



Suggested Formula	Folic Acid 1 mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 003 545v4
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Folic Acid, USP	0.100	g				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	90.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

*Folic Acid*

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Folic Acid, USP §	0.100	g			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	90.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL			
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.	<b><u>Powder-liquid preparation:</u></b>  A. Triturate the Folic Acid to form a fine, homogeneous powder.  B. Levigate the fine, homogeneous powder (Step 1A) with the Tutti Frutti Flavor.  <u>End result:</u> Homogeneous liquid-like dispersion.
2.	<b><u>Medium integration:</u></b>  A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Syrup (Flavored Vehicle) (90.0 mL <i>plus</i> processing error adjustments).  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous liquid-like dispersion.
3.	<b><u>Filling to volume:</u></b>  A. Add additional Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous liquid-like dispersion.



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4.	<p><b><u>pH testing:</u></b></p> <p>A. Draw an appropriate amount of the mixture (Step 3A).</p> <p>B. Test the pH of the sample. It should lie between 8.0 and 8.5.</p> <p>C. <u>If the pH &lt; 8.0, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:</u></p> <ol style="list-style-type: none"> <li>1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.</li> <li>2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.</li> <li>3. Re-test the pH.</li> <li>4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 8.0 to 8.5 is obtained.</li> </ol> <p>IMPORTANT: Do not allow the pH to rise above 8.5.</p> <p><u>End result:</u> Homogeneous liquid-like <b><u>solution.</u></b></p>
5.	<p><b><u>Product transfer</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p>

**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.	Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1 Use as directed. Do not exceed prescribed dose.	4	Keep refrigerated. Do not freeze.
	2 Keep out of reach of children.	5	Cap tightly after use.
	3 Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	6	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.		



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## REFERENCES

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4.	Folic Acid (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #4221.
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