MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Folic Acid 1 mg Oral Disintegrating Tablets (Solid Suspension, 100 x 0.125 in [0.151 mL] Tablets)	FIN	F 006 593

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Folic Acid, USP	TBD					
Mango Flavor (Powder)	0.13	g				
Raspberry Flavor (Powder)	0.07	g				
Vanillin Flavor (Powder)	0.03	g				
Stevia Powder	0.015	g				
F-MELT® (Type C) Base	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Folic Acid*

Hygroscopic *(protect from moisture whenever possible):* *F-MELT® (Type C), Stevia Powder*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

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 Tablets)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Folic Acid, USP §	TBD				
Mango Flavor (Powder)	0.13	g			
Raspberry Flavor (Powder)	0.07	g			
Vanillin Flavor (Powder)	0.03	g			
Stevia Powder §	0.015	g			
F-MELT® (Type C) Base §	TBD				

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

Preparatory Instruction	
1.	**Ingredient quantification:**

A. Determine the potency of Folic Acid based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Folic Acid, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Folic Acid, in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Folic Acid required to make 100 Tablets of Folic Acid 1 mg:

Quantity of Folic Acid needed for each tablet	0.001 g
DIVIDED BY	
Potency of Folic Acid, in decimal (Step 1Ai)	_____
EQUALS	
i. Actual Quantity of Folic Acid needed for each tablet	_____ **g**
MULTIPLIED BY	
Number of tablets	100
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Total Quantity of Folic Acid needed *plus* processing error adjustments	_____ **g**

3. **Calculate the quantity of F-MELT® (Type C) Base required for 100 x 0.125 in [0.151 mL] Tablets:**

A. Determine the average Die fill weight by filling and weighing a TARED Die with the F-MELT® (Type C) Base, **five times**. Divide the total weight by **5** to obtain average weight. _____ g **(A)**

B. Quantity of F-MELT® (Type C) Base required per Die = (A) – (**Step 2Ai*** + 0.00245 g) _____ g **(B)**
*quantity of Folic Acid per tablet.

C. Total quantity of F-MELT® (Type C) Base required for the batch = (B) x 100 Tablets _____ g **(C)**

D. Quantity of F-MELT® (Type C) Base to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g **(D)**

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4. **Powder preparation:**

A. Pass the F-MELT® (Type C) Base through a 40 or 50 mesh sieve and weigh the required quantity (**D**).

B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Folic Acid (amount determined in Step 2Aii)
-Mango Flavor (Powder)
-Raspberry Flavor (Powder)
-Vanillin Flavor (Powder)
-Stevia Powder

C. By geometric addition, combine and mix, using a manual tumbler mixer, (DO NOT TRITURATE) the following ingredients together to form a homogeneous powder blend:

-Sieved F-MELT® (Type C) Base (Step 4A)
-Homogeneous powder blend (Step 4B)

5. **Mold filling:**

A. **Fill the die**: Set the die and its holder on the base of the press with the beveled edge of the die resting on the flat surface in the reversible holder. Pour the charge into the die cavity and tamp with a stirring rod, if necessary.

B. **Compress the charge**: Transfer the die and its holder to the press and push the lever down to compress the charge. To obtain maximum compression, the lever should require a firm push as it moves through its full stroke. If a full stroke is not obtained, turn the anvil to lower or raise the die until the full mechanical advantage of the press can be utilized.

C. **Reverse the die holder**: Raise the lever and slide the die and its holder out of the press. Reverse the holder to bring the deep cavity under the die and return the parts to their original position.

D. **Eject the pellet**: Bring the lever down gently to eject the pellet into the cavity in the holder. If a thick pellet is not ejected by this stroke, turn the anvil to raise the die. The pellet will then drop out freely. Remove the pellet with tweezers or forceps; reverse the holder and **repeat the cycle if additional tablets are required.**

6. **Validation technique:**

A. Weigh 20 tablets separately.

B. The final weight of each tablet should fall between 90 and 110% of the theoretically calculated weight **(A)**, in accordance to USP 795 guidelines.

7. **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		Tightly closed, light-resistant vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.	
	2	Keep out of reach of children.	6	Keep at room temperature (20°C – 23°C).	
	3	Cap tightly after use.	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	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.				

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

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REFERENCES

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