



Suggested Formula	Glutamine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 7.5 mL Pouches)	FIN	F 006 945
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Glutamine (L), USP	15.000	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					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible): FizzMix™ Base, 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 **3 to 5%** 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 30 x 7.5 mL pouches)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Glutamine (L), USP	15.000	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				

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

§ Weigh / measure just prior to use.

**Preparatory Instruction**

<b>1.</b>	<p><b><u>FizzMix™ Base requirements for 30 × 7.5 mL Bins</u></b></p> <p>A. Calculate the amount of FizzMix™ Base required for the batch. Refer to attached appendix for details.</p>
<b>2.</b>	<p><b><u>Powder preparation:</u></b></p> <p>A. Pass the FizzMix™ Base through a 30 mesh sieve and weigh the required quantity (quantity determined in appendix <b>(I)</b>).</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"> <li>-Glutamine (L)</li> <li>-Mango Flavor (Powder)</li> <li>-Raspberry Flavor (Powder)</li> <li>-Vanillin Flavor (Powder)</li> <li>-Stevia Powder</li> </ul> <p>C. By geometric addition, combine and mix, using a manual tumbler mixer (<b>DO NOT TRITURATE</b>) the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none"> <li>-Sieved FizzMix™ Base (Step 2A)</li> <li>-Homogeneous powder blend (Step 2B)</li> </ul>



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3.	<p><b><u>Product transfer:</u></b></p> <p>Fill each of 30 × 7.5 mL bins with the homogeneous powder blend (Step 2C). Do not tap the device on the bench while filling as the API(s) and FizzMix™ Base have been calibrated to determine their <b>BULK DENSITY</b>.</p>		
4.	<p><b><u>Validation technique:</u></b></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 adding the amount in appendix (G) + <b>0.5825 g</b> together.</p>		
5.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the contents of each filled bin into the specified dispensing container (see “Packaging Requirements”).</p>		

**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.	4	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.	5	Keep in a dry place.
	3	Keep at room temperature (20°C – 23°C).	6	Discard container after use.
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredients to the dispensing container as deemed necessary.			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p><b>Note:</b> Disperse one pouch into 6 to 8 ounces of water and mix until homogeneous before taking the mixture.</p>			

\* 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

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.	Glutamine. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1947.
3.	Glutamine (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #4507.
4.	Glutamine (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 4126.
5.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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Appendix	Calculating the quantity of excipient required for the batch		
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**Procedure**

<b>1.</b>	<b><u>Bin filling:</u></b>	<p>a. For <u>each</u> ingredient powder below, determine the average bulk bin fill weight by filling and weighing two TARED BINS. Do not forget to divide the total weight by 2 to obtain an <u>average</u> bulk bin fill weight. Also, crush and triturate the ingredient first if required in formulation (DO NOT TRITURATE THE BASE). <b><u>SIEVE THE BASE AND API BEFORE CALIBRATION. DO NOT TAP THE BASE OR THE API.</u></b></p> <p>Plug each amount into Step 2, column B.</p>		
<b>2.</b>	<b><u>Volume Percent Occupied:</u></b>	<b>Column A</b>	<b>Column B</b>	<b>Column C</b>
	<u>Ingredients</u>	Quantity Required per bin	Average bulk bin fill weight	A/B x 100 equals percent filled
	a. Glutamine (L)	0.500 g	_____ g	_____ %
	b. FizzMix™ Base		_____ g	
	c. Total (add column C together)			_____ % <b>(D)</b>
<b>3.</b>	<b><u>Calculate the quantity of FizzMix™ Base required for the batch:</u></b>	<p>a. Percent of FizzMix™ Base required = 100% – (D) _____ % <b>(E)</b></p> <p>b. Average bulk bin fill weight of FizzMix™ Base (from column B, Step 2b): _____ g <b>(F)</b></p> <p>c. Quantity of FizzMix™ Base required per bin = [(E) ÷ 100 × (F)] – (0.0825 g)* _____ g <b>(G)</b>          *[Quantity of flavors and sweetener per bin]</p> <p>d. Total Quantity of FizzMix™ Base required for the batch = 30 bins × (G) _____ g <b>(H)</b></p> <p>e. Total quantity of FizzMix™ Base <i>plus</i> processing error = (H) × 1.03-1.05 _____ g <b>(I)</b></p>		

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