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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Sodium Acetate 2 mEq/mL Injection (Solution, 100 mL)	FIN	F 004 802

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Sodium Acetate (Anhydrous), USP	16.406	g				
Sterile Water For Injection, USP	80.0	mL				
Sterile Water For Injection, USP	q.s. to 100.0	mL				
Acetic Acid 25% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from humidity whenever possible):* *Sodium Acetate*

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 (*): ____	Processing Error	Qty. to measure
Sodium Acetate (Anhydrous), USP §	16.406	g			
Sterile Water For Injection, USP §	80.0	mL			
Sterile Water For Injection, USP §	q.s. to 100.0	mL			
Acetic Acid 25% 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 to medium integration:**

   A. Incrementally add the Sodium Acetate to the Sterile Water for Injection (80.0 mL *plus* processing error adjustments).

   Specifications: Continuously mix until all solid particles have completely dissolved.

   End result: Homogeneous liquid-like solution.

3. **pH testing:**

   A. Draw an appropriate amount of the mixture (Step 2A).

   B. Test the pH of the sample. It should lie between 6.0 and 7.0.

   C. If the pH > 7.0, carefully add, in a dropwise fashion, the Acetic Acid 25% Solution to the mixture:

      1. Draw and transfer 1 or 2 drops of the Acetic Acid 25% Solution to the mixture.
      2. Stir for at least 5 minutes to evenly disperse the Acetic Acid 25% Solution.
      3. Re-test the pH.
      4. Continue to add the Acetic Acid 25% Solution until the pH of 6.0 and 7.0 is obtained.

         IMPORTANT: Do not allow the pH to fall below 6.0.

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4.	**Filling to volume:** A. Add additional Sterile Water For Injection to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
5.	**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.
6.	**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.
7.	**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 as per USP 797. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tightly closed unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		7	Do not use if discolored.
	2	Keep out of reach of children.		8	Discard in the presence of particulate matter.
	3	Keep refrigerated. Do not freeze.		9	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Keep in a dry place.		10	Equilibrate to room temperature before use.
	5	**Preservative free solution, single use only. Discard any unused portion.**		11	Discard container after use.
	6	**Hypertonic solution, inject slowly.**		12	It must not be administered undiluted.
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 compounded product to the appropriate concentrations 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

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