



Testosterone Cypionate 100mg/mL Oleaginous Sterile Injection, Preserved

Version number: 1.0 Volume: 100 mL

Testosterone Cypionate ,USP (TE118)

Benzyl Alcohol, NF (BE158)

Benzyl Benzoate, USP (BE159)

Cottonseed Oil, NF

10gm

0.900 gm

20mL

Q.S. 100mL

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. Calculate the required quantity of each ingredient for the total amount to be prepared
- 2. Accurately weigh and/or measure each ingredient
- 3. Mix the Testosterone Cypionate and benzyl alcohol until homogenous and geometrically add 50mL cottonseed oil
- 4. Incorporate the benzyl benzoate in 10mL cottonseed oil to form a miscible mixture
- 5. Incorporate the two mixtures until well combined and add cottonseed oil to volume mixing well
- 6. Filter into sterile, depyrogenated vials, stopper with sterilized stoppers, and apply seal, crimp and label.
- 7. Suggested Quality Assessments follow pharmacy SOPs:
 - a. Bubble point filter integrity
 - b. Particulate
 - c. Sterility
 - d. Endotoxins
 - e. Label auxiliary labels, storage, BUD, compounded medication

Protect from light and moisture

Store at Controlled Room Temperature

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.

Beyond-Use Date should be based on the current issue of the USP <797>

Precautions:

Hazardous drugs should be handled according to USP <800>, NIOSH standards and pharmacy SOPs. This preparation should be compounded in a biological safety cabinet or compounding aseptic containment isolator. 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 personal protective equipment.

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