



Suggested Formula	Ursodiol 150 mg Oral Chewable Treats (Solid Suspension, 60 x 4 mL Treats)	FIN	F 005 529v3
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ursodiol, USP	9.000	g				
Beef Flavor (Powder)	12.00	g				
Glycerin, USP**	24.0	mL				
Stevia Powder	0.72	g				
Chew-A-Treat™ Compound A	91.41	g				
Chew-A-Treat™ Compound B	182.82	g				

\*\*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 mL Treats)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Ursodiol, USP	9.000	g			
Beef Flavor (Powder)	12.00	g			
Glycerin, USP §	24.0	mL			
Stevia Powder §	0.72	g			
Chew-A-Treat™ Compound A	91.41	g			
Chew-A-Treat™ Compound B	182.82	g			

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

§ Weigh / measure just prior to use.

**Preparatory Instruction**

1.	<p><b><u>Mold lubrication:</u></b></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><b><u>Powder preparation:</u></b></p> <p>A. Triturate the Chew-A-Treat™ Compound B to form a fine, homogeneous powder blend.</p> <p>B. Triturate the Ursodiol 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"> <li>-Fine, homogeneous powder (Step 2B)</li> <li>-Fine, homogeneous powder blend (Step 2A)</li> <li>-Stevia Powder</li> </ul> <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><b><u>Medium integration:</u></b></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"><li>-Beef Flavor (Powder)</li><li>-Homogeneous moist blend (Step 2D)</li></ul> <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><b><u>Mold filling:</u></b></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><b><u>Validation technique:</u></b></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 5.44 g in accordance to USP guidelines.</p>



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6.	<p><b><u>Product transfer:</u></b></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.			



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## REFERENCES

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5.	Ursodiol (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #9889.
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