MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v2

Note: Chloroquine Phosphate 80.5 mg/5 mL is equivalent to Chloroquine 50 mg/5 mL

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Chloroquine Phosphate, USP	0.161	g				
Tutti Frutti Flavor	0.1	mL				
Medisca Oral Suspend (Suspending Vehicle)	4.9	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 10.0	mL				
Citric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Chloroquine Phosphate*

Light Sensitive *(protect from light whenever possible):* *Chloroquine Phosphate*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and pH testing considerations during preparation, it is suggested to measure an additional **20 to 25%** 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 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Chloroquine Phosphate, USP §	0.161	g			
Tutti Frutti Flavor	0.1	mL			
Medisca Oral Suspend (Suspending Vehicle)	4.9	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 10.0	mL			
Citric Acid 10% Solution	As required				

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

Preparatory Instruction	
1.	**Powder preparation:** A. Triturate the Chloroquine Phosphate to form a fine, homogeneous powder.
2.	**Medium integration:** A. In the given order, sequentially add the following ingredients to the Oral Suspend (Suspending Vehicle): -Fine, homogeneous powder (Step 1A) -Tutti Frutti Flavor Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.

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4. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 3A).

B. Test the pH of the sample. It should lie between 3.4 and 3.5.

C. If the pH > 3.5, carefully add the Citric Acid 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Citric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid.
3. Re-test the pH.
4. Continue to add the Citric Acid 10% Solution until a pH of 3.4 to 3.5 is obtained.

IMPORTANT: Do not allow the pH to fall below 3.4

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 into the recommended dispensing containers in order to maintain homogeneity.

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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	Cap tightly after use.	
	2	Keep out of reach of children.	7	**Shake well before use.**	
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	Keep refrigerated. Do not freeze.	
	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 to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

1.	Solutions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 1998: 157.
2.	Aralen. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2005.* 170.
3.	Chloroquine Phosphate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 34th Edition.* London, England: The Pharmaceutical Press; 2005: 448.
4.	Chloroquine Phosphate (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 373.
5.	Chloroquine Phosphate. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 3rd Edition.* American Pharmaceutical Association; 2005: 93.
6.	Chloroquine Phosphate (Monograph). US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXV / National Formulary 20.* Rockville, MD: US Pharmacopeial Convention, Inc; 2001: 394.
7.	USP <795>. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXV / National Formulary 20.* Rockville, MD: US Pharmacopeial Convention, Inc; 2001: 2053.