MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Famotidine 40 mg/10 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 452v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Famotidine, USP	0.400	g				
Propylene Glycol, USP	1.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	49.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	25.0	mL				
Cherry Syrup	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Moisture Sensitive *(protect from humidity whenever possible):* *Famotidine*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

Light Sensitive *(protect from light whenever possible):* *Famotidine, Propylene Glycol*

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 **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
Famotidine, USP §	0.400	g			
Propylene Glycol, USP §	1.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	49.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	25.0	mL			
Cherry Syrup	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. Triturate the Famotidine to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol. End result: Homogeneous paste-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. B. Incrementally add the homogeneous liquid-like dispersion (Step 2A) to the Oral Syrup (Flavored Vehicle). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

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3. **Filling to volume:**

A. Add Cherry Syrup to the mixture (Step 2B) 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.

4. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 3A).

B. Test the pH of the sample. It should lie between 6.5 and 7.5.

C. If the pH < 6.5, 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 6.5 to 7.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 7.5.

D. If the pH > 7.5, 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 6.5 to 7.5 is obtained.

IMPORTANT: Do not allow the pH to fall below 6.5.

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.

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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	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. 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.				

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REFERENCES

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