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

Suggested Formula	Mycophenolate Mofetil 50 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 106v4

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Mycophenolate Mofetil, USP	5.000	g				
Propylene Glycol, USP	5.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL				
Cherry Syrup (Humco)	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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).

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:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Mycophenolate Mofetil, USP §	5.000	g			
Propylene Glycol, USP §	5.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL			
Cherry Syrup (Humco)	q.s. to 100.0	mL			

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

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. Triturate the Mycophenolate Mofentil to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol. End result: Homogeneous liquid-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle). Specifications: Continuously mix, using high shear mixing techniques. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add Cherry Syrup (Humco) to the mixture 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.

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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 into the recommended dispensing containers in order to maintain homogeneity.

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.	6	**Shake well before use.**
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	Protect from light.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Keep refrigerated. Do not freeze.		
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. Venkataramanan R, McCombs JR, Zuckerman S et al. Stability of mycophenolate mofetil as an extemporaneous suspension. *Ann Pharmacother* 1998; 32(7-8): 755-757.
2. Suspensions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 209.
3. Cellcept IV. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2009.* 479.
4. Propylene Glycol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition.* American Pharmaceutical Association; 2009: 592.
5. Mycophenolate Mofentil In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1836.
6. Mycophenolic Acid (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #6327.
7. Mycophenolate Mofetil (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 3015.
8. Mycophenolate Systemic. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2141.
9. USP <795>. *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.
10. Mycophenolate Mofetil. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 398.