MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Denatonium Benzoate 0.0135% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 674

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Denatonium Benzoate 1% Stock Solution †	1.35	mL				
Benzyl Alcohol (Parenteral Application), NF	1.0	mL				
Sodium Chloride, USP	5.00	g				
Sterile Water for Injection, USP	90.0	mL				
Sterile Water for Injection, USP	q.s. to 100.0	mL				
† **Denatonium Benzoate 1% Stock Solution**						
Denatonium Benzoate (Anhydrous), NF	0.100	g				
Sterile Water for Injection, USP	9.0	mL				
Sterile Water for Injection, USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Benzyl Alcohol*

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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 and sterility 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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Denatonium Benzoate 1% Stock Solution † §	1.35	mL			
Benzyl Alcohol (Parenteral Application), NF §	1.0	mL			
Sodium Chloride, USP §	5.00	g			
Sterile Water for Injection, USP §	90.0	mL			
Sterile Water for Injection, USP §	q.s. to 100.0	mL			
† **Denatonium Benzoate 1% Stock Solution**					
Denatonium Benzoate (Anhydrous), NF §	0.100	g	---	---	
Sterile Water for Injection, USP §	9.0	mL	---	---	
Sterile Water for Injection, 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. **† Denatonium Benzoate 1% Stock Solution preparation:**

   A. Incrementally add the Denatonium Benzoate (Anhydrous) to the Sterile Water for Injection (9.0 mL).

   Specifications: Continuously mix until all solid particles have completely dissolved.

   End result: Homogeneous liquid-like dispersion.

   B. Add additional Sterile Water for Injection 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. **Powder-liquid preparation:**

A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (90.0 mL *plus* processing error adjustments):

-Benzyl Alcohol (Parenteral Application)
-Sodium Chloride
-Denatonium Benzoate 1% Stock Solution (1.35 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.

4. **Filling to volume:**

A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

5. **Product transferring:**

Transfer the final product (Step 4A) into the recommended dispensing containers (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility testing.

6. **Sterilization:**

Following the manufacturer's specifications, autoclave sterilize the homogeneous liquid-like solution (Step 5), then return to ambient temperature and pressure.

Specifications:

Heating temperature: 121°C
Heating time: 20minutes
Pressure: 15 psi

IMPORTANT: The temperature of the heated chamber must reach 121°C before the exposure duration is timed.

7. **Sterility testing:**

Validate the Test sample for sterility, 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.	Packaging Requirements		Sterile, heat stable, tightly closed, light-resistant inhalation bottle.
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		Protect from light.
	3	Do not use if product changes color.	9		Equilibrate to room temperature before use.
	4	Discard in the presence of particulate matter.	10		Cap tightly after use.
	5	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).	11		To be used in aerosol qualitative fit test protocol.
	6	**Hypertonic solution; it may cause irritation.**			
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions		Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

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