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	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Saccharin Sodium (Dihydrate), USP	0.830	g				
Benzyl Alcohol (Parenteral Application), NF	1.0	mL				
Sodium Chloride, USP	0.539	g				
Sterile Water for Injection, USP	90.0	mL				
Sterile Water for Injection, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

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.

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.

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	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

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
Saccharin Sodium (Dihydrate), USP §	0.830	g			
Benzyl Alcohol (Parenteral Application), NF §	1.0	mL			
Sodium Chloride, USP §	0.539	g			
Sterile Water for Injection, USP §	90.0	mL			
Sterile Water for Injection, USP §	q.s. to 100.0	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.	**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 -Saccharin Sodium (Dihydrate) 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.
3.	**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.

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	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

4.	**Product transferring:** Transfer the final product (Step 3A) 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.
5.	**Sterilization:** Following the manufacturer's specifications, autoclave sterilize the homogeneous liquid-like solution (Step 4), 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.
6.	**Sterility testing:** Validate the Test sample for sterility, in accordance to current USP 797 regulatory guidelines.

Suggested Formula	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated as per USP 797. BUD based on a successful sterility test result.	Packaging Requirements		Sterile, heat stable, tightly closed, light-resistant inhalation bottle.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	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.		7	Protect from light.
	3	Do not use if product changes color.		8	Equilibrate to room temperature before use.
	4	Discard in the presence of particulate matter.		9	Cap tightly after use.
	5	Keep refrigerated (2°C – 8°C). Do not freeze.		10	To be used in aerosol qualitative fit test protocol.
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.				

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	Saccharin Sodium 0.83% Inhalation Liquid (Solution, 100 mL)	FIN	F 008 675

REFERENCES

1. Inhalation Preparations. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 387.
2. Benzyl Alcohol. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition*. Pharmaceutical Press and American Pharmacists Association; 2017: 105.
3. Saccharin Sodium. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition*. Pharmaceutical Press and American Pharmacists Association; 2017: 820.
4. Sodium Choride. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition*. Pharmaceutical Press and American Pharmacists Association; 2017: 854.
5. Saccharin Sodium. In: Brayfield, A., ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 2208.
6. Saccharin (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8445.
7. Saccharin Sodium (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 3928.
8. Chapter 8: Buffered and Isotonic Solutions. In: Sinko, D. J. and Singh, Y. *Martin's Physical Pharmacy and Pharmaceutical Sciences, Sixth Edition.* Philadelphia, PA: Lipponcott Williams & Wilkins; 2011: 163-181.
9. Chapter 18: Tonicity, Osmoticity, Osmolaltiy and Osmolarity. In: D.B Troy. *Remington: The Science and Practice of Pharmacy, 21st Edition.* Baltimore, MD: Lippincott Williams & Wilkins; 2006: 250~265.
10. USP <797>. *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6959.

DISCLAIMER: THIS DOCUMENT IS COPYRIGHT© 2020 MEDISCA PHARMACEUTIQUE INC. MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY, SCHEDULING OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW. MEDISCA NETWORK INC. MAKES NO WARRANTIES WITH RESPECT TO INFRINGEMENT OR NON-INFRINGEMENT BY THE FORMULA OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY OF ANY OTHER PARTY, AND IT IS THE RESPONSIBILITY OF THE PHARMACIST OR OTHER APPROPRIATELY STATE LICENSED PROFESSIONAL TO INVESTIGATE AND DETERMINE ANY SUCH ISSUE.