



Suggested Formula	Hydroxychloroquine Sulfate 25 mg/mL Oral Liquid (Suspension, 160 mL)	FIN	F 006 871v2
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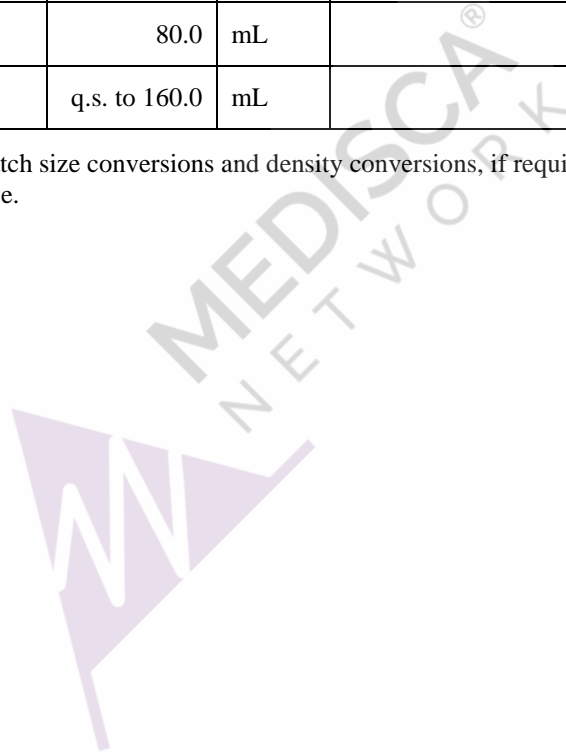
SUGGESTED PREPARATION (for 160 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Hydroxychloroquine Sulfate (200 mg) Tablets §	20	Units			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	8.0	mL			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	80.0	mL			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	q.s. to 160.0	mL			

* 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. **Ingredient quantification (determine the actual quantity of Hydroxychloroquine Sulfate (200 mg) tablet powder mix to weigh):**

A. Weigh the 21 Hydroxychloroquine Sulfate (200 mg) Tablets. Record the total weight here: _____ g

B. Calculate the average weight of powder in each tablet:

Weight of 21 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets:	21
EQUALS	
Average weight of a single Hydroxychloroquine Sulfate (200 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 20 tablets:

Average weight of a single Hydroxychloroquine Sulfate (200 mg) Tablet (from Step 1B):	_____ g
MULTIPLIED BY	
Number of tablets required:	20
EQUALS	
Weight of powder equivalent to 20 tablets:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 20 tablets (from Step 1C):	_____ g
MULTIPLIED BY	
Processing error adjustments (3 to 5%):	1.03 to 1.05
EQUALS	
Weight of powder required <i>plus</i> processing error adjustments:	_____ g



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2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Crush and triturate the 21 Hydroxychloroquine Sulfate (200 mg) Tablets into a fine homogeneous powder.</p> <p>B. Weigh the quantity of Hydroxychloroquine Sulfate (200 mg) tablet powder mix required for the batch (refer to Step 1D) and discard the remaining powder.</p> <p>C. Levigate the Hydroxychloroquine Sulfate (200 mg) tablet powder mix (weighed in Step 2B) with the Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) (8.0 mL <i>plus</i> processing error adjustments).</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><u>Medium incorporation:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 2C) to the Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) (80.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
4.	<p><u>Filling to volume:</u></p> <p>A. Add additional Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) to the mixture (Step 3A) to fill to the required batch size (160.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
5.	<p><u>Product transfer:</u></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process in order to maintain homogeneity.</p>



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	90 days at 4°C or 21°C, based on available stability studies through Medisca*.	Packaging Requirements	Amber PET bottles or PreciseDose Dispenser™ Amber Syringe.	
	<p>*Suggested BUD is based on the exact execution of the indicated ingredient list, quantities and procedures listed within this formulation.</p> <p>Note: <i>This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.</i></p>			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Shake well before use.
	2	Keep out of reach of children.	6	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Keep refrigerated (Do not freeze) OR keep at room temperature (21°C).	7	Cap tightly after use.
	4	Protect from light.	8	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.			



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REFERENCES

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4.	Hydroxychloroquine (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4857.
5.	Hydroxychloroquine Sulfate. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 246.
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