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	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

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 Syrup Vehicle)	q.s. to 10.0	mL				
Citric Acid 10% Solution	As required					

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	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

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: 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.

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	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

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 Syrup 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, 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.
3.	**Filling to volume:** A. Add Oral Syrup (Flavored Syrup Vehicle) to the mixture (Step 2A) to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

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	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

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, in a dropwise fashion, 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 Citric Acid 10% Solution.
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:**

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.

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	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP 795.	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 (2°C – 8°C). 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.				

Suggested Formula	Chloroquine Phosphate 80.5 mg/5 mL Oral Liquid (Suspension, 10 mL)	FIN	F 001 479v3

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.

DISCLAIMER: THIS DOCUMENT IS COPYRIGHT© 2019-2020 MEDISCA PHARMACEUTIQUE INC. MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY, SCHEDULING OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW. MEDISCA NETWORK INC. MAKES NO WARRANTIES WITH RESPECT TO INFRINGEMENT OR NON-INFRINGEMENT BY THE FORMULA OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY OF ANY OTHER PARTY, AND IT IS THE RESPONSIBILITY OF THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO INVESTIGATE AND DETERMINE ANY SUCH ISSUE.