MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Oseltamivir 12 mg/mL Oral Liquid (Suspension, 75 mL)	FIN	F 001 067v4

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Oseltamivir (75 mg) Capsules**	12	Units				
Glycerin, USP	5.0	mL				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	30.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	q.s. to 75.0	mL				

**Delivered as Oseltamivir Phosphate.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Glycerin*

Light Sensitive *(protect from light whenever possible):* *Oseltamivir Phosphate*

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 75 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Oseltamivir (75 mg) Capsules §	12	Units			
Glycerin, USP §	5.0	mL			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	30.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	q.s. to 75.0	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 Oseltamivir (75 mg) capsule powder mix to weigh):**

A. Empty and weigh the contents of 14 Oseltamivir (75 mg) Capsules.
Record the total weight here: _____ g

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

Weight of powder from 14 capsules (from Step 1A):	_____ g
DIVIDED BY	
Number of capsules	14
EQUALS	
Average weight of powder from a single Oseltamivir (75 mg) Capsule:	_____ g

C. Calculate the weight of powder equivalent to 12 capsules:

Average weight of powder from a single Oseltamivir (75 mg) Capsule (from Step 1B):	_____ g
MULTIPLED BY	
Number of capsules required:	12
EQUALS	
Weight of powder equivalent to 12 capsules:	_____ g

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

Weight of powder equivalent to 12 capsules (from Step 1C):	_____ g
MULTIPLED 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 14 Oseltamivir (75 mg) Capsules to form a fine, homogeneous powder. B. Weigh the quantity of Oseltamivir (75 mg) capsule powder mix required for the batch (refer to Step 1D) and discard the remaining powder.
3.	**Powder-liquid preparation:** A. Levigate the Oseltamivir (75 mg) capsule powder mix (amount weighed in Step 2B) with the Glycerin. End result: Homogeneous paste-like dispersion.
4.	**Liquid preparation:** A. Combine and mix the following ingredients together: -Oral Syrup (Flavored Vehicle) -Tutti Frutti Flavor Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
5.	**Phase integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 3A) to the homogeneous liquid-like solution (Step 4A) Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
6.	**Filling to volume:** A. Add Oral Suspend (Suspending Vehicle) to the mixture (Step 5A) to fill to the required batch size (75.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

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7.	**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	May impair mental and/or physical ability. Use care when operating a car or machinery.
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	8	**Shake well before use.**
	4	Protect from light.	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		
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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