



Suggested Formula	Biotin 2 mg, CollaSil OSA 150 mg Oral Capsules (Powder Blend, 60 × Size #1 Capsules)	FIN	F 007 020
-------------------	--	-----	-----------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Biotin, USP	0.120	g				
CollaSil OSA	9.000	g				
Medisca CapsuBlend™-H	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): CollaSil OSA, CapsuBlend-H

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 **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.



Suggested Formula	Biotin 2 mg, CollaSil OSA 150 mg Oral Capsules (Powder Blend, 60 × Size #1 Capsules)	FIN	F 007 020
-------------------	--	-----	-----------

SUGGESTED PREPARATION (for 60 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Biotin, USP	0.120	g			
CollaSil OSA §	9.000	g			
Medisca CapsuBlend™-H §	TBD				
Sodium Chloride, USP	As required				

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

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><u>CapsuBlend™-H requirements for 60 × Size #1 Capsules</u></p> <p>A. Calculate the amount of CapsuBlend™-H required for the batch. Refer to attached appendix for details.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> -Biotin -CollaSil OSA -CapsuBlend™-H (quantity determined in appendix (I))
3.	<p><u>Product transfer:</u></p> <p>Fill each of 60 Size #1 Opaque Capsules with the homogeneous powder blend (Step 2A). Close each capsule tightly.</p> <p>Clean each capsule by placing the capsules in a container filled with Sodium Chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium Chloride to pass through. Finally, roll the capsules on a cloth-covered surface.</p>
4.	<p><u>Validation technique:</u></p> <p>The final weight of each capsule (not including capsule shell) 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) + 0.152 g together.</p>



Suggested Formula	Biotin 2 mg, CollaSil OSA 150 mg Oral Capsules (Powder Blend, 60 × Size #1 Capsules)	FIN	F 007 020
-------------------	--	-----	-----------

5.	<u>Product transfer:</u> Transfer the final product into the specified dispensing container (see “Packaging Requirements”).
----	---

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	Tightly closed capsule shells and vials.	
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 in a dry place.	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	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.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 157.
2.	Biotin. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1931.
3.	Biotin (Monograph). In: O’Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #1236.
4.	Biotin (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 2764.
5.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

DISCLAIMER: MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.



Appendix	Calculating the quantity of excipient required for the batch		
----------	--	--	--

Procedure																			
1.	<p><u>Capsule filling:</u></p> <p>a. For <u>each</u> ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an <u>average</u> capsule fill weight. Also, triturate the powder first, if required in formulation.</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: 20%; text-align: center;">Column A Quantity Required per capsule</th> <th style="width: 20%; text-align: center;">Column B Average capsule fill weight</th> <th style="width: 20%; 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;">0.150 g</td> <td style="text-align: center;">_____ g</td> <td style="text-align: center;">_____ %</td> </tr> <tr> <td>b. CapsuBlend™-H</td> <td></td> <td style="text-align: center;">_____ g</td> <td></td> </tr> <tr> <td>c. Total (add column C together)</td> <td></td> <td></td> <td style="text-align: center;">_____ % (D)</td> </tr> </tbody> </table>				Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled	a. CollaSil OSA	0.150 g	_____ g	_____ %	b. CapsuBlend™-H		_____ g		c. Total (add column C together)			_____ % (D)
	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled																
a. CollaSil OSA	0.150 g	_____ g	_____ %																
b. CapsuBlend™-H		_____ g																	
c. Total (add column C together)			_____ % (D)																
3.	<p><u>Calculate the quantity of CapsuBlend™-H required for the batch:</u></p> <p>a. Percent of CapsuBlend™-H required = 100% – (D) _____ % (E)</p> <p>b. Average capsule fill weight of CapsuBlend™-H (from column B, Step 2b): _____ g (F)</p> <p>c. Quantity of CapsuBlend™-H required per capsule = [(E) ÷ 100 × (F)] - (0.002 g)* *[Quantity of Biotin per capsule] _____ g (G)</p> <p>d. Total Quantity of CapsuBlend™-H required for the batch = 60 capsules × (G) _____ g (H)</p> <p>e. Total quantity of CapsuBlend™-H <i>plus</i> processing error = (H) × 1.05-1.09 _____ g (I)</p>																		

DISCLAIMER: MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.