



Suggested Formula	Oseltamivir 15 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 040
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Oseltamivir (75 mg) Capsules **	20	units				
Cherry Syrup †	30.0	mL				
Cherry Syrup †	q.s. to 100.0	mL				
† Cherry Syrup (100 mL)						
Sucrose, NF (beet sugar)	80.00	g				
Sodium Benzoate, NF	0.10	g				
Citric Acid, USP	0.10	g				
Alcohol (95%), USP	0.1	mL				
F.D. & C. Red No. 3	0.01	g				
F.D. & C. Red No. 40	0.01	g				
Cherry (artificial) Flavor	0.5	mL				
Purified Water, USP	40.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Hydrochloric Acid 10% solution	As required					

** 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			
Cherry Syrup †	30.0	mL			
Cherry Syrup †	q.s. to 100.0	mL			
† Cherry Syrup (100 mL)					
Sucrose, NF (beet sugar)	80.00	g	--	--	
Sodium Benzoate, NF	0.10	g	--	--	
Citric Acid, USP	0.10	g	--	--	
Alcohol (95%), USP	0.1	mL	--	--	
F.D. & C. Red No. 3	0.01	g	--	--	
F.D. & C. Red No. 40	0.01	g	--	--	
Cherry (artificial) Flavor	0.5	mL	--	--	
Purified Water, USP	40.0	mL	--	--	
Purified Water, USP	q.s. to 100.0	mL	--	--	
Hydrochloric Acid 10% solution	As required		--	--	

* 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. † **Cherry Syrup preparation:**

- A. Prepare a hot water bath to between 90 to 95°C.
- B. Using the hot water bath, heat 40.0 mL of Purified Water.
- C. Using the hot water bath, in the given order, sequentially add the following ingredients to the heated Purified Water (Step 1B):

- Sodium Benzoate
- Citric Acid
- F.D. & C. Red No. 3
- F.D. & C. Red No. 40
- Alcohol (95%)
- Sucrose

Specifications: Continuously mix until all solid particles have completely dissolved.
Maintain temperature between 90 to 95°C.

End result: Homogeneous liquid-like solution.

Note: Add the next ingredient, once the previous one has been completely added and dissolved.

- D. Remove the mixture (Step 1C) from the hot water bath and allow to cool to room temperature. Add the Cherry (artificial) flavor and mix thoroughly.
- E. Adjust the pH of the solution to between 3.3 and 3.7.

If the pH > 3.7, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% solution to the mixture:

- i. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% solution to the mixture.
- ii. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% solution.
- iii. Re-test the pH.
- iv. Continue to add the Hydrochloric Acid 10% solution until the pH of 3.3 to 3.7 is obtained.

IMPORTANT: Do not allow the pH to fall below 3.3.

- F. Add additional Purified Water to the above mixture to fill to the required batch size (100.0 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.



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2. **Ingredient quantification (determine the actual quantity of Oseltamivir powder mix 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 2A):	_____ 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 2B):	_____ 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 2C):	_____ 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

3. **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 2D) and discard the remaining powder.



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4.	<p><u>Powder-liquid preparation:</u></p> <p>A. Levigate the Oseltamivir (75 mg) capsule powder (amount weighed in Step 3B) with the Cherry Syrup (30.0 mL <i>plus</i> processing error adjustments).</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>B. Add additional Cherry Syrup to the mixture (Step 4A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</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	35 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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