Suggested Formula
Glutamine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 7.5 mL Pouches)

<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>Glutamine (L), USP</td>
<td>15.000</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 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.
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>Glutamine (L), USP</td>
<td>15.000</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:
      
      - Glutamine (L)
      - 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

| 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 |

### 3. Product transfer:

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**.

### 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) + 0.5825 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 × 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.
- **2.** Keep out of reach of children.
- **3.** Keep at room temperature (20°C – 23°C).

#### 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.
# Glutamine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution
(Powder Blend, 30 × 7.5 mL Pouches)

<table>
<thead>
<tr>
<th>Suggested Formula</th>
<th>FIN</th>
<th>F 006 945</th>
</tr>
</thead>
</table>

## 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 Quantity Required per bin</th>
<th>Column B Average bulk bin fill weight</th>
<th>Column C A/B x 100 equals percent filled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutamine (L)</td>
<td>0.500 g</td>
<td>________ g</td>
<td>________ %</td>
</tr>
<tr>
<td>FizzMix™ Base</td>
<td></td>
<td>________ g</td>
<td></td>
</tr>
<tr>
<td>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 2b): ________ g (F)
   c. Quantity of FizzMix™ Base required per bin = [(E) ÷ 100 × (F)] – (0.0825 g)* ________ g (G) *(Quantity of 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) × 1.03-1.05 ________ g (I)

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