

Draft Guidance on Abiraterone Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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-way crossover in vivo
Strength: 250 mg
Subjects: Healthy males , general population.
Additional Comments:
 - Study population should consist of healthy males at least 18 years old.
 - Study participants must be in good general health as determined by no clinically significant findings on medical history, physical examination, vital signs, 12-lead electrocardiogram consistent with normal cardiac conduction and function, and clinical laboratory measurements.
 - Monitor vital signs and serum electrolytes during the course of the study.
 - Perform a 12-lead ECG at baseline and at the end of the study.
 - Inform study participants that it is not known whether abiraterone or its metabolites are present in semen. Study participants should use adequate contraception during the study and for at least one week after the last abiraterone acetate dose.
 - Applicants may consider using a reference-scaled average bioequivalence approach for this drug product. For general information on this approach, please refer to the Individual Product Bioequivalence Recommendations Guidance on Progesterone Capsules.

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 250 mg
Subjects: Healthy males, general population.
Additional Comments:
 - The reference listed drug (RLD) labeling indicates that abiraterone acetate tablets must be taken on an empty stomach. However, due to the complex food effects associated with abiraterone acetate tablets, FDA recommends applicants conduct a BE study under fed conditions.
 - See the fasted study design above for additional comments.

Analytes to measure (in appropriate biological fluid): Abiraterone in plasma

Bioequivalence based on (90% CI): Abiraterone

Waiver request of in vivo testing: N/A

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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.