



Suggested Formula	Chloroquine Phosphate 250 mg Oral Capsules (Powder blend, 100 x Size #1 Capsules)	FIN	F 000 437v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Chloroquine phosphate	25.000	g				
Lactose (Monohydrate), NF	to be calculated					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): Chloroquine phosphate

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and considerations during preparation, it is suggested to measure an additional **3 to 5%** 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
Chloroquine phosphate (§)	25.000	g			
Lactose (Monohydrate), NF	to be calculated				
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 (API requirements per capsule):

Calculate the quantity (in mL) of Chloroquine phosphate required for one, size #1 capsule:

- A. Calculate the Chloroquine phosphate bulk density. Refer to the attached Appendix for details:
- B. Determine the quantity (in mL) of the Chloroquine phosphate required for each capsule:

Required quantity (in g) of Chloroquine phosphate per capsule:	0.250 g
DIVIDED BY	
Chloroquine phosphate bulk density (from Appendix):	_____ g / mL
EQUALS	
Quantity of Chloroquine phosphate (in mL) required for 1 capsule	_____ mL

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2. **Ingredient quantification (excipient requirements for 100 x size #1 capsules):**

A. Calculate the bulk density of Lactose (Monohydrate). Refer to the attached Appendix for details.

B. Calculate the quantity (in mL) of Lactose (Monohydrate) required for each capsule:

Volume of Size #1 Capsule:	0.50 mL
MINUS	
Quantity (in mL) of Chloroquine phosphate required for 1 capsule (Step 1B):	_____ mL
EQUALS	
Quantity (in mL) of Lactose (Monohydrate) required for 1 capsule	_____ mL

C. Calculate the total quantity (g) of Lactose (Monohydrate) required:

Bulk Density of Lactose (Monohydrate) (from Appendix)	_____ g/mL
MULTIPLIED BY	
Quantity (in mL) of Lactose (Monohydrate) required for 1 capsule (Step B)	_____ mL
EQUALS	
i. Quantity (in g) of Lactose (Monohydrate) required for 1 capsule	_____ g
MULTIPLIED BY	
Conversion factor – 1 to 100 capsules	100
EQUALS	
ii. Quantity of Lactose (Monohydrate) required for 100 capsules	_____ g
MULTIPLIED BY	
Conversion factor for processing error (3 to 5%)	1.03 to 1.05
EQUALS	
iii. Quantity of Lactose (Monohydrate) required plus processing error	_____ g

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2.	<p>D. Calculate the theoretical weight of powder per capsule:</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Required quantity (in g) of Chloroquine phosphate per capsule:</td> <td style="text-align: right;">0.250 g</td> </tr> <tr> <td>PLUS</td> <td></td> </tr> <tr> <td>Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>Theoretical weight of powder (in g) per capsule</td> <td style="text-align: right;">_____ g</td> </tr> </table>	Required quantity (in g) of Chloroquine phosphate per capsule:	0.250 g	PLUS		Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)	_____ g	EQUALS		Theoretical weight of powder (in g) per capsule	_____ g
Required quantity (in g) of Chloroquine phosphate per capsule:	0.250 g										
PLUS											
Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)	_____ g										
EQUALS											
Theoretical weight of powder (in g) per capsule	_____ g										
3.	<p><u>Powder preparation (geometric addition of powder blends):</u></p> <p>A. By geometric addition, combine and mix the following ingredients together:</p> <ul style="list-style-type: none"> - Lactose (Monohydrate) - (quantity determined from Step 2Cii) - Chloroquine phosphate - (25.000 g plus processing error adjustments) <p><u>End result:</u> Homogeneous powder blend.</p>										
4.	<p><u>Product transfer (powder-to-capsule filling):</u></p> <p>Fill each of 100 #1-size 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>										
5.	<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 (Step 2D), in accordance to USP 795 guidelines.</p>										
6.	<p><u>Product transfer (solid-to-dispensing container filling):</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	Light-resistant pill bottle, or wide mouth jar.	
Auxiliary Labels	1	Use as directed.	4	Keep in a dry place.
	2	Keep out of reach of children.	5	Cap tightly after use.
	3	Protect from light.	6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 1998: 91.
2.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
3.	Chloroquine phosphate. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 2nd Edition</i> . American Pharmaceutical Association; 2000: 79.
4.	Chloroquine (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 373.

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Appendix	Bulk Density Calculation for Capsules	
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Bulk Density Calculation											
1.	<p><u>Powder preparation:</u></p> <p>a. Measure a sufficient quantity of the specified ingredient.</p>										
2.	<p><u>Bulk density calculation:</u></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 bulk 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>2.50 mL</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>Ingredient bulk density</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)	2.50 mL	EQUALS		Ingredient bulk density	_____ g/mL
Weight of the ingredient (Step b – Step a)	_____ g										
DIVIDED BY											
Fill volume of five, Size #1 capsules (5 x 0.50 mL)	2.50 mL										
EQUALS											
Ingredient bulk density	_____ g/mL										
3.	Discard the capsules and any remaining powder.										

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