MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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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

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

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Chondroitin Sulfate Sodium, USP	TBD					
Glucosamine Sulfate Potassium Chloride, USP	38.010	g				
Mango Flavor (Powder)	1.05	g				
Raspberry Flavor (Powder)	0.90	g				
Vanillin Flavor (Powder)	0.30	g				
Stevia Powder	0.23	g				
Medisca FizzMix™ Base	TBD					

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.

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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
Chondroitin Sulfate Sodium, USP §	TBD				
Glucosamine Sulfate Potassium Chloride, USP §	38.010	g			
Mango Flavor (Powder)	1.05	g			
Raspberry Flavor (Powder)	0.90	g			
Vanillin Flavor (Powder)	0.30	g			
Stevia Powder §	0.23	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. **Ingredient quantification:**

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

	100%
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	_____

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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.

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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 2Ai) g** together.
7.	**Product transfer:** Transfer the contents of each filled bin into the specified dispensing container (see “Packaging Requirements”).

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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		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

1. Powders and Granules. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 141.
2. Chondroitin Sulfate Sodium. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 2280.
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4. Chondroitin Sulfate Sodium (Monograph). *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 6566.
5. Glucosamine Sulfate. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition*. London, England: The Pharmaceutical Press; 2009: 2313.
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8. USP <795>. *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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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:**

Ingredients	**Column A** Quantity Required per bin	**Column B** Average bulk bin fill weight	**Column C** A/B x 100 equals percent filled
a. Chondroitin Sulfate Sodium	_____ Step 2Ai from Main Formula	_____ **g**	_____ %
b. Glucosamine Sulfate	1.267 g	_____ **g**	_____ %
c. FizzMix™ Base		_____ **g**	
d. Total (add column C together)			_____ % **(D)**

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)**