



Suggested Formula	Disulfiram 250 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 000 272v4
-------------------	--	-----	-------------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Disulfiram, USP	25.000	g				
Medisca CapsuBlend™-P	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible):

Disulfiram

Hygroscopic (protect from moisture whenever possible):

CapsuBlend™-P

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error /

Testing Considerations:

Special Instruction:

To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

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	Disulfiram 250 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 000 272v4
-------------------	--	-----	-------------

SUGGESTED PREPARATION (for 100 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Disulfiram, USP §	25.000	g			
Medisca CapsuBlend™-P §	TBD				
Sodium Chloride, USP	As required		®		

* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><u>CapsuBlend™-P requirements for 100 x size #1 capsules</u></p> <p>A. Calculate the amount of CapsuBlend™-P required for the batch. Refer to attached appendix for details.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. By geometric addition, combine and mix the following ingredients together:</p> <ul style="list-style-type: none"> -Disulfiram -CapsuBlend™-P (Quantity determined in appendix (I))
3.	<p><u>Product transfer:</u></p> <p>Fill each of 100 Size #1 capsules with the powder blend (Step 2A). Close each capsule tightly.</p> <p>Clean each capsule by placing the capsules in a container filled with Sodium chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium chloride to pass through. Finally, roll the capsules on a cloth-covered surface.</p>
4.	<p><u>Validation technique (average capsule weight):</u></p> <p>The final weight of each capsule (not including capsule 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) + 0.250 g together.</p>
5.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>



Suggested Formula	Disulfiram 250 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 000 272v4
-------------------	--	-----	-------------

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months as per USP	Packaging Requirements	Tightly closed, light-resistant vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Keep at room temperature (20°C – 23°C).
	3	Cap tightly after use.	7	Protect from light.
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.		
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.			

REFERENCES

1.	USP <795>. US Pharmacopeial Convention, Inc. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD: US Pharmacopeial Convention, Inc; 2004: 2457.
2.	Disulfiram (Monograph). In: O'Neil MJ. <i>The Merck Index 13th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 592.
3.	Capsules. In: Gennaro AR, ed. <i>Remington: The Science and Practice of Pharmacy, 20th Edition</i> . Baltimore, MD: Lippincott Williams & Wilkins; 2000: 885.
4.	Disulfiram (Monograph). In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 2nd Edition</i> . American Pharmaceutical Association; 2000: 134.

DISCLAIMER: MEDISCA NETWORK INC. & RÉSEAU MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAVE 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.	<p><u>Capsule filling:</u></p> <p>a. For <u>each</u> ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an <u>average</u> capsule fill weight.</p> <p>Plug each amount into Step 2, column B.</p>																		
2.	<p><u>Volume Percent Occupied:</u></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; width: 35%;"><u>Ingredients</u></th> <th style="text-align: center; width: 20%;">Column A Quantity Required per capsule</th> <th style="text-align: center; width: 20%;">Column B Average capsule fill weight</th> <th style="text-align: center; width: 25%;">Column C A/B x 100 equals percent filled</th> </tr> </thead> <tbody> <tr> <td>a. Disulfiram</td> <td style="text-align: center;">0.250 g</td> <td style="text-align: center;">_____ g</td> <td style="text-align: center;">_____ %</td> </tr> <tr> <td>b. CapsuBlend™-P</td> <td></td> <td style="text-align: center;">_____ g</td> <td></td> </tr> <tr> <td>c. Total (add column C together)</td> <td></td> <td></td> <td style="text-align: center;">_____ % (D)</td> </tr> </tbody> </table>			<u>Ingredients</u>	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled	a. Disulfiram	0.250 g	_____ g	_____ %	b. CapsuBlend™-P		_____ g		c. Total (add column C together)			_____ % (D)
<u>Ingredients</u>	Column A Quantity Required per capsule	Column B Average capsule fill weight	Column C A/B x 100 equals percent filled																
a. Disulfiram	0.250 g	_____ g	_____ %																
b. CapsuBlend™-P		_____ g																	
c. Total (add column C together)			_____ % (D)																
3.	<p><u>Calculate the quantity of CapsuBlend™-P required for the batch:</u></p> <p>a. Percent of CapsuBlend™-P required = 100% – (D) _____ % (E)</p> <p>b. Average capsule fill weight of CapsuBlend™-P (from column B, Step 2b): _____ g (F)</p> <p>c. Quantity of CapsuBlend™-P required per capsule = [(E) ÷ 100 × (F)] _____ g (G)</p> <p>d. Total quantity of CapsuBlend™-P required for the batch = 100 capsules × (G) _____ g (H)</p> <p>e. Total quantity of CapsuBlend™-P <i>plus</i> processing error = (H) x 1.05-1.09 _____ g (I)</p>																		

DISCLAIMER: MEDISCA NETWORK INC. & RÉSEAU MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAVE 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.