MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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technicalservices@medisca.net

Suggested Formula	Tacrolimus 1 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 003 067v6

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Tacrolimus (5 mg) Capsules	20	Units				
Propylene Glycol, USP	10.0	mL				
Raspberry Flavor	1.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL				
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Narrow Therapeutic Index: *Tacrolimus*

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

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

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

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 mL)

Weigh and / or measure the following ingredients when appropriate:

	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Tacrolimus (5 mg) Capsules §	20	Units			
Propylene Glycol, USP §	10.0	mL			
Raspberry Flavor	1.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	45.0	mL			
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL			

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

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Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Tacrolimus (5 mg) capsule powder mix to weigh):**

A. Empty and weigh the contents of 22 Tacrolimus (5 mg) Capsules.
Record the total weight here: _____ g

B. Calculate the average weight of powder in each capsule:

Weight of powder from 22 capsules (from Step 1A):	_____ g
DIVIDED BY	
Number of capsules:	22
EQUALS	
Average weight of powder from a single Tacrolimus (5 mg) Capsule:	_____ g

C. Calculate the weight of powder equivalent to 20 capsules:

Average weight of powder from a single Tacrolimus (5 mg) Capsule (from Step 1B):	_____ g
MULTIPLIED BY	
Number of capsules required:	20
EQUALS	
Weight of powder equivalent to 20 capsules:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 20 capsules (from Step 1C):	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required *plus* processing error adjustments:	_____ **g**

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2.	**Powder preparation:** A. Triturate the contents of the 22 Tacrolimus (5 mg) Capsules to form a fine, homogeneous powder. B. Sieve and weigh the quantity of Tacrolimus (5 mg) capsule powder mix required for the batch (refer to Step 1D) and discard the remaining powder.
3.	**Powder-Liquid preparation:** A. Levigate the Tacrolimus (5 mg) capsule powder mix (amount weighed in Step 2B) with the Propylene Glycol. End result: Homogeneous paste-like dispersion.
4.	**Medium integration:** A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle): -Homogeneous paste-like dispersion (Step 3A) -Raspberry Flavor Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. Note: Add the next ingredient, once the previous one has been completely added and dispersed.
5.	**Filling to volume:** A. Add Oral Syrup (Flavored Syrup Vehicle) to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
6.	**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 into the recommended dispensing containers in order to maintain homogeneity.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP 795.	Packaging Requirements		- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		**Shake well before use.**
	2	Keep out of reach of children.	8		Avoid all foods containing Grapefruit.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	9		May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Patient must avoid exposure to sunlight and UV rays.	10		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Keep refrigerated (2°C – 8°C). Do not freeze.	11		Cap tightly after use.
	6	Protect from light.			
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

1. Jacboson PA, Johnson CE, West NJ, Foster JA. Stability of tacrolimus in an extemporaneosuly prepared oral liquid. *Am J Health System Pharm.* 1997; 54:178-80.
2. Propylene Glycol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003:521.
3. Tacrolimus (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #9025.
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5. USP <795>. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.