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Suggested Formula	Midazolam 1 mg/mL Epidural Injection (Solution, 2 mL)	FIN	F 004 214v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Midazolam, BP	0.100	g **				
Sodium Chloride 0.9% for Injection, USP (Sterile, Preservative Free)	100.0	mL				
Hydrochloric Acid 1N solution	As required					

****Note: 0.100 g is the minimum accurate weighable quantity**

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Midazolam*

Controlled substance *(adhere to proper handling and documentation procedures)* *Midazolam*

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 **0 to 0%** 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 2 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Midazolam, BP §	0.100	g**			
Sodium Chloride 0.9% for Injection, USP (Sterile, Preservative Free) §	100.0	mL			
Hydrochloric Acid 1N solution §	As required				

* Takes into account increased batch size conversions and density conversions, if required.
** 0.100 g is the minimum accurate weighable quantity
§ 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.	**Medium integration:** **Note**: All manipulations must be done under a laminar airflow hood. Disinfect the commercial vials with Alcohol 70% prior to withdrawing the required amount of liquid. A. Incrementally add the Midazolam to the Sodium Chloride 0.9% for Injection (Sterile, Preservative Free). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.

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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 3.1 and 3.5 C. If the pH > 3.5, carefully add, in a dropwise fashion, the Hydrochloric Acid 1N solution to the mixture: 1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 1N solution to the mixture. 2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 1N solution. 3. Re-test the pH. **4. Continue to add the Hydrochloric Acid 1N solution until all solid particles have completely dissolved and a pH of 3.1 to 3.5 is obtained.** IMPORTANT: Do not allow the pH to fall below 3.1
4.	**Filtering and transferring:** Aseptically filter the required amount of solution (2 mL plus sterility and endotoxin testing samples) through a 0.22-µm sterile filter into the recommended dispensing container (see Packaging requirements) and sample containers for sterility and endotoxin testing.
5.	**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.
6.	**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, 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	**Preservative free solution, single use only. Discard any unused portion.**
	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	Discard in the presence of particulate matter.
	7	For medical office use only.			
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.				

REFERENCES

1. USP <797>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
2. Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 313.
3. Midazolam (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #6182.