MEDISCA® NETWORK INC.
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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Bupivacaine Hydrochloride 250 mg/250 mL, Sufentanil 0.4 mg/250 mL Intravenous Injection (Solution, 250 mL)	FIN	F 004 775

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Bupivacaine Hydrochloride 0.5% Injection (Sterile), USP	50.00	mL				
Sufentanil Citrate 50 µg Base/mL Injection (Sterile), USP	8.00	mL				
Sodium Chloride 0.9% for Injection, (Sterile), USP	192.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)* — *Sufentanil Citrate*

Light sensitive *(protect from light whenever possible):* — *Sufentanil Citrate*

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 **3 to 5%** 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 250 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
Bupivacaine Hydrochloride 0.5% Injection (Sterile), USP	50.00	mL			
Sufentanil Citrate 50 µg Base/mL Injection (Sterile), USP	8.00	mL			
Sodium Chloride 0.9% for Injection, (Sterile), USP	192.0	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.
2.	**Medium integration:** **Note**: All manipulations must be done under a laminar airflow hood. Disinfect the commercial vials with Alcohol 70% prior to withdrawing the required amount of liquid. A. In the given order, sequentially add the following ingredients to the Sodium Chloride 0.9% for Injection (Sterile). -Bupivacaine Hydrochloride 0.5% Injection (Sterile) -Sufentanil Citrate 50 µg Base/mL Injection (Sterile) Specifications: Continuously mix. End result: Homogeneous liquid-like solution. Note: Add the next ingredient, once the previous one has been completely added and dispersed.
3.	**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.
4.	**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.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		Sterile, tight, light-resistant unit-dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	8		**For medical office use only.**
	2	Keep out of reach of children.	9		Protect from light.
	3	Keep refrigerated. Do not freeze.	10		Equilibrate to room temperature before use.
	4	**Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.**	11		**May produce psychological and/or physical dependence.**
	5	**May impair mental and/or physical ability. Use care when operating a car or machinery.**	12		**Controlled substance. Dangerous unless used as directed**
	6	**Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.**	13		Discard in the presence of particulate matter.
	7	Do not used if discolored.	14		
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. Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 313.
2. Bupivacaine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1854.
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4. Bupivacaine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #1495.
5. Sufentanil (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8887.
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