Suggested Formula

<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>Chondroitin Sulfate Sodium, USP</td>
<td>TBD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucosamine Sulfate Potassium Chloride, USP</td>
<td>38.010</td>
<td>g</td>
<td></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>
<td></td>
</tr>
<tr>
<td>Raspberry Flavor (Powder)</td>
<td>0.90</td>
<td>g</td>
<td></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>
<td></td>
</tr>
<tr>
<td>Stevia Powder</td>
<td>0.23</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>

Note: Glucosamine Sulfate Potassium Chloride 1267 mg is equivalent to Glucosamine 750 mg.

SUGGESTED FORMULATION

SPECIAL PREPARATORY CONSIDERATIONS

**Ingredient-Specific Information**

- **Hygroscopic** (protect from moisture whenever possible): FizzMix™ Base, Stevia Powder
- **Light sensitive** (protect from light whenever possible): Chondroitin Sulfate Sodium, Glucosamine Sulfate Potassium Chloride

**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>Chondroitin Sulfate Sodium, USP §</td>
<td>TBD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucosamine Sulfate Potassium Chloride, USP §</td>
<td>38.010 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mango Flavor (Powder)</td>
<td>1.05 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raspberry Flavor (Powder)</td>
<td>0.90 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanillin Flavor (Powder)</td>
<td>0.30 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stevia Powder §</td>
<td>0.23 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>
</tr>
</tbody>
</table>

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

**Preparatory Instruction**

1. **Ingredient quantification:**

   A. Determine the potency of Chondroitin Sulfate Sodium based on the certificate of analysis:

   MINUS
   
   Loss on drying (from certificate of analysis)  
   __________ %
   
   DIVIDED BY
   
   100
   
   EQUALS
   
   Quantity of dried Chondroitin Sulfate Sodium, in decimal  
   __________
   
   MULTIPLIED BY
   
   Assay on dried basis result (from certificate of analysis)  
   __________ %
   
   DIVIDED BY
   
   100
   
   EQUALS
   
   i. Potency of Chondroitin Sulfate Sodium, in decimal  
   __________
### Ingredient quantification:

A. Determine the quantity (in g) of Chondroitin Sulfate Sodium required to make 30 Pouches of Chondroitin Sulfate Sodium 600 mg:

| Suggested Formula | Chondroitin Sulfate Sodium 600 mg/7.5 mL, Glucosamine Sulfate Potassium Chloride 1267 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 7.5 mL Pouches) | FIN | F 006 947 |

2. **Ingredient quantification:**

   A. Determine the quantity (in g) of Chondroitin Sulfate Sodium required to make 30 Pouches of Chondroitin Sulfate Sodium 600 mg:

   - Quantity of Chondroitin Sulfate Sodium needed for each pouch = 0.600 g
     - DIVIDED BY
     - Potency of Chondroitin Sulfate Sodium, in decimal (Step 2Ai)
       - ________
     - EQUALS
     - i. Quantity of Chondroitin Sulfate Sodium needed for each pouch = ________ g
       - MULTIPLIED BY
       - Number of pouches = 30
       - EQUALS
     - ii. Quantity of Chondroitin Sulfate Sodium needed for the batch = ________ g
       - MULTIPLIED BY
       - Processing error adjustments (3 to 5%) = 1.03 to 1.05
       - EQUALS
     - iii. Quantity of Chondroitin Sulfate Sodium needed plus processing error adjustments = ________ g

3. **FizzMix™ Base requirements for 30 × 7.5 mL Bins**

   A. Calculate the amount of FizzMix™ Base required for the batch. Refer to attached appendix for details.
### Suggested Formula

<table>
<thead>
<tr>
<th>Chondroitin Sulfate Sodium 600 mg/7.5 mL, Glucosamine Sulfate Potassium Chloride 1267 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 7.5 mL Pouches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIN</td>
</tr>
</tbody>
</table>

#### 4. 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:

- Chondroitin Sulfate Sodium (amount determined in Step 2Aiii)
- Glucosamine Sulfate Potassium Chloride
- 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 4A)
- Homogeneous powder blend (Step 4B)

#### 5. Product transfer:

Fill each of 30 × 7.5 mL bins with the homogeneous powder blend (Step 4C). 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**.

#### 6. 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) + 1.349 g + (Step 2A1i) g together.

#### 7. 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.

**REFERENCES**


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### Appendix

Calculating the quantity of excipient required for the batch

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**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>Chondroitin Sulfate Sodium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucosamine Sulfate</td>
<td>1.267 g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FizzMix™ Base</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (add column C together)</td>
<td></td>
<td></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)] − (0.0825 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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