MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
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Suggested Formula	Tacrolimus 0.15% Topical Ointment (Emulsion, 100 g)	FIN	F 004 426v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Tacrolimus, USP	TBD					
Propylene Glycol, USP	5.0	mL				
Medisca Ointment Base (Emulsifying)	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

Light sensitive *(protect from light whenever possible):* *Tacrolimus, Propylene Glycol*

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

Narrow Therapeutic Index *Tacrolimus*

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.

Tacrolimus has a Narrow Therapeutic Index.

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
Tacrolimus, USP §	TBD				
Propylene Glycol, USP §	5.0	mL			
Medisca Ointment Base (Emulsifying)	TBD				

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

Preparatory Instruction	
1.	**Ingredient quantification:**

A. Determine the potency of Tacrolimus based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Tacrolimus, in decimal	_____
MULTIPLY BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Tacrolimus, in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Tacrolimus to make a Tacrolimus 0.15% Topical Ointment, batch size (100 g):

Quantity of Tacrolimus required for 100 g	0.150 g
DIVIDED BY	
Potency of Tacrolimus (Step 1Ai)	_____
EQUALS	
i. Quantity of Tacrolimus needed for 100 g	_____ **g**
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Tacrolimus needed *plus* processing error adjustments	_____ **g**

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3. **Ingredient quantification:**

A. Determine the actual quantity of Ointment Base (Emulsifying) to weigh for the required batch size (100 g):

Total Weight of the batch	100.00 g
MINUS	
Total amount of other ingredients except Tacrolimus	5.19 g
MINUS	
The weight of Tacrolimus (Step 2Ai)	_____ g
EQUALS	
i. Quantity Ointment Base (Emulsifying) needed for 100 g	_____ g
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of Ointment Base (Emulsifying) required *plus* processing error adjustments	_____ g

4. **Powder-liquid preparation:**

A. Triturate the Tacrolimus (amount determined in Step 2Aii) to form a fine, homogeneous powder.

B. Incrementally add the fine, homogeneous powder (Step 4A) to the Propylene Glycol.

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

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5.	**Medium integration:** A. By geometric addition, combine and mix the following ingredients together: -Homogeneous liquid-like solution (Step 4B) -Ointment Base (Emulsifying) (amount determined in Step 3Aii) Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous ointment-like dispersion.
6.	**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 jar/tube.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep at room temperature (20°C – 23°C).
	2	Keep out of reach of children.	7	For external use only.
	3	Cap tightly after use.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	9	Protect from light.
	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	10	Keep in a dry place.
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.		

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REFERENCES

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