Suggested Formula for:
Prednisolone Acetate 25 mg/mL Injection (Preserved)
Version number: 1.0
Volume: 30 mL

Prednisolone Acetate, Micronized, USP (PR100)	0.75 g
Polysorbate 80, NF (PO138)	0.29 mL
Sodium Carboxymethylcellulose, (Med Visc) USP (CA192)	0.271 g
Water for Injection, USP	Q.S. 30 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. Calibrate (depyrogenated) vial to final volume with sterile water.
2. Add Benzyl Alcohol and Polysorbate 80.
3. Weigh Prednisolone Acetate and Sodium Carboxymethylcellulose and add to vial.
4. Add approximately 50% of final volume of sterile water to vial, apply stopper and shake to wet powders.
5. Bring to final volume with sterile water.
6. Apply stopper and seal with crimper.
7. Autoclave for 30 minutes at 121°C (with biological indicator per pharmacy SOPs).
8. When cycle is complete, shake until cooled to prevent clumping.
9. Vial may be subject to sonication to reduce particle size.
10. Quality assessments
    a. Sterility
    b. Particle size
    c. Suspension settling
    d. Label - auxiliary labels, storage, BUD, compounded medication

Note: for larger batch sizes, this compound may be prepared in calibrated, depyrogenated beaker by adding Polysorbate to approximately 50% final volume then remaining ingredients, bringing suspension to final volume and allowing to mix on stir plate for approximately 2 hours until suspension is uniform. Transfer suspension to depyrogenated vials and autoclave per procedure above, followed by shaking and sonication if necessary.

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.

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.

07/18rd

Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: SpectrumRx.com | Email: sales@spectrumrx.com