MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Ciprofloxacin 250 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 002 579v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ciprofloxacin (250 mg) Tablets **	20	Units				
Glycerin, USP	5.0	mL				
Chocolate Flavor	0.5	mL				
Stevia Powder	0.50	g				
Hypromellose (4000 CPS) Methocel E4M, USP	0.20	g				
Purified Water, USP	20.0	mL				
Simple Syrup, NF	60.0	mL				
Simple Syrup, NF	q.s. to 100.0	mL				
Hydrochloric Acid 10% Solution	As required					

** **Delivered as Ciprofloxacin Hydrochloride.**

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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: 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
Ciprofloxacin (250 mg) Tablets** §	20	Units			
Glycerin, USP §	5.0	mL			
Chocolate Flavor	0.5	mL			
Stevia Powder §	0.50	g			
Hypromellose (4000 CPS) Methocel E4M, USP §	0.20	g			
Purified Water, USP	20.0	mL			
Simple Syrup, NF	60.0	mL			
Simple Syrup, NF	q.s. to 100.0	mL			
Hydrochloric Acid 10% Solution	As required				

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

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Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Ciprofloxacin tablet powder to weigh if accounting for processing error):**

   A. Weigh 22 x Ciprofloxacin (250 mg) tablets. Record the total weight here: _____ g

   B. Calculate the average weight of powder in each tablet:

Weight of 22 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets	22
EQUALS	
Average weight of a single Ciprofloxacin (250 mg) tablet:	_____ g

   C. Calculate the weight of powder equivalent to 20 tablets:

Average weight of a single Ciprofloxacin (250 mg) tablet (from Step 1B):	_____ g
MULTIPLED BY	
Number of tablets required:	20
EQUALS	
Weight of powder equivalent to 20 tablets:	_____ g

   D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 20 tablets (from Step 1C):	_____ g
MULTIPLED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required *plus* processing error adjustments:	**_____ g**

2. **Powder preparation:**

   A. Crush and triturate the 22 Ciprofloxacin (250 mg) tablets to form a fine, homogeneous powder.

   B. Weigh the quantity of Ciprofloxacin tablet powder required for the batch (refer to Step 1D) and discard the remaining powder.

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3. **Medium preparation:**

A. Prepare a hot water bath to between 80°C and 90°C.

B. Using the hot water bath, heat 10.0 mL of Purified Water.

Specifications: Maintain temperature between 80°C and 90°C.

C. Slowly add the Hypromellose (4000 CPS) Methocel E4M to the heated Purified Water (Step 3B).

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

D. Remove the mixture from the heat and add an additional 10.0 mL of (cold) Purified Water to the mixture (Step 3C).

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

E. Allow the mixture to cool completely and mix intermittently.

End result: Homogeneous viscous suspension.

4. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a homogenous powder blend:

-Fine homogeneous powder (amount weighed in Step 2B)
-Stevia Powder

B. Combine and mix the following ingredients together to form a homogenous liquid-like solution:

-Glycerin
-Chocolate Flavor

C. Levigate the fine, homogeneous powder (Step 4A) with the homogenous liquid-like solution (Step 4B).

End result: Homogeneous paste-like dispersion.

5. **Medium integration:**

A. In the given order, sequentially add the following ingredients to the Simple Syrup (60.0 mL *plus* processing error adjustments):

-Homogeneous paste-like dispersion (Step 4C)
-Homogeneous viscous suspension (Step 3E)

Specifications: Continuously mix.

End Result: Homogeneous liquid-like dispersion.

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6.	**pH testing:** A. Draw an appropriate amount of the mixture (Step 5A). B. Test the pH of the sample. It should lie between 3.3 and 4.5. C. If the pH > 4.5, 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 3.3 to 4.5 is obtained. IMPORTANT: Do not allow the pH to fall below 3.3.
7.	**Filling to volume:** A. Add additional Simple Syrup 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 dispersion.
8.	**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.

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	Protect from light.
	2	Keep out of reach of children.	7	Cap tightly after 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	May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Keep refrigerated. Do not freeze.
	5	**Shake well before use.**	10	Keep in a dry place.
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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