

## Draft Guidance on Olaparib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Capsule; oral

**Recommended Studies:** One study

Type of study: Steady-state (SS)

Design: Two-way crossover *in vivo*

Strength: 50 mg at the dose of 400 mg (8 x 50 mg)

Subjects: Patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer.

Additional Comments: Submission of an Investigational New Drug Application (IND) is required prior to the conduct of a bioequivalence study for this cytotoxic drug product (See 21 C.F.R § 320.31).

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**Analytes to measure (in appropriate biological fluid):** Olaparib in plasma.

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

In the evaluation of the steady-state bioequivalence study, the following pharmacokinetics data should be submitted for olaparib: AUC<sub>0-tau</sub>, and C<sub>maxSS</sub>. In addition, please report C<sub>minSS</sub> (concentration at the end of a dosing interval), C<sub>avSS</sub> (average concentration during a dosing interval), degree of fluctuation [(C<sub>max</sub>-C<sub>min</sub>)/C<sub>avSS</sub>], swing [(C<sub>maxSS</sub>-C<sub>minSS</sub>)/C<sub>minSS</sub>], and T<sub>max</sub>.

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