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Draft Guidance on Abiraterone Acetate

October 2025

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Active Ingredient: Abiraterone acetate

Dosage Form: Tablet

Route: Oral

Strengths: 250 mg, 500 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: 500 mg
   Subjects: Healthy males
   Additional comments:
   - Exclude subjects with electrocardiogram (ECG) abnormalities. Monitor vital signs, serum electrolytes, and ECG during the study. Subjects with female partners of reproductive potential should use effective contraception during the study and for three weeks after the last dose.
   - Applicants may consider using a reference-scaled average bioequivalence approach for abiraterone. If using this approach, provide evidence of high variability in the pharmacokinetic parameters (i.e., within-subject variability ≥30%) for the reference listed drug (RLD). For detailed information on this approach, refer to the most recent version of the FDA guidance for industry on *Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA*.[a]

Analyte to measure: Abiraterone in plasma

Bioequivalence based on (90% CI): Abiraterone

Waiver request of in vivo testing: 250 mg strength based on (i) an acceptable bioequivalence study on the 500 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

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 both strengths of the test product and reference listed drug (RLD)[1]. Specifications will be determined upon review of the abbreviated new drug application.

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] 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*.