



Suggested Formula	Riboflavin 100 mg Oral Gummy Gels (Solid Suspension, 30 x 0.9 mL Gummy Gels)	FIN	F 006 588
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Riboflavin, USP	3.000	g				
Stevia Powder	0.105	g				
Acacia (Spray Dried), NF	0.30	g				
Tutti Frutti Flavor	1.0	mL				
Glycerin, USP	1.0	mL				
Medisca Gelatin Gum Base	30.97	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): *Stevia Powder, Glycerin, Acacia, Gelatin Gum Base*

Light Sensitive (protect from light whenever possible): *Riboflavin*

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 **12 to 15%** 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 30 x 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
Riboflavin, USP §	3.000	g			
Stevia Powder §	0.105	g			
Acacia (Spray Dried), NF §	0.30	g			
Tutti Frutti Flavor	1.0	mL			
Glycerin, USP §	1.0	mL			
Medisca Gelatin Gum Base §	30.97	g			

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Preparatory step:</u></p> <p>A. Prepare a hot water bath.</p> <p><u>Specifications:</u> Temperature: 60 to 65°C.</p>
2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">-Riboflavin-Stevia Powder-Acacia (Spray Dried) <p>B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution.</p> <ul style="list-style-type: none">-Glycerin-Tutti Frutti Flavor <p>C. Levigate the fine, homogeneous powder blend (Step 2A) with the homogeneous paste-like solution (Step 2B).</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>



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3.	<p><u>Medium integration:</u></p> <p>A. Using the hot water bath, heat the Gelatin Gum Base until molten.</p> <p><u>Specifications:</u> Maintain temperature between 60°C and 65°C.</p> <p>IMPORTANT: Do not allow the temperature to exceed 65°C.</p> <p>B. Using the hot water bath, incrementally add the homogeneous paste-like dispersion (Step 2C) to the molten Gelatin Gum Base (Step 3A).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p>IMPORTANT: Do not allow the temperature to exceed 65°C.</p> <p>C. Remove the mixture from the heat and allow it to cool down to 55°C.</p>
4.	<p><u>Mold filling:</u></p> <p>A. Fill each of the 30 mold cavities with the mixture (Step 3C). If the mixture starts to solidify while filling, reheat to 55 to 60°C, and continue.</p> <p>B. Allow to cool until the mixture has completely solidified.</p>
5.	<p><u>Validation technique:</u></p> <p>A. Weigh 6 Gummy Gels separately.</p> <p>B. The final weight of each Gummy Gel from Step 5A (not including the weight of the empty gummy gel mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight for each unit, 1.22 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, refrigerated, as per USP.	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.	5	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	7	Keep in a dry place.
	4	Protect from light.		
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

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3.	Acacia. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 1.
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5.	Riboflavin. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1977.
6.	Riboflavin (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8325.
7.	Riboflavin (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 5164.
8.	USP <795>. <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.

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