MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Fluoxetine Hydrochloride 5.6 mg Oral Chewable Treats (Solid Suspension, 60 x 1 mL Chewable Treats)	FIN	F 005 950v2

Note: Fluoxetine Hydrochloride 5.6 mg is equivalent to Fluoxetine 5 mg.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fluoxetine Hydrochloride, USP	0.336	g				
Glycerin (A), USP**	6.0	mL				
Stevia Powder	0.18	g				
Beef Flavor (Powder)	1.50	g				
Medisca Gelatin Gum Base	TBD					
Commercial Dried Dog Food Pellets	TBD					

**Note: Caprylic/Capric Triglyceride can be used to replace Glycerin to reduce stickiness.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Fluoxetine Hydrochloride*

Hygroscopic *(protect from moisture whenever possible):* *Glycerin, Stevia Powder, Gelatin Gum Base*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** 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 60 x 1 mL Chewable Treats)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Fluoxetine Hydrochloride, USP §	0.336	g			
Glycerin (A), USP §	6.0	mL			
Stevia Powder §	0.18	g			
Beef Flavor (Powder)	1.50	g			
Medisca Gelatin Gum Base §	TBD				
Commercial Dried Dog Food Pellets	TBD				

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

Preparatory Instruction	
1.	**Mold calibration:** Determine the required quantity of each individual excipient for 60 Chewable Treats. Refer to Appendix for details.
2.	**Mold lubrication:** A. Lubricate all parts of the Chew-A-Treat™ Mold with suitable vegetable spray and set aside. Note: Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.

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3. **Powder preparation:**

A. Triturate the Commercial Dried Dog Food Pellets (amount calculated in Appendix Step 7Aii) to form a fine, homogeneous powder blend.

B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend.

-Fluoxetine Hydrochloride
-Beef Flavor (Powder)
-Stevia Powder

C. By geometric addition, combine and mix the following ingredients together to form a homogeneous mixture:

-Fine, homogeneous powder blend (Step 3B)
-Fine, homogeneous powder blend (Step 3A)

D. Transfer the mixture (Step 3C) to a beaker and incrementally add the Glycerin (A).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous moist blend.

Note: The mixture will have a sand-like texture. If it begins to stick to your stirring device or beaker, you can simply scrape it off and continue mixing.

4. **Medium integration:**

A. Using a sharp blade or scissors, cut and weigh the required quantity of the Gelatin Gum Base (amount calculated in Appendix Step 7Ai).

B. Using the hot plate, heat this quantity of Gelatin Gum Base until molten.

Specifications: Maintain temperature between 60°C and 65°C.

IMPORTANT: Do not allow the temperature to exceed 65°C.

C. Using the hot plate, incrementally add the homogeneous moist blend (Step 3D) to the Molten Gelatin Gum Base (Step 4B).

Specifications: Continuously mix until homogeneous.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous thick, sticky paste-like dispersion.

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5.	**Mold filling:** A. Properly lubricate gloves (thumbs, forefingers, and palms) throughout filling. B. Continuing to heat the mixture between 60 to 65°C, remove a marble-sized quantity of the mixture at a time and roll it between your thumb and forefinger to form a cylinder. Pack the 60 mold cavities with these cylinders and scrape off any excess with pre-lubricated plastic scraper. C. Once the treats have been packed down with an extractor, apply a thin layer of lubricant to give a shining surface. D. Allow the treats to cool at room temperature for at least 15 minutes and then remove them from the mold using the extractor.
6.	**Validation technique:** A. Weigh 12 chewable treats. B. The final weight of each chewable treat shall not be less than 90% and not more than 110% of the theoretically calculated weight in accordance to USP guidelines. The theoretically calculated weight can be determined by adding the following values: **0.15996 g + [from the Appendix (Step 6Ai/60)]**.
7.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP.	Packaging Requirements		Manually put into light-resistant Chew-A-Treat blisters and cold sealed with foil labels.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep in a dry place.	
	2	Keep out of reach of children.	7	Protect from light.	
	3	Keep at room temperature (20°C – 23°C).	8	Discard container after use.	
	4	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	For canine use only.	
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	10	May impair mental and/or physical ability.	
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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REFERENCES

1. Lozenges/Troches. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 153.
2. Prozac. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2014*: 2237.
3. Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 283.
4. Fluoxetine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 391.
5. Fluoxetine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #4185.
6. Fluoxetine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 4th Edition.* American Pharmaceutical Association; 2009: 245.
7. Fluoxetine Hydrochloride (Monograph). *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 3035.
8. Fluoxetine Systemic. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1517.
9. USP <795>. *United States Pharmacopeia XXXVII / National Formulary 32.* Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.

