MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Labetalol Hydrochloride 40 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 001 131v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Labetalol Hydrochloride, USP	4.000	g				
Propylene Glycol, USP	2.0	mL				
Tutti Frutti Flavor	1.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light Sensitive *(protect from light whenever possible):* *Labetalol Hydrochloride, 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
Labetalol Hydrochloride, USP §	4.000	g			
Propylene Glycol, USP §	2.0	mL			
Tutti Frutti Flavor	1.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 100.0	mL			

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Triturate the Labetalol Hydrochloride to form a fine, homogeneous powder. B. Combine and mix the following ingredients together to form a homogeneous liquid-like dispersion: -Tutti Frutti Flavor -Propylene Glycol C. Levigate the fine, homogeneous powder (Step 1A) with the homogeneous liquid-like dispersion (Step 1B). End result: Homogeneous paste-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 1C) to the Oral Suspend (Suspending Vehicle). Specifications: Vigorously mix. End result: Homogeneous liquid-like dispersion.

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3.	**Filling to volume:** A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Vigorously mix. End result: Homogeneous liquid-like dispersion.
4.	**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.	6	Cap tightly after use.
	2	Keep out of reach of children.	7	**Shake well before use.**
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	Keep refrigerated. Do not freeze.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Protect from light.
	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 active to the dispensing container as deemed necessary.		
Patient Instructions		Contact your pharmacist in the event of adverse reactions.		

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