



Suggested Formula	Mepivacaine Hydrochloride 2% Subcutaneous Injection (Solution, 100 mL)	FIN	F 003 162v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Mepivacaine Hydrochloride, USP	2.000	g				
Potassium Chloride, USP	0.030	g				
Calcium Chloride, USP	0.033	g				
Sodium Chloride, USP	0.44	g				
Sterile Water for Injection, USP	90.0	mL				
Sterile Water for Injection, USP	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As needed					
Hydrochloric Acid 10% Solution	As needed					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible): Mepivacaine Hydrochloride

**Moisture sensitive** (protect from humidity whenever possible): Calcium Chloride

#### 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 **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 100 mL)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Mepivacaine Hydrochloride, USP §	2.000	g			
Potassium Chloride, USP §	0.030	g			
Calcium Chloride, USP §	0.033	g			
Sodium Chloride, USP §	0.44	g			
Sterile Water for Injection, USP §	90.0	mL			
Sterile Water for Injection, USP §	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution §	As needed				
Hydrochloric Acid 10% Solution §	As needed				

\* 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.	<p><b><u>Equipment sterilization:</u></b></p> <p>Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.</p>
2.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Mepivacaine Hydrochloride</li> <li>-Potassium Chloride</li> <li>-Calcium Chloride</li> <li>-Sodium Chloride</li> </ul> <p>B. Incrementally add the fine, homogeneous powder blend (Step 2A) to the following ingredient:</p> <ul style="list-style-type: none"> <li>-Sterile Water for Injection (90.0 mL <i>plus</i> processing error adjustments)</li> </ul> <p><u>Specifications:</u> Continuously mix, until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>



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3.	<p><b><u>pH testing:</u></b></p> <p>A. Draw an appropriate amount of the mixture (Step 2B).</p> <p>B. Test the pH of the sample. It should lie between 4.5 and 6.8.</p> <p>C. <u>If the pH &lt; 4.5, carefully add in a dropwise manner the Sodium Hydroxide 10% Solution to the mixture:</u></p> <ol style="list-style-type: none"><li>1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.</li><li>2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.</li><li>3. Re-test the pH.</li><li>4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 4.5 to 6.8 is obtained.</li></ol> <p>IMPORTANT: Do not allow the pH to rise above 6.8.</p> <p>D. <u>If the pH &gt; 6.8, carefully add in a dropwise manner the Hydrochloric Acid 10% Solution to the mixture:</u></p> <ol style="list-style-type: none"><li>1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.</li><li>2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.</li><li>3. Re-test the pH.</li><li>4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 4.5 to 6.8 is obtained.</li></ol> <p>IMPORTANT: Do not allow the pH to fall below 4.5.</p>		
4.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogenous liquid-like solution.</p>		
5.	<p><b><u>Filtering and transferring:</u></b></p> <p>Aseptically filter the solution through a 0.22-<math>\mu</math>m 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.</p>		
6.	<p><b><u>Filter integrity test:</u></b></p> <p>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.</p>		
7.	<p><b><u>Sterility testing:</u></b></p> <p>Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.</p>		



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**SUGGESTED PRESENTATION**

<b>Estimated Beyond-Use Date</b>	14 days, refrigerated as per USP <797>. BUD based on a successful sterility and endotoxin test result.	<b>Packaging Requirements</b>	Sterile, tightly closed, light-resistant unit dose injection vials.
<b>Auxiliary Labels</b>	1 Use as directed. Do not exceed prescribed dose.	7	Equilibrate to room temperature before use.
	2 Keep out of reach of children.	8	Discard container after use.
	3 For veterinary use only.	9	Protect from light.
	4 Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	10	Discard in the presence of particulate matter.
	5 Do not use if discolored.	11	Keep refrigerated. Do not freeze.
	6 <b>May impair mental and/or physical ability.</b>	12	<b>Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.</b>
<b>Pharmacist Instructions</b>	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.		
<b>Patient Instructions</b>	Contact your pharmacist in the event of adverse reactions.		



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## REFERENCES

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7.	Mepivacaine (Monograph). In: O’Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #5859.
8.	Chapter 8: Buffered and Isotonic Solutions. In: Martin, A. <i>Physical Pharmacy, Fourth Edition</i> . Philadelphia, PA: Lippincott Williams & Wilkins; 1993: 169~189.
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