



Suggested Formula	Anagrelide Hydrochloride 0.61 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 008 908
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Note: Anagrelide Hydrochloride 0.61 mg is equivalent to Anagrelide 0.5 mg

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Anagrelide Hydrochloride (Monohydrate), USP	0.0610	g				
Medisca CapsuBlend®-S	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): CapsuBlend®-S

Light Sensitive (protect from light whenever possible): Anagrelide Hydrochloride (Monohydrate)





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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

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 (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 100 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Anagrelide Hydrochloride (Monohydrate), USP §	0.0610	g			
Medisca CapsuBlend®-S §	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>Calculate the quantity of CapsuBlend®-S required for 100 x Size #1 Capsules:</u></p> <p>i. Determine the average capsule fill weight by filling and weighing five TARED capsules with the CapsuBlend®-S. Divide the total weight by 5 to obtain <u>average</u> weight. _____ g (A)</p> <p>ii. Quantity of CapsuBlend®-S required per capsule = (A) – 0.00061 g* _____ g (B) *quantity of Anagrelide Hydrochloride (Monohydrate), per capsule.</p> <p>iii. Total quantity of CapsuBlend®-S required for the batch = (B) x 100 capsules _____ g (C)</p> <p>iv. Quantity of CapsuBlend®-S to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g (D)</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> <p>-Anagrelide Hydrochloride (Monohydrate) -CapsuBlend®-S (D)</p>
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>



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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 (A), in accordance to USP 795 guidelines.</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	6 months, 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	Protect from light.
	2	Keep out of reach of children.	6	Keep in a dry place.
	3	Keep at controlled room temperature (20°C – 25°C).	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Cap tightly after use.	8	
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.			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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REFERENCES

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding 5th Edition</i> . American Pharmaceutical Association; 2016: 189.
2.	Anagrelide Hydrochloride. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 38th Edition</i> . London, England: The Pharmaceutical Press; 2014: 2442.
3.	Anagrelide Hydrochloride (Monograph). <i>United States Pharmacopeia XLIII / National Formulary 38</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 332.
4.	Anagrelide Capsules (Monograph). <i>United States Pharmacopeia XLIII / National Formulary 38</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 334.
5.	USP <795>. <i>United States Pharmacopeia XLIII/ National Formulary 38</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.

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