



Suggested Formula	Scopolamine Hydrobromide 75 µg/2.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 2.5 mL Pouches)	FIN	F 006 636
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Scopolamine Hydrobromide 1% Stock Powder Blend †	0.225	g				
Mango Flavor (Powder)	1.050	g				
Raspberry Flavor (Powder)	0.900	g				
Vanillin Flavor (Powder)	0.300	g				
Stevia Powder	0.225	g				
Medisca FizzMix™ Base	TBD					
† Scopolamine Hydrobromide 1% Stock Powder Blend						
Scopolamine Hydrochloride, USP	0.100	g				
Mannitol, USP	9.90	g				

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
<i>Light sensitive (protect from light whenever possible):</i>	<i>Scopolamine Hydrobromide</i>
<i>Hygroscopic (protect from moisture whenever possible):</i>	<i>FizzMix™ Base, Stevia Powder</i>
<u>Suggested Preparatory Guidelines</u>	
<input checked="" type="checkbox"/> Non-Sterile Preparation	<input type="checkbox"/> Sterile Preparation
<u>Processing Error / Testing Considerations:</u>	To account for processing errors and considerations during preparation, it is suggested to measure an additional 3 to 5% of the required quantities of ingredients.
<u>Special Instruction:</u>	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 30 x 2.5 mL pouches)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Scopolamine Hydrobromide 1% Stock Powder Blend † §	0.225	g			
Mango Flavor (Powder)	1.05	g			
Raspberry Flavor (Powder)	0.90	g			
Vanillin Flavor (Powder)	0.30	g			
Stevia Powder §	0.225	g			
Medisca FizzMix™ Base §	TBD				
† Scopolamine Hydrobromide 1% Stock Powder Blend					
Scopolamine Hydrochloride, USP	0.100	g	--	--	
Mannitol, USP	9.90	g	--	--	

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Calculate the quantity of FizzMix™ Base required for 30 × 2.5 mL Pouches:</u></p> <p>A. Determine the average BULK bin fill weight by filling and weighing TWO TARED bins with the sieved FizzMix™ Base (DO NOT TRITIURATE or TAP THE BASE). Divide the total weight by 2 to obtain <u>average</u> weight. _____ g (A)</p> <p>B. Quantity of FizzMix™ Base required per bin = (A) – (0.09 g) * _____ g (B) *[Quantity of Scopolamine Hydrobromide 1% Stock, Flavors and Sweetener per bin]</p> <p>C. Total quantity of FizzMix™ Base required for the batch = (B) x 30 bins _____ g (C)</p> <p>D. Quantity of FizzMix™ Base to weigh with processing error = (C) x 1.03 ~ 1.05 _____ g (D)</p>
2.	<p><u>† Scopolamine Hydrobromide 1% Stock Powder Blend preparation:</u></p> <p>A. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <p>-Scopolamine Hydrobromide (0.100 g) -Mannitol (9.90 g)</p>



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3.	<p><u>Powder preparation:</u></p> <p>A. Pass the FizzMix™ Base through a 30 mesh sieve and weigh the required quantity (quantity determined in Step 1D).</p> <p>B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">-Scopolamine Hydrobromide 0.1% Stock Powder Blend (0.225 g <i>plus</i> processing error adjustments)-Mango Flavor (Powder)-Raspberry Flavor (Powder)-Vanillin Flavor (Powder)-Stevia Powder <p>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:</p> <ul style="list-style-type: none">-Sieved FizzMix™ Base (Step 3A)-Homogeneous powder blend (Step 3B)
4.	<p><u>Product transfer:</u></p> <p>Fill each of 30 × 2.5 mL bins with the homogeneous powder blend (Step 3C). Do not tap the device on the bench while filling as the API(s) and FizzMix™ Base have been calibrated to determine their BULK DENSITY.</p>
5.	<p><u>Validation technique:</u></p> <p>The final weight of each bin (not including the bin shell) should fall between 90 and 110% of the theoretically calculated weight, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by the amount in Step 1A.</p>
6.	<p><u>Product transfer:</u></p> <p>Transfer the contents of each filled bin into the specified dispensing container (see “Packaging Requirements”).</p>



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	- Pack into 100 × 80 mm moisture barrier bags and put into suitable container.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	6	Keep in a dry place.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep at room temperature (20°C – 23°C).	8	Discard container after use.
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredients to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions. Note: Disperse one pouch into 6 to 8 ounces of water and mix until homogeneous before taking the mixture.			

* 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.	Powders and Granules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 141.
2.	Hyoscine Hydrobromide. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1734.
3.	Scopolamine (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8406.
4.	Scopolamine Hydrobromide. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 433.
5.	Scopolamine Hydrobromide (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 5813.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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