MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
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Suggested Formula	Hydroxychloroquine Sulfate 100 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 003 495v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydroxychloroquine Sulfate (200 mg) Tablets	10	Units				
Stevia Powder	0.20	g				
Glycerin, USP	5.0	mL				
Tutti Frutti Flavor	0.1	mL				
Chocolate Flavor	0.2	mL				
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				

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: 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 100 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 §	10	Units			
Stevia Powder §	0.20	g			
Glycerin, USP §	5.0	mL			
Tutti Frutti Flavor	0.1	mL			
Chocolate Flavor	0.2	mL			
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL			
Medisca Oral Syrup (Flavored 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.

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

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

Weight of 11 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets:	11
EQUALS	
Average weight of a single Hydroxychloroquine Sulfate (200 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 10 tablets:

Average weight of a single Hydroxychloroquine Sulfate (200 mg) Tablet (from Step 1B):	_____ g
MULTIPLED BY	
Number of tablets required:	10
EQUALS	
Weight of powder equivalent to 10 tablets:	_____ g

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

Weight of powder equivalent to 10 tablets (from Step 1C):	_____ g
MULTIPLED BY	
Processing error adjustments (5% to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required *plus* processing error adjustments:	_____ **g**

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2. **Powder preparation:**

A. Crush and triturate the 11 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.

3. **Powder-liquid preparation:**

A. Combine and mix the following ingredients together to form a homogeneous powder blend:

-Hydroxychloroquine Sulfate (200 mg) tablet powder mix (amount weighed in Step 2B)
-Stevia Powder

B. Levigate the homogeneous powder blend (Step 3A) with the Glycerin.

End result: Homogeneous liquid-like dispersion.

4. **Medium Integration:**

A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle):

-Tutti Frutti Flavor
-Chocolate Flavor

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.

B. Incrementally add the homogeneous liquid-like dispersion (Step 3B) to the homogeneous liquid-like dispersion (Step 4A).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous liquid-like dispersion.

5. **Filling to volume:**

A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 4B) 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.

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6.	**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	Use as directed. Do not exceed prescribed dose.	6	Keep refrigerated. Do not freeze.	
	2	**Shake well before use.**	7	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.	8	Cap tightly after use.	
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	9	Protect from light.	
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.			
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.	Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition.* American Pharmaceutical Association; 2003: 257.
2.	Hydroxychloroquine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4818.
3.	Hydroxychloroquine Sulfate (Monograph). *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
4.	USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
5.	Hydroxychloroquine. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1677.