Name: _____ Date: _____

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

Compounded Non-Sterile Preparation - Emulsion & Gel

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
    - Gels In-Class Procedure video
    - Gels Lecture podcast
    - Emulsions Lecture podcast
  - Practice Compounding Prescriptions
    - Calamine and Zinc Oxide Topical Emulsion
  - 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 - Emulsion & Gel

QA and Check-Out Form

Compound #1 Dry Lab - Mineral Oil Emulsion (Bottle Method)

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

Compound #2 Wet Lab - Acyclovir/Lidocaine (PLO Microemulsion)

_____ 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 (14 days) and storage requirements (room temperature)

_____ Label Drug Name and Auxiliary Labels

- Complete, accurate and appropriate
- MUST include External Use Only, Do Not Refrigerate

_____ Final Product/Quality Control

- Product is a turbid brownish-yellow opaque gel
- Product is homogenously mixed and completely emulsified
- Product has adequate viscosity, is not too thin and has an aesthetic appearance
- Volume dispensed = 10 mL in dispensing pen
- Completed Dispensing Pen Calibration Worksheet, volume per pump = _____ mL/pump

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: Mark Sawyer R_X Mineral Oil 30 mL Span 20 qs Tween 80 qs Cherry Syrup qs ad 60 mL M and Ft. O/W Emulsion SIG: 2 tsp po at HS prn constipation Refills: PRN Dr. Cynthia McDonald	**Emulsion - Dry** Additional Information: • Use the Digital Balance • Least Weighable Quantity = 40 mg • **Total emulisifier required = 5%** • Use bottle method, do not compound excess

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Mineral Oil	50% (v/v)	laxative	active
Span 20	q.s.	emulsifier	vehicle
Tween 80	q.s.	emulsifier	vehicle
Cherry Syrup	q.s.	flavoring agent	vehicle

Required HLB Values for Some Emulsions		
Ingredient	**W/O**	**O/W**
Acid, Lauric	—	15-16
Acid, Oleic	—	17
Acid, Stearic	6	15
Alcohol, Cetyl	—	15
Alcohol, Lauryl	—	14
Alcohol, Stearyl	—	14
Lanolin, anhydrous	8	10
Oil, Castor	6	14
Oil, Cottonseed	5	10
Oil, Mineral	5	12
Oil, Olive	6	14
Petrolatum	5	12
Wax, Beeswax	4	12
Wax, Paraffin	4	11

HLB Values of Some Surfactants	
Surfactant	HLB
Sorbitan trioleate (Span 85)	1.8
Sorbitan trioleate (Span 65)	2.1
Sorbitan sesquioleate (Arlacel 83)	3.7
Glyceryl monosterate, NF	3.8
Sorbitan monooleate, NF (Span 80)	4.3
Sorbitan monooleate, NF (Span 60)	4.7
Sorbitan monooleate, NF (Span 40)	6.7
Sorbitan monooleate, NF (Span 20)	8.6
Polyoxyethylene sorbitan tristerate (Tween 65)	10.5
Polyoxyethylene sorbitan trioleate (Tween 85)	11.0
Polyethylene glycol 400 monosterate	11.6
Polysorbate 60, NF (Tween 60)	14.9
Polyoxyethylene monosterate (Myrj 49)	15.0
Polysorbate 80, NF (Tween 80)	15.0
Polysorbate 40, NF (Tween 40)	15.6
Polysorbate 20, NF (Tween 20)	16.7

HLB values are tools for determining ratios of hydrophilic lipophilic emulsifiers used in formulation of different emulsion types.

Compounding Calculations:

1. HLB value required to form O/W mineral oil emulsion = _____

2. HLB value of Span 20 = _____

3. HLB value of Tween 80 = _____

4. Total weight (g) of emulsifier needed (see additional information section) = _____

5. Required weight of Span 20 = _____

6. Required weight of Tween 80 = _____

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Mineral Oil, USP	GoodSense/B261	2/2023		
Sorbitan Monolaurate (Span 20)	PCCA/C105733	4/2023		
Polysorbate 80 (Tween 80)	PCCA/C121821	8/2024		
Cherry Syrup	Humco/533024	10/2023		

QA Documentation

Product Weights(s) or Volume:

Visual Inspection & Testing:

Formulation Record #:
MFR-342872

Compounding Record #:
CMPD-309593

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 - large weigh boats, 4 oz. prescription bottle

1. Measure 30ml of mineral oil in a 4 oz. dispensing bottle.
2. Place a large weigh boat on the digital scale. Place bottle containing mineral oil in the weigh boat and tare scale.
3. Add Span 20 drop-wise to bottle with mineral oil until required weight of Span 20 has been added.
4. Tare scale and add Tween 80 drop-wise to bottle with mineral oil until required weight of Tween 80 has been added.
5. Remove the bottle from the scale, cap bottle securely and shake vigorously to disperse the emulsifiers throughout.
6. Uncap bottle, slowly add cherry syrup bring the final volume up to 60 mL.
7. Recap the bottle securely and shake vigorously to emulsify the product.
8. Label and Dispense.

