



Suggested Formula	Carisoprodol 175 mg Oral Capsules (powder blend, 200 #1 capsules)	FIN	F 000 234 v3
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Carisoprodol, USP	35.000	g				
Cellulose (Microcrystalline), NF	as needed					
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 errors and 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.

All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 200 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 (§)	as needed				
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 bulk 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 bulk density (from Appendix):	_____ g / mL
EQUALS	
Quantity of Carisoprodol (in mL) required for 1 capsule	_____ mL

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

A. Calculate the Cellulose (Microcrystalline) bulk 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	
Quantity (in mL) of Cellulose (Microcrystalline) required for 1 capsule	_____ mL

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

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

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2.	D. Calculate the theoretical weight of powder per capsule: <table border="1" data-bbox="305 512 1333 764"><tr><td>Required quantity (in g) of Carisoprodol per capsule:</td><td>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>_____ g</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td>Theoretical weight of powder (in g) per capsule</td><td>_____ g</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		Theoretical weight of powder (in g) per capsule	_____ g
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											
Theoretical weight of powder (in g) per capsule	_____ g										
3.	<u>Powder preparation:</u> By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend: - Carisoprodol – (35.000 g <i>plus</i> processing error adjustments) - Cellulose (Microcrystalline) - (quantity determined from Step 2Ciii)										
4.	<u>Product transfer (powder-to-capsule filling):</u> Fill each of 200 #1-size capsules with the API-excipient blend (Step 3). 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.										
5.	<u>Validation technique (average capsule weight):</u> 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.										
6.	<u>Product transfer (solid-to-dispensing container filling):</u> Transfer the final product into the specified dispensing container (see “Packaging Requirements”).										

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months	Packaging Requirements	Wide mouth jar, or similar dispensing container.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4
	2	Keep out of reach of children.	5
	3	Close container tightly after use.	6
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.	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, 3rd Edition</i> . American Pharmaceutical Association; 2000:108.
6.	Carisoprodol (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 310.
7.	Cellulose (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 337.

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

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