MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Etomidate 2 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 008 668

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Etomidate 1% Stock Solution †	2.00	mL				
Propylene Glycol, USP	1.50	mL				
Sterile Water for Irrigation, USP	6.0	mL				
Sterile Water for Irrigation, USP	q.s. to 10.0	mL				
† Etomidate 1% Stock Solution						
Etomidate, USP	0.100	g				
Propylene Glycol, USP	9.0	mL				
Propylene Glycol, USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Etomidate, Propylene Glycol*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

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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, pH adjusting, sterility and endotoxin testing considerations during preparation, it is suggested to measure an additional **20 to 25%** 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 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Etomidate 1% Stock Solution † §	2.00	mL			
Propylene Glycol, USP §	1.50	mL			
Sterile Water for Irrigation, USP §	6.0	mL			
Sterile Water for Irrigation, USP §	q.s. to 10.0	mL			
† Etomidate 1% Stock Solution					
Etomidate, USP §	0.100	g	---	---	
Propylene Glycol, USP §	9.0	mL	---	---	
Propylene Glycol, USP §	q.s. to 10.0	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.	† **Etomidate 1% Stock Solution preparation:** A. Incrementally add the Etomidate (0.100 g) to the Propylene Glycol (9.0 mL). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution. B. Add additional Propylene Glycol to the mixture (Step 2A) to fill to the required batch size (10.0 mL). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.

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3.	**Medium integration:** A. In the given order, sequentially add the following ingredients to the Sterile Water for Irrigation (6.0 mL *plus* processing error adjustments): -Etomidate 1% Stock Solution (2.00 mL plus processing error adjustments) -Propylene Glycol (1.5 mL plus processing error adjustments) Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
4.	**Filling to volume:** A. Add additional Sterile Water for Irrigation to the above mixture to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specifications: Continuously mix until homogeneous. End result: Homogeneous liquid-like solution. B. Test the pH, it should lie between 4.0 to 7.0.
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.	**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 specifications.
8.	**Sterility and Endotoxin 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	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, tightly closed, light-resistant unit-dose injection vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	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.	8	Do not use if discolored.	
	3	Hypertonic solution, inject slowly.	9	Protect from light.	
	4	Equilibrate to room temperature before use.	10	Discard in the presence of particulate matter.	
	5	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).	11	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	
	6	May impair mental and/or physical ability. Use care when operating a car or machinery.	12	For intravenous use only.	
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **INTRAVENOUS ETOMIDATE SHOULD BE ADMINISTERED ONLY BY PERSONS TRAINED IN THE ADMINISTRATION OF GENERAL ANESTHETICS AND IN THE MANAGEMENT OF COMPLICATIONS ENCOUNTERED DURING THE CONDUCT OF GENERAL ANESTHESIA.** **THIS FORMULATION IS NOT INTENDED FOR ADMINISTRATION BY PROLONGED INFUSION.**				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

1.	Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 399.
2.	Etomidate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 1901.
3.	Etomidate (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 1752.
4.	USP <797>. *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6959.