



Suggested Formula	Ramipril 10 mg/5 mL Oral Liquid (Suspension, 50 mL)	FIN	F 003 381v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ramipril, USP	0.100	g				
Glycerin, USP	2.5	mL				
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL				
Medisca Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free)	q.s. to 50.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

#### 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 **10 to 12%** 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 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : _____	Processing Error	Qty. to measure
Ramipril, USP	0.100	g			
Glycerin, USP §	2.5	mL			
Medisca Oral Suspend (Suspending Vehicle)	25.0	mL			
Medisca Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free)	q.s. to 50.0	mL			

\* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Triturate the Ramipril to form a fine, homogeneous powder.</p> <p>B. Levigate the fine homogeneous powder (Step 1A) with the Glycerin.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
2.	<p><b><u>Medium integration:</u></b></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Oral Syrup SF (Flavored Syrup Vehicle Sugar-Free) to the mixture to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



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4.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>
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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	<b>4 days, refrigerated. Discard any unused portion 4 days after preparation.</b>	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	May impair mental and/or physical ability. Use care when operating a car or machinery.
	2	Keep out of reach of children.	6	Cap tightly after use.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep refrigerated. Do not freeze.	8	<b>Shake well before use.</b>
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.			



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## REFERENCES

1.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2003: 257.
2.	Ramipril (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8103.
3.	Ramipril. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 3<sup>rd</sup> Edition</i> . American Pharmaceutical Association; 2005: 377.
4.	Ramipril (Monograph). <i>United States Pharmacopeia XXXI / National Formulary 26</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2008.
5.	Ramipril. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26<sup>th</sup> Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 210.
6.	USP <795>. <i>United States Pharmacopeia XXXI / National Formulary 26</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2008.

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