MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Calcium Citrate 285 mg, Magnesium Citrate 618 mg, Potassium Citrate 276 mg, Pyridoxine Hydrochloride 37 mg, Sodium Chloride 61 mg Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 × 5 mL Pouches)	FIN	F 008 258

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Calcium Citrate (Hydrate), USP	8.550	g				
Magnesium Citrate (Anhydrous), USP	18.540	g				
Potassium Citrate, USP	8.280	g				
Pyridoxine Hydrochloride, USP	1.110	g				
Sodium Chloride, USP	1.830	g				
Orange Flavor (Powder)	2.00	g				
Stevia Powder (Stevioside)	1.00	g				
Citric Acid (Monohydrate), USP	TBD					
Sodium Bicarbonate, USP	TBD					

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SPECIAL PREPARATORY CONSIDERATIONS.

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):*	*Pyridoxine Hydrochloride*
Hygroscopic *(protect from moisture whenever possible):*	*Potassium Citrate, Sodium Chloride, Stevia Powder*
Moisture Sensitive *(protect from humidity whenever possible):*	*Citric Acid, Sodium Bicarbonate*

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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 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 (Hydrate), USP	8.550	g			
Magnesium Citrate (Anhydrous), USP	18.540	g			
Potassium Citrate, USP §	8.280	g			
Pyridoxine Hydrochloride, USP §	1.110	g			
Sodium Chloride, USP §	1.830	g			
Orange Flavor (Powder)	2.00	g			
Stevia Powder (Stevioside) §	1.00	g			
Citric Acid (Monohydrate), USP §	TBD				
Sodium Bicarbonate, USP §	TBD				

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

Preparatory Instruction	
1.	**Excipient requirements for 30 × 5 mL Bins** A. Calculate the amount of Citric Acid (Monohydrate) and Sodium Bicarbonate required for the batch. Refer to attached appendix for details.

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2.	**Powder preparation:** A. Weigh the required quantities of Sodium Bicarbonate (quantities determined in appendix **(K)**) then pass through a 30 mesh sieve and mix to form a homogeneous powder (DO NOT TRITURATE). B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Citric Acid (Monohydrate) (quantities determined in appendix **(M)**) -Calcium Citrate (Hydrate) -Magnesium Citrate (Anhydrous) -Potassium Citrate -Pyridoxine Hydrochloride -Sodium Chloride -Orange Flavor (Powder) -Stevia Powder (Stevioside) 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 homogeneous powder (Step 2A) -Fine, homogeneous powder blend (Step 2B)
3.	**Product transfer:** Fill each of 30 × 5 mL bins with the homogeneous powder blend (Step 2C). Do not tap the device on the bench while filling as the API(s), Citric Acid (Monohydrate) and Sodium Bicarbonate 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 **(E) + (I) + 1.377 g** together.
5.	**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	180 days, controlled room temperature, as per USP*.		Packaging Requirements	Pack into 100 × 80 mm moisture barrier pouches and put into suitable container.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	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.	7	Keep in a dry place.	
	3	Keep at room temperature (20°C – 25°C)	8	Discard container after use.	
	4	Protect from light.	9	May impair mental and/or physical ability. Use care when operating a car or machinery.	
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.			
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.				

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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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 -- CITRIC ACID (MONOHYDRATE) AND SODIUM BICARBONATE). **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. Calcium Citrate (Hydrate)	0.285 g	_____ **g**	_____ %
b. Magnesium Citrate (Anhydrous)	0.618 g	_____ **g**	_____ %
c. Potassium Citrate	0.276 g	_____ **g**	_____ %
d. Partial Total (add column C together)			_____ % **(D)**
e. Citric Acid (Monohydrate)	_____ **g (E)** (100% - **(D)**) x 0.455 x column B	_____ **g**	_____ %
f. Sodium Bicarbonate		_____ **g**	
g. Total (add column C together)			_____ % **(F)**

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Appendix	Calculating the quantity of excipient required for the batch		

3. **Calculate the quantity of Citric Acid (Monohydrate) and Sodium Bicarbonate required for the batch**:

a. Percent of Sodium Bicarbonate required = 100% – F _____ % **(G)**

b. Average bulk bin fill weight of Sodium Bicarbonate (from column B, Step 2f): _____ g **(H)**

c. Quantity of Sodium Bicarbonate required per bin = [(G) ÷ 100 × (H)] – 0.198 g* _____ g **(I)**
*Quantity of Pyridoxine HCl + Sodium Chloride + Flavors and Sweetener per bin

d. Total quantity of Sodium Bicarbonate required for the batch = 30 bins × (I) _____ g **(J)**

e. Total quantity of Sodium Bicarbonate *plus* processing error = (J) × 1.01-1.03 _____ g **(K)**

f. Total quantity of Citric Acid (Monohydrate) required for the batch = 30 bins × (E) _____ g **(L)**

g. Total quantity of Citric Acid (Monohydrate) *plus* processing error = (L) × 1.01-1.03 _____ g **(M)**