

## Draft Guidance on Testosterone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Testosterone

**Form/Route:** Pellet/Implantation

**Recommended studies:** 1 study

Type of study: Fasting

Design: Single-dose, two-arm, parallel, in vivo

Strength: 75 mg [Dose: 150 mg (two x 75 mg pellet)]

Subjects: Healthy, hypogonadal male patients

Additional comments:

- Subjects should not currently be receiving any treatment for their hypogonadism.
- The inclusion criterion for hypogonadal males is serum testosterone levels below 2.5 ng/mL.
- The parallel groups should be well-balanced with respect to the study population demographics
- An average baseline correction is obtained by averaging the three predose sampling times (-1.0, -0.5 and 0 hours). The baseline corrected and uncorrected data and statistical analyses should be submitted to the Agency.

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**Analytes to measure:** Total testosterone (free and protein bound) in plasma

**Bioequivalence based on (90% CI):** Total testosterone (baseline-corrected) in plasma

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.