MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Omeprazole 2 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 007 405

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Omeprazole (Powder), USP 200 mg Bottle	1.00	Bottle				
Oral Mix Dry Alka, SF (Cherry Flavored) 6.35 g Bottle	1.0	Bottle				
Purified Water, USP	5.0	mL				
Purified Water, USP	5.0	mL				
Purified Water, USP	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Omeprazole*

Moisture Sensitive *(protect from humidity whenever possible):* *Omeprazole*

Oxygen Sensitive *(protect from oxygen whenever possible):* *Omeprazole*

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 **0%** 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 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Omeprazole (Powder), USP 200 mg Bottle §	1.00	Bottle			
Oral Mix Dry Alka, SF (Cherry Flavored) 6.35 g Bottle	1.0	Bottle			
Purified Water, USP	5.0	mL			
Purified Water, USP	5.0	mL			
Purified Water, USP	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

	Preparatory Instruction
1.	**Powder preparation:** A. Gently tap the Omeprazole (Powder) 200 mg Bottle and transfer the contents into the Oral Mix Dry Alka, SF (Cherry Flavored) 6.35 g Bottle. Specifications: Gently shake the bottle horizontally until homogeneous. B. Rinse the Omeprazole (Powder) 200 mg Bottle, including the seal liner with Purified Water (5.0 mL) **TWICE** and transfer into the Oral Mix Dry Alka, SF (Cherry Flavored) 6.35 g Bottle (Step 1A).
2.	**Powder integration:** A. Incrementally add the Purified Water (70.0 mL) into the Oral Mix Dry Alka, SF (Cherry Flavored) 6.35 g Bottle (Step 1B). Close the cap and gently shake the bottle vertically until all the powder is well dispersed. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Allow the suspension to settle for 30-60 seconds and then add additional Purified Water to the mixture (Step 2A) to fill to the required batch size (100.0 mL). Specifications: Close the cap and shake vigorously in a vertical motion until the mixture is uniformly suspended. End result: Homogeneous liquid-like dispersion.

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4.	**Product transfer:** Use press-in bottle adapter and seal the bottle with the use of the child resistant cap. (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date & Packaging Requirements	Amber PP bottles: 70 days at 4°C, based on available stability studies through Medisca. To be administered with a metered-dose measuring device.*			
	*Suggested BUD is based on the **exact** execution of the indicated ingredient list, quantities and procedures listed within this formulation. ***Note:*** ***This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.***			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Protect from light.
	2	May impair mental and or physical ability. Use care when operating a car or machinery.	7	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	**Shake well before use.**	8	Keep out of reach of children.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Cap tightly after use.
	5	Keep refrigerated. Do not freeze.		
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

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2. Omeprazole. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 1753.
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5. Omeprazole (Monograph). *United States Pharmacopeia XL / National Formulary 35*. Rockville, MD. US Pharmacopeial Convention, Inc. 2017: 5433.
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