

Draft Guidance on Abiraterone Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

Active Ingredient: Abiraterone acetate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 125 mg
Subjects: Males, general population
Additional comments: 1) A reference-scaled average bioequivalence approach may be considered if the drug product exhibits high intra-subject variability. If using this approach, provide evidence of high variability in the bioequivalence parameters, AUC and/or C_{max} (i.e., within-subject variability $\geq 30\%$). 2) Males with female partners of reproductive potential should use effective contraception during the study and for at least three weeks after the last dose.

 2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 125 mg
Subjects: Males, general population
Additional comments: See comments above
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Analyte to measure (in appropriate biological fluid): Abiraterone in plasma

Bioequivalence based on (90% CI): Abiraterone

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.