**Toll Free** 1-866-333-7811
**Phone** 514-905-5096
**Fax** 514-905-5097
**Email** compoundingservices@medisca.com
mau-compoundingservices@medisca.com



| **Suggested Formula** | Hydroxychloroquine Sulfate 25 mg/mL Oral Liquid (Suspension, 160 mL) | **FIN** | F 006 871v3 |
|---|---|---|---|

## Suggested Formulation

| Ingredient Listing | Qty | Unit | Product Code | Supplier | LOT No. | Expiry Date |
|---|---|---|---|---|---|---|
| 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 | | | | |

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## 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:** This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800,* when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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

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

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

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## Suggested Presentation

<table>
<tr><td rowspan="2">Estimated Beyond-Use Date</td><td colspan="2">90 days at 4°C or 21°C, based on available stability studies through Medisca*.</td><td>Packaging Requirements</td><td colspan="2">Tightly closed, light-resistant, plastic container.</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.<br><br><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 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 (4°C) (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>

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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## References


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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. |
| **2.** | Plaquenil. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2015*: 2278. |
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