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Draft Guidance on Futibatinib

October 2024

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Active Ingredient: Futibatinib

Dosage Form: Tablet

Route: Oral

Strength: 4 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 4 mg at a dose of 8 mg (2 x 4 mg)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Perform a comprehensive ophthalmological examination prior to enrollment and exclude subjects with ophthalmological abnormalities. Females of reproductive potential should use non-hormonal contraception during the study and for one week after the last dose. Males with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose.

Analyte to measure: Futibatinib in plasma

Bioequivalence based on (90% CI): Futibatinib

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, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each 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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[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*.