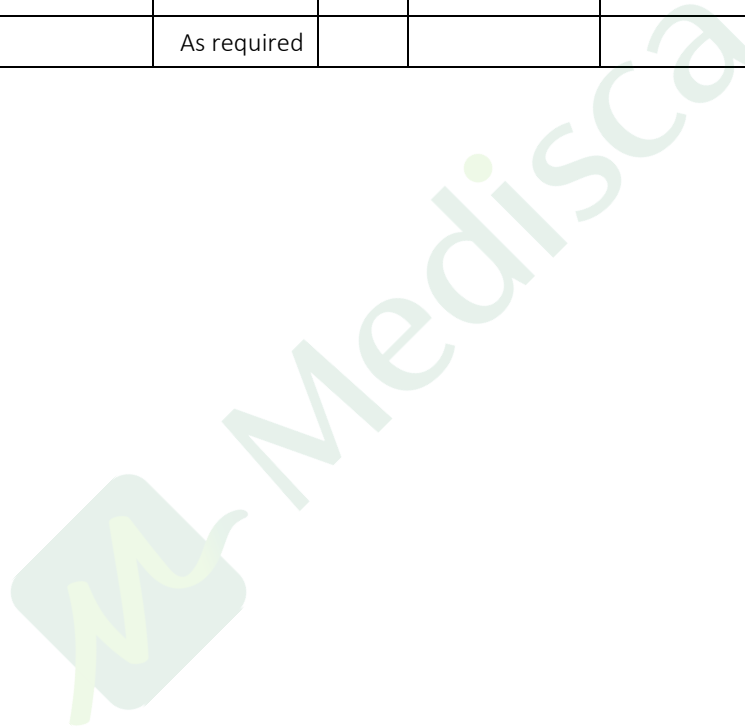


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Suggested Formula	Methylene Blue 200 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 010 065
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Suggested Formulation

Ingredient Listing	Qty	Unit	Product Code	Supplier	LOT No.	Expiry Date
Methylene Blue (Trihydrate), USP	20.000	g				
Medisca CapsuBlend®-H	TBD					
Sodium Chloride, USP	As required					



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Special Preparatory Considerations

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible): *Methylene Blue*

Hygroscopic (protect from moisture whenever possible): *Methylene Blue, CapsuBlend[®]-H*

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: 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. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

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 (GFI) 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

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty	Unit	Multiplication factor (*): _____	Processing Error	Qty to measure
Methylene Blue (Trihydrate), USP §	20.000	g			
Medisca CapsuBlend®-H §	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®-H requirements for 100 x Size #0 Capsules</u></p> <p>A. Calculate the amount of CapsuBlend®-H 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 triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> -Methylene Blue (Trihydrate) -CapsuBlend®-H (amount determined in appendix, (I)) <p>B. Pass the above powder mixture through a 40 or 50 mesh sieve.</p> <p>C. Mix the sieved powder blend using a manual tumbler mixer to ensure homogeneity.</p>
3.	<p><u>Product transfer:</u></p> <p>Fill each of the 100 Size #0 Capsules with the powder blend (Step 2C). 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>

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Suggested Formula	Methylene Blue 200 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 010 065
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4.	<p><u>Validation technique:</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) + 0.200 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 Presentation

Estimated Beyond-Use Date	180 days, controlled room temperature or refrigerator, as per USP 795*.	Packaging Requirements	Tightly closed, light-resistant, capsule shells and 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.	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3.	May impair mental and/or physical ability. Use care when operating a car or machinery.	7.	Cap tightly after use.
	4.	Keep at controlled room temperature (20°C – 25°C) OR keep refrigerated (2°C – 8°C). Do not freeze.	8.	Protect from light.
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.			

* 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		
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Procedure				
1.	<u>Capsule filling:</u>			
	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. Also, triturate the ingredient first if required to do so in the formulation.			
	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 capsule	Average capsule fill weight	A/B x 100 equals percent filled
	a. Methylene Blue (Trihydrate)	0.200 g	_____ g	_____ %
	b. CapsuBlend®-H		_____ g	
	c. Total (add column C together)			_____ % (D)
3.	<u>Calculate the quantity of CapsuBlend®-H required for the batch:</u>			
	a. Percent of CapsuBlend®-H required = 100% – (D)			_____ % (E)
	b. Average capsule fill weight of CapsuBlend®-H (from column B, Step 2b):			_____ g (F)
	c. Quantity of CapsuBlend®-H required per capsule = [(E) ÷ 100 × (F)]			_____ g (G)
	d. Total Quantity of CapsuBlend®-H required for the batch = 100 capsules × (G)			_____ g (H)
	e. Total quantity of CapsuBlend®-H <i>plus</i> processing error = (H) x 1.05-1.09			_____ g (I)