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	Potassium Acetate 40 mEq/ 20 mL for Intravenous Injection (Solution, 100 mL)	FIN	F 004 810v2

Note: Potassium Acetate 40 mEq/20 mL is equivalent to Potassium Acetate 3.92 g/20 mL.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Potassium Acetate, USP	19.600	g				
Benzyl Alcohol, NF	1.0	mL				
Sterile water for injection, USP	70.0	mL				
Sterile water for injection, USP	q.s. to 100.0	mL				
Acetic Acid 25% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Benzyl Alcohol*

Hygroscopic *(protect from moisture whenever possible):* *Potassium Acetate*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, pH, 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
Potassium Acetate, USP §	19.600	g			
Benzyl Alcohol, NF §	1.0	mL			
Sterile water for injection, USP §	70.0	mL			
Sterile water for injection, USP §	q.s. to 100.0	mL			
Acetic Acid 25% Solution §	As required				

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

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:** A. Sequentially add the following ingredients to the Sterile Water for Injection (70.0 mL *plus* processing error adjustments): -Benzyl Alcohol -Potassium Acetate Specifications: Continuously mix until all particles have been dissolved. End result: Homogeneous liquid-like solution.

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3.	**pH testing:** A. Draw an appropriate amount of the mixture (Step 2A). B. Test the pH of the sample. It should lie between 7.1 and 7.7 C. If the pH > 7.7, 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 7.1 to 7.7 is obtained. IMPORTANT: Do not allow the pH to fall below 7.1.
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. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tightly closed, light-resistant unit dose injections vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.	7		Discard container after use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8		**Hypertonic solution, not for direct injection. Must be diluted before use.**
	4	Discard in the presence of particulate matter.	9		Do not use if discolored.
	5	Protect from light.	10		Equilibrate to room temperature before use.
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

REFERENCES

1.	Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 313.
2.	Benzyl Alcohol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 64.
3.	Potassium Acetate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1684.
4.	Potassium Acetate (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #7605.
5.	Potassium Acetate (Monograph). *United States Pharmacopeia XXXIV / National Formulary 29.* Rockville, MD. US Pharmacopeial Convention, Inc. 2011: 3959.
6.	USP <797>. *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 318.