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TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Bupivacaine Hydrochloride 0.125% Epidural Injection (Solution, 250 mL)	FIN	F 003 654

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Bupivacaine Hydrochloride 0.5% Injection (Sterile, Preservative Free)	62.50	mL				
Sodium Chloride 0.9% for Injection, USP (Sterile, Preservative Free)	187.5	mL				

SPECIAL PREPARATORY CONSIDERATIONS

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 **5 to 9%** 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, Preservative Free) §	62.50	mL			
Sodium Chloride 0.9% for Injection, USP (Sterile, Preservative Free) §	187.5	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, mix the following ingredients together: -Bupivacaine Hydrochloride 0.5% Injection (Sterile, Preservative Free) -Sodium Chloride 0.9% for Injection (Sterile, Preservative Free) 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.	**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, 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	**Preservative free solution, single use only. Discard any unused portion.**
	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 product changes color.		
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredients 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. USP <797>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
2. Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 313.
3. Bupivacaine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #1495.
4. Bupivacaine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 3rd Edition.* American Pharmaceutical Association; 2005: 59.
5. Bupivacaine Hydrochloride (Monograph). *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
6. USP <797>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.