



Suggested Formula	Oxybutynin Chloride 5 mg Oral Gummy Gels (Solid Suspension, 60 × 0.9 mL Gummy Gels)	FIN	F 000 657v5
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Oxybutynin Chloride, USP	0.300	g				
Methylparaben, NF	0.10	g				
Raspberry Flavor (Concentrate)	0.2	mL				
Medisca Gelatin Gum Base	71.49	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): *Gelatin Gum Base*

Light Sensitive (protect from light whenever possible): *Oxybutynin Chloride*

Plastic reactive / adsorbent (do not allow to come into contact): *Methylparaben*

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and considerations during preparation, it is suggested to measure an additional **10 to 12%** 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 × 0.9 mL Gummy Gels)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Oxybutynin Chloride, USP §	0.300	g			
Methylparaben, NF §	0.10	g			
Raspberry Flavor (Concentrate)	0.2	mL			
Medisca Gelatin Gum Base §	71.49	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1. **Preparatory step:**

A. Prepare a hot water bath.

Specifications: Temperature: 60 to 65°C.

2. **Powder and liquid to medium integration:**

A. Using the hot water bath, heat the Gelatin Gum Base until molten.

Specifications: Maintain temperature between 60°C and 65°C.

IMPORTANT: Do not allow the temperature to exceed 65°C.

B. Using the hot water bath, in the given order, incrementally and sequentially add the following ingredients to the molten Gelatin Gum Base (Step 2A):

- Methylparaben
- Oxybutynin Chloride
- Raspberry Flavor (Concentrate)

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

End result: Homogeneous liquid-like dispersion.

IMPORTANT: Do not allow the temperature to exceed 65°C.

C. **Remove the mixture from the heat and allow it to cool down to 55°C.**



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3.	<p><u>Mold filling:</u></p> <p>A. Fill each of the 60 mold cavities with the homogeneous liquid-like dispersion (Step 2C). If the mixture starts to solidify while filling, reheat to 55 to 60°C, and continue.</p> <p>B. Allow to cool until the API mixture has completely solidified.</p>
4.	<p><u>Validation technique:</u></p> <p>A. Weigh 12 Gummy Gels separately.</p> <p>B. The final weight of each Gummy Gel from Step 4A (not including the weight of the Gummy Gel mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 1.20 g in accordance to USP guidelines.</p>
5.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or wide-mouth container.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Protect from light.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Keep in a dry place.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			



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REFERENCES

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4.	Oxybutynin (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 1245.
5.	Oxybutynin chloride. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 2nd Edition</i> . American Pharmaceutical Association; 2000: 284.
6.	<USP 795>. US Pharmacopeial Convention, Inc. <i>United States Pharmacopeia XXV / National Formulary 20</i> . Rockville, MD: US Pharmacopeial Convention, Inc; 2001: 2053.

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