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| Suggested Formula | Oseltamivir 15 mg/mL Oral Liquid (Suspension, 100 mL) | FIN | F 004 075V2 |
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SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|--|---------------|-------|-------|----------|------------|-------------|
| Oseltamivir (75 mg) Capsules ** | 20 | units | | | | |
| Methylcellulose 1% Preserved Suspension † | 30.0 | mL | | | | |
| Methylcellulose 1% Preserved Suspension † | q.s. to 100.0 | mL | | | | |
| † Methylcellulose 1% Preserved Suspension | | | | | | |
| Methylcellulose (1500 CPS), USP | 1.00 | g | | | | |
| Sodium Benzoate, NF | 0.10 | g | | | | |
| Purified Water, USP | 50.0 | mL | | | | |
| Purified Water, USP | q.s. to 100.0 | mL | | | | |

** Delivered as Oseltamivir Phosphate.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): Methylcellulose (1500 CPS)

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 | | | |
| Methylcellulose 1% Preserved Suspension † § | 30.0 | mL | | | |
| Methylcellulose 1% Preserved Suspension † § | q.s. to 100.0 | mL | | | |
| | | | | | |
| † Methylcellulose 1% Preserved Suspension | | | | | |
| Methylcellulose (1500 CPS), USP § | 1.00 | g | -- | -- | |
| Sodium Benzoate, NF | 0.10 | g | -- | -- | |
| Purified Water, USP | 50.0 | mL | -- | -- | |
| Purified Water, USP | 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 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 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>Methylcellulose 1% Preserved Suspension preparation:</u></p> <p>A. Prepare a hot water bath to between 80°C and 90°C.</p> <p>B. Using the hot water bath, heat the Purified Water (50.0 mL).</p> <p><u>Specifications:</u> Maintain temperature between 80°C and 90°C.</p> <p>C. In the given order, slowly and sequentially add the following ingredients to the heated Purified Water (Step 3B):</p> <ul style="list-style-type: none">-Sodium Benzoate-Methylcellulose (1500 CPS) <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.</p> <p>D. Remove the mixture from the heat and add additional (cold) Purified Water to fill to the required batch size (100.0 mL).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>E. Allow the mixture to cool completely and mix intermittently.</p> <p><u>End result:</u> Homogeneous viscous suspension.</p> <p><u>Note:</u> Maximum transparency and hydration of the suspension will be obtained if stored at a temperature between 0 and 10 °C for at least one hour.</p> | | |
| 4. | <p><u>Powder-liquid preparation:</u></p> <p>A. Incrementally add the Oseltamivir (75 mg) capsule powder (amount weighed in Step 2B) to Methylcellulose 1% Preserved Suspension (30.0 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>Filling to volume:</u></p> <p>A. Add additional Methylcellulose 1% Preserved Suspension 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, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> | | |



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| 6. | <p>Product transfer:</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> |
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SUGGESTED PRESENTATION

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|---------------------------|---|--|---|--|
| 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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