MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Hydroxychloroquine Sulfate 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 008 654

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydroxychloroquine Sulfate, USP	2.000	g				
Stevia Powder	0.20	g				
Glycerin, USP	5.0	mL				
Tutti Frutti Flavor	0.5	mL				
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL				
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Hygroscopic *(protect from moisture whenever possible):* *Stevia Powder, Glycerin*

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 **5 to 9%** 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/usp-800-context-for-implementation-fs.pdf.

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 (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Hydroxychloroquine Sulfate, USP§	2.000	g			
Stevia Powder §	0.20	g			
Glycerin, USP §	5.0	mL			
Tutti Frutti Flavor	0.5	mL			
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL			
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction	
1.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a homogeneous powder blend: -Hydroxychloroquine Sulfate -Stevia Powder B. Levigate the homogeneous powder blend (Step 3A) with the Glycerin. End result: Homogeneous liquid-like dispersion.
2.	**Medium Integration:** A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle): -Tutti Frutti Flavor -Homogeneous powder blend (Step 1B) Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. Note: Add the next ingredient, once the previous one has been completely added and dispersed.

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3.	**Filling to volume:** A. Add Oral Syrup (Flavored Syrup Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.
4.	**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 into the recommended dispensing containers in order to maintain homogeneity.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.		Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	**Shake well before use.**	5	Use as directed. Do not exceed prescribed dose.
	2	Keep refrigerated (2°C – 8°C). Do not freeze.	6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Keep out of reach of children.	7	Cap tightly after use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Protect from light.
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

1. Suspensions. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 317.
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7. USP <795>. *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6951.