MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Penicillin G Potassium 40 000 000 IU per 100 mL vial for Injection (Powder blend for reconstitution, 1 vial)	FIN	F 003 325v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Penicillin G Potassium, USP	TBD					
Sodium Citrate (Dihydrate), USP	0.50	g				
Sterile Water for Injection, USP	80.0	mL				
Sterile Water for Injection, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Penicillin G Potassium*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

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 may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797* and *USP 800* when handling hazardous drugs. 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.

Compounder needs to verify as per USP, if every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

All required personal protective equipment (sterile and hazardous if applicable), such as but not limited to, gowns, aprons, sleeves, gloves both inner and outer if applicable, shoe covers, hairnet, head cap, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

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.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 1 vial)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Penicillin G Potassium, USP §	TBD				
Sodium Citrate (Dihydrate), USP §	0.50	g			
Sterile Water for Injection, USP §	80.0	mL			
Sterile Water for Injection, USP §	q.s. to 100.0	mL			

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

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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. **Ingredient quantification:**

A. Determine the quantity (in g) of Penicillin G Potassium required for the entire batch (1 vial):

Quantity of Penicillin G Potassium (in Units) required for 100 mL	40,000,000 U
DIVIDED BY	
Penicillin G Potassium assay result, dried basis (from Certificate of Analysis)	_____ U/mg
EQUALS	
i. Quantity of Penicillin G Potassium (in milligrams) required for 100 mL	_____ mg
MULTIPLIED BY	
Multiplication factor – milligrams to grams	0.001
EQUALS	
ii. Quantity of Penicillin G Potassium (in grams) required for 100 mL	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
iii. Quantity of Penicillin G Potassium needed *plus* processing error adjustments	_____ **g**

3. **Powder Preparation:**

A. Combine and mix the following ingredients together to form a homogeneous powder blend:

-Penicillin G Potassium (amount determined in Step 2Aiii)
-Sodium Citrate (Dihydrate)

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4.	**Powder to medium incorporation:** A. Incrementally add the homogeneous powder blend (Step 3A) 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.
5.	**Filling to Volume:** A. Add additional Sterile Water for Injection to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
6.	**Filtering and transferring:** Aseptically filter the 100 mL solution through a 0.22-µm sterile filter into single unit dose (100 mL size) injection vial suitable for lyophilization (see Packaging requirements). Transfer the remainder into a separate single unit dose injection vial suitable for lyophilization. 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.
8.	**Lyophilization:** A. Freeze-dry the sterile liquid, and seal the single unit dose injection vials, following the instructions indicated by the Lyophilizer manufacturer. B. Remove the samples from the machine and store appropriately.
9.	**Terminal Sterilization:** In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specification.
10.	**Sterility and Endotoxin testing:** Validate the freeze-dried Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	24 hours controlled room temperature, 3 days refrigerated, or 45 days frozen, as per USP 797. BUD based on successful endotoxin test result.		Packaging Requirements	Sterile, unit-dose (100 mL size) injection vials suitable for lyophilization.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.		7	Discard container after use.
	3	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).		8	Hypertonic, use in the infusion liquid only.
	4	Discard in the presence of particulate matter.		9	Do not use if discolored.
	5	Equilibrate to room temperature before use.			
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary. **<u>Reconstitution Procedure:</u>** **Allow vial to warm to room temperature before reconstitution.** **Prior to use, reconstitute <u>using appropriate aseptic technique</u>, each vial with 100 mL of Sterile Water for Injection, USP to reconstitute the powder blend (40 000 000 units/100 mL).** **(BUD: 1 hour, once reconstituted and kept refrigerated.)** **<u>Note</u>: Following reconstitution, use vial only once and discard any remaining solution.**				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

1. Penicillin G Potassium (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #7094
2. Penicillin G Potassium. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 287.
3. Penicillin G Potassium (Monograph). *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
4. USP <797>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.