

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

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

SPECIAL PREPARATORY CONSIDERATIONS

In	gredient-S	pecific	Informa	ation

Light sensitive (protect from light whenever possible):

Narrow Therapeutic Index

Cyclosporin A (Cyclosporin	e)
Cyclosporin A (Cyclosporin	e)

Suggested Preparatory Guidelines

Non-Sterile Preparation

Sterile Preparation

<u>Processing Error /</u> <u>Testing Considerations</u> :	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.



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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	\odot		
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. §

1.

	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 <i>plus</i> 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").



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days as per USP.	Packa Requirem	0 0	Tight, light-resistant dispensing bottle with a metered dosing device.
	1	Use as directed. Do not exceed dose.	l prescribed	5	Protect from light.
Auxiliary Labels	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					
Patient Instructions	Contact your pharmacist in the event of adverse reactions				



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