MEDISCA® NETWORK INC.
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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Baclofen 2%, Cyclobenzaprine Hydrochloride 2%, Diclofenac Sodium 3%, Lidocaine Hydrochloride 2% Topical Cream (Emulsion, 50 g)	FIN	F 005 491

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Baclofen, USP	1.000	g				
Cyclobenzaprine Hydrochloride, USP	1.000	g				
Diclofenac Sodium, USP	1.500	g				
Lidocaine Hydrochloride, USP	TBD					
Pentylene Glycol	1.75	mL				
Medisca VersaPro™ Cream Base	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Diclofenac Sodium*

Hygroscopic *(protect from moisture whenever possible):* *Diclofenac Sodium, Pentylene Glycol*

Narrow Therapeutic Index *Lidocaine Hydrochloride*

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 **10 to 12%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

Lidocaine Hydrochloride 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 50 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Baclofen, USP	1.000	g			
Cyclobenzaprine Hydrochloride, USP	1.000	g			
Diclofenac Sodium, USP §	1.500	g			
Lidocaine Hydrochloride, USP	TBD				
Pentylene Glycol §	1.75	mL			
Medisca VersaPro™ Cream Base	TBD				

§ 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 potency of Lidocaine Hydrochloride based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Lidocaine Hydrochloride, in decimal	_____
MULTIPLY BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Lidocaine Hydrochloride, in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride to make a Lidocaine Hydrochloride 2% Topical Cream, batch size (50 g):

Quantity of Lidocaine Hydrochloride required for 50 g	1.000 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride (Step 1Ai)	_____
EQUALS	
i. Quantity of Lidocaine Hydrochloride needed for 50 g	_____ **g**
MULTIPLED BY	
Processing error adjustments (10 to 12%):	1.10 to 1.12
EQUALS	
ii. Quantity of Lidocaine Hydrochloride needed *plus* processing error adjustments	_____ **g**

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3. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Cream Base to weigh for the required batch size (50 g):

Total Weight of the batch	50.00 g
MINUS	
Total amount of other ingredients except Lidocaine Hydrochloride	5.20 g
MINUS	
The weight of Lidocaine Hydrochloride (Step 2Ai)	_____ g
EQUALS	
i. Quantity of VersaPro™ Cream Base needed for 50 g	_____ g
MULTIPLED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
EQUALS	
ii. Weight of VersaPro™ Cream Base required *plus* processing error adjustments	_____ g

4. **Powder-liquid preparation:**

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

-Baclofen
-Cyclobenzaprine Hydrochloride
-Diclofenac Sodium
-Lidocaine Hydrochloride (amount determined in Step 2Aii)

B. Levigate the fine, homogeneous powder blend (Step 4A) with the Pentylene Glycol.

End result: Homogeneous paste-like dispersion.

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5.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 4B) to the VersaPro™ Cream Base (amount determined in Step 3Aii). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous cream-like dispersion. B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
6.	**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.	Packaging Requirements		Tightly closed, light-resistant container with metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	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		For external use only.
	4	Keep in a dry place.	9		May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Keep at room temperature (20°C – 23°C).	10		Protect from light.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT:** - Small batch is prepared due to inherent potential of systemic toxicity. - Limits as to the total amount of product used should be established by a physician. - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas. - Continued application of this product might produce systemic side effects. Advise patient accordingly. **IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN BACLOFEN AND CYCLOBENZAPRINE HYDROCHLORIDE. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.**				
Patient Instructions	Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** - Do not cover the site of application. - The quantity of API administered is directly dependent on the quantity of product applied.				

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