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Appendix	Chewable Treat mold calibration		

Preparatory Instruction

1. A. Weigh and / or measure the following ingredients:

Ingredient	Quantities
Glycerin (B), USP	4 mL
Stevia Powder	0.12 g
Beef Flavor (Powder)	1.00 g
Medisca Gelatin Gum Base	15.66 g
Commercial Dried Dog Food Pellets	31.80 g

Notes: Measure the exact amount specified. Do not consider processing error for calibration step. Data in this calibration table are based on a 4.0 mL mold size.

2. **Powder preparation:**

A. Triturate the Commercial Dried Dog Food Pellets to form a fine, homogeneous powder blend.

B. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend.

-Beef Flavor (Powder)
-Stevia Powder

C. By geometric addition, combine and mix the following ingredients together to form a homogeneous mixture:

-Fine, homogeneous powder blend (Step 2B)
-Fine, homogeneous powder blend (Step 2A)

D. Transfer the mixture (Step 2C) to a beaker and incrementally add the Glycerin (B).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous moist blend.

Note: The mixture will have a sand-like texture. If it begins to stick to your stirring device or beaker, you can simply scrape it off and continue mixing.

Appendix	Chewable Treat mold calibration		

3. **Medium integration:**

A. Using the hot plate, heat the Gelatin Gum Base until molten.

Specifications: Maintain temperature between 60°C and 65°C.

IMPORTANT: Do not allow the temperature to exceed 65°C.

B. Using the hot plate, incrementally add the homogeneous moist blend (Step 2D) to the Molten Gelatin Gum Base (Step 3A).

Specifications: Continuously mix until homogeneous.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous thick, sticky paste-like dispersion.

4. **Mold filling:**

A. Lubricate all parts of the Chew-A-Treat™ Mold with suitable vegetable spray and set aside.

Note: Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.

B. Properly lubricate gloves (thumbs, forefingers, and palms) throughout filling.

C. Continuing to heat the mixture between 60 to 65°C, remove a marble-sized quantity of the mixture at a time and roll it between your thumb and forefinger to form a cylinder. Pack the 5 mold cavities with these cylinders and scrape off any excess with pre-lubricated plastic scraper.

D. Once the treats have been packed down with an extractor, apply a thin layer of lubricant to give a shining surface.

E. Allow the treats to cool at room temperature for at least 15 minutes and then remove them from the mold using the extractor.

Appendix	Chewable Treat mold calibration		

5. **Calculate the average chewable treat weight:**

A. Weigh the five treats and record the total weight here (not including weight of the empty chewable treat mold): _____ g

B. Calculate the average Chewable Treat weight:

Combined weight of the Chewable Treat (from Step 5A)	_____ g
DIVIDED BY	
Number of Chewable Treats	5
EQUALS	
i. Average (theoretical) Chewable Treat weight (4 mL)	_____ **g**
DIVIDED BY	
Volume of the Chewable Treats	4 mL
EQUALS	
ii. Average (theoretical) Chewable Treat weight (1 mL)	_____ **g**

Appendix	Chewable Treat mold calibration		

6. **Ingredient calculation:**

A. Determine the actual quantity of Chewable Treats Base required for the batch (60 Chewable Treats):

Total Volume of the batch (60 x 1.0 mL)	60.0 mL
MINUS	
Glycerin (A) from main formula	6.0 mL
EQUALS	
Quantity of Chewable Treats Base in mL	54.0 mL
MULTIPLED BY	
Average treat weight [from Step 5Bii (g/1 mL = g/mL)]	_____ g
MINUS	
Quantity (in g) of [Fluoxetine Hydrochloride (0.336 g) + Stevia Powder (0.18 g) + Beef Flavor (1.50 g)] x 0.7 (Displacement factor) for the batch	1.4112 g
EQUALS	
i. Quantity of Chewable Treats Base required for 60 treats	_____ g

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Appendix	Chewable Treat mold calibration		

7. **Ingredient calculation:**

A. Determine the actual quantity of Gelatin Gum Base and Commercial Dried Dog Food Pellets fraction required for the batch (60 Chewable Treats):

Gelatin Gum Base fraction **(6Ai × ⅓)**	_____ **g**
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
i. Weight of Gelatin Gum Base required for 60 Chewable Treats	_____ g
Commercial Dried Dog Food Pellets fraction **(6Ai × ⅔)**	_____ g
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of Commercial Dried Dog Food Pellets required for 60 Chewable Treats	_____ g