

Sun Pharmaceutical Industries Ltd.

Tandalja, Vadodara -390 020 INDIA.

Tel. : 91-265-6615500/6615600/6615700

Fax: 91-265-2354897



September 6, 2016

Testosterone Cypionate Injection USP, C III

Sun pharma has investigated the product complaints on Testosterone Cypionate Injection USP regarding crystallization of contents in 200 mg/mL vials. The investigation has found that although crystals have been observed, the formulation of crystals does not impact patient safety, efficacy, or product quality when the US Product Insert (USPI) instructions are followed prior to administration.

Testosterone Cypionate Injection USP 100 mg/mL is a very highly concentrated and 200 mg/mL is a supersaturated sterile solution for injection, comprised of cottonseed oil, testosterone cypionate and benzyl alcohol. The high concentrations of active ingredient makes the product very susceptible to crystallization when exposed to temperatures lower than the ranges recommended on the label [20°C to 25°C (68°F to 77°F)]. The composition of Sun's product is similar to RLD product Depo[®]-Testosterone and the phenomenon of crystallization has also been reported for RLD product.

Investigation at Sun Pharma has concluded that the product meets all registered product specifications when the USPI and product packaging instructions are followed prior to administration.

Testing from study conducted confirms two key product quality attributes:

- product can be warmed, shaken, and the crystals re-dissolved, when prepared according to instructions found in the product insert and on the vial label; and,
- potency of representative samples after redissolving the crystals by warming confirm product potency at the labeled strength.

This product attribute is addressed with specific instructions within the USPI, on the product vial label, and also on product carton.

The USPI states:

“Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.”

In addition, the current approved vial label states (see Appendix):

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

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Based on our testing and evaluation of representative samples containing crystals, distributed lots of Testosterone Cypionate Injection USP continue to be acceptable for use, even with the presence of crystals, when used as directed in the product insert.

This communication and updated product information is available on the Sun Pharma Web site www.sunpharma.com.

Please direct any questions related to the content of this letter to Sun Pharmaceutical Industries, Inc. at 1-800-818-4555.

Sincerely,

Sun Pharmaceutical Industries Limited

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Appendix

Item Code	Item Description	NDC# (for Vial)	NDC# (for Box of 1 Vial)
PJLB1565B	Testosterone Cypionate Injection, USP, 100 mg/mL, 10 mL, Multiple-Dose Vial	62756-017-40	62756-017-40
PJLB1566A	Testosterone Cypionate Injection, USP, 200 mg/mL, 1 mL Vial	62756-015-40	62756-015-40
PJLB1567B	Testosterone Cypionate Injection, USP, 200 mg/mL, 10 mL, Multiple-Dose Vial	62756-016-40	62756-016-40

Each mL contains testosterone cypionate, USP 100 mg. Also contains benzyl benzoate, 0.1 mL; benzyl alcohol added as preservative, 9.45 mg; in cottonseed oil, 736 mg.

USUAL DOSAGE: See accompanying prescribing information.

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

Vials should be stored at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Protect from light. Retain in carton until time of use.

NDC 62756-017-40

Testosterone Cypionate Injection, USP

1,000 mg/10 mL (100 mg/mL)

FOR INTRAMUSCULAR USE ONLY

Rx only
10 mL Multiple-Dose Vial

N 3 6275610174015

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Manufactured by:
Sun Pharmaceutical Industries Ltd.
Halol-Baroda Highway,
Halol-389 350, Gujarat, India.

PJLB1565C ISS. 07/2016
GUJ/DRUGS/28/396

B. No.:
Exp.:

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

Vials should be stored at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Protect from light.

NDC 62756-015-40

Testosterone Cypionate Injection, USP

200 mg/mL

FOR INTRAMUSCULAR USE ONLY

Rx only **1 mL Vial**

N 3 6275610154011

Distributed by:
Sun Pharma Ind. Inc, NJ 08512

Manufactured by:
Sun Pharma Ind. Ltd., India.

PJLB1566C ISS. 07/2016
GUJ/DRUGS/28/396

B. No.:
Exp.:

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Each mL contains testosterone cypionate, USP 200 mg. Also contains benzyl benzoate, 0.2 mL; benzyl alcohol added as preservative, 9.45 mg; in cottonseed oil, 560 mg.


USUAL DOSAGE: See accompanying prescribing information.

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

Vials should be stored at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Protect from light. Retain in carton until time of use.


NDC 62756-016-40

Testosterone Cypionate Injection, USP 

2,000 mg/10 mL (200 mg/mL)

FOR INTRAMUSCULAR USE ONLY

Rx only
10 mL Multiple-Dose Vial

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01640
62756
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Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Manufactured by:
Sun Pharmaceutical Industries Ltd.
Halol-Baroda Highway,
Halol-389 350, Gujarat, India.

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B. No.:

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