MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Blank Oral Troches (Solid Suspension, 30 x 0.9 mL Troches)	FIN	F 008 741

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
APIs**	TBD					
Gelatin (Powder), USP	0.30	g				
Stevia Powder	0.90	g				
Tutti Frutti Flavor	1.0	mL				
Polyethylene Glycol 400, NF	0.3	mL				
Colloidal Silicon Dioxide, NF	0.30	g				
Polyethylene Glycol 1450, NF	26.77	g				

**Note: APIs can be added by using 0.7 displacement factor to accordingly reduce Polyethylene Glycol 1450.

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Stevia Powder, Colloidal Silicon Dioxide, Polyethylene Glycol 400*

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. 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 30 x 0.9 mL Troches)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
APIs	TBD				
Gelatin (Powder), USP	0.30	g			
Stevia Powder	0.90	g			
Tutti Frutti Flavor	1.0	mL			
Polyethylene Glycol 400, NF	0.3	mL			
Colloidal Silicon Dioxide, NF	0.30	g			
Polyethylene Glycol 1450, NF	26.77	g			

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

Preparatory Instruction	
1.	**Preparatory step:** A. Prepare a hot water bath. Specifications: Temperature: 60 to 65°C.
2.	**Powder preparation:** A. Triturate the APIs to form a fine, homogeneous powder blend. B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend: -Fine, homogeneous powder blend (Step 2A) -Gelatin (Powder) -Stevia Powder -Colloidal Silicon Dioxide

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3. **Powder-liquid to medium integration:**

A. Using the hot water bath, melt the Polyethylene Glycol 1450.

Specifications: Continuously mix.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous liquid-like solution.

B. Using the hot water bath, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 3A):

-Polyethylene Glycol 400
-Tutti Frutti Flavor
-Homogeneous powder blend (Step 2B)

Specifications: Continuously mix, using high-shear mixing techniques.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous liquid-like dispersion.

Important: Do not allow the temperature to exceed 65°C.

4. **Mold filling:**

A. Fill the 30 mold cavities with the homogeneous liquid-like dispersion (Step 3B). If the mixture starts to solidify while filling, reheat to 60 to 65°C, and continue.

B. Allow to cool until the API mixture has completely solidified.

Note: Continuously mix the final product during the mold filling in order to maintain homogeneity.

5. **Validation technique:**

A. Weigh 6 troches separately.

B. The final weight of each troche from Step 5A (not including the weight of the troche mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight in accordance to USP guidelines.

6. **Product transfer:**

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.		Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or wide-mouth jar, or dispensed in a troche mold and covered with light-resistant sleeve.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4	Keep in a dry place.
	2	Keep out of reach of children.	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Keep at controlled room temperature (20°C – 25°C).		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

*** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.**

REFERENCES

1. Lozenges, Troches, and Films. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmaceutical Association; 2016: 215.
2. Polyethylene Glycol. In: Rowe RC. Handbook of Pharmaceutical Excipients, 7th Edition. American Pharmaceutical Association; 2012: 585.
3. USP <795>. *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.