

**Draft Guidance on Pazopanib Hydrochloride**

**March 2021**

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This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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In September 2012, FDA issued a draft product-specific guidance for industry on generic pazopanib hydrochloride. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

**Active Ingredient:** Pazopanib hydrochloride

**Dosage Form; Route:** Tablet; oral

**Recommended Study:** One study

1. Type of study: Steady-state  
Design: Multiple-dose, two-period, two-treatment, fasting crossover  
Strength: EQ 200 mg Base at the dose of EQ 800 mg Base (4 x EQ 200 mg Base tablet)  
Subjects: Advanced renal cell carcinoma adult patients for whom pazopanib is indicated, who are already receiving pazopanib hydrochloride tablets in standard therapy, and who are tolerating a stable dosing regimen of EQ 800 mg Base per day  
Additional comments: Alternatively, a parallel study design may be considered due to the long elimination half-life of pazopanib. Attainment of steady state should be based on at least three consecutive trough concentrations. Blood sampling for bioequivalence should consist of appropriate sampling times over a 24-hour period following attainment

of steady state. Exclude pregnant or lactating females. Advise females of reproductive potential to be on adequate contraceptive methods during treatment and for at least two weeks after treatment discontinuation. Advise males (including those who have had vasectomies) with female partners of reproductive potential to use condoms during treatment with pazopanib and for at least two weeks after the last dose. Exclude patients with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor patients during the study for electrocardiogram changes.

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**Analyte to measure:** Pazopanib in plasma

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

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database <https://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

**Revision History:** Recommended September 2012; Revised March 2021

**Unique Agency Identifier:** PSG\_022465