MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Diltiazem Hydrochloride 10 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 148v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Diltiazem Hydrochloride, USP	1.000	g				
Glycerin, USP	2.0	mL				
Stevia Powder	0.30	g				
Xanthan Gum, NF	0.25	g				
Potassium Sorbate, NF	0.20	g				
Tutti Frutti Flavor	1.0	mL				
Purified Water, USP	50.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light Sensitive *(protect from light whenever possible):* *Diltiazem Hydrochloride, Potassium Sorbate*

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 **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/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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Diltiazem Hydrochloride, USP §	1.000	g			
Glycerin, USP §	2.0	mL			
Stevia Powder §	0.30	g			
Xanthan Gum, NF	0.25	g			
Potassium Sorbate, NF §	0.20	g			
Tutti Frutti Flavor	1.0	mL			
Purified Water, USP	50.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				
Hydrochloric Acid 10% Solution	As required				

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Diltiazem Hydrochloride -Stevia Powder -Xanthan Gum -Potassium Sorbate B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Glycerin -Tutti Frutti Flavor C. Levigate the fine, homogeneous powder blend (Step 1A) with the homogeneous liquid-like solution (Step 1B). End result: Homogeneous liquid-like dispersion.

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2. **Medium integration:**

A. Incrementally add the homogeneous liquid-like dispersion (Step 1C) to the Purified Water (50.0 mL *plus* processing error adjustments).

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

End result: Homogeneous liquid-like dispersion.

3. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 2A).

B. Test the pH of the sample. It should lie between 3.7 and 4.7.

C. If the pH < 3.7, carefully add the Sodium Hydroxide 10% Solution in a dropwise manner to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 3.7 to 4.7 is obtained.

IMPORTANT: Do not allow the pH to rise above 4.7.

D. If the pH > 4.7, carefully add the Hydrochloric Acid 10% Solution in a dropwise manner to the mixture:

1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.
3. Re-test the pH.
4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 3.7 to 4.7 is obtained.

IMPORTANT: Do not allow the pH to fall below 3.7.

4. **Filling to volume:**

A. Add additional Purified Water to the above mixture 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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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.

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	Keep out of reach of children.
	2	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	7	Cap tightly after use.
	3	Keep refrigerated (2°C – 8°C). Do not freeze.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	**Shake well before use.**	9	Protect from light.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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