



March 13, 2020

Testosterone Cypionate Injection, USP (CIII)

200 mg/mL

Wilshire Pharmaceuticals has investigated the product complaints for Testosterone Cypionate Injection, USP (CIII) (1 mL single dose & 10 mL multiple dose vials) regarding *atypical appearance of the product solution* (e.g., crystallization, cloudy product, residue in product, etc.). Our investigation has found that although these attributes have been observed, they do not impact patient safety, efficacy, or product quality when the instructions found in the prescribing information are followed prior to administration.

The high concentration of Testosterone Cypionate present in the solution may cause the product to be susceptible to crystallization (and other forms of atypical product appearance) when exposed to temperatures lower than the ranges recommended on the label (20°C to 25°C [68°F to 77°F]).

Test data confirms key product quality attributes:

- Product can be warmed, shaken, and the crystals re-dissolved, when prepared according to instructions found on all product labeling.
- Potency of crystalized product that has been returned to solution has been confirmed to maintain product potency at the labeled strength.

The prescribing information, carton and vial labeling state (see Appendix):

Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

Based on our testing, distributed lots of Testosterone Cypionate Injection, USP (CIII) continue to be acceptable for use when used as directed in the prescribing information.

We apologize for any confusion this may have caused and, as always, we thank you for your business.

Sincerely,

Wilshire Pharmaceuticals, Inc.