MEDISCA® NETWORK INC.
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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Heparin Sodium 5000 Units/mL Injection (Solution, 10 mL)	FIN	F 001 515

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Heparin Sodium 10,000 Units/mL Stock Solution †	5.00	mL				
Sodium Chloride, USP	0.056	g				
Benzyl Alcohol, NF	0.20	mL				
Sterile Water For Injection, USP	q.s. to 10.0	mL				
† **Heparin Sodium 10,000 Units/mL Stock Solution**						
Heparin Sodium (Powder) (1 MU), USP	1	Vial				
Sterile Water For Injection, USP	100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Benzyl Alcohol*

Hygroscopic *(protect from moisture whenever possible):* *Heparin Sodium*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility 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.

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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
Heparin Sodium 10,000 Units/mL Stock Solution § †	5.00	mL			
Sodium Chloride, USP §	0.056	g			
Benzyl Alcohol, NF §	0.20	mL			
Sterile Water For Injection, USP §	q.s. to 10.0	mL			
† **Heparin Sodium 10,000 Units/mL Stock Solution**					
Heparin Sodium (Powder) (1 MU), USP §	1	Vial	---	---	
Sterile Water For Injection, USP §	100.0	mL	---	---	

* 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.

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2.	† **Heparin Sodium 10,000 Units/mL Solution preparation:** A. Add the Sterile water for injection (100.0 mL) into the following ingredient: - Heparin Sodium (Powder) (1 MU) (1 vial) Specification: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
3.	**Liquid preparation:** A. Combine and mix the following ingredients together until homogeneously dispersed: - Heparin Sodium 10,000 Units/mL Stock Solution (5.00 mL plus processing error adjustments) - Benzyl Alcohol End result: Homogeneous liquid-like solution.
4.	**Powder to medium integration:** A. Incrementally add the Sodium Chloride into the following ingredient: - Homogeneous liquid-like solution (Step 3A) Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
5.	**Filling to volume and transfer into dispensing container:** A. Add Sterile Water For Injection to the mixture (Step 4A) to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution. B. Transfer the final product into the recommended dispensing container (see Packaging requirements). **Note:** After sterilization, a sample is to be used as the Test sample for sterility testing.

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6.	**Sterilization:** Following the manufacturer's specifications, autoclave sterilize the mixture, then return to ambient temperature and pressure. Specifications: Heating temperature: 121°C Heating time: 20 minutes Pressure: 15 psi IMPORTANT: The temperature of the heated chamber must reach 121°C before the exposure duration is timed.
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. BUD based on a successful sterility and endotoxin test result.		Packaging Requirements	Sterile, light-resistant, heat stable injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Discard in the presence of particulate matter.
	2	Keep out of reach of children.	7	Equilibrate to room temperature before use.
	3	Keep refrigerated. Do not freeze.	8	Protect from light.
	4	Do not use if discolored.	9	**Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.**
	5	Discard container after use.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **Important: To be administered only by the prescribing physician.**			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

1. Heparin Sodium. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 34th Edition.* London, England: The Pharmaceutical Press; 2005: 928.
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5. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 2461.