MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Cetirizine Hydrochloride 1 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 003 714

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Cetirizine Hydrochloride	0.100	g				
Stevia Powder	0.30	g				
Potassium Sorbate	0.20	g				
Purified Water, USP	90.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Sodium Hydroxide 10% solution	As required					
Hydrochloric Acid 10% solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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
Cetirizine Hydrochloride §	0.100	g			
Stevia Powder §	0.30	g			
Potassium Sorbate §	0.20	g			
Purified Water, USP	90.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Hydroxide 10% solution	As required				
Hydrochloric 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-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Cetirizine Hydrochloride -Stevia Powder -Potassium Sorbate
2.	**Medium preparation:** A. Incrementally add the fine, homogeneous powder blend (Step 1A) to the Purified Water (90.0 mL *plus* processing error adjustments). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.

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3. **pH testing:**

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

B. Test the pH of the sample. It should lie between 4 and 5.

C. If the pH < 4, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% solution 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 4 to 5 is obtained.

IMPORTANT: Do not allow the pH to rise above 5.

D. If the pH > 5, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% solution 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 4 to 5 is obtained.

IMPORTANT: Do not allow the pH to fall below 4

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.

End result: Homogeneous liquid-like solution.

5. **Product transfer:**

Transfer the final product into the specified dispensing container (see "Packaging requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		35 days, refrigerated.	Packaging Requirements		-Tight, light-resistant dispensing bottle -To be administered with metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.	7		Cap tightly after use.
	3	Keep in a dry place.	8		Protect from light.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9		May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	10		
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.				

REFERENCES

1. Solutions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 195.
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3. Cetirizine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 570.
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6. USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.