



Suggested Formula	Benzoyl Peroxide 5%, Clindamycin 1%, Salicylic Acid 5% Topical Lotion (Emulsion, 100 mL)	FIN	F 008 881
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydrous Benzoyl Peroxide, USP	TBD					
Clindamycin Phosphate, USP	TBD					
Salicylic Acid, USP	5.000	g				
Sodium Metabisulfite, NF	0.10	g				
Propylene Glycol, USP	10.0	mL				
Medisca VersaPro™ Lotion Base	70.0	mL				
Medisca VersaPro™ Lotion Base	q.s. to 100.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light Sensitive** (protect from light whenever possible):

*Hydrous Benzoyl Peroxide, Salicylic Acid, Propylene Glycol, Sodium Metabisulfite*

**Hygroscopic** (protect from moisture whenever possible):

*Clindamycin Phosphate, Propylene Glycol*

**Narrow Therapeutic Index**

*Clindamycin Phosphate*

**Shock Sensitive** (handle with care)

*Hydrous Benzoyl Peroxide*

**Explosive** (Keep away from elevated temperature. Store at controlled room temperature)

*Hydrous Benzoyl Peroxide*

**Flammable** (Keep away from heat and flame)

*Hydrous Benzoyl Peroxide*

**Air Sensitive** (protect from air whenever possible):

*Sodium Metabisulfite*

**Moisture Sensitive** (protect from humidity whenever possible):

*Sodium Metabisulfite*



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## SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error / Testing Considerations:    To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction:    This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFI) and Compliance Policy Guides (CPGs).

#### **Clindamycin Phosphate has a Narrow Therapeutic Index.**

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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**SUGGESTED PREPARATION (for 100 mL)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Hydrous Benzoyl Peroxide, USP §	TBD				
Clindamycin Phosphate, USP §	TBD				
Salicylic Acid, USP §	5.000	g			
Sodium Metabisulfite, NF §	0.10	g			
Propylene Glycol, USP §	10.0	mL			
Medisca VersaPro™ Lotion Base	70.0	mL			
Medisca VersaPro™ Lotion Base	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.

\* Takes into account increased batch size conversions and density conversions, if required.

**Preparatory Instruction**

**1. Ingredient quantification:**

A. Determine the quantity (in g) of Hydrous Benzoyl Peroxide required to make a Benzoyl Peroxide 5% Topical Lotion, batch size (100 mL):

Quantity of Benzoyl Peroxide required for 100 mL	5.000 g
DIVIDED BY	
Assay result (from certificate of analysis)	_____ %
MULTIPLIED BY	
	100
EQUALS	
<b>i. Quantity of Hydrous Benzoyl Peroxide needed for 100 mL</b>	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
<b>ii. Quantity of Hydrous Benzoyl Peroxide needed <i>plus</i> processing error adjustments</b>	_____ g



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2. **Ingredient quantification:**

A. Determine the potency of Clindamycin Phosphate based on the certificate of analysis:

MINUS	100%
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Clindamycin Phosphate, in decimal	_____
MULTIPLIED BY	
Assay (base equivalent) on anhydrous basis result (from certificate of analysis)	_____ µg/mg
MULTIPLIED BY (Multiplication factor – µg to grams /mg to grams)	0.001
EQUALS	
<b>i. Potency of Clindamycin Phosphate (Base equivalent) in g/g</b>	_____



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3.	<b><u>Ingredient quantification:</u></b>	<p>A. Determine the quantity (in g) of Clindamycin Phosphate required to make a <b>Clindamycin</b> 1% Topical Lotion, batch size (100 mL):</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Quantity of <b>Clindamycin</b> required for 100 mL</td> <td style="text-align: right; padding: 5px;">1.000 g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">DIVIDED BY</td> </tr> <tr> <td style="padding: 5px;">Potency of Clindamycin Phosphate (Base equivalent) in g/g (Step 2Ai)</td> <td style="text-align: right; padding: 5px;">_____</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;"><b>i. Quantity of Clindamycin Phosphate needed for 100 mL</b></td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">MULTIPLIED BY</td> </tr> <tr> <td style="padding: 5px;">Processing error adjustments (5 to 9%)</td> <td style="text-align: right; padding: 5px;">1.05 to 1.09</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;"><b>ii. Quantity of Clindamycin Phosphate needed <i>plus</i> processing error adjustments</b></td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> </table>	Quantity of <b>Clindamycin</b> required for 100 mL	1.000 g	DIVIDED BY		Potency of Clindamycin Phosphate (Base equivalent) in g/g (Step 2Ai)	_____	EQUALS		<b>i. Quantity of Clindamycin Phosphate needed for 100 mL</b>	_____ g	MULTIPLIED BY		Processing error adjustments (5 to 9%)	1.05 to 1.09	EQUALS		<b>ii. Quantity of Clindamycin Phosphate needed <i>plus</i> processing error adjustments</b>	_____ g
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4.	<b><u>Powder-liquid preparation:</u></b>	<p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Hydrous Benzoyl Peroxide (amount determined in Step 1Aii)</li> <li>-Clindamycin Phosphate (amount determined in Step 3Aii)</li> <li>-Salicylic Acid</li> <li>-Sodium Metabisulfite</li> </ul> <p>B. Levigate the fine homogeneous powder blend (Step 4A) with the Propylene Glycol.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>																		
5.	<b><u>Powder-liquid to medium integration:</u></b>	<p>A. Incrementally add the homogeneous liquid-like dispersion (Step 4B) to the VersaPro™ Lotion Base (70.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous lotion-like dispersion.</p>																		



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6.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add additional VersaPro™ Lotion Base to the mixture (Step 5A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous lotion-like dispersion.</p>
7.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>

**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	30 days, as per USP 795.	Packaging Requirements	- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 <b>Shake well before use.</b>
	2	Keep out of reach of children.	7 Cap tightly after use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8 Do not allow applicator tip to come into contact with surrounding tissue.
	4	Keep at controlled room temperature (20°C – 25°C).	9 For external use only.
	5	Protect from light.	10 Keep in a dry place.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.		
Patient Instructions	Contact your pharmacist in the event of adverse reactions. <b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.		



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## REFERENCES

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