MEDISCA® NETWORK INC.
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Suggested Formula	Fluticasone Propionate 1%, Levocetirizine Hydrochloride 2%, Pentoxifylline 0.5%, Tranilast 1% Topical Gel (Suspension, 100 g)	FIN	F 006 355

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fluticasone Propionate, USP	1.000	g				
Levocetirizine Hydrochloride	2.000	g				
Pentoxifylline, USP	0.500	g				
Tranilast	1.000	g				
Ethoxy Diglycol	6.0	mL				
Medisca CopaSil™	89.34	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Fluticasone Propionate, Levocetirizine Hydrochloride, Pentoxifylline, Tranilast*

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

Moisture sensitive *(protect from humidity whenever possible):* *Levocetirizine Hydrochloride*

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.

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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
Fluticasone Propionate, USP §	1.000	g			
Levocetirizine Hydrochloride §	2.000	g			
Pentoxifylline, USP §	0.500	g			
Tranilast §	1.000	g			
Ethoxy Diglycol §	6.0	mL			
Medisca CopaSil™	89.34	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: -Fluticasone Propionate -Levocetirizine Hydrochloride -Pentoxifylline -Tranilast B. Levigate the fine homogeneous powder blend (Step 1A) with the Ethoxy Diglycol. End result: Homogeneous liquid-like dispersion.
2.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous liquid-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	For external use only.	
	4	Keep at room temperature (20°C – 23°C).	9	Protect from light.	
	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.				

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

Suggested Formula	Fluticasone Propionate 1%, Levocetirizine Hydrochloride 2%, Pentoxifylline 0.5%, Tranilast 1% Topical Gel (Suspension, 100 g)	FIN	F 006 355

REFERENCES

1. Ointments, Creams, and Pastes. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 265.
2. Fluticasone Propionate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1533.
3. Levocetirizine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 583.
4. Pentoxifylline. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition*. London, England: The Pharmaceutical Press; 2009: 1367.
5. Tranilast. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition*. London, England: The Pharmaceutical Press; 2009: 1149.
6. Fluticasone Propionate (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4240.
7. Pentoxifylline (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #7249.
8. Cetirizine (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #2021.
9. Tranilast (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #9731.
10. Fluticasone Propionate. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 215.
11. Pentoxifylline. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 377.
12. Fluticasone Propionate (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 3578.
13. Pentoxifylline (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 4812.
14. USP <795>. *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.