



Suggested Formula	Dicyclomine Hydrochloride 10 mg Oral Capsules (Powder Blend, 100 x Size #4 Capsules)	FIN	F 004 340
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Dicyclomine Hydrochloride, USP	1.000	g				
Cellulose (Microcrystalline), NF	TBD					
Sodium Chloride, USP	q.s.					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible): Dicyclomine Hydrochloride

Moisture Sensitive (protect from humidity whenever possible): Dicyclomine Hydrochloride

Hygroscopic (protect from moisture whenever possible): Cellulose(microcrystalline)

Heat Sensitive (protect from heat whenever possible): Dicyclomine Hydrochloride

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 100 Size #4 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Dicyclomine Hydrochloride, USP §	1.000	g			
Cellulose (Microcrystalline), NF §	TBD				
Sodium Chloride, USP	q.s.				

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

§ Weigh / measure just prior to use.



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Preparatory Instruction

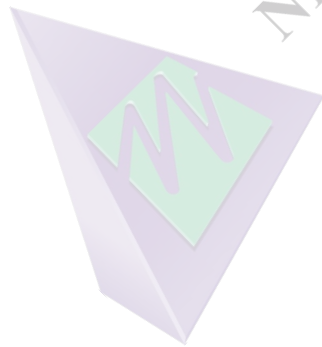
1.	<p><u>Calculate the quantity of Excipient (Cellulose (microcrystalline)) for 100 x size #4 capsules:</u></p> <p>A. Determine the average capsule fill weight by filling and weighing five TARED capsules with the Cellulose (microcrystalline). Divide the total weight by 5 to obtain <u>average</u> weight. _____ g (A)</p> <p>B. Quantity of Cellulose (microcrystalline) required per capsule = (A) – 0.010 g* _____ g (B) *quantity of Dicyclomine Hydrochloride per capsule</p> <p>C. Total quantity of Cellulose (microcrystalline) required for the batch = (B) x 100 capsules _____ g (C)</p> <p>D. Quantity of Cellulose (microcrystalline) to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g (D)</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Dicyclomine Hydrochloride to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend: -fine, homogeneous powder (Step 2A) -Cellulose (microcrystalline) (D)</p>
3.	<p><u>Product transfer:</u></p> <p>Fill each of 100 Size #4 capsules with the mixture (Step 2B). 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 (average capsule weight):</u></p> <p>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight (A), in accordance to USP 795 guidelines.</p>
5.	<p><u>Product transfer:</u></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, light-resistant pill vial.	
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	Cap tightly after use.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Protect from light.	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Keep at room temperature (20°C - 23°C).		
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			





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REFERENCES

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