MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Dopamine Hydrochloride 40 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 008 667

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Dopamine Hydrochloride, USP	0.400	g				
Sodium Metabisulfite, NF	0.09	g				
Sterile Water for Injection, USP	8.0	mL				
Sterile Water for Injection, USP	q.s. to 10.0	mL				
Citric Acid 5% Solution	As required					
Sodium Citrate 5% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Dopamine Hydrochloride, Sodium Metabisulfite*

Air Sensitive *(protect from air whenever possible):* *Sodium Metabisulfite*

Moisture Sensitive *(protect from humidity whenever possible):* *Sodium Metabisulfite*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, pH testing and sterility testing considerations during preparation, it is suggested to measure an additional **20 to 25%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797* and *USP 800* when handling hazardous drugs. 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.

All required personal protective equipment (sterile and hazardous if applicable), such as but not limited to, gowns, aprons, sleeves, gloves both inner and outer if applicable, shoe covers, hairnet, head cap, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

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.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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
Dopamine Hydrochloride, USP §	0.400	g			
Sodium Metabisulfite, NF	0.09	g			
Sterile Water for Injection, USP §	8.0	mL			
Sterile Water for Injection, USP §	q.s. to 10.0	mL			
Citric Acid 5% Solution §	As required				
Sodium Citrate 5% 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 preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Dopamine Hydrochloride -Sodium Metabisulfite
3.	**Medium incorporation:** A. Incrementally add the fine, homogeneous powder blend (Step 2A) to the following ingredient: - Sterile Water for Injection (8.0 mL *plus* processing error adjustments) Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.

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4. **pH testing:**

A. Draw an appropriate amount of the mixture.

B. Test the pH of the sample. It should lie between 2.5 and 5.0.

C. If the pH < 2.5, carefully add in a dropwise manner the Sodium Citrate 5% solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Citrate 5% solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Citrate 5% solution.
3. Re-test the pH.
4. Continue to add the Sodium Citrate 5% solution until the pH of 2.5 to 5.0 is obtained.

IMPORTANT: Do not allow the pH to rise above 5.0.

D. If the pH > 5.0, carefully add in a dropwise manner the Citric Acid 5%solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Citric Acid 5% solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Citric Acid 5% solution.
3. Re-test the pH.
4. Continue to add the Citric Acid 5% solution until the pH of 2.5 to 5.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 2.5.

5. **Filling to volume:**

A. Add additional Sterile Water for Injection to the mixture (Step 3A) to fill to the required batch size (10.0 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. **Terminal Sterilization:**

In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specifications.

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9.	**Sterility testing:** Validate the Test samples for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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, unit-dose injection vial.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Discard container after use.
	2	Keep out of reach of children.		6	Equilibrate to room temperature before use.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.		7	Keep refrigerated (2°C – 8°C). Do not freeze.
	4	Discard in the presence of particulate matter.		8	**Hypertonic solution. Inject slowly.**
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: Using proper aseptic techniques, one must dilute the Dopamine Hydrochloride injection to the appropriate concentration with the appropriate sterile diluent prior to intravenous injection. Also, it must be administered accordingly as determined by the prescribing physician.** **NOTE: Once diluted it must be used immediately and any unused portion must be discarded.**				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

1.	Parental Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmaceutical Association; 2016: 399.
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6.	Dopamine Hydrochloride Injection (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 1464.
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