



Suggested Formula	Carisoprodol 175 mg Oral Capsules (Powder Blend, 200 x Size #1 Capsules)	FIN	F 000 234v3
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**SUGGESTED FORMULATION**

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Carisoprodol, USP	35.000	g				
Cellulose (Microcrystalline), NF	TBD					
Sodium Chloride, USP	As required					

**SPECIAL PREPARATORY CONSIDERATIONS**

Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible):

*Cellulose (Microcrystalline)*

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 **10 to 12%** 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 200 x Size #1 Capsules)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Carisoprodol, USP	35.000	g	Ⓜ		
Cellulose (Microcrystalline), NF §	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. **Ingredient quantification (API requirements per capsule):**

Calculate the quantity (in mL) of Carisoprodol required for one, size #1 capsule:

- A. Calculate the tapped density of Carisoprodol. Refer to the attached Appendix for details.
- B. Determine the quantity (in mL) of the Carisoprodol required for each capsule:

Required quantity (in g) of Carisoprodol per capsule:	0.175 g
DIVIDED BY	
Carisoprodol tapped density (from Appendix):	_____ g / mL
EQUALS	
<b>Quantity of Carisoprodol (in mL) required for 1 capsule</b>	<b>_____ mL</b>

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2. **Ingredient quantification (excipient requirements for 200 x size #1 capsules):**

A. Calculate the Cellulose (Microcrystalline) tapped density. Refer to the attached Appendix for details.

B. Calculate the quantity (in mL) of Cellulose (Microcrystalline) required for each capsule:

Volume of Size #1 Capsule:	0.50 mL
MINUS	
Quantity (in mL) of Carisoprodol powder required for 1 capsule (Step 1B):	_____ mL
EQUALS	
<b>Quantity (in mL) of Cellulose (Microcrystalline) required for 1 capsule</b>	<b>_____ mL</b>

C. Calculate the total quantity (in g) of Cellulose (Microcrystalline) required:

Tapped Density of Cellulose (Microcrystalline) (from Appendix)	_____ g/mL
MULTIPLIED BY	
Quantity (in mL) of Cellulose (Microcrystalline) required for 1 capsule (Step 2B)	_____ mL
EQUALS	
<b>i. Quantity (in g) of Cellulose (Microcrystalline) required for 1 capsule</b>	<b>_____ g</b>
MULTIPLIED BY	
Conversion factor – 1 to 200 capsules	200
EQUALS	
<b>ii. Quantity of Cellulose (Microcrystalline) required for 200 capsules</b>	<b>_____ g</b>
MULTIPLIED BY	
Conversion factor for processing error (10 to 12%)	1.10 to 1.12
EQUALS	
<b>iii. Quantity of Cellulose (Microcrystalline) required <i>plus</i> processing error</b>	<b>_____ g</b>

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2.	<p>D. Calculate the theoretical weight of powder per capsule:</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Required quantity (in g) of Carisoprodol per capsule:</td> <td style="text-align: right;">0.175 g</td> </tr> <tr> <td>PLUS</td> <td></td> </tr> <tr> <td>Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td><b>Theoretical weight of powder (in g) per capsule</b></td> <td style="text-align: right;"><b>_____ g</b></td> </tr> </table>	Required quantity (in g) of Carisoprodol per capsule:	0.175 g	PLUS		Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)	_____ g	EQUALS		<b>Theoretical weight of powder (in g) per capsule</b>	<b>_____ g</b>
Required quantity (in g) of Carisoprodol per capsule:	0.175 g										
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EQUALS											
<b>Theoretical weight of powder (in g) per capsule</b>	<b>_____ g</b>										
3.	<p><b><u>Powder preparation:</u></b></p> <p>A. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>- Carisoprodol</li> <li>- Cellulose (Microcrystalline) - (quantity determined from Step 2Ciii)</li> </ul>										
4.	<p><b><u>Product transfer (powder-to-capsule filling):</u></b></p> <p>Fill each of 200 #1-size capsules with the API-excipient blend (Step 3A). 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>										
5.	<p><b><u>Validation technique (average capsule weight):</u></b></p> <p>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight (Step 2D), in accordance to USP 795 guidelines.</p>										
6.	<p><b><u>Product transfer (solid-to-dispensing container filling):</u></b></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	Packaging Requirements	Tight, wide-mouth jar or similar dispensing container.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep in a dry place.
	2	Keep out of reach of children.	7	<b>Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.</b>
	3	Cap tightly after use.	8	<b>Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.</b>
	4	Keep at room temperature (20°C - 23°C).	9	<b>May impair mental and/or physical ability. Use care when operating a car or machinery.</b>
	5	<b>May produce psychological and/or physical dependence.</b>		
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.			

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## REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 1998: 91.
2.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
3.	Cellulose, NF (Microcrystalline). Material Safety Data Sheet. 2004. Medisca Pharmaceutique Inc.
4.	Cellulose, NF 19 (Microcrystalline). Certificate of Analysis. 2004. Medisca Pharmaceutique Inc.
5.	Cellulose, Microcrystalline (Monograph). In: Kibbe AH. <i>Handbook of Pharmaceutical Excipients, 3<sup>rd</sup> Edition</i> . American Pharmaceutical Association; 2000:108.
6.	Carisoprodol (Monograph). In: O'Neil MJ. <i>The Merck Index 13<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 310.
7.	Cellulose (Monograph). In: O'Neil MJ. <i>The Merck Index 13<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 337.

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Appendix	Tapped Density Calculation for Capsules		
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Tapped Density Calculation											
1.	<p><b><u>Powder preparation:</u></b></p> <p>a. Measure a sufficient quantity of the specified ingredient.</p>										
2.	<p><b><u>Tapped density calculation:</u></b></p> <p>a. Weigh five empty capsules. Record the total weight here: _____ g</p> <p>b. Fill the five capsules with the Ingredient powder and weigh. Record the total weight here: _____ g</p> <p>c. Calculate the tapped density:</p> <table border="1" style="margin-left: 40px;"> <tr> <td style="padding: 5px;">Weight of the ingredient (Step b – Step a)</td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> <tr> <td style="padding: 5px;">DIVIDED BY</td> <td></td> </tr> <tr> <td style="padding: 5px;">Fill volume of five, Size #1 capsules (5 x 0.50 mL)</td> <td style="text-align: right; padding: 5px;">2.50 mL</td> </tr> <tr> <td style="padding: 5px;">EQUALS</td> <td></td> </tr> <tr> <td style="padding: 5px;"><b>Ingredient tapped density</b></td> <td style="text-align: right; padding: 5px;"><b>_____ g/mL</b></td> </tr> </table>	Weight of the ingredient (Step b – Step a)	_____ g	DIVIDED BY		Fill volume of five, Size #1 capsules (5 x 0.50 mL)	2.50 mL	EQUALS		<b>Ingredient tapped density</b>	<b>_____ g/mL</b>
Weight of the ingredient (Step b – Step a)	_____ g										
DIVIDED BY											
Fill volume of five, Size #1 capsules (5 x 0.50 mL)	2.50 mL										
EQUALS											
<b>Ingredient tapped density</b>	<b>_____ g/mL</b>										
3.	Discard the capsules and any remaining powder.										

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