MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Hydroxychloroquine Sulfate 25 mg/mL Oral Liquid (Suspension, 160 mL)	FIN	F 006 870v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydroxychloroquine Sulfate (200 mg) Tablets	20	Units				
Medisca Oral Mix (Flavored Suspending Vehicle)	8.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	80.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 160.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Hydroxychloroquine Sulfate*

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 **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.

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 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 (Flavored Suspending Vehicle)	8.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	80.0	mL			
Medisca Oral Mix (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 *plus* processing error adjustments:	_____ **g**

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

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SUGGESTED PRESENTATION

<table>
<tr><td rowspan="2">Estimated Beyond-Use Date</td><td colspan="3">90 days at 4°C or 21°C, based on available stability studies through Medisca*.</td><td>Packaging Requirements</td><td>Amber PET bottles or PreciseDose Dispenser™ Amber Syringe.</td></tr>
<tr><td colspan="5">*Suggested BUD is based on the <u>exact</u> execution of the indicated ingredient list, quantities and procedures listed within this formulation.

<u>Note</u>: 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.</td></tr>
<tr><td rowspan="4">Auxiliary Labels</td><td>1</td><td>Use as directed. Do not exceed prescribed dose.</td><td>5</td><td colspan="2">Shake well before use.</td></tr>
<tr><td>2</td><td>Keep out of reach of children.</td><td>6</td><td colspan="2">Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.</td></tr>
<tr><td>3</td><td>Keep refrigerated (Do not freeze) OR keep at room temperature (21°C).</td><td>7</td><td colspan="2">Cap tightly after use.</td></tr>
<tr><td>4</td><td>Protect from light.</td><td>8</td><td colspan="2">May impair mental and/or physical ability. Use care when operating a car or machinery.</td></tr>
<tr><td>Pharmacist Instructions</td><td colspan="5">Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.</td></tr>
<tr><td>Patient Instructions</td><td colspan="5">Contact your pharmacist in the event of adverse reactions.</td></tr>
</table>

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1. Suspensions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 239.
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8. USP <795>. *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.