



Suggested Formula	Ascorbic Acid 120 mg, Coenzyme Q ₁₀ 20 mg, CollaSil OSA 200 mg, Zinc Picolinate 47.3 mg Oral Capsules (Powder Blend, 60 × Size #0 Capsules)	FIN	F 007 021
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Notes: Zinc Picolinate 47.3 mg is equivalent to Zinc 10 mg.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ascorbic Acid, USP	7.200	g				
Coenzyme Q ₁₀ (Ubidecarenone), USP	1.200	g				
CollaSil OSA	12.000	g				
Zinc Picolinate	2.838	g				
Medisca CapsuBlend™-H	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): Ascorbic Acid, Coenzyme Q₁₀

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.



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SUGGESTED PREPARATION (for 60 Size #0 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ascorbic Acid, USP §	7.200	g			
Coenzyme Q ₁₀ (Ubidecarenone), USP §	1.200	g			
CollaSil OSA §	12.000	g			
Zinc Picolinate	2.838	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.	<u>CapsuBlend™-H requirements for 60 × Size #0 Capsules</u> A. Calculate the amount of CapsuBlend™-H required for the batch. Refer to attached appendix for details.
2.	<u>Powder preparation:</u> A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Ascorbic Acid -Coenzyme Q ₁₀ (Ubidecarenone) -Zinc Picolinate -CollaSil OSA -CapsuBlend™-H (quantity determined in appendix (I))
3.	<u>Product transfer:</u> Fill each of 60 Size #0 Opaque Capsules with the homogeneous powder blend (Step 2A). Close each capsule tightly. 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.



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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) + 0.387 g together.</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	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.



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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.	Ascorbic Acid. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1983.
3.	Ubidecarenone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2407.
4.	Ascorbic Acid (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #819.
5.	Ubiquinones (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #10025.
6.	Ascorbic Acid. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 48.
7.	Ascorbic Acid (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 2598.
8.	Ubidecarenone (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 6870.
9.	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>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="text-align: left; padding: 5px;"><u>Ingredients</u></th> <th style="text-align: center; padding: 5px;">Column A Quantity Required per capsule</th> <th style="text-align: center; padding: 5px;">Column B Average capsule fill weight</th> <th style="text-align: center; padding: 5px;">Column C A/B x 100 equals percent filled</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">a. Ascorbic Acid</td> <td style="text-align: center; padding: 5px;">0.120 g</td> <td style="text-align: center; padding: 5px;">_____ g</td> <td style="text-align: center; padding: 5px;">_____ %</td> </tr> <tr> <td style="padding: 5px;">b. CollaSil OSA</td> <td style="text-align: center; padding: 5px;">0.200 g</td> <td style="text-align: center; padding: 5px;">_____ g</td> <td style="text-align: center; padding: 5px;">_____ %</td> </tr> <tr> <td style="padding: 5px;">c. Zinc Picolinate</td> <td style="text-align: center; padding: 5px;">0.047 g</td> <td style="text-align: center; padding: 5px;">_____ g</td> <td style="text-align: center; padding: 5px;">_____ %</td> </tr> <tr> <td style="padding: 5px;">d. CapsuBlend™-H</td> <td style="padding: 5px;"></td> <td style="text-align: center; padding: 5px;">_____ g</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">c. Total (add column C together)</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="text-align: center; padding: 5px;">_____ % (D)</td> </tr> </tbody> </table>	<u>Ingredients</u>	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled	a. Ascorbic Acid	0.120 g	_____ g	_____ %	b. CollaSil OSA	0.200 g	_____ g	_____ %	c. Zinc Picolinate	0.047 g	_____ g	_____ %	d. CapsuBlend™-H		_____ g		c. Total (add column C together)			_____ % (D)
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c. Zinc Picolinate	0.047 g	_____ g	_____ %																						
d. 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 2d): _____ g (F)</p> <p>c. Quantity of CapsuBlend™-H required per capsule = [(E) ÷ 100 × (F)] - (0.02 g)* _____ g (G) *[Quantity of Coenzyme Q10 per capsule]</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>																								

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