MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Albuterol Sulfate 3.6 mg/3 mL Inhalation Liquid (Solution, 90 mL)	FIN	F 008 679

Note: Albuterol Sulfate 3.6 mg/3 mL is equivalent to Albuterol 3.0 mg/3 mL.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Albuterol Sulfate, USP	0.108	g				
Sodium Chloride, USP	0.79	g				
Benzalkonium Chloride 5% Stock Solution †	0.36	mL				
Sterile Water for Injection, USP	80.0	mL				
Sterile Water for Injection, USP	q.s. to 90.0	mL				
Hydrochloric Acid 10% solution	As required					
† **Benzalkonium Chloride 5% Stock Solution**						
Benzalkonium Chloride Solution (50%), NF	1.0	mL				
Sterile Water for Injection, USP	8.0	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):* *Albuterol Sulfate, Benzalkonium Chloride Solution*

Air Sensitive *(protect from air whenever possible):* *Benzalkonium Chloride Solution*

Metal Reactive *(do not allow to come into contact):* *Benzalkonium Chloride Solution*

Hygroscopic *(protect from moisture whenever possible):* *Benzalkonium Chloride Solution*

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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 testing, 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.

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 90 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Albuterol Sulfate, USP §	0.108	g			
Sodium Chloride, USP §	0.79	g			
Benzalkonium Chloride 5% Stock Solution † §	0.36	mL			
Sterile Water for Injection, USP §	80.0	mL			
Sterile Water for Injection, USP §	q.s. to 90.0	mL			
Hydrochloric Acid 10% Solution §	As required				
† **Benzalkonium Chloride 5% Stock Solution**					
Benzalkonium Chloride Solution (50%), NF §	1.0	mL	---	---	
Sterile Water for Injection, USP §	8.0	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.

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2. † **Benzalkonium Chloride 5% Stock Solution preparation:**

A. Incrementally add the Benzalkonium Chloride Solution (50%) (1.0 mL) to the Sterile Water for Injection (8.0 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

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.

3. **Medium incorporation:**

A. In the given order, sequentially add the following ingredients to the Sterile Water for Injection (80.0 mL *plus* processing error adjustments):

-Albuterol Sulfate
-Benzalkonium Chloride 5% Stock Solution (0.36 mL *plus* processing error adjustments)
-Sodium Chloride

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

Note: Add the next ingredient, once the previous one has been completely added and dissolved.

4. **pH testing:**

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

B. Test the pH of the sample. It should lie between 3.0 and 5.0.

C. If the pH > 5.0, 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 3.0 to 5.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 3.0.

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5.	**Filling to volume:** A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (90.0 mL *plus* processing error adjustments). Specifications: 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 a separate dispensing container. This is to be used as the Test sample for sterility 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.	**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.
9.	**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		14 days, refrigerated as per USP 797. BUD based on successful sterility test result.	Packaging Requirements		Sterile, tightly closed, light-resistant inhalation bottle.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Discard in the presence of particulate matter.
	2	Keep out of reach of children.	8		For inhalation use only.
	3	Keep refrigerated (2°C – 8°C). Do not freeze.	9		Cap tightly after use.
	4	Do not use if product changes color.	10		Protect from light.
	5	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	11		May impair mental and/or physical ability. Use care when operating a car or machinery.
	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.			
Pharmacist Instructions		Add any auxiliary labels specific to the active ingredient 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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REFERENCES

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2.	Benzalkonium Chloride. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition*. Pharmaceutical Press and American Pharmacists Association; 2017: 96.
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