MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Hydromorphone Hydrochloride 2 mg/mL Intravenous Injection (Solution, 50 mL)	FIN	F 005 004v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydromorphone Hydrochloride, USP	0.100	g				
Sodium Citrate, USP	0.10	g				
Sodium Chloride, USP	0.29	g				
Citric Acid, USP	0.10	g				
Benzyl Alcohol, NF	0.5	mL				
Sterile Water for Injection, USP	40.0	mL				
Sterile Water for Injection, USP	q.s. to 50.0	mL				
Hydrochloric Acid 10% solution	As required					
Sodium Hydroxide 10% solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)* — *Hydromorphone Hydrochloride*

Light sensitive *(protect from light whenever possible):* — *Hydromorphone Hydrochloride, Benzyl Alcohol*

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 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Hydromorphone Hydrochloride, USP §	0.100	g			
Sodium Citrate, USP §	0.10	g			
Sodium Chloride, USP §	0.29	g			
Citric Acid, USP §	0.10	g			
Benzyl Alcohol, NF §	0.5	mL			
Sterile Water for Injection, USP §	40.0	mL			
Sterile Water for Injection, USP §	q.s. to 50.0	mL			
Hydrochloric Acid 10% solution §	As required				
Sodium Hydroxide 10% 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-liquid preparation:** A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (40.0 mL *plus* processing error adjustments). -Benzyl Alcohol -Sodium Citrate -Sodium Chloride -Citric Acid -Hydromorphone Hydrochloride 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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3.	**pH testing:** A. Draw an appropriate amount of the mixture (Step 2A). B. Test the pH of the sample. It should lie between 3.5 and 5.5. C. If the pH <3.5, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% solution to the mixture: 1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% solution to the mixture. 2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% solution. 3. Re-test the pH. 4. Continue to add the Sodium Hydroxide 10% solution until the pH of 3.5 and 5.5 is obtained. IMPORTANT: Do not allow the pH to rise above 5.5. D. If the pH > 5.5, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% solution to the mixture: 1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% solution to the mixture. 2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% solution. 3. Re-test the pH. 4. Continue to add the Hydrochloric Acid 10% solution until the pH of 3.5 and 5.5 is obtained. IMPORTANT: Do not allow the pH to fall below 3.5
4.	**Filling to volume:** A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (50.0 mL *plus* processing error adjustments). Specification: Continuously mix End result: Homogeneous liquid-like solution
5.	**Filtering and transferring:** Aseptically filter the required amount of solution through a 0.22-µm sterile filter into the recommended dispensing containers (see Packaging requirements) and sample containers 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 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 <797>. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tight, light-resistant unit-dose, injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	8		Do not used if product changes color.
	2	Keep out of reach of children.	9		Protect from light.
	3	Keep refrigerated. Do not freeze.	10		Discard container after use.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	11		May produce psychological and/or physical dependence.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	12		Controlled substance. Dangerous unless used as directed.
	6	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	13		For medical office use only.
	7	Discard in the presence of particulate matter.	14		Equilibrate to room temperature before use.
Pharmacist Instructions		Add any auxiliary labels specific to the active ingredients to the dispensing container as deemed necessary. **IMPORTANT: TO BE ADMINISTERED ONLY BY THE PRESCRIBING PHYSICIAN.**			
Patient Instructions		Contact your pharmacist in the event of adverse reactions.			

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