MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Famotidine 10 mg/mL Intramuscular Injection (Solution, 20 mL)	FIN	F 004 918

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Famotidine, USP	0.200	g				
L-Aspartic Acid, USP	0.08	g				
Mannitol, USP	0.40	g				
Benzyl Alcohol. NF	0.18	mL				
Sodium Chloride, USP	0.042	g				
Sterile Water for Injection, USP	15.0	mL				
Sterile Water for Injection, USP	q.s. to 20.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Famotidine, L-Aspartic Acid, Benzyl Alcohol*

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

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, pH testing, sterility and endotoxin testing considerations during preparation, it is suggested to measure an additional **15 to 20%** of the required quantities of ingredients.

Special Instruction: This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

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 20 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Famotidine, USP §	0.200	g			
L-Aspartic Acid, USP §	0.08	g			
Mannitol, USP §	0.40	g			
Benzyl Alcohol. NF §	0.18	mL			
Sodium Chloride, USP §	0.042	g			
Sterile Water for Injection, USP §	15.0	mL			
Sterile Water for Injection, USP §	q.s. to 20.0	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 **IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique**	
1.	**Equipment sterilization:** Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.
2.	**Powder-liquid preparation:** A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (15.0 mL *plus* processing error adjustments). -Benzyl Alcohol -L-Aspartic Acid -Mannitol -Famotidine -Sodium Chloride Specifications: Continuously mix. 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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3.	**pH testing:** A. Draw an appropriate amount of the mixture (Step 2A). B. Test the pH of the sample. It should lie between 5.0 and 5.6. C. If the pH < 5.0, 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 5.0 to 5.6 is obtained. IMPORTANT: Do not allow the pH to rise above 5.6. D. If the pH > 5.6, 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 5.0 to 5.6 is obtained. IMPORTANT: Do not allow the pH to fall below 5.0.
4.	**Filling to volume:** A. Add additional Sterile water for injection to the above mixture to fill to the required batch size (20.0 mL *plus* processing error adjustments). Specification: Continuously mix until all solid particles have completely **dissolved**. End result: Homogeneous liquid-like **solution.**
5.	**Filtering and transferring:** Aseptically filter the solution through a 0.22-µm sterile filter into the recommended dispensing container (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility and endotoxin testing.
6.	**Filter integrity test:** Validate filter integrity by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.
7.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated as per USP 797. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tight, light-resistant unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		7	Protect from light.
	2	Keep out of reach of children.		8	Keep refrigerated. Do not freeze.
	3	Discard in the presence of particulate matter.		9	Discard container after use.
	4	Do not used if product changes color.		10	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.		11	Equilibrate to room temperature before use.
	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.			
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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REFERENCES

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