MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Fentanyl Citrate 78.5 mcg/mL Injection (Solution, 30 mL)	FIN	F 004 979v2

NOTE: Fentanyl Citrate 78.5 µg is equivalent to Fentanyl 50 µg.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fentanyl Citrate 0.3925% Stock Solution	0.60	mL				
Sodium Chloride, USP	0.22	g				
Benzyl Alcohol, NF	0.3	mL				
Sterile Water for Injection, USP	20.0	mL				
Sterile Water for Injection, USP	q.s. to 30.0	mL				
Sodium Hydroxide 1 N Solution	As needed					
† **Fentanyl Citrate 0.3925% Stock Solution**						
Fentanyl Citrate, USP	0.157	g				
Sterile Water for Injection, USP	40.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)* — *Fentanyl Citrate*

Light sensitive *(protect from light whenever possible):* — *Fentanyl Citrate, Benzyl Alcohol*

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 **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.

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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
Fentanyl Citrate 0.3925% Stock Solution §	0.60	mL			
Sodium Chloride, USP §	0.22	g			
Benzyl Alcohol, NF §	0.3	mL			
Sterile Water for Injection, USP §	20.0	mL			
Sterile Water for Injection, USP §	q.s. to 30.0	mL			
Sodium Hydroxide 1 N Solution	As needed				
† **Fentanyl Citrate 0.3925% Stock Solution**					
Fentanyl Citrate, USP §	0.157	g	---	---	
Sterile Water for Injection, USP §	40.0	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.	**Fentanyl Citrate 0.3925% Stock Solution preparation:** Add Fentanyl Citrate (0.157 g) to the Sterile Water for Injection (40.0 mL) and mix until dissolved.
3.	**Powder-liquid preparation:** A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (20.0 mL *plus* processing error adjustments). -Benzyl Alcohol -Sodium Chloride -Fentanyl Citrate 0.3925% Stock Solution (0.60 mL *plus* processing error adjustments) Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution. Note: Add the next ingredient, once the previous one has been completely added and dissolved.

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4. **pH testing:**

   A. Draw an appropriate amount of the mixture (Step 3A).

   B. Test the pH of the sample. It should lie between 5.0 and 6.0.

   C. If the pH < 5.0, carefully add, in a dropwise fashion, the Sodium Hydroxide 1 N Solution to the mixture:

      1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 1 N Solution to the mixture.
      2. Stir for at least 5 minutes to evenly disperse the Sodium hydroxide 1 N Solution.
      3. Re-test the pH.
      4. Continue to add the Sodium hydroxide 1 N Solution until the pH of 5.0 to 6.0 is obtained.

         IMPORTANT: Do not allow the pH to rise above 6.0.

5. **Filling to volume:**

   A. Add additional Sterile Water for Injection to the above mixture 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 separate dispensing containers. These are to be used as the Test samples 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. **Sterility testing:**

   Validate the Test samples 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 injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		May produce psychological and/or physical dependence.
	2	Keep out of reach of children.	8		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	Keep refrigerated. Do not freeze.	9		May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Protect from light.	10		**Controlled substance. Dangerous unless used as directed.**
	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	11		Equilibrate to room temperature before use.
	6	Discard in the presence of particulate matter.	12		Do not use if discolored.
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **Important: Avoid contact with skin and the inhalation of particles of Fentanyl citrate.**			
Patient Instructions		Contact your pharmacist in the event of adverse reactions.			

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