MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Baclofen 10 mg/mL Oral Liquid (Suspension, 100 mL)	FIN	F 004 932v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Baclofen, USP	1.000	g				
Propylene Glycol, USP	4.0	mL				
Tutti Frutti Flavor	2.0	mL				
Medisca Oral Mix (Flavoured Suspending Vehicle)	25.0	mL				
Medisca Oral Mix (Flavoured Suspending Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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 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
Baclofen, USP	1.000	g			
Propylene Glycol, USP §	4.0	mL			
Tutti Frutti Flavor	2.0	mL			
Medisca Oral Mix (Flavoured Suspending Vehicle)	25.0	mL			
Medisca Oral Mix (Flavoured 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 Baclofen to form a fine, homogeneous powder. B. Combine and mix the following ingredients together: -Propylene Glycol -Tutti Frutti Flavor End result: Homogeneous liquid-like solution. C. Levigate the fine, homogeneous powder (Step 1A) with the homogeneous liquid-like solution (Step 1B). End result: Homogeneous liquid-like dispersion.
2.	**Medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 1C) to the Oral Mix (Flavoured Suspending Vehicle) (25.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion.

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3.	**Filling to volume:** A. Add additional Oral Mix (Flavoured Suspending Vehicle) to the mixture (Step 2A) 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.
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		90 days at 4°C, based on available stability studies through Medisca*.	Packaging Requirements	Amber Glass Bottle
		*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	Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	**Shake well before use.**	8	May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9	Protect from light.
	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.		
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

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