MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
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technicalservices@medisca.net

Suggested Formula	Amiodarone Hydrochloride 50 mg/mL Oral Liquid (Suspension, 50 mL)	FIN	F 003 363v5

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amiodarone Hydrochloride, USP	2.500	g				
Glycerin, USP	2.0	mL				
Cherry Flavor	0.25	mL				
Methylcellulose (1500 CPS), USP	0.35	g				
Sodium Benzoate, NF	0.07	g				
Purified Water, USP	17.5	mL				
Purified Water, USP	q.s. to 35.0	mL				
Syrup (Simple), NF	q.s. to 50.0	mL				
Citric Acid 20% Solution	As Required					
Monohydrate Potassium Citrate 20% Solution	As Required					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Amiodarone Hydrochloride*

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

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing considerations during preparation, it is suggested to measure an additional **10 to 12%** 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 (for 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Amiodarone Hydrochloride, USP §	2.500	g			
Glycerin, USP §	2.0	mL			
Cherry Flavor	0.25	mL			
Methylcellulose (1500 CPS), USP §	0.35	g			
Sodium Benzoate, NF	0.07	g			
Purified Water, USP	17.5	mL			
Purified Water, USP	q.s. to 35.0	mL			
Syrup (Simple), NF	q.s. to 50.0	mL			
Citric Acid 20% Solution	As Required				
Monohydrate Potassium Citrate 20%	As Required				

* 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. **Powder-medium preparation:**

A. Using direct heat, heat the Purified Water (17.5 mL *plus* processing error adjustments) between 90°C and 100°C.

B. In the given order, sequentially add the following ingredients to the heated water:

-Sodium Benzoate
-Methylcellulose (1500 CPS)

Specifications: Continuously mix.
Maintain temperature between 90°C and 100°C.

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dissolved/dispersed.

C. Remove the mixture from the heat, and add ICE COLD Purified Water to the mixture (Step 1B) to fill to the required batch size (35.0 mL *plus* processing error adjustments).

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

2. **Powder-liquid preparation:**

A. Triturate the Amiodarone Hydrochloride to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 2A) with the Glycerin.

End result: Homogeneous liquid-like dispersion.

3. **Powder-medium integration:**

A. In the given order, sequentially add the following ingredients to the homogeneous liquid like solution (step 1C):

-Amiodarone Hydrochloride (Step 2B)
-Cherry 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.

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4. **Filling to volume:**

A. Add Syrup (Simple) to the mixture (Step 3A) to fill to the required batch size (50.0 mL *plus* processing error adjustments).

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

End result: Homogeneous liquid-like dispersion.

5. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 4A).

B. Test the pH of the sample. It should lie between 4.3 and 4.5.

C. If the pH < 4.3, carefully add in a dropwise manner the Monohydrate Potassium Citrate 20% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Monohydrate Potassium Citrate 20% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Monohydrate Potassium Citrate 20% Solution.
3. Re-test the pH.
4. Continue to add the Monohydrate Potassium Citrate 20% Solution until the pH of 4.3 to 4.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 4.5.

D. If the pH > 4.5, carefully add in a dropwise manner the Citric Acid 20% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Citric Acid 20% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Citric Acid 20% Solution.
3. Re-test the pH.
4. Continue to add the Citric Acid 20% Solution until the pH of 4.3 to 4.5 is obtained.

IMPORTANT: Do not allow the pH to fall below 4.3.

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.

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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.	7		Protect from light.
	2	Keep out of reach of children.	8		Cap tightly after use.
	3	Keep refrigerated (2°C – 8°C). Do not freeze.	9		**Shake well before use.**
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	10		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	11		Do not take with grapefruit juice.
	6	Patient must avoid exposure to sunlight or artificial UV rays.			
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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