



Suggested Formula	Bethanechol Chloride 25 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 003 676
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Bethanechol Chloride, USP	2.500	g				
Cellulose (microcrystalline), NF	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):

Bethanechol Chloride , 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 **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 #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Bethanechol Chloride, USP §	2.500	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.



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Preparatory Instruction

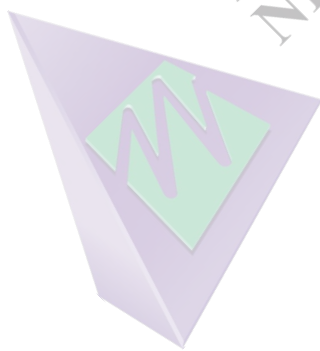
1.	<p><u>Calculate the quantity of Cellulose (microcrystalline) for 100 x size #1 capsules:</u></p> <p>i. Determine the average capsule fill weight by filling and weighing five TARED capsules with the cellulose (microcrystalline). Divide the total weight by 5 to obtain <u>average</u> weight. _____ g (A)</p> <p>ii. Quantity of cellulose (microcrystalline) required per capsule = (A) – 0.025 g* _____ g (B) * Quantity of Bethanechol Chloride per capsule</p> <p>iii. Total quantity of cellulose (microcrystalline) required for the batch = (B) x 100 capsules _____ g (C)</p> <p>iv. 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 Bethanechol Chloride to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together: -Bethanechol Chloride (2.500 g <i>plus</i> processing error adjustments) -Cellulose (microcrystalline) (D)</p> <p><u>End result:</u> Homogeneous powder blend.</p>
3.	<p><u>Product transfer:</u></p> <p>Fill each of 100 Size #1 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 vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Keep at room temperature (20°C - 23°C).	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	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.
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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