



Suggested Formula	Simethicone 40 mg/mL Oral Liquid (Suspension, 50 mL)	FIN	F 002 531v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Simethicone, USP	2.000	g				
Cellulose (Microcrystalline), NF	4.00	g				
Polysorbate 80, NF	2.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 50.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): Polysorbate 80, Cellulose

Light Sensitive (protect from light whenever possible): Polysorbate 80

Oxygen Sensitive (protect from oxygen whenever possible): Polysorbate 80

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: 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 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Simethicone, USP	2.000	g			
Cellulose (Microcrystalline), NF §	4.00	g			
Polysorbate 80, NF §	2.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 50.0	mL			

§ Weigh / measure just prior to use.

* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction	
1.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and mix the following ingredients together to form a homogeneous paste-like dispersion:</p> <ul style="list-style-type: none">-Simethicone-Cellulose (Microcrystalline) <p>B. Incrementally add the Polysorbate 80 to the homogeneous paste-like dispersion (Step 1A).</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
2.	<p><u>Medium integration:</u></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><u>Filling to volume:</u></p> <p>A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



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4.	<p><u>Product transfer:</u></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>
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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.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	Shake well before 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.	7	Keep refrigerated. Do not freeze.
	4	Protect from light.		
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			



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REFERENCES

1.	Cellulose, microcrystalline. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 108.
2.	Polyoxyethylene Sorbitan Fatty Acid Esters. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 479.
3.	Simethicone. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 541.
4.	Simethicone (Monograph). <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 1768.
5.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.

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