

**Draft Guidance on Methyltestosterone**

**October 2024**

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**Active Ingredient:** Methyltestosterone

**Dosage Form:** Capsule

**Route:** Oral

**Strength:** 10 mg

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting

Design: Single-dose, two-treatment, two-period crossover in vivo

Strength: 10 mg

Subjects: Healthy males

Additional comments: For safety reasons, females should not be enrolled in this study.

**Analyte to measure:** Methyltestosterone in plasma

**Bioequivalence based on (90% CI):** Methyltestosterone

**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 for each of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended June 2013; Revised October 2024

**Unique Agency Identifier:** PSG\_083976

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<sup>1</sup> If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.