MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

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

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: 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.	**Powder preparation:** By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend: - Carisoprodol – (35.000 g *plus* processing error adjustments) - Cellulose (Microcrystalline) - (quantity determined from Step 2Ciii)
4.	**Product transfer (powder-to-capsule filling):** 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.	**Validation technique (average capsule weight):** 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.	**Product transfer (solid-to-dispensing container filling):** 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. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 1998: 91.
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5. Cellulose, microcrystalline (Monograph). In: Kibbe AH. *Handbook of Pharmaceutical Excipients, 3rd Edition.* American Pharmaceutical Association; 2000:108.
6. Carisoprodol (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 310.
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Appendix	Bulk Density Calculation for Capsules		

Bulk Density Calculation	
1.	**Powder preparation:** a. Measure a sufficient quantity of the specified ingredient.
2.	**Bulk density calculation:** a. Weigh five empty capsules. Record the total weight here: _____ g b. Fill the five capsules with the Ingredient powder and weigh. Record the total weight here: _____ g c. Calculate the bulk density: 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.