



Suggested Formula	Tramadol Hydrochloride 10 mg Oral Chewable Treats (Solid Suspension, 30 x 1 mL Treats)	FIN	F 004 737v8
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Tramadol Hydrochloride, EP	0.300	g				
Stevia Powder	0.15	g				
Glycerin, USP**	3.0	mL				
Beef Flavor (Powder)	2.00	g				
Chew-A-Treat™ Compound A	11.49	g				
Chew-A-Treat™ Compound B	22.98	g				

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

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
Light sensitive (protect from light whenever possible):	Tramadol Hydrochloride
Hygroscopic (protect from moisture whenever possible):	Glycerin, Stevia Powder
Controlled substance (adhere to proper handling and documentation procedures)	Tramadol Hydrochloride
<u>Suggested Preparatory Guidelines</u>	
<input checked="" type="checkbox"/> Non-Sterile Preparation	<input type="checkbox"/> Sterile Preparation
<u>Processing Error / Testing Considerations:</u>	To account for processing error considerations during preparation, it is suggested to measure an additional 12 to 15% of the required quantities of ingredients.
<u>Special Instruction:</u>	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 30 x 1 mL Treats)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Tramadol Hydrochloride, EP §	0.300	g			
Stevia Powder §	0.15	g			
Glycerin, USP §	3.0	mL			
Beef Flavor (Powder)	2.00	g			
Chew-A-Treat™ Compound A	11.49	g			
Chew-A-Treat™ Compound B	22.98	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 Tramadol Hydrochloride to form a fine, homogeneous powder.</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 (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 30 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 6 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 1.36 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	120 days, based on available stability studies through Medisca*.	Packaging Requirements	Manually put into light-resistant Chew-A-Treat blisters and cold seal with foil labels.	
	<p>*Suggested BUD is based on the exact execution of the indicated ingredient list, quantities and procedures listed within this formulation.</p> <p>Note: <i>This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.</i></p>			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Controlled substance. Dangerous unless used as directed.	9	Keep at room temperature (20°C – 23°C).
	4	For Canine use only.	10	Keep in a dry place.
	5	Protect from light.	11	May produce psychological and/or physical dependence.
	6	May impair mental and/or physical ability.		
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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