MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Ascorbic Acid 2%, Epigallocatechin Gallate 1%, Methylsulfonylmethane 2%, Tranilast 1% Topical Gel (Suspension, 30 g)	FIN	F 006 354

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ascorbic Acid, USP	0.600	g				
(-)-Epigallocatechin 3-O-Gallate (EGCG)	0.300	g				
Methylsulfonylmethane (Dimethyl Sulfone, MSM), USP	0.600	g				
Tranilast	0.300	g				
Ethoxy Diglycol	0.9	mL				
Medisca CopaSil™	27.28	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Ascorbic Acid, (-)-Epigallocatechin 3-O-Gallate, Methylsulfonylmethane, Tranilast*

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

Oxygen sensitive *(protect from oxygen whenever possible):* *Ascorbic Acid*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error during preparation, it is suggested to measure an additional **12 to 15%** 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 30 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ascorbic Acid, USP §	0.600	g			
(-)-Epigallocatechin 3-O-Gallate (EGCG) §	0.300	g			
Methylsulfonylmethane (Dimethyl Sulfone, MSM), USP §	0.600	g			
Tranilast §	0.300	g			
Ethoxy Diglycol §	0.9	mL			
Medisca CopaSil™	27.28	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. By geometric addition, combine and triturate the following ingredients together to form a fine homogeneous powder blend: -Ascorbic Acid -Tranilast -(-)-Epigallocatechin 3-O-Gallate (EGCG) -Methylsulfonylmethane (Dimethyl Sulfone, MSM) B. Levigate the fine homogeneous powder blend (Step 1A) with the Ethoxy Diglycol. 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.

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

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.	5	Protect from light.	
	2	Keep out of reach of children.	6	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.	7	For external use only.	
	4	Keep in a dry place.	8	Keep at room temperature (20°C – 23°C).	
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	Ascorbic Acid 2%, Epigallocatechin Gallate 1%, Methylsulfonylmethane 2%, Tranilast 1% Topical Gel (Suspension, 30 g)	FIN	F 006 354

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.
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