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

Suggested Formula	Sulfamethoxazole 40 mg/mL, Trimethoprim 8 mg/mL Oral Liquid (Suspension, 150 mL)	FIN	F 007 893

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Sulfamethoxazole, USP	6.000	g				
Trimethoprim, USP	1.200	g				
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	8.0	mL				
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	120.0	mL				
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	q.s. to 150.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Sulfamethoxazole, Trimethoprim*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error 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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 150 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Sulfamethoxazole, USP §	6.000	g			
Trimethoprim, USP §	1.200	g			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	8.0	mL			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	120.0	mL			
Medisca Oral Mix SF (Sugar-Free Flavored Suspending Vehicle)	q.s. to 150.0	mL			

* 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. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Sulfamethoxazole -Trimethoprim B. Levigate the fine, homogeneous powder blend (Step 1A) with the Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) (8.0 mL *plus* processing error adjustments). End result: Homogeneous paste-like dispersion.
2.	**Powder-liquid integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) (120.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add additional Oral Mix SF (Sugar-Free Flavored Suspending Vehicle) to the mixture (Step 2A) to fill to the required batch size (150.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.

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4.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements"). Note: Continuously mix the final product during the transfer process in order to maintain homogeneity.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date & Packaging Requirements	Amber PET bottle or PreciseDose Dispenser™ Amber Syringe: 90 days at 5°C or 25°C, based on available stability studies through Medisca*.			
	*Suggested BUD is based on the **exact** execution of the indicated ingredient list, quantities and procedures listed within this formulation. ***Note:*** ***This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.***			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	Keep out of reach of children.	7	Protect from light.
	3	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	8	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Keep refrigerated (Do not freeze) OR keep at room temperature (25°C).	9	**Shake well before use.**
	5	Keep in a dry place.	10	
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.			

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