MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Methenamine Hippurate 500 mg Oral Capsules (Powder Blend, 100 x Size #00 Capsules)	FIN	F 003 375

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Methenamine Hippurate, USP	50.000	g				
Cellulose (Microcrystalline), NF	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Cellulose*

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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 #00 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Methenamine Hippurate, USP §	50.000	g			
Cellulose (Microcrystalline), NF §	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.	**Excipient requirements for 100 x Size #00 Capsules** A. Calculate the amount of Cellulose (Microcrystalline) required for the batch. Refer to attached appendix for details.
2.	**Powder preparation:** A. By geometric addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Methenamine Hippurate -Cellulose (Microcrystalline) (Quantity determined in appendix **(I)**) B. Pass the above powder mixture through a 40 or 50 mesh sieve. C. Mix the sieved powder blend using a manual tumbler mixer to ensure homogeneity.
3.	**Product transfer:** Fill each of 100 Size #00 capsules with the homogeneous powder blend (Step 2C). Close each capsule tightly. 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.
4.	**Validation technique:** 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)** + 0.500 g together.

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5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP.*	Packaging Requirements		Tightly closed prescription vial.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4		Keep at room temperature (20ºC - 23ºC).
	2	Keep out of reach of children.	5		Cap tightly after use.
	3	Keep in a dry place.	6		Consult your health care practitioner if any 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 active ingredient 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. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 127.
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8. USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.

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Appendix	Calculating quantity of excipient required for batch		

Procedure

1. **Capsule filling:**

   a. For each 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 average capsule fill weight. Also, crush and triturate the ingredient first if required in formulation.

   Plug each amount into Step 2, column B.

2. **Volume Percent Occupied:**

Ingredients	**Column A** Quantity Required per capsule	**Column B** Average capsule fill weight	**Column C** A/B x 100 equals percent filled
a. Methanamine Hippurate	0.500 **g**	_____ **g**	_____ %
b. Cellulose (Microcrystalline)		_____ **g**	
c. Total (add column C together)			_____ % **(D)**

3. **Calculate the quantity of Cellulose (Microcrystalline) required for the batch:**

   a. Percent of Cellulose (Microcrystalline) required = 100% – (D) _____ % **(E)**

   b. Average capsule fill weight of Cellulose (Microcrystalline) (from column B, Step 2b) _____ g **(F)**

   c. Quantity of Cellulose (Microcrystalline) required per capsule = [(E) ÷ 100 × (F)] _____ g **(G)**

   d. Total Quantity of Cellulose (Microcrystalline) required for the batch = 100 capsules × (G) _____ g **(H)**

   e. Total quantity of Cellulose (Microcrystalline) *plus* processing error = (H) × 1.05-1.09 _____ g **(I)**