



Suggested Formula	Metoprolol Tartrate 3 mg/0.5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 150
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Metoprolol Tartrate, USP	0.600	g				
Propylene Glycol, USP	2.0	mL				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	48.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Metoprolol Tartrate, Propylene Glycol

Hygroscopic (protect from moisture whenever possible):

Metoprolol Tartrate, Propylene Glycol

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:

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
Metoprolol Tartrate, USP §	0.600	g			
Propylene Glycol, USP §	2.0	mL			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	48.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	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-liquid preparation:**

- A. Triturate the Metoprolol Tartrate to form a fine, homogeneous powder.
- B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol.

End result: Homogeneous liquid-like dispersion.

2. **Medium incorporation:**

- A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (48.0 mL *plus* processing error adjustments):

- Tutti Frutti Flavor
- Homogeneous liquid-like dispersion (Step 1A)

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

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.



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3.	<p><u>Filling to volume:</u></p> <p>A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 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>
4.	<p><u>Product transfer:</u></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>

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.	Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be dispensed with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 Keep refrigerated. Do not freeze.
	2	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.
	3	Shake well before use.	8 Cap tightly after use.
	4	Protect from light.	9 Keep out of reach of children.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.	
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.		



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REFERENCES

1.	Suspensions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 239.
2.	Lopresor. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2014</i> : 1572.
3.	Propylene Glycol. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 672.
4.	Metoprolol Tartrate. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1338.
5.	Metoprolol (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #6228.
6.	Metoprolol Tartrate. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 324.
7.	Metoprolol Tartrate (Monograph). <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 3812.
8.	Metoprolol. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 601.
9.	USP <795>. <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.

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