**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 x 7.5 mL Pouches)

**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**

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>NDC #</th>
<th>Supplier</th>
<th>Lot Number</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Citrate Tetrahydrate, USP</td>
<td>21.330</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Citrate (Tribasic), USP</td>
<td>18.570</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zinc Sulfate (Monohydrate), USP</td>
<td>1.028</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mango Flavor (Powder)</td>
<td>1.050</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raspberry Flavor (Powder)</td>
<td>0.900</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanillin Flavor (Powder)</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stevia Powder</td>
<td>0.225</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca FizzMix™ Base</td>
<td>TBD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 **1 to 3%** 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.
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 x 7.5 mL Pouches)

SUGGESTED PREPARATION (for 30 x 7.5 mL pouches)

Weigh and / or measure the following ingredients when appropriate:

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>Multiplication factor (*)</th>
<th>Processing Error</th>
<th>Qty. to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Citrate Tetrahydrate, USP</td>
<td>21.330</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Citrate (Tribasic), USP</td>
<td>18.570</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zinc Sulfate (Monohydrate), USP</td>
<td>1.028</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mango Flavor (Powder)</td>
<td>1.05</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raspberry Flavor (Powder)</td>
<td>0.90</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanillin Flavor (Powder)</td>
<td>0.30</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stevia Powder §</td>
<td>0.225</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca FizzMix™ Base §</td>
<td>TBD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

§ Weigh / measure just prior to use.

Preparatory Instruction

1. **FizzMix™ Base requirements for 30 x 7.5 mL Bins**
   
   A. Calculate the amount of FizzMix™ Base required for the batch. Refer to attached appendix for details.

2. **Powder preparation:**
   
   A. Pass the FizzMix™ Base through a 30 mesh sieve and weigh the required quantity (quantity determined in appendix (I)).
   
   B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:
      
      - Calcium Citrate Tetrahydrate
      - Magnesium Citrate (Tribasic)
      - Zinc Sulfate (Monohydrate)
      - Mango Flavor (Powder)
      - Raspberry Flavor (Powder)
      - Vanillin Flavor (Powder)
      - Stevia Powder
   
   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:
      
      - Sieved FizzMix™ Base (Step 2A)
      - Homogeneous powder blend (Step 2B)
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 x 7.5 mL Pouches) | FIN | F 006 946 |

3. **Product transfer:**

   Fill each of 30 x 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**.

4. **Validation technique:**

   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.

5. **Product transfer:**

   Transfer the contents of each filled bin into the specified dispensing container (see “Packaging Requirements”).

**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months, as per USP*</td>
<td>- Pack into 100 mm x 80 mm moisture barrier bags and put into suitable container.</td>
</tr>
</tbody>
</table>

| 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**

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.
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)

REFERENCES


### Appendix

Calculating the quantity of excipient required for the batch

---

#### Procedure

1. **Bin filling:**
   
a. For each 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 **average** bulk bin fill weight. Also, crush and triturate the ingredient first if required in formulation (DO NOT TRITURATE THE BASE). **SIEVE THE BASE AND API BEFORE CALIBRATION. DO NOT TAP THE BASE OR THE API.**

   Plug each amount into Step 2, column B.

2. **Volume Percent Occupied:**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Column A</th>
<th>Column B</th>
<th>Column C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity Required per bin</td>
<td>Average bulk bin fill weight</td>
<td>A/B x 100 equals percent filled</td>
</tr>
<tr>
<td>a. Calcium Citrate Tetrahydrate</td>
<td>0.711 g</td>
<td>_______ g</td>
<td>_______ %</td>
</tr>
<tr>
<td>b. Magnesium Citrate (Tribasic)</td>
<td>0.619 g</td>
<td>_______ g</td>
<td>_______ %</td>
</tr>
<tr>
<td>c. FizzMix™ Base</td>
<td></td>
<td>_______ g</td>
<td></td>
</tr>
<tr>
<td>d. Total (add column C together)</td>
<td></td>
<td>_______ g</td>
<td>_______ % (D)</td>
</tr>
</tbody>
</table>

3. **Calculate the quantity of FizzMix™ Base required for the batch:**

   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)* _______ g (G)*[Quantity of Zinc Sulfate, Flavors and Sweetener per bin]
   
d. Total Quantity of FizzMix™ Base required for the batch = 30 bins × (G) _______ g (H)
   
e. Total quantity of FizzMix™ Base plus processing error = (H) × 1.01-1.03 _______ g (I)

---

**DISCLAIMER:** MEDISCA NETWORK INC., HEREBY REFERRED TO AS ‘THE NETWORK’, HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY OR ACCURACY OF THIS INFORMATION OR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER’S PRESCRIPTION. THE PHARMACIST MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.