MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Sertraline 100 mg/5 mL Oral Liquid (Solution, 100 mL)	FIN	F 008 758

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Sertraline Hydrochloride, USP*	2.240	g				
Alcohol 95%, USP	12.0	mL				
Tutti Frutti Flavor	0.50	mL				
Stevia Powder	0.20	g				
Medisca Oral Syrup SF (Sugar-Free Flavored Vehicle)	80.0	mL				
Medisca Oral Syrup SF (Sugar-Free Flavored Vehicle)	q.s. to 100.0	mL				
Hydrochloric Acid 10% Solution	As required					
Sodium Hydroxide 10% Solution	As required					

*Sertraline Hydrochloride 2.24 g is equivalent to Sertraline 2 g.

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Sertraline Hydrochloride*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH 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 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

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.

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
Sertraline Hydrochloride, USP §	2.240	g			
Alcohol 95%, USP	12.0	mL			
Tutti Frutti Flavor	0.50	mL			
Stevia Powder	0.20	g			
Medisca Oral Syrup SF (Sugar-Free Flavored Vehicle)	80.0	mL			
Medisca Oral Syrup SF (Sugar-Free Flavored Vehicle)	q.s. to 100.0	mL			
Hydrochloric Acid 10% Solution	As required				
Sodium Hydroxide 10% Solution	As required				

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Sertraline Hydrochloride -Stevia Powder B. Levigate the fine, homogeneous powder blend (Step 1A) with the Alcohol 95%. End result: Homogeneous liquid-like dispersion.

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2. **Medium Integration:**

A. In the given order, sequentially add the following ingredients to the Oral Syrup SF (Sugar-Free Flavored Vehicle) (80.0 mL plus processing error adjustments.)

-Tutti Frutti Flavor
-Homogeneous liquid-like dispersion (Step 1B)

Specifications: Continuously mix until all particles have dissolved.

End result: Homogeneous liquid-like solution.

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

3. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 2A).

B. Test the pH of the sample. It should lie between 4.5 and 6.0.

C. If the pH < 4.5, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 4.5 to 6.0 is obtained.

IMPORTANT: Do not allow the pH to rise above 6.0.

D. If the pH >6.0, 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 4.5 to 6.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 4.5.

4. **Filling to volume:**

A. Add additional Oral Syrup SF (Sugar-Free Flavored Vehicle) to the above mixture (Step 2A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous liquid-like solution.

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5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		Tightly closed, light-resistant dispensing bottle with metered-dose measuring device.
7Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Cap tightly after use.
	2	Keep out of reach of children.		6	Keep refrigerated (2°C – 8°C). Do not freeze.
	3	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.		8	Protect from light.
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: Sertraline Oral Liquid must be diluted before use. Mix with 4 ounces (1/2 cup) of water, ginger ale, lemon/lime soda, lemonade or orange juice ONLY. After mixing, a slight haze may appear, which is normal.**				

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REFERENCES

1. Solutions. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 263.
2. Sertraline Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 448.
3. Sertraline (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8606.
4. Sertraline Hydrochloride (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 4030.
5. USP <795>. *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.