MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Gabapentin 10% Topical Gel (Suspension, 15 g)	FIN	F 006 611

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Gabapentin, USP	1.500	g				
Propylene Glycol, USP	1.1	mL				
Medisca CopaSil™	12.36	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Gabapentin, Propylene Glycol, CopaSil™*

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

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 **15 to 20%** 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.

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 15 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Gabapentin, USP §	1.500	g			
Propylene Glycol, USP §	1.1	mL			
Medisca CopaSil™ §	12.36	g			

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Triturate the Gabapentin to form a fine, homogeneous powder. B. Levigate the fine homogeneous powder (Step 1A) with the 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 CopaSil™. Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion. B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP*.	Packaging Requirements		- Tightly closed, light-resistant container. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Keep in a dry place.
	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	Protect from light.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.		9	Keep at room temperature (20°C – 23°C).
	5	For external use only.		10	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
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.				

*** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.**

REFERENCES

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5.	Gabapentin (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4348.

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6.	Gabapentin. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 221.
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8.	Gabapentin. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1561.
9.	USP <795>. *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.