

TELEPHONE: 514-905-5096 FAX: 514-905-5097 technicalservices@medisca.net

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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

Ingredient-Specific Information	
Hygroscopic (protect from moists	ure whenever possible): Prednisolone Sodium Phosphate, Glycerin
Suggested Preparatory Guidelines	
Non-Sterile Preparati	ion Sterile Preparation
<u>Processing Error /</u> <u>Testing Considerations</u> :	To account for processing error considerations during preparation, it is suggested to measure an additional <b>5 to 9%</b> 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	<b>⊗</b>		
Medisca Oral Mix (Flavored Suspending Vehicle)	q.s. to 100.0	mL	, X.C.		

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



# MEDISCA® NETWORK INC. TECHNICAL SUPPORT SERVICES FORMULATION CHEMISTRY DEPARTMENT TOLL-FREE: 866-333-7811 TELEPHONE: 514-905-5096 FAX: 514-905-5097

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Determine the potency of Prednisolone Sodium Phosphate based on the	e certificate of analysis:
	100%
MINUS	
Water Content (from certificate of analysis)	<u> </u>
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	



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	ggested ormula	Prednisolone 15 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 006 159v2
2.	Ingr	edient quantification:		
		Determine the quantity (in g) of Prednisolone Sodium Phosphate required to make a 100 prednisolone (Base) 15 mg/5 mL Oral Liquid:	mL bat	ch of
	(	Quantity of <b>Prednisolone</b> ( <b>Base</b> ) required for a 100 mL Oral Liquid		0.300 g
	I	DIVIDED BY		
	I	Potency of Prednisolone Sodium Phosphate (base equivalent), in decimal (Step 1Ai)	_	
	I	EQUALS		
	i	. Quantity of Prednisolone Sodium Phosphate needed for a 100 mL Oral Liquid	_	g
	ľ	MULTIPLED BY		
	I	Processing error adjustments (5 to 9%)	1	.05 to 1.09
	I	EQUALS		
	i	i. Quantity of Prednisolone Sodium Phosphate needed plus processing error adjustments	_	g
3.	Powe	der-liquid preparation:		
		Levigate the Prednisolone Sodium Phosphate (amount determined from Step 2Aii) with the	he Gly	cerin.
	<u>I</u>	End result: Homogeneous liquid-like dispersion.		
4.	Med	ium incorporation:		
		In the given order, sequentially add the following ingredients to the Oral Mix (Flavo 50.0 mL <i>plus</i> processing error adjustments):	red Su	spending Vehicle)
		Cherry Flavor Homogeneous liquid-like dispersion (Step 3A)		
	<u>S</u>	Specifications: Continuously mix, using high-shear mixing techniques.		
	<u>I</u>	End result: Homogeneous liquid-like dispersion.		
	1	Note: Add the next ingredient, once the previous one has been completely added and disp	persed.	



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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").

<u>Note</u>: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

#### SUGGESTED PRESENTATION

GGESTED PK	LOL	MIATION			
Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirement		<ul><li>Tightly closed dispensing bottle.</li><li>To be dispensed with a metered-dose measuring device.</li></ul>
	1	Use as directed. Do not exceed dose.	prescribed	5	Keep out of reach of children.
Auxiliary Labels	2	Consult your health care practiti prescription or overmedications are currently being prescribed for future use.	the-counter	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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#### **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</i> , 7 <sup>th</sup> <i>Edition</i> . American Pharmaceutical Association; 2012: 324.
3.	Prednisolone Sodium Phosphate. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference</i> , 36 <sup>th</sup> Edition. London, England: The Pharmaceutical Press; 2009: 1541.
4.	Prednisolone (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #7841.
5.	Prednisolone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations</i> , 5 <sup>th</sup> Edition. 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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