*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

# Draft Guidance on Testosterone Undecanoate

**December 2025**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

---

**Active Ingredient:** Testosterone undecanoate

**Dosage Form:** Capsule

**Route:** Oral

**Strength:** 112.5 mg

**Recommended Studies:** Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 112.5 mg
   Subjects: Asymptomatic hypogonadal males with morning serum testosterone measurements below 300 ng/dL on at least two separate occasions
   Additional comments: Exclude geriatric males. Subjects should not be currently receiving any treatment for their hypogonadism.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 112.5 mg
   Subjects: Asymptomatic hypogonadal males with morning serum testosterone measurements below 300 ng/dL on at least two separate occasions
   Additional comments: See comments above.

**Analytes to measure:** Testosterone undecanoate and testosterone in plasma

Testosterone undecanoate may undergo limited ex vivo conversion to testosterone during sample collection and processing. This risk will be mitigated by using enzyme-inhibited plasma and controlled handling conditions and evaluated during method validation to ensure accurate measurement of testosterone undecanoate and testosterone. Since testosterone is an endogenous substance, the mean of the pre-dose testosterone should be used for the baseline correction. Pharmacokinetics and statistical analyses should be performed on both baseline uncorrected and baseline corrected data.

**Bioequivalence based on (90% CI):** Testosterone undecanoate and baseline corrected testosterone

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

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

---

**Document History**: Recommended December 2025

**Unique Agency Identifier:** PSG_208088

[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions.*