

## SUGGESTED PROCEDURE

Item	Prednisolone 10mg/ml Suspension	Formula Date	19 May 2023
API(s)	Prednisolone Anhydrous, USP Micronized	Procedure No.	P2574
Base	Suspend S267™	Revision	R1
		Compound Type	Aqueous Suspension

**Beyond Use Date: Ref Current USP <795>**

Rx	Quantity	Unit of Measure	Comment
Prednisolone Anhydrous USP	1.0	g	
Propylene Glycol, USP	4.0	ml	
Water Soluble Flavor Concentrate	2.0	ml	To Taste
Suspend S267 Suspension Vehicle Stock Solution	25.0	ml	
Suspend S267 Suspension Vehicle Stock Solution	q.s. to 100.0	ml	

\*If using a powder flavor, add powder to Step#2 and dry triturate with Prednisolone. Alternatively it can be added to the Suspend S267 Suspension Stock Solution. If using a liquid flavor add directly to the bottle.

Suspend S267 Suspension Stock Solution (Flavored)	Quantity	Unit of Measure	Comment
Suspend S267	2.53	g	Target 2-3% total soln
Flavor Powder Conc	4.70	g	To Taste
Potassium Sorbate* (0.1% target)	0.12	g	Preservative Preference
Stevia	0.33	g	To Taste
Citric Acid	1.36	g	q.s. pH 4.2 target
Sodium Phosphate Dibasic	2.35	g	Buffer
Distilled Purified Water	108.54	g	q.s.
<b>Total</b>	<b>120</b>	<b>g</b>	

\*Preservative system used is formulator's preference. Several factors affect the stability profile of an aqueous preparation. A preservative efficacy study including storage temperature should be conducted if extended beyond use dating outside of USP <795> is required. The preservative system used is up to the discretion of the formulator.

### Method of Preparation Stock Suspension Solution

1. Weigh each ingredient except for water and place in glass mortar and pestle
2. Dry triturate to break down any clumps in the chemical to form a homogeneous powder
3. Combine and mix into a homogeneous liquid solution (flavor to taste preference)
4. Levigate the fine powder with the water slowly to prevent clumping.
5. Continuously mix using high shear mixing techniques until all solids are dissolved. Desired consistency can be slightly adjusted with additional water, noting target solution pH and preservative used concentration per preference.

### Method of Preparation

1. Weigh Prednisolone and place in glass mortar and pestle
2. Dry triturate to break down any clumps in the chemical to form a homogeneous powder
3. Combine and mix into a homogeneous liquid solution (flavor to taste preference)
  - a) Propylene Glycol
  - b) WS Flavor Concentrate
4. Levigate the fine API powder with the homogeneous liquid solution from step 3.
5. Triturate until all Prednisolone is broken down and incorporated into liquid

6. Incrementally add the mixture from step 5 into the 25ml of Suspend S267 Suspension Vehicle. Continuously mix using high shear mixing techniques.
7. Perform liquid “washes” in mortar and pestle to integrate remaining chemical
8. Pour each “wash” into final container taking precaution not to go over the final volume
9. Q.S. Suspend S267 Suspension Solution and continue mixing using high-shear mixing.
10. Suggested Quality Assessments – follow pharmacy SOPs:
  - a. Weight to Volume calculation
  - b. Color
  - c. Pourability
  - d. Settling
  - e. Resuspendability

Store in air-tight, light-resistant plastic containers

Store at Room Temperature

**Beyond-Use Date should be based on the current USP General Chapter <795>.** Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist. Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

**WARNING!** Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.

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