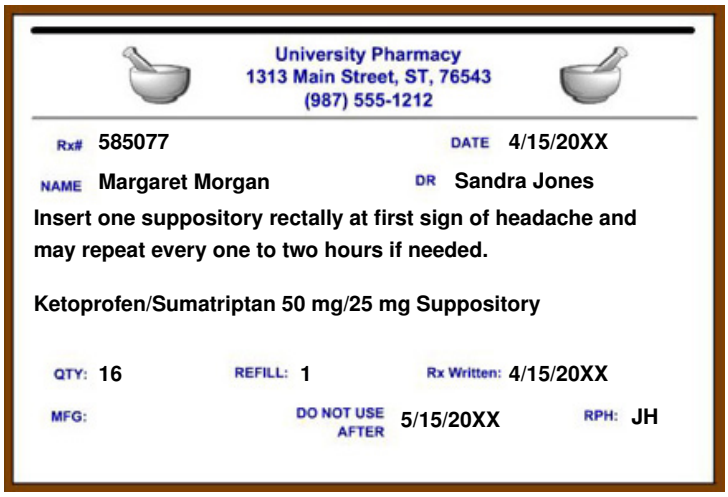
Compounding Personnel Signature(s):

Date: 4/15/20XX Patient Name: Margaret Morgan R_X Ketoprofen 50 mg Sumatriptan 25 mg Fattibase qs M and Ft. Rectal Suppository Dispense #12 SIG: one rectally at first sign of headache and may repeat one time in 1-2 hours if needed Refills: 1 Dr. Sandra Jones	**Suppository EO-RX Practice** Additional Information: • Use the Digital Balance • Least Weighable Quantity = 40 mg • Calculate for 4 extra suppositories • Use the Plastic Suppository Molds • Plastic Mold Calibration with fattibase = 2.1 grams • DDF ketoprofen in fattibase = 1.5 • DDF sumatriptan in fattibase = 0.8 • DDF excipients in fattibase = 1 • Ketoprofen 50 mg capsules available - weight of the contents of one capsule = 165 mg • Sumatriptan 50mg tablets available - weight of one tablet = 110 mg

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Ketoprofen	50 mg	analgesic	active
Sumatriptan	25 mg	anti-migraine	active
Fattibase	q.s.	diluent	vehicle



Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Ketoprofen 50 mg capsules	Mylan/650923	8 months	16 caps	16 caps
Sumatriptan 50 mg tablets	UDL/63924	16 months	8 tabs	8 tabs
Fattibase	PCCA/540KJ	14 months	32.6 g	32.54 g

QA Documentation

Product Weights(s) or Volume:

ave supp wt = 2.08 g

Visual Inspection & Testing:

opaque, off-white, smooth suppository with a pointed tip

Formulation Record #:
MFR-838347

Compounding Record #:
CMPD-585077

Date & Time Prepared:
4/15/20XX

Beyond-use Date:
5/15/20XX

Reference Source for BUD:
USP 795

Container-Closure System:
suppostiory box

Storage Requirements:
Room Temperature

Final Product Name, Strength, and Dosage Form:
Ketoprofen/Sumatriptan 50 mg/25 mg Rectal Suppository

Auxiliary Label(s):
See Labels Above

Required Equipment & Procedure (step-by-step):

REQUIRED EQUIPMENT - Wood suppository rack, plastic suppository molds, 50 or 100 mL glass beaker, small metal spatula, stainless steel 40 mesh sieve, glass stirring rod, hot plate with magnetic stirrer, stir bar, small and medium weigh boats, suppository box

1. Carefully inspect and place 16 plastic suppository shells in a wooden suppository rack.
2. Empty the contents of 16 ketoprofen 50 mg capsules into a medium weigh boat.
3. Place 8 sumatriptan 50 mg tablets into a mortar and triturate to a fine powder.
4. Geometrically add the ketoprofen capsule powder to the mortar and triturate after each addition until uniform. Transfer the ketoprofen/sumatriptan powder to a sieve resting in a medium weigh boat.
5. Weigh the required amount of of grated fattibase in a glass 100 mL beaker.
6. Place fattibase in a microwave for 1 - 2 minutes on high power.
7. Carefully remove the beaker and place on a hot plate turned to a medium heat setting of 5. Place a stir bar in the beaker. Stir the base using a medium rate of 5.
8. Sift the ketoprofen/sumatriptan powder into the molten base with continuous stirring.
9. Immediately pour the mixture into the center of the mold cavities ensuring that you overfill each cavity before proceeding to the next.
10. Allow the poured suppositories to congeal at room temperature for approximately 20-30 minutes. Once the suppositories have set, remove the suppositories from the mold, trim the excess from the top with a razor blade and place 12 in a suppository box.
11. Label and dispense.

Compounding Personnel Signature(s): ***Jaye Hawc, PharmD***

Worksheet: Density Displacement Factor (DDF)

Step 1 - Calibrate suppository mold and determine the average weight of a suppository using pure base

This has already been completed with PEG base in the metal (aluminum) suppository molds.

Average weight of one PEG base-only suppository: **2.3 g**

Step 2 - Make the suppositories with drug in PEG base using the double casting method

Total weight of all suppositories prepared: _____ g

Average weight of one drug & base suppository (divide by # prepared): _____ g

Step 3 - Calculate the weight of PEG base in your final suppository

Weight of PEG base in a drug & base suppository: _____ g

average weight of one drug & base suppository (step 2) – weight of drug in one suppository

Step 4 - Calculate the weight of PEG base that was displaced by the drug

Weight of PEG base displaced by the drug: _____ g

wt of PEG base only supp (step 1) – wt of PEG base in a drug & base supp (step 3)

Step 5 - Calculate the DDF for the drug

DDF for this drug in PEG Base: _____ g

$$\frac{\text{wt. (g) of drug in 1 supp}}{\text{wt. (g) of PEG base displaced (step 4)}} = \frac{x}{1 \text{ g PEG base}}$$

$$x = \text{wt. of drug (g) that displaces 1 g of PEG base}$$