

# Testosterone Enanthate (Cas No 315-37-7) Specification USP/BP

TAJCPG-DCYHEAPAZQ

Taj Active Pharmaceuticals Ingredients

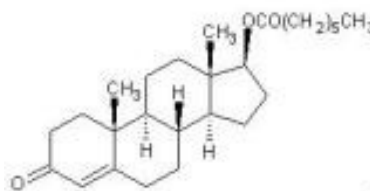
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Active Pharmaceutical Ingredients  
TAJ PHARMACEUTICALS LIMITED INDIA



Raw Material / Chemicals Index

Taj Pharmaceuticals Ltd.  
**Testosterone  
Enanthate**  
(CAS No.: 315-37-7)



## Product Description

<b>Product name</b>	testosterone enanthate
<b>Chemical name</b>	4-Androsten-17 $\beta$ -ol-3-one Enanthate

<b>CAS No.</b>	315-37-7
<b>Molecular formula</b>	C <sub>26</sub> H <sub>40</sub> O <sub>3</sub>
<b>Appearance</b>	white crystalline powder or brown liquid.
<b>Specification</b>	USP/BP

### **Description:**

#### **Testosterone enanthate**

is used in androgen substitution to replace testosterone at levels as close to physiological levels as is possible. For some androgen-dependent functions testosterone is a pro-hormone, peripherally converted to 5alpha-dihydrotestosterone (DHT) and 17beta-estradiol (E2), of which the levels preferably should be within normal physiological ranges. Furthermore, androgens should have a good safety profile without adverse effects on the prostate, serum lipids, liver or respiratory function, and they must be convenient to use and patient-friendly, with a relative independence from medical services. Natural testosterone is viewed as the best androgen for substitution in hypogonadal men. testosterone enanthate is used to treat male hypogonadism. Male hypogonadism is one of the most common endocrinologic syndromes. The diagnosis is based on clinical signs and symptoms plus laboratory confirmation via the measurement of low morning testosterone levels on two different occasions. Serum luteinizing hormone and follicle-stimulating hormone levels distinguish between primary (hypergonadotropic) and secondary (hypogonadotropic) hypogonadism. Osteoporosis in male hypogonadism: responses to androgen substitution differ among men with primary and secondary hypogonadism. In primary hypogonadal men the on bone mineral density (BMD) responds dose dependently to testosterone substitution, whereas in secondary hypogonadism only testosterone enanthate treatment significantly increased the BMD. In all mammalian species studied to date, testosterone has been found to be the predominant intratesticular steroid. In volunteers receiving hormonal contraception by using a combination of testosterone enanthate and levonorgestrel, there is a profound reduction of both intratesticular testosterone concentration and androgen bioactivity. High doses of testosterone enanthate can normalize hematocrit values of maintenance hemodialysis patients with replenished bone marrow iron stores. testosterone enanthate is classified as a prohibited substance by the World Anti-Doping Agency (WADA) and its use may be detected by way of the urinary testosterone/epitestosterone (T/E) ratio. (PMID: 16185098, 16467270, 15329035, 17530941, 17484401, 4028529, 12792150)

#### **Testosterone enanthate Synonyms:**

Testosterone Enanthate  
 17β-Hydroxy-4-androsten-3-one 17-enanthate, 4-Androsten-17β-ol-3-one 17-enanthate, Testosterone 17β-heptanoate  
 TESTOSTERONE ENANTHATE--DEA\*SCHEDULE III  
 testosterone entanoate  
 17β-hydroxy-4-androsten-3-one 17-enanthate  
 17b-hydroxyandrost-4-en-3-one-17-ethanate  
 17BETA-HYDROXY-4-ANDROSTEN-3-ONE 17-ENANTHATE  
 4-ANDROSTEN-17-BETA-OL-3-ONE ENANTHATE

#### **Chemical IUPAC Name**

[(8R,9S,10R,13S,14S,17S)-10,13-dimethyl-3-oxo-1,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-17-yl] heptanoate

