*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Abiraterone Acetate; Niraparib Tosylate**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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**Active Ingredients:** Abiraterone acetate; Niraparib tosylate

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 500 mg; EQ 50 mg Base, 500 mg; EQ 100 mg Base

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

1. Type of study: Fasting
   Design: Multiple-dose, two-treatment, two-period crossover in vivo
   Strength: 500 mg; EQ 100 mg Base
   Subjects: Male patients who are receiving a stable dose of 1000 mg; EQ 200 mg Base (2x 500 mg; EQ 100 mg Base) of abiraterone acetate; niraparib tosylate tablets based on the indications in the approved labeling
   Additional comments: Exclude patients who require dosage modification or with expected changes in concomitant medications that may potentially affect the pharmacokinetics of abiraterone or niraparib during the study. Males with female partners of reproductive potential should use effective contraception during treatment and for 4 months after the last dose. Implement safety precautions and monitoring including complete blood count during treatment as recommended in the labeling. Submission of an investigational new drug application is required prior to the conduct of a bioequivalence study for a cytotoxic drug such as niraparib pursuant to 21 CFR § 320.31.

**Analytes to measure:** Abiraterone and niraparib in plasma

**Bioequivalence based on (90% CI):** Abiraterone and niraparib

**Waiver request of in vivo testing:** 500 mg; EQ 50 mg Base strength based on (i) an acceptable bioequivalence study on the 500 mg; EQ 100 mg Base 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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**Document History:** Recommended October 2025

**Unique Agency Identifier:** PSG_216793

[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*.