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Draft Guidance on Pemigatinib

October 2024

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Active Ingredient: Pemigatinib

Dosage Form: Tablet

Route: Oral

Strengths: 4.5 mg, 9 mg, 13.5 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: 13.5 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 (e.g., corneal or retinal disorders). Females of reproductive potential and males with female partners of reproductive potential should use effective contraception during the study and for 1 week after the final dose.

Analyte to measure: Pemigatinib in plasma

Bioequivalence based on (90% CI): Pemigatinib

Waiver request of in vivo testing: 4.5 mg and 9 mg strengths based on (i) acceptable bioequivalence study on the 13.5 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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 all strengths 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*.