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	Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)	FIN	F 006 055

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Baclofen, USP	2.500	g				
Dexamethasone (Micronized), USP	0.500	g				
Flurbiprofen, USP	5.000	g				
Ethoxy Diglycol	4.0	mL				
Medisca Transdermal Pain Base	87.89	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Dexamethasone*

Hygroscopic *(protect from moisture whenever possible):* *Ethoxy Diglycol*

Heat Sensitive *(protect from heat whenever possible):* *Dexamethasone*

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	Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)	FIN	F 006 055

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
Baclofen, USP	2.500	g			
Dexamethasone (Micronized), USP §	0.500	g			
Flurbiprofen, USP	5.000	g			
Ethoxy Diglycol §	4.0	mL			
Medisca Transdermal Pain Base	87.89	g			

* 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 geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Baclofen -Dexamethasone (Micronized) -Flurbiprofen B. Levigate the fine, homogeneous powder blend (Step 1A) with the Ethoxy Diglycol. End result: Homogeneous paste-like dispersion.
2.	**Powder-liquid to base incorporateion:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Transdermal Pain Base. Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous cream-like dispersion.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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	Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)	FIN	F 006 055

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP.	Packaging Requirements		Tightly closed, light-resistant, metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Protect from light.
	2	Keep out of reach of children.	7		Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	For external use only.	8		Cap tightly after use.
	4	Keep at room temperature (20°C – 23°C).	9		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	May impair mental and or physical ability. Use care when operating a car or machinery.	10		Keep in a dry place.
Pharmacist Instructions		Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary. **IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN DEXAMETHASONE AND FLURBIPROFEN. 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.	Lioresal Intrathecal. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2014*: 1554.
3.	PMS-Dexamethasone Elixir/Tablets. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2014*: 2095.
4.	Ansaid. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2014*: 209.
5.	Baclofen. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1888.
6.	Dexamethasone. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1526.

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	Baclofen 2.5%, Dexamethasone 0.5%, Flurbiprofen 5% Topical Cream (Emulsion, 100 g)	FIN	F 006 055

7.	Flurbiprofen. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 61.
8.	Baclofen (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #937.
9.	Dexamethasone (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #2943.
10.	Flurbiprofen (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4199.
11.	Baclofen. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 61.
12.	Dexamethasone. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 176.
13.	Baclofen (Monograph). *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 1908.
14.	Dexamethasone (Monograph). *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 2542.
15.	Flurbiprofen (Monograph). *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 3054.
16.	Baclofen Systemic. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 520.
17.	Dexamethasone. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1021.
18.	Flurbiprofen. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 419.
19.	USP <795>. *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.