



Suggested Formula	Misoprostol 100 mcg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 004 851v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Misoprostol 1% Stock Powder Blend	1.000	g				
Medisca CapsuBlend™-S	TBD					
Sodium Chloride, USP	As needed					
† Misoprostol 1% Stock Powder Blend						
Misoprostol, USP	0.100	g				
Cellulose (Microcrystalline), NF	9.90	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): CapsuBlend™-S, Cellulose (Microcrystalline), Misoprostol

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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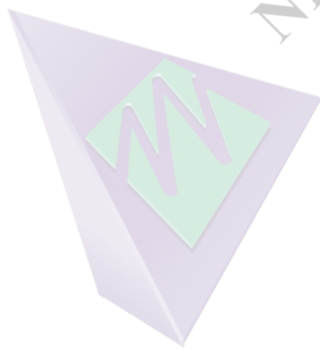
SUGGESTED PREPARATION (for 100 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : ____	Processing Error	Qty. to measure
Misoprostol 1% Stock Powder Blend §	1.000	g			
Medisca CapsuBlend™-S §	TBD				
Sodium Chloride, USP	As needed				
† Misoprostol 1% Stock Powder Blend					
Misoprostol, USP §	0.100	g	---	---	
Cellulose (Microcrystalline), NF §	9.90	g	---	---	

* 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>Misoprostol 1% Stock Powder Blend Preparation:</u></p> <p>A. Triturate the Misoprostol (0.100) 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:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder (Step 1A) -Cellulose (Microcrystalline) (9.90 g)
2.	<p><u>Calculate the quantity of CapsuBlend™-S for 100 x size #1 capsules:</u></p> <p>A. Determine the average capsule fill weight by filling and weighing five TARED capsules with the CapsuBlend™-S. Divide the total weight by 5 to obtain <u>average</u> weight. _____ g (A)</p> <p>B. Quantity of CapsuBlend™-S required per capsule = (A) – 0.01 * _____ g (B) * Quantity of Misoprostol 1% Powder Blend per capsule</p> <p>C. Total quantity of CapsuBlend™-S required for the batch = (B) x 100 capsules _____ g (C)</p> <p>D. Quantity of CapsuBlend™-S to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g (D)</p>
3.	<p><u>Powder preparation:</u></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"> -Misoprostol 1% Powder Blend (1.000 g <i>plus</i> processing error adjustments) -CapsuBlend™-S (amount determined above, 2D)
4.	<p><u>Product transfer:</u></p> <p>Fill each of 100 Size #1 capsules with the mixture (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><u>Validation technique:</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>
6.	<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, as per USP.	Packaging Requirements	Tightly closed vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Keep in a dry place.
	2	Keep out of reach of children.	8	Cap tightly after use.
	3	Misoprostol is classified as "Pregnancy Category X". It should not be used or handled by anyone who is pregnant or may be pregnant.	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Keep at room temperature (20°C – 23°C).	10	Caution should be employed with pre-existing cardiovascular disease.
	5	Caution should be exercised with nursing mother.	11	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	6	May impair mental and/or physical ability. Use care when operating a car or machinery.		
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.			

REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 127.
2.	Misoprostol. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2013.
3.	Misoprostol (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #6210.
4.	Misoprostol (Monograph). <i>United States Pharmacopeia XXXIV / National Formulary 29</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2011: 3542.
5.	USP <795>. <i>United States Pharmacopeia XXXIV / National Formulary 29</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2011: 330.

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