



Suggested Formula	Blank Oral Chewable Treats (Solid Suspension, 60 x 4.0 mL Treats)	FIN	F 005 250v3
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
APIs**	TBD					
Stevia Powder	2.40	g				
Glycerin, USP***	24.0	mL				
Beef Flavor (Powder)	12.00	g				
Chew-A-Treat™ Compound A	93.12	g				
Chew-A-Treat™ Compound B	186.24	g				

**Note: APIs can be added by using 0.7 displacement factor to accordingly reduce Compound A and B in the 1:2 ratio.

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

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): *Glycerin, Stevia Powder*

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 **3 to 5%** 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 4.0 mL Treats)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
APIs	TBD				
Stevia Powder §	2.40	g			
Glycerin, USP §	24.0	mL			
Beef Flavor (Powder)	12.00	g			
Chew-A-Treat™ Compound A	93.12	g			
Chew-A-Treat™ Compound B	186.24	g			

* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Mold lubrication:</u></p> <p>A. Lubricate all parts of the Chew-A-Treat™ Mold with suitable vegetable spray and set aside.</p> <p><u>Note:</u> Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Chew-A-Treat™ Compound B to form a fine, homogeneous powder blend.</p> <p>B. Triturate the APIs to form a fine, homogeneous powder blend.</p> <p>C. By geometric addition, combine and mix the following ingredients together to form a homogeneous mixture:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder blend (Step 2B) -Stevia Powder -Beef Flavor (Powder) -Fine, homogeneous powder blend (Step 2A) <p>D. Transfer the mixture (Step 2C) to a beaker and incrementally add the Glycerin.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous moist blend.</p> <p><u>Note:</u> 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.</p>



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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. Incrementally add the homogeneous moist blend (Step 2D) to the melted Chew-A-Treat™ Compound A (Step 3B).</p> <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>		
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 shiny 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 shall not be less than 90% and not more than 110% of the theoretically calculated weight 5.40 g in accordance to USP guidelines.</p>		
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	30 days, as per USP.	Packaging Requirements	Manually put into Chew-A-Treat blisters and cold seal with foil labels.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4	Keep in a dry place.
	2	Keep out of reach of children.	5	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 Canine use only.	6	Keep at room temperature (20°C – 23°C).
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.			

REFERENCES

1.	Lozenges/Troches. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 153.
2.	Gelatin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6th Edition</i> . American Pharmaceutical Association; 2009: 278.
3.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6th Edition</i> . American Pharmaceutical Association; 2009: 283.
4.	USP <795>. <i>United States Pharmacopeia XXXV / National Formulary 30</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 344.

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