#### **Chemical Taxonomy**

##### **Kingdom**

\* Organic

##### **Super Class**

\* Cholesterols and derivatives

##### **Class**

\* Steroids and Steroid Derivatives

**Sub Class**

\* Ketosteroids

**Family**

\* Mammalian Metabolite

**Species**

\* ketone  
\* carboxylic acid ester  
\* alkene

**Biofunction**

\* Hormones, Membrane component

**Application**

—

**Source**

\* Exogenous

**Average Molecular Weight**

400.594

**Monoisotopic Molecular Weight**

400.297760

**Isomeric SMILES**

CCCCCCC(=O)O[C@H]1CC[C@H]2[C@@H]3CCC4=CC(=O)CC[C@]4(C)[C@H]3CC[C@]12C

**Canonical SMILES**

CCCCCCC(=O)OC1CCC2C3CCC4=CC(=O)CCC4(C)C3CCC12C

**InChI Identifier**

InChI=1/C26H40O3/c1-4-5-6-7-8-24(28)29-23-12-11-21-20-10-9-18-17-19(27)13-15-25(18,2)22(20)14-16-/h17,20-23H,4-16H2,1-26(21,23)3  
3H3/t20-,21-,22-,23-,25-,26-/m0/s1

**Synthesis Reference**

19600615 CAN

Ulrich, Miroslav; Novacek, Alois; Stejskal, Frantisek.  
Testosterone enanthate. (1960), CS 95825  
55:81895 AN 1961:81895

**Melting Point  
(Experimental)**

36-37.5 oC

**Predicted Water Solubility**

4.63e-04 mg/mL [Predicted by ALOGPS]; 5.43e-06 mg/mL at 25 oC [MEYLAN,WM et al. (1996)]

**Physiological Charge**

0

**State**

Solid

**Predicted LogP/Hydrophobicity**

5.11 [Predicted by ALOGPS]; 5.6 [Predicted by PubChem via XLOGP]; 6.73 [MEYLAN,WM & HOWARD,PH (1995)]

**Fire and Explosion Data****Flammability of the Product**

May be combustible at high temperature.

**Flash Points**

CLOSED CUP: Higher than 93.3°C (200°F).

**Products of Combustion**

These products are carbon oxides (CO, CO2).

**Fire Hazards in Presence of Various Substances**

Slightly flammable to flammable in presence of heat.  
Non-flammable in presence of shocks.

**Explosion Hazards in Presence of Various Substances**

Slightly explosive in presence of open flames and sparks.  
Non-explosive in presence of shocks.

**Fire Fighting Media**

SMALL FIRE: Use DRY chemical powder.

**and Instructions**

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

**Special Remarks on Hazards**

As with most organic solids, fire is possible at elevated Fire temperatures

**Special Remarks on Explosion Hazards**

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Accidental Release Measures****Small Spill**

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

**Large Spill**

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

**Handling and Storage****Precautions**

Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

**Storage**

Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light. Store in light-resistant containers. Refrigerate

**Exposure Controls/Personal Protection****Engineering Controls**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal Protection**

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

**Personal Protection in Case of a Large Spill**

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

**Physical and Chemical Properties**

**Physical state and appearance** Solid. (Crystalline solid. Powdered solid.)

**Molecular Weight** 400.59 g/mole

**Melting Point** 34°C (93.2°F) - 39 C.

**Solubility**

Insoluble in cold water, hot water. Soluble in chloroform.

**Stability and Reactivity Data**

**Stability** The product is stable.

**Conditions of Instability** Excess heat, incompatible materials

**Incompatibility with various substances** Reactive with oxidizing agents.

## **Testosterone Enanthate**

**Special Remarks on Reactivity** Sensitive to light.

**Polymerization** Will not occur.

## **Toxicological Information**

**Routes of Entry** Absorbed through skin. Inhalation. Ingestion.

**Toxicity to Animals** Acute oral toxicity (LD50): >1000 mg/kg [Rat].

## **Chronic Effects on Humans**

TERATOGENIC EFFECTS: Classified POSSIBLE for human.

DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male [POSSIBLE].

May cause damage to the following organs: blood, the reproductive system, liver.

## **Other Toxic Effects on Humans**

Slightly hazardous in case of skin contact (irritant, permeator), of ingestion, of inhalation.

## **Special Remarks on Chronic Effects on Humans**

May affect genetic material (mutagenic).

May cause adverse reproductive effects and birth defects (teratogenic).

May cause cancer

## **Ecological Information**

## **Products of Biodegradation**

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

## **Toxicity of the Products of Biodegradation**

The products of degradation are less toxic than the product itself.

## **Waste Disposal**

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## **Other Regulations**

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

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