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	Progesterone 0.025%, Spironolactone 0.05% Topical Foam (Suspension, 50 mL)	FIN	F 006 843v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Progesterone 0.25%/Spironolactone 0.5% Stock Solution †	5.00	mL				
Medisca Foamil™ Base	45.00	g				
Alcohol (95%), USP	q.s. to 50.0	mL				
† **Progesterone 0.25%/Spironolactone 0.5% Stock Solution**						
Progesterone (Micronized), USP	0.100	g				
Spironolactone, USP	0.200	g				
Alcohol (95%), USP	1. 0	mL				
Alcohol(95%), USP	q.s. to 40.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Spironolactone, Progesterone, Foamil™ Base*

Oxygen sensitive *(protect from air whenever possible):* *Spironolactone*

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.

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	Progesterone 0.025%, Spironolactone 0.05% Topical Foam (Suspension, 50 mL)	FIN	F 006 843v2

SUGGESTED PREPARATION (for 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Progesterone 0.25%/Spironolactone 0.5% Stock Solution † §	5.00	mL			
Medisca Foamil™ Base §	45.00	g			
Alcohol (95%), USP	q.s. to 50.0	mL			
† **Progesterone 0.25%/Spironolactone 0.5% Stock Solution**					
Progesterone (Micronized), USP §	0.100	g	---	---	
Spironolactone, USP §	0.200	g	---	---	
Alcohol (95%), USP	1.0	mL	---	---	
Alcohol (95%), USP	q.s. to 40.0	mL	---	---	

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

Preparatory Instruction	
1.	† **<u>Progesterone 0.25%/Spironolactone 0.5% Stock Solution preparation</u>:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Progesterone (Micronized) -Spironolactone B. Levigate the fine, homogeneous powder blend (Step 1A) with the Alcohol (95%) (1.0 mL). C. Add additional Alcohol (95%) to the homogeneous liquid-like dispersion (Step 1A) to fill the required amount (40.0 mL). <u>Specifications</u>: Continuously mix until all solid particles have completely dissolved. <u>End result</u>: Homogeneous liquid-like solution.

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	Progesterone 0.025%, Spironolactone 0.05% Topical Foam (Suspension, 50 mL)	FIN	F 006 843v2

2.	**Powder-liquid to medium integration:** A. Incrementally add the Progesterone 0.25%/Spironolactone 0.5% Stock Solution (5.00 mL *plus* processing error adjustments) to the Foamil™ Base. Specifications: Continuously mix until homogenous. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add additional Foamil™ Base to the mixture (Step 2A) to fill to the required batch size (50.0 mL *plus* processing error adjustments). Specifications: Continuously mix until homogeneous. End result: Homogeneous liquid-like dispersion.
4.	**Product transfer:** A. Transfer the final product into the specified dispensing container (see "Packaging requirements"). Note: Continuously mix the final product during the transfer process in order to maintain homogeneity.

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	Progesterone 0.025%, Spironolactone 0.05% Topical Foam (Suspension, 50 mL)	FIN	F 006 843v2

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP.	Packaging Requirements		- Tightly closed, light-resistant topical dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.	
	2	Gently mix to ensure homogeneity before use.	7	Keep at room temperature (20°C – 23°C).	
	3	Keep out of reach of children.	8	Protect from light.	
	4	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.	
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	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.			

Suggested Formula	Progesterone 0.025%, Spironolactone 0.05% Topical Foam (Suspension, 50 mL)	FIN	F 006 843v2

REFERENCES

1. Cosmetics for special populations and for use as vehicles. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 441.
2. Progesterone. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 2125.
3. Spironolactone. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1400.
4. Progesterone (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #7889.
5. Spironolactone (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #8887.
6. Progesterone. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 409.
7. Spironolactone. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 445.
8. Progesterone (Monograph). *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 5545.
9. Spironolactone (Monograph). *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 5905.
10. USP <795>. *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.