MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Folic Acid 5 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 003 199v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Folic Acid, USP	0.050	g				
Ascorbic Acid, USP	0.01	g				
Methylparaben, NF	0.02	g				
Sodium Chloride, USP	0.04	g				
Propylene Glycol, USP	0.1	mL				
Sterile Water For Injection, USP	9.0	mL				
Sterile Water For Injection, USP	q.s. to 10.0	mL				
Sodium Hydroxide 1N Solution	As required					

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Folic Acid 5 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 003 199v2

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Plastic reactive / adsorbent *(do not allow to come into contact)*	*Methylparaben*
Light Sensitive *(protect from light whenever possible):*	*Folic Acid, Propylene Glycol, Ascorbic Acid*
Hygroscopic *(protect from moisture whenever possible):*	*Propylene Glycol*
Oxygen sensitive *(protect from air whenever possible):*	*Ascorbic Acid*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility, pH and endotoxin testing considerations during preparation, it is suggested to measure an additional **25% to 30%** 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Folic Acid 5 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 003 199v2

SUGGESTED PREPARATION (for 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Folic Acid, USP §	0.050	g			
Ascorbic Acid, USP §	0.01	g			
Methylparaben, NF §	0.02	g			
Sodium Chloride, USP §	0.04	g			
Propylene Glycol, USP §	0.1	mL			
Sterile Water For Injection, USP §	9.0	mL			
Sterile Water For Injection, USP §	q.s. to 10.0	mL			
Sodium Hydroxide 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 preparations:**

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

   -Folic Acid
   -Ascorbic Acid
   -Sodium Chloride

3. **Liquid preparation:**

   A. Combine and mix the following ingredients together:

   -Methylparaben
   -Propylene Glycol

   End result: Homogeneous liquid-like solution.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Folic Acid 5 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 003 199v2

4.	**Powder-Liquid integration:** A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (9.0 mL *plus* processing error adjustments): -Homogeneous liquid-like solution (Step 3A) -Fine homogeneous powder blend (Step 2A) Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion. Note: Add the next ingredient, once the previous one has been completely added and dispersed.
5.	**pH testing:** A. Draw an appropriate amount of the mixture (Step 4A). B. Test the pH of the sample. It should lie between 8.0 and 9.0. C. If the pH < 8.0, 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 8.0 to 9.0 is obtained. IMPORTANT: Do not allow the pH to rise above 9.0.
6.	**Filling to volume:** A. Add additional Sterile Water For Injection to the above mixture to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
7.	**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.
8.	**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.
9.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Folic Acid 5 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 003 199v2

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, tightly closed, light-resistant unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5		Discard container after use.
	2	Keep out of reach of children.	6		Keep refrigerated. Do not freeze.
	3	Protect from light.	7		Do not use if discolored.
	4	**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		Discard in the presence of particulate matter.
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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.				

REFERENCES

1.	USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 2461.
2.	Methylparaben. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 390.
3.	Ascorbic Acid. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 32.
4.	Folic Acid (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4221.
5.	Chapter 8: Buffered and Isotonic Solutions. In: Martin, A. *Physical Pharmacy, Fourth Edition.* Philadelphia, PA: Lipponcott Williams & Wilkins; 1993: 169~189.
6.	Folic Acid. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 164.
7.	Folic Acid (Monograph). *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 869.