



Suggested Formula	Calcium Citrate 711 mg/7.5 mL, Magnesium Citrate 619 mg/7.5 mL, Zinc Sulfate 34.25 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 7.5 mL Pouches)	FIN	F 006 946
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Note: Calcium Citrate Tetrahydrate 711 mg is equivalent to Calcium 150 mg;
Magnesium Citrate (Tribasic) 619 mg is equivalent to Magnesium 100 mg;
Zinc Sulfate (Monohydrate) 34.25 mg is equivalent to Zinc 12.5 mg.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Calcium Citrate Tetrahydrate, USP	21.330	g				
Magnesium Citrate (Tribasic), USP	18.570	g				
Zinc Sulfate (Monohydrate), USP	1.028	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

<u>Ingredient-Specific Information</u>	
Hygroscopic (protect from moisture whenever possible):	FizzMix™ Base, Stevia Powder
<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 1 to 3% 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 7.5 mL pouches)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Calcium Citrate Tetrahydrate, USP	21.330	g			
Magnesium Citrate (Tribasic), USP	18.570	g			
Zinc Sulfate (Monohydrate), USP	1.028	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

1.	<p><u>FizzMix™ Base requirements for 30 × 7.5 mL Bins</u></p> <p>A. Calculate the amount of FizzMix™ Base required for the batch. Refer to attached appendix for details.</p>
2.	<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 appendix (I)).</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"> -Calcium Citrate Tetrahydrate -Magnesium Citrate (Tribasic) -Zinc Sulfate (Monohydrate) -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 2A) -Homogeneous powder blend (Step 2B)



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3.	<p><u>Product transfer:</u></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 BULK DENSITY.</p>
4.	<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 adding the amount in appendix (G) + 1.447 g together.</p>
5.	<p><u>Product transfer:</u></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 mm × 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>Note: 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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2.	Calcium Citrate. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1675.
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Appendix	Calculating the quantity of excipient required for the batch		
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Procedure

1.	<u>Bin filling:</u>			
	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). <u>SIEVE THE BASE AND API BEFORE CALIBRATION. DO NOT TAP THE BASE OR THE API.</u>		
		Plug each amount into Step 2, column B.		
2.	<u>Volume Percent Occupied:</u>	Column A	Column B	Column C
	<u>Ingredients</u>	Quantity Required per bin	Average bulk bin fill weight	A/B x 100 equals percent filled
	a.	Calcium Citrate Tetrahydrate 0.711 g	_____ g	_____ %
	b.	Magnesium Citrate (Tribasic) 0.619 g	_____ g	_____ %
	c.	FizzMix™ Base	_____ g	
	d.	Total (add column C together)		_____ % (D)
3.	<u>Calculate the quantity of FizzMix™ Base required for the batch:</u>			
	a.	Percent of FizzMix™ Base required = 100% – (D)		_____ % (E)
	b.	Average bulk bin fill weight of FizzMix™ Base (from column B, Step 2c):		_____ g (F)
	c.	Quantity of FizzMix™ Base required per bin = [(E) ÷ 100 × (F)] – (0.117 g)* *[Quantity of Zinc Sulfate, Flavors and Sweetener per bin]		_____ g (G)
	d.	Total Quantity of FizzMix™ Base required for the batch = 30 bins × (G)		_____ g (H)
	e.	Total quantity of FizzMix™ Base <i>plus</i> processing error = (H) × 1.01-1.03		_____ g (I)

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