



Suggested Formula	Hydrocortisone 5mg, 10 mg, 20 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 002 000
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydrocortisone (micronized), USP	TBD					
Lactose (Monohydrate), NF	TBD					
Sodium Chloride, USP	As required					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

*Hydrocortisone*

#### 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.  
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
Hydrocortisone (micronized), USP §	TBD				
Lactose (Monohydrate), 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.

**Preparatory Instruction**

**1. Ingredient quantification:**

Based on the desired strength of the capsules, determine the required quantity of Hydrocortisone to weigh for a 100 capsule batch size:

Required strength of Hydrocortisone per capsule	Hydrocortisone to weigh		Processing Error		Hydrocortisone to weigh (plus processing error adjustments)
5 mg	0.500 g	Multiply	1.05-1.09	Equals	_____ g
10 mg	1.000 g				_____ g
20 mg	2.000 g				_____ g



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2.	<p><b><u>Ingredient quantification (excipient requirements per capsule):</u></b></p> <p>A. Calculate the tapped density of Lactose (Monohydrate). Refer to the attached Appendix for details.</p> <p>B. Calculate the total quantity (g) of Lactose (Monohydrate) required:</p> <table border="1" style="margin-left: 40px;"><tr><td>Tapped Density of Lactose (from Appendix)</td><td>_____ g/mL</td></tr><tr><td>MULTIPLIED BY</td><td></td></tr><tr><td>Quantity (in mL) of Lactose to fill 1 x Size #1 capsule</td><td>0.50 mL</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td><b>i. Theoretical weight (in g) of powder per capsule</b></td><td>_____ g</td></tr><tr><td>MULTIPLIED BY</td><td></td></tr><tr><td>Total number of capsules required</td><td>100</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td>Quantity (in g) of Lactose (Monohydrate) to fill 100 x Size #1 capsules</td><td>_____ g</td></tr><tr><td>MINUS</td><td></td></tr><tr><td>Quantity of Hydrocortisone (micronized) powder required for 100 capsules (0.500 g, 1.000 g or 2.000 g)</td><td>_____ g</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td><b>ii. Quantity (in g) of Lactose (Monohydrate) required for 100 capsules</b></td><td>_____ g</td></tr><tr><td>MULTIPLIED BY</td><td></td></tr><tr><td>Conversion factor for processing error (5 to 9%)</td><td>1.05-1.09%</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td><b>iii. Quantity of Lactose (Monohydrate) required <i>plus</i> processing error</b></td><td>_____ g</td></tr></table>	Tapped Density of Lactose (from Appendix)	_____ g/mL	MULTIPLIED BY		Quantity (in mL) of Lactose to fill 1 x Size #1 capsule	0.50 mL	EQUALS		<b>i. Theoretical weight (in g) of powder per capsule</b>	_____ g	MULTIPLIED BY		Total number of capsules required	100	EQUALS		Quantity (in g) of Lactose (Monohydrate) to fill 100 x Size #1 capsules	_____ g	MINUS		Quantity of Hydrocortisone (micronized) powder required for 100 capsules (0.500 g, 1.000 g or 2.000 g)	_____ g	EQUALS		<b>ii. Quantity (in g) of Lactose (Monohydrate) required for 100 capsules</b>	_____ g	MULTIPLIED BY		Conversion factor for processing error (5 to 9%)	1.05-1.09%	EQUALS		<b>iii. Quantity of Lactose (Monohydrate) required <i>plus</i> processing error</b>	_____ g
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3.	<p><b><u>Powder preparation:</u></b></p> <p>A. By geometric addition, combine the following ingredients to together:</p> <ul style="list-style-type: none"><li>- Hydrocortisone (Micronized) (amount determined in Step 1)</li><li>- Lactose (Monohydrate) (Amount determined in Step 2Biii)</li></ul> <p><u>End result:</u> Homogeneous powder blend.</p>																																		
4.	<p><b><u>Product transfer (powder-to-capsule filling):</u></b></p> <p>Fill each of 100 Size #1 capsules with the Homogeneous powder blend (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>																																		



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5.	<b><u>Validation technique (average capsule weight):</u></b> The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight (Step 2Bi) in accordance with USP guidelines.
6.	<b><u>Product transfer (solid-to-dispensing container filling):</u></b> Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	6 months	Packaging Requirements	Tight, light-resistant pill bottles.
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	Protect from light.	8 <b>Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.</b>
	4	Do not take with Alcohol.	9 <b>May impair mental and/or physical ability. Use care when operating a car or machinery.</b>
	5	Keep at room temperature (20°C - 23°C).	10 This medication should be taken with food.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.		
Patient Instructions	Contact your pharmacist in the event of adverse reactions.		



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## REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 1998: 91.
2.	Cortef Tablets. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2005</i> . 524.
3.	Lactose. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2003: 323.
4.	Hydrocortisone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 34<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2005: 1103.
5.	Hydrocortisone (Monograph). In: O'Neil MJ. <i>The Merck Index 13<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 855.
6.	Hydrocortisone (Monograph). <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 958.
7.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.

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Appendix	Tapped Density Calculation for Capsules		
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Tapped Density Calculation											
1.	<p><b><u>Powder preparation:</u></b></p> <p>a. Measure a sufficient quantity of the specified ingredient.</p>										
2.	<p><b><u>Tapped density calculation:</u></b></p> <p>a. Weigh five empty capsules. Record the total weight here: _____ g</p> <p>b. Fill the five capsules with the Ingredient powder and weigh. Record the total weight here: _____ g</p> <p>c. Calculate the tapped density:</p> <table border="1" style="margin-left: 40px;"><tr><td>Weight of the ingredient (Step b – Step a)</td><td>_____ g</td></tr><tr><td>DIVIDED BY</td><td></td></tr><tr><td>Fill volume of five, Size #1 capsules (5 x 0.50 mL)</td><td>2.5 mL</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td><b>Ingredient tapped density</b></td><td>_____ g/mL</td></tr></table>	Weight of the ingredient (Step b – Step a)	_____ g	DIVIDED BY		Fill volume of five, Size #1 capsules (5 x 0.50 mL)	2.5 mL	EQUALS		<b>Ingredient tapped density</b>	_____ g/mL
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EQUALS											
<b>Ingredient tapped density</b>	_____ g/mL										
3.	Discard the capsules and any remaining powder.										