MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Epinephrine 5 mcg/mL, Lidocaine Hydrochloride 10 mg/mL Intravenous Injection (Solution, 3 mL)	FIN	F 004 764v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Epinephrine 0.025 mg/mL Stock Solution	0.60	mL				
Lidocaine Hydrochloride 12.5 mg/mL Stock Solution	2.40	mL				
† **Epinephrine 1 mg/mL Stock Solution**						
Epinephrine, USP	0.100	g				
Sterile Water For Injection, USP	90.0	mL				
Sterile Water For Injection, USP	q.s. to 100.0	mL				
Hydrochloric Acid 10% Solution	As required					
†† **Epinephrine 0.025 mg/mL Stock Solution**						
Epinephrine 1 mg/mL Stock Solution	1.00	mL				
Sodium Chloride, USP	0.36	g				
Sterile Water For Injection, USP	30.0	mL				
Sterile Water For Injection, USP	q.s. to 40.0	mL				
††† **Lidocaine Hydrochloride 12.5 mg/mL Stock Solution**						
Lidocaine Hydrochloride, USP	0.125	g				
Citric Acid (Anhydrous), USP	0.09	g				
Sodium Citrate (Dihydrate), USP	0.20	g				
Benzyl Alcohol, NF	0.1	mL				
Sterile Water For Injection, USP	8.0	mL				
Sterile Water For Injection, USP	q.s. to 10.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):*	*Epinephrine, Benzyl Alcohol*
Narrow Therapeutic Index	*Lidocaine Hydrochloride*
Air sensitive *(protect from air whenever possible):*	*Epinephrine*

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 **30 to 40%** 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.

Lidocaine Hydrochloride has a narrow therapeutic index.

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 3 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Epinephrine 0.025 mg/mL Stock Solution §	0.60	mL			
Lidocaine Hydrochloride 12.5 mg/mL Stock Solution §	2.40	mL			
† **Epinephrine 1 mg/mL Stock Solution**					
Epinephrine, USP §	0.100	g	---	---	
Sterile Water For Injection, USP §	90.0	mL	---	---	
Sterile Water For Injection, USP §	q.s. to 100.0	mL	---	---	
Hydrochloric Acid 10% Solution §	As required				
†† **Epinephrine 0.025 mg/mL Stock Solution**					
Epinephrine 1 mg/mL Stock Solution §	1.00	mL	---	---	
Sodium Chloride, USP §	0.36	g	---	---	
Sterile Water For Injection, USP §	30.0	mL	---	---	
Sterile Water For Injection, USP §	q.s. to 40.0	mL	---	---	
††† **Lidocaine Hydrochloride 12.5 mg/mL Stock Solution**					
Lidocaine Hydrochloride, USP §	0.125	g	---	---	
Citric Acid (Anhydrous), USP §	0.09	g	---	---	
Sodium Citrate (Dihydrate), USP §	0.20	g	---	---	
Benzyl Alcohol, NF §	0.1	mL	---	---	
Sterile Water For Injection, USP §	8.0	mL	---	---	
Sterile Water For Injection, USP §	q.s. to 10.0	mL	---	---	

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

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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. † **Epinephrine 1 mg/mL Stock Solution preparation:**

   A. Incrementally add the Epinephrine (0.100 g) to the Sterile Water for Injection (90.0 mL). Then, **VERY SLOWLY** add and mix the Hydrochloric Acid 10% Solution in a drop-wise manner into the mixture. Test the pH of the solution. It should lie between 4.8 and 5.2.

   Specifications: Continuously mix until all solid particles have completely dissolved.

   End result: Homogeneous liquid-like solution.

   B. Add additional Sterile Water for Injection to the mixture (Step 2A) to fill to the required amount (100.0 mL).

   Specifications: Continuously mix.

   End result: Homogeneous liquid-like solution.

3. †† **Epinephrine 0.025 mg/mL Stock Solution preparation:**

   A. Sequentially add the following ingredients into the Sterile Water for Injection (30.0 mL).

   -Epinephrine 1 mg/mL Stock Solution (1.00 mL)
   -Sodium Chloride

   Specifications: Continuously mix until all solid particles have completely dissolved.

   End result: Homogeneous liquid-like solution.

   B. Add additional Sterile Water for Injection to the mixture (Step 3A) to fill to the required amount (40.0 mL).

   Specifications: Continuously mix.

   End result: Homogeneous liquid-like solution.

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4.	††† **Lidocaine Hydrochloride 12.5 mg/mL Stock Solution preparation:** A. Sequentially add the following ingredients into the Sterile Water for Injection (8.0 mL). -Lidocaine Hydrochloride -Citric Acid (Anhydrous) -Sodium Citrate (Dihydrate) -Benzyl Alcohol Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution. B. Add additional Sterile Water for Injection to the mixture (Step 4A) to fill to the required amount (10.0 mL). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
5.	**Medium integration:** A. Incrementally add the Epinephrine 0.05 mg/mL Stock Solution (0.60 mL *plus* processing error adjustments) to the Lidocaine Hydrochloride 12.5 mg/mL Stock Solution (2.40 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
6.	**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.
7.	**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.
8.	**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. 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.		6	Do not used if product changes color.
	2	Keep out of reach of children.		7	Protect from light.
	3	Keep refrigerated. Do not freeze.		8	Discard container after use.
	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	Discard in the presence of particulate matter.
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredients to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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