



Suggested Formula	Carnitine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 x 7.5 mL Pouches)	FIN	F 006 655
-------------------	---	-----	-----------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Carnitine (L), USP	TBD					
Mango Flavor (Powder)	1.05	g				
Raspberry Flavor (Powder)	0.90	g				
Vanillin Flavor (Powder)	0.30	g				
Stevia Powder	0.225	g				
Medisca FizzMix™ Base	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): FizzMix™ Base, Stevia Powder, Carnitine

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 Formula	Carnitine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 x 7.5 mL Pouches)	FIN	F 006 655
-------------------	---	-----	-----------

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
Carnitine (L), USP §	TBD				
Mango Flavor (Powder)	1.05	g			
Raspberry Flavor (Powder)	0.90	g			
Vanillin Flavor (Powder)	0.30	g			
Stevia Powder §	0.225	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 Carnitine (L) based on the certificate of analysis:

MINUS	100%
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Carnitine (L), in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Carnitine (L), in decimal	_____



Suggested Formula	Carnitine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 x 7.5 mL Pouches)	FIN	F 006 655
-------------------	---	-----	-----------

2.	<p><u>Ingredient quantification:</u></p> <p>A. Determine the quantity (in g) of Carnitine (L) required to make 30 Pouches of Carnitine (L) 500 mg:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Quantity of Carnitine (L) needed for each pouch</td> <td style="text-align: right; padding: 5px;">0.500 g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">DIVIDED BY</td> </tr> <tr> <td style="padding: 5px;">Potency of Carnitine (L), in decimal (Step 1Ai)</td> <td style="text-align: right; padding: 5px;">_____</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;">i. Quantity of Carnitine (L) needed for each pouch</td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">MULTIPLIED BY</td> </tr> <tr> <td style="padding: 5px;">Number of pouches</td> <td style="text-align: right; padding: 5px;">30</td> </tr> <tr> <td colspan="2" style="padding: 5px;">MULTIPLIED BY</td> </tr> <tr> <td style="padding: 5px;">Processing error adjustments (3 to 5%)</td> <td style="text-align: right; padding: 5px;">1.03 to 1.05</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;">ii. Quantity of Carnitine (L) needed <i>plus</i> processing error adjustments</td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> </table>	Quantity of Carnitine (L) needed for each pouch	0.500 g	DIVIDED BY		Potency of Carnitine (L), in decimal (Step 1Ai)	_____	EQUALS		i. Quantity of Carnitine (L) needed for each pouch	_____ g	MULTIPLIED BY		Number of pouches	30	MULTIPLIED BY		Processing error adjustments (3 to 5%)	1.03 to 1.05	EQUALS		ii. Quantity of Carnitine (L) needed <i>plus</i> processing error adjustments	_____ g
Quantity of Carnitine (L) needed for each pouch	0.500 g																						
DIVIDED BY																							
Potency of Carnitine (L), in decimal (Step 1Ai)	_____																						
EQUALS																							
i. Quantity of Carnitine (L) needed for each pouch	_____ g																						
MULTIPLIED BY																							
Number of pouches	30																						
MULTIPLIED BY																							
Processing error adjustments (3 to 5%)	1.03 to 1.05																						
EQUALS																							
ii. Quantity of Carnitine (L) needed <i>plus</i> processing error adjustments	_____ g																						
3.	<p><u>FizzMix™ Base requirements for 30 x 7.5 mL Bins</u></p> <p>A. Calculate the amount of FizzMix™ Base required for the batch. Refer to attached appendix for details.</p>																						



Suggested Formula	Carnitine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 x 7.5 mL Pouches)	FIN	F 006 655
4.	<p><u>Powder preparation:</u></p> <p>A. Pass the FizzMix™ Base through a 30 mesh sieve and weigh the required quantity (quantity determined in appendix (I)).</p> <p>B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">-Carnitine (L) (amount determined from Step 2Aii)-Mango Flavor (Powder)-Raspberry Flavor (Powder)-Vanillin Flavor (Powder)-Stevia Powder <p>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:</p> <ul style="list-style-type: none">-Sieved FizzMix™ Base (Step 4A)-Homogeneous powder blend (Step 4B)		
5.	<p><u>Product transfer:</u></p> <p>Fill each of 30 x 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.</p>		
6.	<p><u>Validation technique:</u></p> <p>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 Step 2Ai + 0.0825 g + the amount in appendix (G) together.</p>		
7.	<p><u>Product transfer:</u></p> <p>Transfer the contents of each filled bin into the specified dispensing container (see “Packaging Requirements”).</p>		



Suggested Formula	Carnitine 500 mg/7.5 mL Oral Effervescent Powder Blend for Reconstitution (Powder Blend, 30 x 7.5 mL Pouches)	FIN	F 006 655
-------------------	---	-----	-----------

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	- Pack into 100 x 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. <u>Note:</u> 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. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 141.
2.	Carnitine. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1932.
3.	Carnitine (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #1849.
4.	Carnitine. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 91.
5.	Levocarnitine (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 4074.
6.	Levocarnitine Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1921.
7.	USP <795>. <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.

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 FOR 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.



Appendix	Calculating the quantity of excipient required for the batch		
----------	--	--	--

Procedure

1.	<u>Bin filling:</u>			
	a.	For <u>each</u> 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 <u>average</u> bulk bin fill weight. <u>SIEVE THE BASE AND API BEFORE CALIBRATION. DO NOT TAP THE BASE OR THE API. (DO NOT TRITURATE THE BASE).</u>		
		Plug each amount into Step 2, column B.		
2.	<u>Volume Percent Occupied:</u>	Column A	Column B	Column C
	<u>Ingredients</u>	Quantity Required per bin	Average bulk bin fill weight	A/B x 100 equals percent filled
	a. Carnitine (L)	_____ g (Main formula, Step 2Ai)	_____ g	_____ %
	b. FizzMix™ Base		_____ g	
	c. Total (add column C together)			_____ % (D)
3.	<u>Calculate the quantity of FizzMix™ Base required for the batch:</u>			
	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)* *[Quantity of flavors and sweetener per bin]		_____ g (G)
	d.	Total Quantity of FizzMix™ Base required for the batch = 30 bins × (G)		_____ g (H)
	e.	Total quantity of FizzMix™ Base <i>plus</i> processing error = (H) x 1.03-1.05		_____ 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 FOR 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.