



Suggested Formula	Oseltamivir 15 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 097
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Oseltamivir (75 mg) Capsules **	20	units				
Ora-Sweet (Oral Syrup Vehicle)	30.0	mL				
Ora-Sweet (Oral Syrup Vehicle)	q.s. to 100.0	mL				

** Delivered as Oseltamivir Phosphate.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): *Oseltamivir*

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
Oseltamivir (75 mg) Capsules ** §	20	units			
Ora-Sweet (Oral Syrup Vehicle)	30.0	mL			
Ora-Sweet (Oral Syrup Vehicle)	q.s. to 100.0	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 powder to weigh if accounting for processing error adjustments):**
 - A. Empty and weigh the contents of 22 x Oseltamivir (75 mg) Capsules. Record the total weight here: _____ g
 - B. Calculate the average weight of powder in each capsule:

Weight of powder from 22 capsules (from Step 1A):	_____ g
DIVIDED BY	
Number of capsules	22
EQUALS	
Average weight of powder from a single Oseltamivir (75 mg) capsule:	_____ g
 - C. Calculate the weight of powder equivalent to 20 capsules:

Average weight of powder from a single Oseltamivir (75 mg) capsule (from Step 1B):	_____ g
MULTIPLIED BY	
Number of capsules required:	20
EQUALS	
Weight of powder equivalent to 20 capsules:	_____ g
 - D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 20 capsules (from Step 1C):	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required <i>plus</i> processing error adjustments:	_____ g
2. **Powder preparation:**
 - A. Triturate the contents of the 22 Oseltamivir (75 mg) capsules to form a fine, homogeneous powder.
 - B. Weigh the quantity of Oseltamivir (75 mg) capsule powder required for the batch (refer to Step 1D) and discard the remaining powder.



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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Levigate the Oseltamivir (75 mg) capsule powder (amount weighed in Step 2B) with Ora-Sweet (Oral Syrup Vehicle) (30.0 mL <i>plus</i> processing error adjustments).</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>		
4.	<p><u>Filling to volume:</u></p> <p>A. Add additional Ora-Sweet (Oral Syrup Vehicle) to the mixture (Step 3A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>		
5.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>		

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated.	Packaging Requirements	- Tight, amber glass bottle. - To be administered with a metered dose-measuring device	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep refrigerated. Do not freeze.
	2	May impair mental and/or physical ability. Use care when operating a car or machinery.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Shake well before use.	8	Keep out of reach of children.
	4	Cap tightly after use.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Protect from light.		
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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