



Suggested Formula	CollaSil OSA 300 mg Oral Disintegrating Tablets (Solid Suspension, 60 x 0.375 in [1.808 mL] Tablets)	FIN	F 007 023
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
CollaSil OSA	18.000	g				
Mango Flavor (Powder)	0.90	g				
Raspberry Flavor (Powder)	0.48	g				
Vanillin Flavor (Powder)	0.24	g				
Stevia Powder	0.108	g				
F-MELT® (Type C) Base	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): CollaSil OSA, F-MELT® (Type C), Stevia Powder

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 **5 to 9%** 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 Tablets)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
CollaSil OSA §	18.000	g			
Mango Flavor (Powder)	0.90	g			
Raspberry Flavor (Powder)	0.48	g			
Vanillin Flavor (Powder)	0.24	g			
Stevia Powder §	0.108	g			
F-MELT® (Type C) Base §	TBD				

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Calculate the quantity of F-MELT® (Type C) Base required for 60 x 0.375 in [1.808 mL] Tablets:</u></p> <p>A. Calculate the amount of F-MELT® (Type C) Base required for the batch. Refer to attached appendix for details.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Pass the F-MELT® (Type C) Base through a 40 or 50 mesh sieve and weigh the required quantity.</p> <p>B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> -CollaSil OSA -Mango Flavor (Powder) -Raspberry Flavor (Powder) -Vanillin Flavor (Powder) -Stevia Powder <p>C. By geometric addition, combine and mix, using a manual tumbler mixer (DO NOT TRITURATE) the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none"> -Sieved F-MELT® (Type C) Base (amount determined in appendix, (I)) -Homogeneous powder blend (Step 2B) <p>D. Prior to filling the die, pass the homogeneous powder blend (Step 2C) through a 40 or 50 mesh sieve to improve flow properties and obtain content uniformity.</p>



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3.	<p><u>Mold filling:</u></p> <p>A. Fill the die: With the beveled edge of the die facing up, set the die on the flat surface of the reversible holder. Pour the sieved homogeneous powder blend (Step 2D) into the die cavity and tamp with a stirring rod, if necessary.</p> <p>B. Compression: Transfer the die and its holder to the press and push the lever down to compress the homogeneous powder blend. To obtain maximum compression, the lever should require a firm push as it moves through its full stroke. If a full stroke is not obtained, turn the anvil to lower or raise the die until the full mechanical advantage of the press can be utilized.</p> <p>C. Reverse the die holder: Raise the lever and slide the holder out of the press. Reverse the holder so that the deep cavity is facing up. Transfer the holder to the press.</p> <p>D. Eject the pellet: Bring the lever down gently to eject the pellet into the cavity in the holder. If a thick pellet is not ejected by this stroke, turn the anvil to raise the die. The pellet will then drop out freely. Remove the pellet with tweezers or forceps. Reverse the holder and repeat the cycle for all additional tablets.</p>
4.	<p><u>Validation technique:</u></p> <p>A. Weigh 12 tablets separately.</p> <p>B. The final weight of each tablet should fall between 90 and 110% of the theoretically calculated weight, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding the amount in appendix (G) + 0.3288 g together.</p>
5.	<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	6 months, as per USP*.	Packaging Requirements	Tightly closed vials.	
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	Keep at room temperature (20°C – 23°C).
	3	Cap tightly after use.	6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
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.			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

REFERENCES

1.	Tablets. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 175.
2.	Colloidal Silicon Dioxide. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2146.
3.	Silicic Acid (Monograph). In: O’Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8629.
4.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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Appendix	Calculating the quantity of excipient required for the batch		
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Procedure

1.	<p><u>Die (tablet mold) filling:</u></p> <p>a. For <u>each</u> ingredient powder below, determine the average die fill weight by filling and weighing a TARED die five times. Do not forget to divide the total weight by 5 to obtain an <u>average</u> die fill weight.</p> <p>Also, triturate the powder first, if required in the formulation, but do not tap the powder in the die.</p> <p>Plug each amount into Step 2, column B.</p>																		
2.	<p><u>Volume Percent Occupied:</u></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 15%; text-align: center;">Column A Quantity Required per die</th> <th style="width: 20%; text-align: center;">Column B Average die fill weight</th> <th style="width: 25%; text-align: center;">Column C A/B x 100 equals percent filled</th> </tr> </thead> <tbody> <tr> <td>a. CollaSil OSA</td> <td style="text-align: center;">0.300 g</td> <td style="text-align: center;">_____ g</td> <td style="text-align: center;">_____ %</td> </tr> <tr> <td>b. F-MELT® (Type C) Base</td> <td></td> <td style="text-align: center;">_____ g</td> <td></td> </tr> <tr> <td>c. Total (Column C)</td> <td></td> <td></td> <td style="text-align: center;">_____ % (D)</td> </tr> </tbody> </table>				Column A Quantity Required per die	Column B Average die fill weight	Column C A/B x 100 equals percent filled	a. CollaSil OSA	0.300 g	_____ g	_____ %	b. F-MELT® (Type C) Base		_____ g		c. Total (Column C)			_____ % (D)
	Column A Quantity Required per die	Column B Average die fill weight	Column C A/B x 100 equals percent filled																
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b. F-MELT® (Type C) Base		_____ g																	
c. Total (Column C)			_____ % (D)																
3.	<p><u>Calculate the quantity of F-MELT® (Type C) required for the batch:</u></p> <p>a. Percent of F-MELT® (Type C) Base required = 100% – (D) _____ % (E)</p> <p>b. Average die fill weight of F-MELT® (Type C) Base (from column B, Step 2b): _____ g (F)</p> <p>c. Quantity of F-MELT® (Type C) Base required per die = [(E) ÷ 100 × (F)] – 0.0288* _____ g (G) *Combined quantity of Flavors and Stevia Powder</p> <p>d. Total quantity of F-MELT® (Type C) Base required for the batch = 60 Die × (G) _____ g (H)</p> <p>e. Total quantity of F-MELT® (Type C) Base <i>plus</i> processing error = (H) x 1.05-1.09 _____ g (I)</p>																		

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