MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Baclofen 2%, Diclofenac Sodium 3% Topical Cream (Emulsion, 10 mL)	FIN	F 007 842

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Baclofen, USP	0.200	g				
Diclofenac Sodium, USP	0.300	g				
Propylene Glycol, USP	0.3	mL				
Medisca VersaPro™ Cream Base	7.0	mL				
Medisca VersaPro™ Cream Base	q.s. to 10.0	mL				
Medisca LiquiGel Complex™	As needed					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Diclofenac Sodium, Propylene Glycol*

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

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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 **20 to 25%** 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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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).

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 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Baclofen, USP	0.200	g			
Diclofenac Sodium, USP §	0.300	g			
Propylene Glycol, USP §	0.3	mL			
Medisca VersaPro™ Cream Base	7.0	mL			
Medisca VersaPro™ Cream Base	q.s. to 10.0	mL			
Medisca LiquiGel Complex™	As needed				

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Baclofen -Diclofenac Sodium B. Levigate the fine homogeneous powder blend (Step 1A) with Propylene Glycol. End result: Homogeneous paste-like dispersion.
2.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the VersaPro™ Cream Base (7.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous cream-like dispersion.

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3.	**Filling to volume:** A. Add additional VersaPro™ Cream Base to the mixture (Step 2A) to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous cream-like dispersion.
4.	**Viscosity adjustment:** A. If the final result is not thick enough, incrementally add the LiquiGel Complex™, about 0.5 mL at a time, to the homogeneous cream-like dispersion (Step 3A) and thoroughly mix for 2 minutes. Repeat the procedure until the desired viscosity is attained. Note: The amount of LiquiGel Complex™ should 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.
5.	**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		- To be administered in a tightly closed, light-resistant metered-dose MD Mini Pump measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.	
	2	Keep out of reach of children.	7	For external use only.	
	3	May impair mental and or physical ability. Use care when operating a car or machinery.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Keep in a dry place.	
	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.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

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