



Suggested Formula for:

Prednisolone Acetate 1% Ophthalmic Suspension PF

Version number: 1.0

Volume: 100 mL

Prednisolone Acetate, Micronized, USP	1 g
Polysorbate 80, NF	1 mL
Sodium Carboxymethylcellulose, (Med Visc) USP	0.9 g
Sodium Phosphate, Dibasic, USP, Dried	0.352 g
Sodium Phosphate, Monobasic USP, Anhydrous	0.246 g
Water for Injection, USP	Q.S. 100 mL

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.

SUGGESTED COMPOUNDING PROCEDURES

1. In an appropriate size container dissolve Sodium Phosphate Dibasic and Sodium Phosphate Monobasic in Water for Injection. Use an amount of Water for Injection that is approximately 75% of the final volume.
2. Add Polysorbate 80 to step 1 with stirring.
3. Add Sodium Carboxymethylcellulose and Prednisolone Acetate to step 2 while stirring.
4. Allow mixture to continue mixing, Sodium Carboxymethylcellulose and Prednisolone Acetate to wet and hydrate. Suspension will form and become milky in appearance. May take 1-2 hours.
5. Bring suspension to final volume with Water for Injection
6. Transfer preparation into appropriate sized serum bottles. Provide frequent mixing during the transfer process. Crimp and seal the vial.
7. Autoclave the preparation until contents within the vial have reached 121°C, 15 psi for 20 minutes.
8. Provide constant agitation while the preparation is cooling to prevent clumping of the suspension.
9. When preparation is cool, in ISO Class 5 PEC transfer to sterile dropper and seal.

10. Quality assessments
 - a. Sterility
 - b. Uniformity
 - c. Suspension settling
 - d. Label - auxiliary labels, storage, BUD, compounded medication

Protect from light

Store at Room Temperature

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours

Cold Temperature: not more than 3 days

Refer to USP chapter <797>.

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, 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.

Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

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