



Suggested Formula	Methimazole 5 mg Oral Chewable Treats (Solid Suspension, 60 x 1 mL Treats)	FIN	F 005 948v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Methimazole, USP	0.300	g				
Tuna Flavor	1.50	g				
Glycerin, USP**	6.0	mL				
Chew-A-Treat™ Compound A	22.80	g				
Chew-A-Treat™ Compound C	46.30	g				

**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

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 60 x 1 mL Treats)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Methimazole, USP §	0.300	g			
Tuna Flavor	1.50	g			
Glycerin, USP §	6.0	mL			
Chew-A-Treat™ Compound A	22.80	g			
Chew-A-Treat™ Compound C	46.30	g			

* 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.



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3.	<p><u>Medium integration:</u></p> <p>A. Prepare a hot water bath to between 60°C and 65°C.</p> <p>B. Using the hot water bath, melt the Chew-A-Treat[™] Compound A.</p> <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous thick, sticky liquid-like dispersion.</p> <p>C. In the given order, sequentially add the following ingredients to the melted Chew-A-Treat[™] Compound A (Step 3B):</p> <ul style="list-style-type: none">-Tuna Flavor-Homogeneous moist blend (Step 2D) <p><u>Specifications:</u> Continuously mix until homogeneous. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous thick, sticky paste-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>
4.	<p><u>Mold filling:</u></p> <p>A. Properly lubricate gloves (thumbs, forefingers, and palms) throughout filling.</p> <p>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.</p> <p>C. Once the treats have been packed down with an extractor, apply a thin layer of lubricant to give a shining surface.</p> <p>D. Allow the treats to cool at room temperature for at least 15 minutes and then remove them from the mold using the extractor.</p>
5.	<p><u>Validation technique:</u></p> <p>A. Weigh 12 chewable treats.</p> <p>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.</p>



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6.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>
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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		Packaging Requirements		
	30 days, as per USP.		Manually put into light-resistant Chew-A-Treat blisters and cold seal with foil labels.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep in a dry place.
	2	Keep out of reach of children.	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	For Feline use only.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	May impair mental or physical ability.	9	Keep at room temperature (20°C – 23°C).
	5	Protect from light.	10	Discard container after use.
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.			



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REFERENCES

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