



Suggested Formula	Chloroquine Phosphate 161 mg Oral Capsules (Powder blend, 10 x Size #3 Capsules)	FIN	F 002 310v2
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Note: Chloroquine Phosphate 161 mg is equivalent to Chloroquine 100 mg.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Chloroquine Phosphate (Diphosphate), USP	1.610	g				
Lactose (Monohydrate), NF	TBD					
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 **20 to 25%** 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.

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 10 Size #3 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : ____	Processing Error	Qty. to measure
Chloroquine Phosphate (Diphosphate), USP §	1.610	g			
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.	<p><u>Lactose (Monohydrate) requirements for 10 x size #3 capsules</u></p> <p>A. Calculate the amount of Lactose (Monohydrate) required for the batch. Refer to attached appendix for details.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Chloroquine Phosphate to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder (Step 2A) -Lactose (Monohydrate) (Quantity determined in appendix (I))
3.	<p><u>Product transfer:</u></p> <p>Fill each of 10 Size #3 capsules with the powder blend (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, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding the amount in appendix (G) + 0.161 g together.</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, as per USP.	Packaging Requirements	Tightly closed, light-resistant vials.	
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	Keep at room temperature (20°C – 23°C).
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.		
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.	Lactose. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 323.
3.	Chloroquine (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 373.
4.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
5.	Chloroquine Phosphate (Monograph). <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 444.
6.	Chloroquine Phosphate. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 2nd Edition</i> . American Pharmaceutical Association; 2000: 79.

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Appendix	Calculating the quantity of excipient required for the batch		
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Procedure																			
1.	<u>Capsule filling:</u> a. For <u>each</u> 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 <u>average</u> capsule fill weight. Also, triturate the ingredient powder first if required in formulation Plug each amount into Step 2, column B.																		
2.	<u>Volume Percent Occupied:</u> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 20%; text-align: center;">Column A Quantity Required per capsule</th> <th style="width: 20%; text-align: center;">Column B Average capsule fill weight</th> <th style="width: 20%; text-align: center;">Column C A/B x 100 equals percent filled</th> </tr> </thead> <tbody> <tr> <td style="padding-left: 20px;">a. Chloroquine Phosphate</td> <td style="text-align: center;">0.161 g</td> <td style="text-align: center;">_____ g</td> <td style="text-align: center;">_____ %</td> </tr> <tr> <td style="padding-left: 20px;">b. Lactose (Monohydrate)</td> <td></td> <td style="text-align: center;">_____ g</td> <td></td> </tr> <tr> <td style="padding-left: 20px;">c. Total (add column C together)</td> <td></td> <td></td> <td style="text-align: center;">_____ % (D)</td> </tr> </tbody> </table>				Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled	a. Chloroquine Phosphate	0.161 g	_____ g	_____ %	b. Lactose (Monohydrate)		_____ g		c. Total (add column C together)			_____ % (D)
	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled																
a. Chloroquine Phosphate	0.161 g	_____ g	_____ %																
b. Lactose (Monohydrate)		_____ g																	
c. Total (add column C together)			_____ % (D)																
3.	<u>Calculate the quantity of Lactose (Monohydrate) required for the batch:</u> a. Percent of Lactose (Monohydrate) required = 100% – (D) _____ % (E) b. Average capsule fill weight of Lactose (Monohydrate) (from column B, Step 2b): _____ g (F) c. Quantity of Lactose (Monohydrate) required per capsule = [(E) ÷ 100 × (F)] _____ g (G) d. Total quantity of Lactose (Monohydrate) required for the batch = 10 capsules × (G) _____ g (H) e. Total quantity of Lactose (Monohydrate) <i>plus</i> processing error = (H) x 1.20-1.25 _____ g (I)																		

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