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Draft Guidance on Talazoparib Tosylate

December 2025

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Active Ingredient: Talazoparib tosylate

Dosage Form: Capsule

Route: Oral

Strengths: EQ 0.1 mg Base, EQ 0.25 mg Base, EQ 0.35 mg Base, EQ 0.5 mg Base, EQ 0.75 mg Base, EQ 1 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Steady state
   Design: Multiple-dose, two-treatment, two-period crossover
   Strength: EQ 1 mg Base
   Subjects: Male and female patients who are receiving a stable dose of talazoparib tosylate capsules based on the approved indications
   Additional comments:
   - Females of reproductive potential should use effective contraception during treatment and 6 months after the last dose of talazoparib tosylate. Implement safety precautions and monitoring including complete blood count during treatment as recommended in the labeling.

- Exclude patients who may require dosage modification or with expected changes in concomitant medications that may potentially affect the pharmacokinetics of talazoparib during the study. Talazoparib tosylate can be administered with or without food per the labeling. For the purpose of a bioequivalence study, patients should be instructed to take the drug under similar food conditions during both periods of the study. A parallel study design may be considered as an alternative bioequivalence approach due to the long elimination half-life of talazoparib. Blood sampling should allow sufficient time on both the test product and reference listed drug (RLD) to reach steady state. Blood sampling should consist of appropriate sampling times over a 24-hour period following attainment of steady state, confirmed with at least three consecutive trough concentrations. Submission of an investigational new drug application is required prior to the conduct of a bioequivalence study for a cytotoxic product pursuant to 21 C.F.R § 320.31(a).

Analyte to measure: Talazoparib in plasma

Bioequivalence based on (90% CI): Talazoparib

Waiver request of in vivo testing: EQ 0.1 mg Base, EQ 0.25 mg Base, EQ 0.35 mg Base, EQ 0.5 mg Base, and EQ 0.75 mg Base strengths based on (i) an acceptable bioequivalence study on the EQ 1 mg Base strength, (ii) proportional similarity of the formulations 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 in FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test product and RLD.[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.