MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Benzoyl Peroxide 5%, Clindamycin 1% Topical Gel (Suspension, 25 g)	FIN	F 006 875v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydrous Benzoyl Peroxide, USP	TBD					
Clindamycin Phosphate, USP	TBD					
Ethoxy Diglycol, NF	1.5	mL				
Medisca VersaPro™ Gel Base	TBD					
Medisca LiquiGel Complex™	As needed					
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):*	*Hydrous Benzoyl Peroxide*
Hygroscopic *(protect from moisture whenever possible):*	*Clindamycin Phosphate, Ethoxy Diglycol*
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*

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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 and pH testing considerations during preparation, it is suggested to measure an additional **12 to 15%** 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 (GFIs) 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 25 g)

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				
Ethoxy Diglycol, NF §	1.5	mL			
Medisca VersaPro™ Gel Base	TBD				
Medisca LiquiGel Complex™	As needed				
Sodium Hydroxide 10% Solution	As required				
Hydrochloric Acid 10% Solution	As required				

§ 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 to make a Benzoyl Peroxide 5% Topical Gel, batch size (25 g):

Quantity of Benzoyl Peroxide required for 25 g	1.250 g
DIVIDED BY	
Assay result (from certificate of analysis)	_____ %
MULTIPLIED BY	100
EQUALS	
i. Quantity of Hydrous Benzoyl Peroxide needed for 25 g	_____ g
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Hydrous Benzoyl Peroxide needed *plus* processing error adjustments	_____ **g**

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2. **Ingredient quantification:**

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

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of 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	
i. Potency of Clindamycin Phosphate (Base equivalent) in g/g	_____

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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Clindamycin Phosphate required to make a **Clindamycin** 1% Topical Gel, batch size (25 g):

Quantity of **Clindamycin** required for 25 g	0.250 g
DIVIDED BY	
Potency of Clindamycin Phosphate (Base equivalent) in g/g (Step 2Ai)	_____
EQUALS	
i. Quantity of Clindamycin Phosphate needed for 25 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Clindamycin Phosphate needed *plus* processing error adjustments	_____ **g**

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4. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Gel Base to weigh for the required batch size (25 g):

Total Weight of the batch	25.00 g
MINUS	
Total amount of other ingredients except Hydrous Benzoyl Peroxide and Clindamycin Phosphate	1.482 g
MINUS	
The weight of Hydrous Benzoyl Peroxide (Step 1Ai)	_____ g
MINUS	
The weight of Clindamycin Phosphate (Step 3Ai)	_____ g
EQUALS	
i. Quantity of VersaPro™ Gel Base needed for 25 g	_____ g
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Weight of VersaPro™ Gel Base required *plus* processing error adjustments	_____ g

5. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine homogeneous powder blend:

-Hydrous Benzoyl Peroxide (amount determined in Step 1Aii)
-Clindamycin Phosphate (amount determined in Step 3Aii)

B. Levigate the fine, homogeneous powder blend (Step 5A) with the Ethoxy Diglycol.

End result: Homogeneous paste-like dispersion.

IMPORTANT NOTE: It is very important to have a smooth dispersion at this stage!!

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6. **Powder-liquid to medium integration:**

A. Incrementally add the homogeneous paste-like dispersion (Step 5B) to the VersaPro™ Gel Base (amount determined in Step 4Aii).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous gel-like dispersion.

7. **Viscosity adjustment**

A. If the final result is too liquid or not thick enough, incrementally add the LiquiGel Complex™, about 0.5 mL at a time, to the homogeneous gel-like dispersion (Step 6A) and thoroughly mix for 2 minutes. Repeat the procedure until the desired viscosity is attained.

Note: The amount of LiquiGel Complex™ could be within the range of 1% to 6%.

B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.

8. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 7B).

B. Test the pH of the sample. It should lie between 4.5 and 6.5.

C. If the pH < 4.5, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 4.5 to 6.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 6.5.

D. If the pH > 6.5, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.
3. Re-test the pH.
4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 4.5 to 6.5 is obtained.

IMPORTANT: Do not allow the pH to fall below 4.5.

9. **Product transfer:**

Transfer the final product into the specified dispensing container (see “Packaging requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP 795.	Packaging Requirements		Tightly closed, light-resistant container with topical applicator.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Cap tightly after use.
	2	Keep out of reach of children.	7		Do not allow applicator tip to come into contact with surrounding tissue.
	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		For external use only.
	4	Do not allow to come into contact with eyes/ears/nose/mouth.	9		Do not touch the medication with your hands.
	5	Keep at controlled room temperature (20°C – 25°C).	10		Protect from light.
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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.				

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