Compounding Personnel Signature(s):

Date: X/XX/XXXX

Patient Name: Don Wright

R_X

Acyclovir	1%
Lidocaine	2%
L.I.P.S.	25%
Poloxamer 20% Solution	qs 10 mL

M and Ft. PLO Gel

SIG: Squirt 1-2 pumps on fingertip and apply to lip lesions q3h while awake. Wash hands after each use.

Refills: 1

Dr. George Platz

Gel Rx - Wet

Additional Information:

- Use the Digital Balance
- Least Weighable Quantity = 40 mg
- **Do not prepare excess**
- Acyclovir freely soluble in lidocaine solution

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Acyclovir	1%	antiviral	active
Lidocaine	2%	anesthetic	active
LIPS	25%	absorption enhancer	vehicle
Poloxamer 20% Soln.	q.s.	gelling agent	vehicle

Compounding Calculations:

1. Required weight of Acyclovir powder = _____ g

2. Required volume of 20% Lidocaine solution = _____ mL

3. Required volume of L.I.P.S. = _____ mL

4. Required volume of Poloxamer 20% solution = _____ mL

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt

QA Documentation

Product Weights(s) or Volume:

Visual Inspection & Testing:

Formulation Record #:
MFR-794012

Compounding Record #:
CMPD-745372

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 - 1 oz. graduated conical, 3 mL syringe with needle, two 10 mL luer-lock syringes, glass stir rod, red luer-lock syringe connector, small metal spatula, small and medium weigh boats, AccuPen

1. Mark one of the 10 mL syringes and weigh the empty syringe. Record this weight on the calibration worksheet (step 1).
2. Weigh the required amount of acyclovir powder and place in a one ounce graduated conical.
3. Measure the required volume of lidocaine 20% solution in a 3 mL syringe. Slowly add the lidocaine solution to the conical containing the acyclovir powder. Safely recap the needle and save the needle and syringe for step 4.
4. Dissolve the acyclovir in the lidocaine solution. Stir the lidocaine/acyclovir with a stir rod until the acyclovir goes into solution. It will take several minutes to dissolve.
5. Extract all of the solution containing the acyclovir/lidocaine into the 3 mL syringe. Safely recap the needle and discard the needle into a sharps container.
6. Measure the required volume of poloxamer 20% solution in a 10 mL syringe (aqueous phase) and the required volume of L.I.P.S. in a second 10 mL syringe (oil phase).
7. Connect the 3 mL syringe containing the acyclovir/lidocaine solution to the syringe containing the poloxamer 20% solution using a syringe connector.
8. Add the acyclovir/lidocaine solution to the poloxamer 20% solution. Remove the empty 3 mL syringe.
9. Check to make sure there is no air in either of the 10 mL syringes. Using the syringe connector, securely connect the syringe containing LIPS to syringe containing poloxamer/acyclovir/lidocaine mixture.
10. Forcefully mix the contents back-and-forth between syringes through the connector until a turbid, creamy, homogenous product is formed.
11. Be sure all of the gel ends up in the syringe you marked previously. Weigh the syringe with the gel and record this weight on the calibration worksheet (step 3).
12. Transfer the product into the AccuPen per manufacturer instructions.
13. Prime the device and appropriately discard any excess product.
14. Label and Dispense.

Compounding Personnel Signature(s):

Date: 3/15/20XX

Patient Name: Mandi Miller

R_X

Promethazine	12.5 mg in 0.1 mL
L.I.P.S.	22%
Purified Water	qs
Poloxamer 20% Solution	qs ad 16 mL

M and Ft. PLO Gel

SIG: 0.1 mL to inner wrist and rub in q4h prn nausea.

