



Suggested Formula	CollaSil OSA 300 mg Oral Gummy Gels (Solid Suspension, 30 x 0.9 mL Gummy Gels)	FIN	F 007 022
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
CollaSil OSA	9.000	g				
Stevia Powder	0.105	g				
Acacia (Spray Dried), NF	0.30	g				
Cherry Flavor	0.5	mL				
Vanilla Flavor	0.5	mL				
Glycerin, USP	2.0	mL				
Medisca Gelatin Gum Base	25.43	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):

CollaSil OSA, Stevia Powder, Glycerin, Acacia, Gelatin Gum Base

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
CollaSil OSA §	9.000	g			
Stevia Powder §	0.105	g			
Acacia (Spray Dried), NF §	0.30	g			
Cherry Flavor	0.5	mL			
Vanilla Flavor	0.5	mL			
Glycerin, USP §	2.0	mL			
Medisca Gelatin Gum Base §	25.43	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-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

- CollaSil OSA
- Stevia Powder
- Acacia (Spray Dried)

B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution.

- Glycerin
- Cherry Flavor
- Vanilla Flavor

C. Levigate the fine, homogeneous powder blend (Step 2A) with the homogeneous liquid-like solution (Step 2B).

End result: Homogeneous paste-like dispersion.



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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, 1.28 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.	4	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.	5	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	6	Keep in a dry place.
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 Fourth Edition</i> . American Pharmaceutical Association; 2012: 183.
2.	Acacia. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 1.
3.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 324.
4.	Colloidal Silicon Dioxide. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2146.
5.	Silicic Acid (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8629.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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