**SUGGESTED FORMULATION**

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>NDC #</th>
<th>Supplier</th>
<th>Lot Number</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methimazole, USP</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuna Flavor</td>
<td>1.50</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerin, USP**</td>
<td>6.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chew-A-Treat™ Compound A</td>
<td>22.80</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chew-A-Treat™ Compound C</td>
<td>46.30</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Caprylic/Capric Triglyceride can be used to replace Glycerin to reduce stickiness.

**SPECIAL PREPARATORY CONSIDERATIONS**

**Ingredient-Specific Information**

*Light Sensitive* (protect from light whenever possible):
- Methimazole

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

**Suggested Preparatory Guidelines**

- **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.
SUGGESTED PREPARATION (for 60 x 1 mL Treats)

Weigh and / or measure the following ingredients when appropriate:

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>Multiplication factor (*)</th>
<th>Processing Error</th>
<th>Qty. to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methimazole, USP §</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuna Flavor</td>
<td>1.50</td>
<td>g</td>
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<tr>
<td>Glycerin, USP §</td>
<td>6.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chew-A-Treat™ Compound A</td>
<td>22.80</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chew-A-Treat™ Compound C</td>
<td>46.30</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Mold lubrication:**
   
   A. Lubricate all parts of the Chew-A-Treat™ Mold with suitable vegetable spray and set aside.

   _Note:_ Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.

2. **Powder preparation:**
   
   A. Triturate the Chew-A-Treat™ Compound C to form a fine, homogeneous powder blend.
   
   B. Triturate the Methimazole to form a fine, homogeneous powder.
   
   C. By geometric addition, combine and mix the following ingredients together to form a homogeneous mixture:

   - Fine, homogeneous powder (Step 2B)
   - Fine, homogeneous powder blend (Step 2A)

   D. Transfer the mixture (Step 2C) to a beaker and incrementally add the Glycerin.

   _Specifications:_ Continuously mix until homogeneous.

   _End result:_ Homogeneous moist blend.

   _Note:_ The mixture will have a sand-like texture. If it begins to stick to your stirring device or beaker, you can simply scrape it off and continue mixing.
3. **Medium integration:**

A. Prepare a hot water bath to between 60°C and 65°C.

B. Using the hot water bath, melt the Chew-A-Treat™ Compound A.

   **Specifications:** Continuously mix.
   Maintain temperature between 60°C and 65°C.

   **End result:** Homogeneous thick, sticky liquid-like dispersion.

C. In the given order, sequentially add the following ingredients to the melted Chew-A-Treat™ Compound A (Step 3B):

   - Tuna Flavor
   - Homogeneous moist blend (Step 2D)

   **Specifications:** Continuously mix until homogeneous.
   Maintain temperature between 60°C and 65°C.

   **End result:** Homogeneous thick, sticky paste-like dispersion.

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

4. **Mold filling:**

A. Properly lubricate gloves (thumbs, forefingers, and palms) throughout filling.

B. Continuing to heat the mixture between 60 to 65°C, remove a marble-sized quantity of the mixture at a time and roll it between your thumb and forefinger to form a cylinder. Pack the 60 mold cavities with these cylinders and scrape off any excess with pre-lubricated plastic scraper.

C. Once the treats have been packed down with an extractor, apply a thin layer of lubricant to give a shining surface.

D. Allow the treats to cool at room temperature for at least 15 minutes and then remove them from the mold using the extractor.

5. **Validation technique:**

A. Weigh 12 chewable treats.

B. The final weight of each chewable treat (not including chewable treat mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight for each unit (1.31 g), in accordance to USP guidelines.
### Suggested Formula

<table>
<thead>
<tr>
<th>Suggested Formula</th>
<th>Methimazole 5 mg Oral Chewable Treats (Solid Suspension, 60 x 1 mL Treats)</th>
<th>FIN</th>
<th>F 005 948v2</th>
</tr>
</thead>
</table>

### 6. Product transfer:

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

### SUGGESTED PRESENTATION

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days, as per USP.</td>
<td>Manually put into light-resistant Chew-A-Treat blisters and cold seal with foil labels.</td>
</tr>
</tbody>
</table>

#### Auxiliary Labels

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use as directed. Do not exceed prescribed dose.</td>
</tr>
<tr>
<td>2</td>
<td>Keep out of reach of children.</td>
</tr>
<tr>
<td>3</td>
<td>For Feline use only.</td>
</tr>
<tr>
<td>4</td>
<td>May impair mental or physical ability.</td>
</tr>
<tr>
<td>5</td>
<td>Protect from light.</td>
</tr>
</tbody>
</table>

#### Pharmacist Instructions

Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.

#### Patient Instructions

If allergic reactions occur, consult your pharmacist.
Suggested Formula | Methimazole 5 mg Oral Chewable Treats (Solid Suspension, 60 x 1 mL Treats) | FIN | F 005 948v2
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