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Suggested Formula	Prednisolone 15 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 159v3
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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				





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light Sensitive (protect from light whenever possible): *Prednisolone Sodium Phosphate*

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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFI) and Compliance Policy Guides (CPGs).

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	_____
MULTIPLIED 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.	<p><u>Ingredient quantification:</u></p> <p>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:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Quantity of Prednisolone (Base) required for a 100 mL Oral Liquid</td> <td style="text-align: right; padding: 5px;">0.300 g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">DIVIDED BY</td> </tr> <tr> <td style="padding: 5px;">Potency of Prednisolone Sodium Phosphate (base equivalent), in decimal (Step 1Ai)</td> <td style="text-align: right; padding: 5px;">_____</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;">i. Quantity of Prednisolone Sodium Phosphate needed for a 100 mL Oral Liquid</td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> <tr> <td colspan="2" style="padding: 5px;">MULTIPLIED BY</td> </tr> <tr> <td style="padding: 5px;">Processing error adjustments (5 to 9%)</td> <td style="text-align: right; padding: 5px;">1.05 to 1.09</td> </tr> <tr> <td colspan="2" style="padding: 5px;">EQUALS</td> </tr> <tr> <td style="padding: 5px;">ii. Quantity of Prednisolone Sodium Phosphate needed plus processing error adjustments</td> <td style="text-align: right; padding: 5px;">_____ g</td> </tr> </table>	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	MULTIPLIED 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
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EQUALS																			
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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Levigate the Prednisolone Sodium Phosphate (amount determined from Step 2Aii) with the Glycerin.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>																		
4.	<p><u>Medium incorporation:</u></p> <p>A. In the given order, sequentially add the following ingredients to the Oral Mix (Flavored Suspending Vehicle) (50.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none"> -Cherry Flavor -Homogeneous liquid-like dispersion (Step 3A) <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>																		



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5.	<p>Filling to volume:</p> <p>A. Add additional Oral Mix (Flavored Suspending Vehicle) to the mixture (Step 4A) 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>
6.	<p>Product transfer:</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 795.	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 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.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	Shake well before use.	8	Cap tightly after use.
	4	Keep refrigerated (2°C – 8°C). Do not freeze.	9	May produce psychological and/or physical dependence.
	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.			



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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.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 324.
3.	Prednisolone Sodium Phosphate. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1541.
4.	Prednisolone (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #7841.
5.	Prednisolone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 402.
6.	Prednisolone Sodium Phosphate (Monograph). <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 4395.
7.	USP <795>. <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 403.

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