MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Gabapentin 6%, Ketamine Hydrochloride 9.2%, Ketoprofen 8% Topical Cream (Emulsion, 100 g)	FIN	F 004 550v3

Note: Ketamine Hydrochloride 9.2% is equivalent to Ketamine 8%.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Gabapentin, USP	6.000	g				
Ketamine Hydrochloride, USP	9.200	g				
Ketoprofen, USP	8.000	g				
Pentylene Glycol	5.0	mL				
Ethoxy Diglycol	7.0	mL				
Medisca VersaPro™ Cream Base	64.75	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)* — *Ketamine Hydrochloride*

Light sensitive *(protect from light whenever possible):* — *Ketamine Hydrochloride, Gabapentin, Ketoprofen*

Hygroscopic *(protect from moisture whenever possible):* — *Ethoxy Diglycol, Pentylene 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 **5 to 9%** 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Gabapentin 6%, Ketamine Hydrochloride 9.2%, Ketoprofen 8% Topical Cream (Emulsion, 100 g)	FIN	F 004 550v3

SUGGESTED PREPARATION (for 100 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Gabapentin, USP §	6.000	g			
Ketamine Hydrochloride, USP §	9.200	g			
Ketoprofen, USP §	8.000	g			
Pentylene Glycol §	5.0	mL			
Ethoxy Diglycol §	7.0	mL			
Medisca VersaPro™ Cream Base	64.75	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. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Gabapentin -Ketamine Hydrochloride -Ketoprofen B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Ethoxy Diglycol -Pentylene Glycol C. Levigate the fine, homogeneous powder blend (Step 1A) with the homogeneous liquid-like solution (Step 1B). End result: Homogeneous liquid-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1C) to the VersaPro™ Cream Base. Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous cream-like dispersion.

Suggested Formula	Gabapentin 6%, Ketamine Hydrochloride 9.2%, Ketoprofen 8% Topical Cream (Emulsion, 100 g)	FIN	F 004 550v3

3.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	30 days, as per USP.		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.	7	Keep in a dry place.
	2	Keep out of reach of children.	8	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.	9	For external use only.
	4	Protect from light.	10	May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Keep at room temperature (20°C – 23°C).	11	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	6	Controlled substance. Dangerous unless used as directed.	12	May produce psychological and/or physical dependence.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN GABAPENTIN AND KETAMINE 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:** The quantity of API administered is directly dependent on the quantity of product applied.			

REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 235.
2.	Neurontin. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2010.* 1551.
3.	Apo-Keto-E. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2010.* 211.

Suggested Formula	Gabapentin 6%, Ketamine Hydrochloride 9.2%, Ketoprofen 8% Topical Cream (Emulsion, 100 g)	FIN	F 004 550v3

4.	Ketamine Hydrochloride Injection. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2010.* 1219.
5.	Gabapentin. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 482.
6.	Ketoprofen. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 73.
7.	Ketamine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1787.
8.	Ketoprofen (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #5305.
9.	Ketamine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #5295.
10.	Gabapentin (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4319.
11.	Gabapentin. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 254.
12.	Ketoprofen. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 315.
13.	Ketamine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 313.
14.	Gabapentin (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2462.
15.	Ketoprofen (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2739.
16.	Ketamine Hydrochloride (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2736.
17.	Gabapentin. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1561.
18.	Ketoprofen. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 423.
19.	USP <795>. *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.