MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Prednisolone 15 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 159v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Prednisolone Sodium Phosphate, USP	TBD					
Cherry Flavor	0.3	mL				
Glycerin, USP	2.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	mL				
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Prednisolone Sodium Phosphate, 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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Prednisolone Sodium Phosphate, USP §	TBD				
Cherry Flavor	0.3	mL			
Glycerin, USP §	2.0	mL			
Medisca Oral Mix (Flavored Suspending Vehicle)	50.0	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.

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Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the potency of Prednisolone Sodium Phosphate based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Prednisolone Sodium Phosphate, in decimal	_____
MULTIPLY BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Potency of Prednisolone Sodium Phosphate, in decimal	_____
DIVIDED BY (Salt to Base conversion)	1.344
EQUALS	
i. Potency of Prednisolone Sodium Phosphate (base equivalent), in decimal	_____

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Prednisolone Sodium Phosphate required to make a 100 mL batch of **Prednisolone (Base)** 15 mg/5 mL Oral Liquid:

Quantity of **Prednisolone (Base)** required for a 100 mL Oral Liquid	0.300 g
DIVIDED BY	
Potency of Prednisolone Sodium Phosphate (base equivalent), in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Prednisolone Sodium Phosphate needed for a 100 mL Oral Liquid	_____ **g**
MULTIPLED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Prednisolone Sodium Phosphate needed *plus* processing error adjustments	_____ **g**

3. **Powder-liquid preparation:**

A. Levigate the Prednisolone Sodium Phosphate (amount determined from Step 2Aii) with the Glycerin.

End result: Homogeneous liquid-like dispersion.

4. **Medium incorporation:**

A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL *plus* processing error adjustments):

-Cherry Flavor
-Homogeneous liquid-like dispersion (Step 3A)

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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5.	**Filling to volume:** A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 4A) 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.
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.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements	- Tightly closed dispensing bottle. - To be dispensed with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep out of reach of children.
	2	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	**Shake well before use.**	7	Cap tightly after use.
	4	Keep refrigerated. Do not freeze.	8	May produce psychological and/or physical dependence.
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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