

Name: _____

Date: _____

Lab Day: Mon Tues Wed Thurs Friday

Time: AM PM

Compounded Non-Sterile Preparation - Cream & Ointment (semisolids)

Required Pre-Lab Preparation

- Review this packet Dry Lab and Wet Lab Prescriptions/Calculations/Procedures
- PSK Lab Website Compounding Area
 - Compounding Terminology Definitions
Levigation
 - Compounding Lectures and Procedure Videos
Creams & Ointments In-Class Procedure video
Creams & Ointments Lecture podcast
 - Practice Compounding Prescriptions
Hydrocortisone 1% and Menthol 0.25% in Aquaphilic Topical Ointment
 - 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 - Cream & Ointment

QA and Check-Out Form

Compound #1 Dry Lab - LCD/Hydrocortisone in Aquaphor

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

Compound #2 Wet Lab - Urea/TAC in Aquaphilic Ointment

_____ 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 (35 days) and storage requirements (room temperature)

_____ Label Drug Name and Auxiliary Labels

- Complete, accurate and appropriate
- MUST include External Use Only

_____ Final Product/Quality Control

- Product is smooth, non-gritty
- Product is white and slightly translucent in appearance, uniform in color and texture throughout
- Product has moderate consistency, is not too thin or runny
- Product has aesthetic appearance and is properly dressed
- Final actual weight = _____ (acceptable range is 28.5 - 31.5 g)

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: Sylvia Jones</p> <p>R_x</p> <p>LCD 5%</p> <p>Hydrocortisone 2.5%</p> <p>Aquaphor qs ad 30 g</p> <p>M and Ft. ointment</p> <p>SIG: apply to affected area BID</p> <p>Refills: 2</p> <p>Dr. Norman Keyes</p>	<p>Cream & Ointment Rx - Dry</p> <p>Additional Information:</p> <ul style="list-style-type: none"> • Use the Digital Balance • Least Weighable Quantity = 40 mg • Make 10% extra - dispense prescribed amount • LCD: specific gravity = 0.87 • Glycerin, USP: specific gravity = 1.26 • Mineral Oil, USP: specific Gravity = 0.88
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Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Liquor Carbonis Detergens (LCD)	5%	eczema/psoriasis	active
Hydrocortisone	2.5%	anti-inflammatory	active
Aquaphor	q.s.	occlusive/diluent	vehicle

Compounding Calculations:

1. Weight to prepare (based on excess) = _____ g

2. Required weight of LCD = _____ g

3. Required volume of LCD _____ mL

4. Required weight of Hydrocortisone = _____ g

5. Required weight of Aquaphor = _____ g

Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Hydrocortisone Powder, USP	PCCA/78943	9/2022		
LCD	Humco/6773277	6/2023		
Aquaphor Ointment	Belersdorf/H424	4/2023		

QA Documentation

Product Weights(s) or Volume:

Visual Inspection & Testing:

<p>Formulation Record #: MFR-709254</p> <p>Compounding Record #: CMPD-619027</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, ointment paper, tape, large and small metal spatulas, rubber spatula, 3 mL slip tip syringe, small/medium/large weigh boats, 1 oz. ointment jar</p> <ol style="list-style-type: none"> 1. Weigh required amounts of hydrocortisone powder and Aquaphor ointment. 2. Measure the required amount of LCD in a 3 mL syringe. 3. Place the hydrocortisone powder on the ointment paper and wet the powder with a small amount of LCD. <u>Levigate the powder and LCD using spatulation</u> until a smooth paste is formed. 4. Place the Aquaphor ointment on the ointment paper and geometrically incorporate the Aquaphor ointment into the LCD/hydrocortisone paste. Spatulate after each addition until uniform. 5. Incorporate small amounts of the remaining LCD into a concave depression formed in the Aquaphor/hydrocortisone ointment. Spatulate after each addition until the product is uniform and homogenous in appearance. 6. Transfer <u>30 g</u> to a <u>1 oz.</u> ointment jar. 7. <u>Dress</u> the final product and <u>clean</u> the ointment jar. 8. Appropriately discard any excess product. 9. Label and Dispense.
<p>Compounding Personnel Signature(s):</p>	

<p>Date: X/XX/XXXX</p> <p>Patient Name: Coleen Bontrager</p> <p>R_x</p> <p>Urea 10%</p> <p>Triamcinolone acetonide 0.01%</p> <p>Aquaphilic/vanishing cream base qs ad 30 g</p> <p>M and Ft. Cream</p> <p>SIG: apply to rash BID</p> <p>Refills: 3</p> <p>Dr. Cynthia McDonald</p>	<p>Cream & Ointment Rx - Wet</p> <p>Additional Information:</p> <ul style="list-style-type: none"> • Use the Digital Balance • Least Weighable Quantity = 40 mg • Make 10% extra - dispense prescribed amount • Glycerin, USP: specific gravity = 1.26 • Mineral Oil, USP: specific Gravity = 0.88 • <u>Note</u>: source of triamcinolone is 0.1% cream
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Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Urea	10%	keratolytic	active
Triamcinolone acetonide (TAC)	0.01%	anti-inflammatory	active
Glycerin	q.s.	levigating agent	vehicle
Aquaphilic/vanishing cream base	q.s.	diluent	vehicle

Compounding Calculations:

