MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Haloperidol 0.5 mg Oral Capsules (Powder Blend, 100 x size #1 Capsules)	FIN	F 008 147

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Haloperidol, USP	0.050	g				
Medisca CapsuBlend®-P	TBD					
Sodium Chloride, USP	As required					

*Note: The amount of Haloperidol to weigh is very small therefore, it is recommended to use a 4 decimal analytical balance.

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light sensitive *(protect from light whenever possible):* *Haloperidol*

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 #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Haloperidol, USP §	0.050	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.

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Preparatory Instruction	
1.	**Calculate the quantity of CapsuBlend®-P required for 100 x Size #1 Capsules:** i. Determine the average capsule fill weight by filling and weighing **five** TARED capsules with the CapsuBlend®-P. Divide the total weight by **5** to obtain average weight. _____ g **(A)** ii. Quantity of CapsuBlend®-P required per capsule = (A) – 0.0005 g* _____ g **(B)** *quantity of Haloperidol per capsule. iii. Total quantity of CapsuBlend®-P required for the batch = (B) x 100 capsules _____ g **(C)** iv. Quantity of CapsuBlend®-P to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g **(D)**
2.	**Powder preparation:** A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Haloperidol -CapsuBlend®-P **(D)** 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.

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3.	**Product transfer (powder-to-capsule filling):** Fill each of 100 Size #1 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 **(A)**, in accordance to USP 795 guidelines.
5.	**Product transfer (solid-to-dispensing container filling):** 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, light-resistant capsule shells and vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Protect from light.
	2	Keep out of reach of children.	7	Keep in a dry place.
	3	Keep at room temperature (20°C - 23°C).	8	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.	9	**May impair mental and/or physical ability. Use care when operating a car or machinery.**
	5	**Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.**		
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

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