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Suggested Formula	Diclofenac Sodium 50 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 004 676v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Diclofenac Sodium, USP	5.000	g				
Medisca CapsuBlend™-H	TBD					
Sodium Chloride, USP	As needed					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Diclofenac Sodium*

Hygroscopic *(protect from moisture whenever possible):* *Diclofenac Sodium, CapsuBlend™-H*

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
Diclofenac Sodium, USP §	5.000	g			
Medisca CapsuBlend™-H §	TBD				
Sodium Chloride, USP	As needed				

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

	Preparatory Instruction
1.	**CapsuBlend™-H requirements for 100 x size #1 capsules** A. Calculate the amount of CapsuBlend™-H required for the batch. Refer to attached appendix for details.
2.	**Powder preparation:** A. Triturate the Diclofenac Sodium to form a fine, homogeneous powder. B. By geometric addition, combine and mix the following ingredients together: -Fine, homogeneous powder (Step 2A) -CapsuBlend™-H (Quantity determined in appendix **(I)**)
3.	**Product transfer:** Fill each of 100 Size #1 capsules with the mixture (Step 2B). 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.
4.	**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, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding the amount in appendix **(G)** + 0.050 g together.
5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP		Packaging Requirements	Tightly closed, light-resistant capsule shells and vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Protect from light.	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	Keep at room temperature (20°C – 23°C).	8	Keep in a dry place.
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

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5. Diclofenac Sodium. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 44.
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Appendix	Calculating the quantity of excipient required for the batch		

Procedure

1. **Capsule filling:**

   a. For each ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an average capsule fill weight. Also, triturate the ingredient powder first if required in formulation

   Plug each amount into Step 2, column B.

2. **Volume Percent Occupied:**

Ingredients	**Column A** Quantity Required per capsule	**Column B** Average capsule fill weight	**Column C** A/B x 100 equals percent filled
a. Diclofenac Sodium	0.050 **g**	_____ **g**	_____ %
b. CapsuBlend™-H		_____ **g**	
c. Total (add column C together)			_____ % **(D)**

3. **Calculate the quantity of CapsuBlend™-H required for the batch:**

   a. Percent of CapsuBlend™-H required = 100% – (D) _____ % **(E)**

   b. Average capsule fill weight of CapsuBlend™-H (from column B, Step 2b): _____ g **(F)**

   c. Quantity of CapsuBlend™-H required per capsule = [(E) ÷ 100 × (F)] _____ g **(G)**

   d. Total quantity of CapsuBlend™-H required for the batch = 100 capsules × (G) _____ g **(H)**

   e. Total quantity of CapsuBlend™-H *plus* processing error = (H) x 1.05-1.09 _____ g **(I)**