1. Weight to prepare (based on excess) = _____ g

2. Required weight of Urea = _____ g

3. Required weight of triamcinolone acetonide 0.1% cream to use in prescription = _____ g

Dilution : mass does not change, thus $M_1 = M_2$

4. Volume of levigating agent used _____ mL (range is 1 to 1.5 mL)

5. Weight of levigating agent used = _____ g

6. Required weight of Aquaphilic/vanishing cream base = _____ g

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-654556</p> <p>Compounding Record #: CMPD-381801</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, ointment paper, tape, large and small metal spatulas, rubber spatula, small/medium/large weigh boats, 1 oz. ointment jar</p> <ol style="list-style-type: none"> 1. Place some urea in the mortar and triturate to a fine powder. Weigh the required amount of urea. 2. Weigh the required amount triamcinolone 0.1% cream. 3. Measure _____ mL glycerin (levigating agent) in a 3 mL slip tip syringe. 4. Place the urea powder on the ointment paper. 5. Use small amounts of glycerin to <u>levigate</u> the urea powder until a thick paste is formed. <u>Spatulate</u> thoroughly after each addition of glycerin. 6. Record the amount of glycerin used in the compounding record and above in the procedure. Calculate the amount of aquaphilic/vanishing cream required. 7. Weigh the required amount of aquaphilic/vanishing cream. 8. Place the 0.1% triamcinolone acetone cream on the ointment paper and spatulate with the urea/glycerin paste until uniform. 9. Geometrically combine the aquaphilic/vanishing cream with the urea/triamcinolone mixture. Spatulate after each addition until the product is uniform, smooth and non-gritty. 10. Transfer <u>30 g</u> to a <u>1 oz.</u> ointment jar. 11. <u>Dress</u> the final product and <u>clean</u> the ointment jar. 12. Appropriately discard any excess product. 13. Label and Dispense.
<p>Compounding Personnel Signature(s):</p>	

<p>Date: 1/15/20XX</p> <p>Patient Name: Don Wright</p> <p>R_x</p> <p>Acyclovir 5%</p> <p>Hydrocortisone 0.5%</p> <p>Aquaphilic Ointment qs ad 60 g</p> <p>M and Ft. Topical Cream</p> <p>SIG: Apply to affected area qid as directed</p> <p>Refills: 1</p> <p>Dr. Carolyn Abman</p>	<p>Cream & Ointment EO-RX Practice</p> <p>Additional Information:</p> <ul style="list-style-type: none"> • Use the Digital Balance • Least Weighable Quantity = 40 mg • Make 10% extra - dispense prescribed amount • Glycerin USP specific gravity = 1.26 • Mineral Oil USP specific Gravity = 0.88 • Powder in prescription requires 0.8 mL of liquid to levigate • Source of APIs are acyclovir bulk powder, and hydrocortisone 5% cream
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Formulation Record

Ingredient Identities & Amounts

Ingredient	Dose/Amt.	Activity	Purpose
Acyclovir	5%	antiviral	active
Hydrocortisone	0.5%	antiinflammamatory	active
Glycerin	q.s.	levigating agent	vehicle
Aquaphilic Ointment	q.s.	diluent	vehicle

University Pharmacy
1313 Main Street, ST, 76543
(987) 555-1212

Rx# 479225

DATE 3/15/20XX

NAME Don Wright

DR Carolyn Abman

Apply to the affected area four times daily as directed.

Acyclovir 5% and Hydrocortisone 0.5% in Aquaphilic

QTY: 60 g

REFILL: 1

Rx Written: 1/15/20XX

MFG: PCCA

DO NOT USE
AFTER 5/15/20XX

RPH: JH



Compounding Record

Ingredient	Mft./Lot #	Exp Date	Target Amt	Actual Amt
Acyclovir Powder	PCCA/522866	8 months	3.3 g	3.326 g
Hydrocortisone 5% Cream	PCCA/C102967	12 months	6.6 g	6.621 g
Glycerin	Humco/507774	16 months	0.8 mL	0.8 mL
Aquaphilic Ointment	Medco/1416	24 months	49.1 g	49.34 g

QA Documentation

Product Weights(s) or Volume:
61 g

Visual Inspection & Testing:
The preparation is a smooth, white, opaque cream of soft consistency having a slight sheen.

<p>Formulation Record #: MFR-556466</p> <p>Compounding Record #: CMPD-479225</p> <p>Date & Time Prepared: 3/15/20XX, 10:25 AM</p> <p>Beyond-use Date: 5/15/20XX</p> <p>Reference Source for BUD: USP 795</p> <p>Container-Closure System: 2 oz. ointment jar</p> <p>Storage Requirements: Room Temperature</p> <p>Final Product Name, Strength, and Dosage Form: Acyclovir 5% and Hydrocortisone 5% in Aquaphilic Topical Cream</p> <p>Auxiliary Label(s): See Labels Above</p>	<p>Required Equipment & Procedure (step-by-step):</p> <p>REQUIRED EQUIPMENT - mortar, pestle, ointment paper, tape, large and small metal spatulas, rubber spatula, 3 slip tip syringe, small/medium/large weigh boats, 2 oz. ointment jar</p> <ol style="list-style-type: none"> In a mortar triturate some acyclovir to a very fine powder and weigh the required amount of acyclovir powder. Weigh the required amount of hydrocortisone 5% cream. Measure 0.8 mL glycerin in a 3 mL slip tip syringe. Place the acyclovir powder on the ointment paper and levigate the acyclovir powder with 0.8 mL glycerin. Place the hydrocortisone cream on the paper and incorporate the acyclovir/glycerin paste into the hydrocortisone cream. Spatulate until uniform. Weigh the required amount of Aquaphilic ointment. Geometrically incorporate the Aquaphilic into the acyclovir/HC. Spatulate until uniform after each addition. Transfer the final product to a 2 oz. ointment jar. Label and Dispense.
<p>Compounding Personnel Signature(s): <i>Jaye Hawc, PharmD</i></p>	