Refills: 1

Dr. Sandra Jones

Emulsion & Gel EO-RX Practice

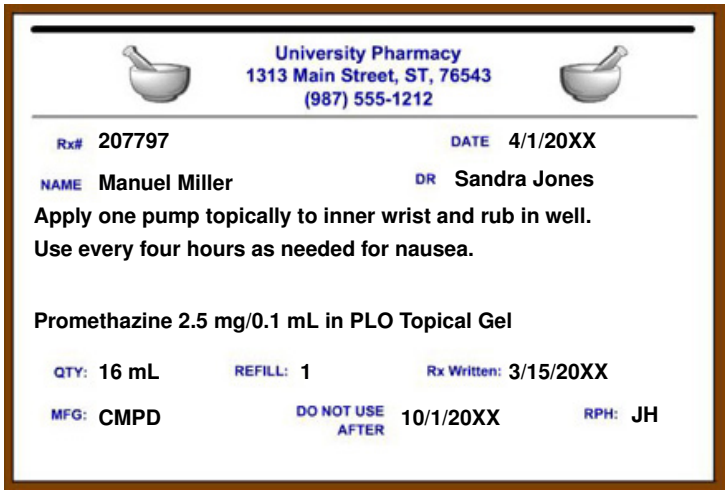
Additional Information:

- Use the Digital Balance
- Least Weighable Quantity = 40 mg
- Compound exact volume (16 mL)
- 1 mL, 3 mL, 6 mL & 20 mL syringes available
- Syringe filling connectors available
- Promethazine solubility is 1 g in 0.5 mL water
- Accupen calibration for promethazine PLO is 0.1 mL per actuation

Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Promethazine	12.5 mg/0.1 mL	antiemetic	active
L.I.P.S.	22%	absorption enhancer	vehicle
Water	q.s.	diluent	vehicle
Poloxamer 20% Soln	q.s.	gelling agent	vehicle



Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Promethazine Powder	PCCA/8Y6521	12 months	2 g	2.013 g
LIPS	PCCA/7562135T	8 months	5.3 mL	5.3 mL
Water (purified)	N/A	N/A	1 mL	1 mL
Poloxamer 20% Soln	PCCA/0091AR	16 months	9.7 mL	9.7 mL

QA Documentation

Product Weights(s) or Volume:

16 mL in one AccuPen

Visual Inspection & Testing:

Yellowish, opaque, medium viscosity gel at room temperature

Formulation Record #:
MFR-573708

Compounding Record #:
CMPD-207797

Date & Time Prepared:
4/1/20XX

Beyond-use Date:
10/1/20XX

Reference Source for BUD:
USP 795

Container-Closure System:
1 oz. Accupen

Storage Requirements:
Refrigerate

Final Product Name, Strength, and Dosage Form:
Promethazine 12.5 mg/0.1 mL in PLO Topical Gel

Auxiliary Label(s):
See Labels Above

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

REQUIRED EQUIPMENT - 1 oz. graduated conical, 3 mL luerlock syringe, two 20 mL luer-lock syringes, glass stir rod, red luer-lock syringe connector, small metal spatula, small weigh boats, AccuPen

1. Weigh the required amount of promethazine.
2. Measure required amount of purified water in a 3 mL syringe. Place the promethazine and the water in a one ounce graduated conical and stir until in solution.
3. Transfer the promethazine solution into a 3 mL syringe.
4. Measure required amount of poloxamer 20% solution in a 20 mL syringe.
5. Measure the required amount of LIPS in a second 20 mL syringe.
6. Using a syringe filling connector add the promethazine solution to the LIPS.
7. Check to make sure there is no air in either 20 mL syringe. Using a syringe filling connector securely connect the syringe containing the poloxamer to the syringe containing the LIPS.
8. Forcefully mix the contents back-and-forth between syringes through the connector until a turbid, creamy, homogenous product is formed.
9. Transfer 16 mL of the promethazine PLO gel into a 1 oz. AccuPen.
10. Label and Dispense.

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

Worksheet: Calibration of Accupen Dispensing Pen (mL/pump)

Step 1 - Mark a 12 mL syringe, tare scale and weigh empty 12 mL syringe: _____ g

Step 2 - Compound the PLO gel. End the mixing process with all the gel in the syringe that you marked in Step 1.

Step 3 - Weigh the syringe and gel: _____ g

Step 4 - Calculate the weight of the gel: _____ g

$$\text{weight of syringe and gel (step 3)} - \text{weight of syringe only (step 1)} = \text{weight of gel (g)}$$

Step 5 - Calculate the density of the gel. _____ g/mL

$$\frac{\text{Weight of gel (step 4)}}{\text{10 mL (volume of gel)}} = \text{density (g/mL)}$$

Step 6 - Prime the pen (squirt 5 pumps into a paper towel & discard). Ensure there are no air bubbles in the gel.

Step 7 - Record the weight of 20 pumps: _____ g

Place a weigh boat on the scale and tare. Carefully count and place 20 pumps of the gel into the weigh boat.

Step 8 - Calculate the average weight of one pump: _____ g

$$\frac{\text{weight of 20 pumps (step 7)}}{\text{20 pumps}} = \text{weight per pump}$$

Step 9 - Calculate the volume per pump using the density calculated in Step 5: _____ mL/pump

$$\frac{\text{average weight of one pump (g/pump) (step 8)}}{\text{density of gel (g/mL) (step 5)}}$$