MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Rabeprazole Sodium 20 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 472v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Rabeprazole Sodium (10 mg) Tablets	40	Units				
Propylene Glycol, USP	20.0	mL				
Sodium Bicarbonate, USP	8.40	g				
Medisca Oral Suspend (Suspending Vehicle)	30.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Propylene Glycol*

Moisture Sensitive *(protect from humidity whenever possible):* *Rabeprazole Sodium, Sodium Bicarbonate*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

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
Rabeprazole Sodium (10 mg) Tablets §	40	Units			
Propylene Glycol, USP §	20.0	mL			
Sodium Bicarbonate, USP §	8.40	g			
Medisca Oral Suspend (Suspending Vehicle)	30.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	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. **Ingredient quantification (determine the actual quantity of Rabeprazole Sodium (10 mg) tablet powder to weigh if accounting for processing error adjustments):**

A. Weigh the 44 x Rabeprazole Sodium (10 mg) Tablets. Record the total weight here: _____ g

B. Calculate the average weight of powder in each tablet:

Weight of 44 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets	44
EQUALS	
Average weight of a single Rabeprazole Sodium (10 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 40 tablets:

Average weight of a single Rabeprazole Sodium (10 mg) Tablet (from Step 1B):	_____ g
MULTIPLED BY	
Number of tablets required:	40
EQUALS	
Weight of powder equivalent to 40 tablets:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 40 tablets (from Step 1C):	_____ g
MULTIPLED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required *plus* processing error adjustments:	_____ **g**

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2. **Powder preparation:**

   A. Crush and triturate the 44 Rabeprazole Sodium (10 mg) Tablets to form a fine, homogeneous powder.

   B. Weigh the quantity of Rabeprazole Sodium (10 mg) tablets powder required for the batch (refer to Step 1D) and discard the remaining powder.

3. **Liquid preparation:**

   A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

   -Fine, homogeneous powder (amount weighed in Step 2B)
   -Sodium Bicarbonate

   B. Levigate the fine, homogeneous powder blend (Step 3A) with the Propylene Glycol.

   End result: Homogeneous paste-like dispersion.

4. **Medium integration:**

   A. Incrementally add the homogeneous paste-like dispersion (Step 3B) to the Oral Suspend (Suspending Vehicle).

   Specifications: Continuously mix, using high-shear mixing techniques.

   End result: Homogeneous liquid-like dispersion.

5. **Filling to volume:**

   A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).

   Specifications: Continuously mix, using high-shear mixing techniques.

   End result: Homogeneous liquid-like dispersion.

6. **pH testing:**

   A. Draw an appropriate amount of the mixture (Step 5A).

   B. Test the pH of the sample. It should lie between 8.3 and 8.7

   C. If the pH < 8.3, carefully add in a dropwise manner the Sodium Hydroxide 10% solution to the mixture:

      1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% solution to the mixture.
      2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% solution.
      3. Re-test the pH.
      4. Continue to add the Sodium Hydroxide 10% solution until the pH of 8.3 to 8.7 is obtained.

      IMPORTANT: Do not allow the pH to rise above 8.7

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7.	**Product transfer:** A. Transfer the final product into the specified dispensing container (see "Packaging requirements"). Note: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.		Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Keep refrigerated. Do not freeze.	7	**Shake well before use.**
	4	Protect from light.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **CAUTION: SAFETY AND EFFICACY OF RABEPRAZOLE IS NOT ESTABLISHED IN CHILDREN UNDER 18 YEARS.**			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

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