MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
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Suggested Formula	Mycophenolate Mofetil 50 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 106v3

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				

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: 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 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.	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

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