MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Cyclosporine 100 mg/mL Oral Liquid (Solution, 30 mL)	FIN	F 004 615

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Cyclosporin A (Cyclosporine), USP	3.000	g				
Dehydrated Alcohol, USP	3.8	mL				
Oleoyl Polyoxylglycerides, NF	7.3	mL				
Olive Oil, NF	q.s. to 30.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Cyclosporin A (Cyclosporine)*

Narrow Therapeutic Index *Cyclosporin A (Cyclosporine)*

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.

Cyclosporin A (Cyclosporine) 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Cyclosporine 100 mg/mL Oral Liquid (Solution, 30 mL)	FIN	F 004 615

SUGGESTED PREPARATION (for 30 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Cyclosporin A (Cyclosporine), USP §	3.000	g			
Dehydrated Alcohol, USP	3.8	mL			
Oleoyl Polyoxylglycerides, NF	7.3	mL			
Olive Oil, NF	q.s. to 30.0	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. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Dehydrated Alcohol -Oleoyl Polyoxylglycerides B. Incrementally add the Cyclosporin A (Cyclosporine) to the homogeneous liquid-like solution (Step 1A). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
4.	**Filling to volume:** A. Add Olive Oil to the mixture (Step 1B) to fill to the required batch size (30.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Cyclosporine 100 mg/mL Oral Liquid (Solution, 30 mL)	FIN	F 004 615

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	30 days as per USP.		Packaging Requirements	Tight, light-resistant dispensing bottle with a metered dosing device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Protect from light.
	2	Keep out of reach of children.	6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Cap tightly after use.	7	Keep in a dry place.
	4	Keep cool but do not refrigerate.	8	
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: To be dispensed and administered only under the close supervision of the prescribing physician.**			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

Suggested Formula	Cyclosporine 100 mg/mL Oral Liquid (Solution, 30 mL)	FIN	F 004 615

REFERENCES

1. Solutions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 195.
2. Olive Oil. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 470.
3. Alcohol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 17.
4. Ciclosporin. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1822.
5. Cyclosporins (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #2752
6. Cyclosporine (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2044.
7. Oleoyl Polyoxylglycerides (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 1290.
8. USP <795>. *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.