Contains Nonbinding Recommendations

Draft Guidance on Rucaparib Camsylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Rucaparib camsylate
Dosage Form; Route:	Tablet; oral
Recommended Studies:	One study
1. Type of study:	Pharmacokinetic endpoint, steady-state
Design:	Multiple-dose, two-way crossover
Strength:	Eq. 300 mg (base) tablet (dose = 2x300 mg=600 mg daily with or without food)
Subjects:	The study should be conducted in female patients with deleterious BRCA mutation (germline and/or somatic) associated with advanced cancer who have been treated with two or more chemotherapies and are receiving a regimen of rucaparib camsylate.
Additional Comments:	1) Attainment of steady state should be confirmed with at least 3 consecutive trough levels. 2) Blood sampling for bioequivalence should consist of appropriate sampling times over a 12 hr period following attainment of steady state. 3) Females should not be pregnant or lactating. 4) Women of child bearing potential should be advised to use an effective method of contraception while using Rucaparib and for up to 8 weeks after ending the treatment 5) Investigators should refer to Warnings, Precautions, Contraindications and Adverse Reactions in the FDA-approved labeling and follow the recommendations closely. 6) The study should be designed around each patient's existing Rucaparib regimen and no changes in dose or regimen should be made for the purpose of the bioequivalence study. 7) Considering that this is a cytotoxic drug, a Bio-IND is required for this drug product[1]

[1] The Bio-IND should be filed as per the requirements outlined in 21 CFR Section 320.31

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

Bioequivalence based on (90% CI): Rucaparib

Waiver request of in-vivo testing: EQ 200 mg (base) and EQ 250 mg (base) strength tablets based on (i) acceptable bioequivalence studies on the EQ 300 mg (base) strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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).