MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Bupivacaine Hydrochloride (Monohydrate), USP	0.900	g				
Sodium Chloride, USP	0.12	g				
Sterile Water For Injection, USP	29.0	mL				
Sterile Water For Injection, USP	q.s. to 30.0	mL				

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

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 **12 to 15%** 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

SUGGESTED PREPARATION (for 30 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Bupivacaine Hydrochloride (Monohydrate), USP §	0.900	g			
Sodium Chloride, USP §	0.12	g			
Sterile Water For Injection, USP §	29.0	mL			
Sterile Water For Injection, USP §	q.s. to 30.0	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.	**Preparatory step:** A. Prepare a hot water bath Specifications: Temperature: 48 to 53°C.

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

3.	**Powder to medium integration:** A. Using the hot water bath, in the given order, sequentially add the following ingredients to the Sterile Water For Injection (29.0 mL *plus* processing error adjustments): - Bupivacaine Hydrochloride (Monohydrate) - Sodium Chloride Specifications: Continuously mix until all solid particles have completely dissolved. Maintain temperature between 48 and 53°C. End result: Homogenous liquid-like solution Note: Add the next ingredient, once the previous one has been completely added and dissolved.
4.	**Cooling:** A. Remove from the hot water bath and gently stir the homogeneous liquid-like solution (Step 3A) as it cools down to room temperature (20°C - 23°C). End result: Homogeneous liquid-like solution.
5.	**Filling to volume:** A. Add additional Sterile Water For Injection to the mixture (Step 4A) to fill to the required batch size (30.0 mL *plus* processing error adjustments). Specification: 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.

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

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

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.		6	Do not use if discolored.
	3	Equilibrate to room temperature before use.		7	Discard container after use.
	4	Discard in the presence of particulate matter.		8	**Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.**
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions		If adverse reactions occur, contact your pharmacist.			

Suggested Formula	Bupivacaine Hydrochloride 30 mg/mL Injection (Solution, 30 mL)	FIN	F 000 213v2

REFERENCES

1. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 2461.
2. Marcaine (Monograph). In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2003.*
3. Sensorcaine (Monograph). In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2003.*
4. Bupivacaine (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 251.
5. Buffered Isotonic Solutions. In: Martin A. *Physical Pharmacy, Fourth Edition*. Philadelphia, PA: Lipponcott Williams & Wilkins; 1993:169-89.
6. Gennaro AR, ed. *Remington: The Science and Practice of Pharmacy, 20th Edition.* Baltimore, MD: Lippincott Williams & Wilkins; 2000: 613-27.
7. Bupivacaine Hydrochloride (Monograph). In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 47.