MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Linezolid 100 mg/5 mL Oral Liquid (Suspension, 90 mL)	FIN	F 003 820v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Linezolid (600 mg) Tablets	3	Units				
Glycerin, USP	5.0	mL				
Orange Flavor (Concentrate) (Natural)	0.1	mL				
Medisca Oral Suspend (Suspending Vehicle)	40.0	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 90.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Linezolid*

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 **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 90 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Linezolid (600 mg) Tablets §	3	Units			
Glycerin, USP §	5.0	mL			
Orange Flavor (Concentrate) (Natural)	0.1	mL			
Medisca Oral Suspend (Suspending Vehicle)	40.0	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 90.0	mL			

* 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 Linezolid (600 mg) tablet powder mix to weigh):**

A. Weigh 4 Linezolid (600 mg) Tablets. Record the total weight here: _____ g

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

Weight of 4 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets:	4
EQUALS	
Average weight of a single Linezolid (600 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 3 tablets:

Average weight of a single Linezolid (600 mg) Tablet (from Step 1B):	_____ g
MULTIPLED BY	
Number of tablets required:	3
EQUALS	
Weight of powder equivalent to 3 tablets:	_____ g

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

Weight of powder equivalent to 3 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-liquid preparation:** A. Crush and triturate the 4 Linezolid (600 mg) Tablets into a **fine** homogeneous powder. B. Weigh the quantity of Linezolid (600 mg) tablet powder mix required for the batch (refer to Step 1D) and discard the remaining powder.
3.	**Powder-liquid preparation:** A. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Glycerin -Orange Flavor (Concentrate) (Natural) B. Levigate the Linezolid (600 mg) tablet powder mix (amount weighed in Step 2B) with the homogeneous liquid-like solution (Step 3A). End result: Homogeneous liquid-like dispersion.
4.	**Medium incorporation:** A. Incrementally add the homogeneous liquid-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 (90.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous suspension.
6.	**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.

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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		Keep out of reach of children.
	3	**Shake well before use.**	8		Cap tightly after use.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9		May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Protect from light.			
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.			

REFERENCES

1. Suspensions. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 209.
2. Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 5th Edition.* American Pharmaceutical Association; 2006: 301.
3. Linezolid (600 mg) tablet (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #5504.
4. USP <795>. *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.