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Draft Guidance on Lazertinib Mesylate

November 2025

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Active Ingredient: Lazertinib mesylate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 80 mg Base, EQ 240 mg Base

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: EQ 240 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   - Subjects should be advised to limit sun exposure and use appropriate sun protection during the study to prevent dermatologic adverse reactions. Females of reproductive potential and males with female partners of reproductive potential should use effective contraception during the study and for three weeks after the last dose.
   - Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of lazertinib. Alternatively, a parallel study design may be considered.

Analyte to measure: Lazertinib in plasma

Bioequivalence based on (90% CI): Lazertinib

Waiver request of in vivo testing: EQ 80 mg Base strength based on (i) an acceptable bioequivalence study on the EQ 240 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both 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 both 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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Unique Agency Identifier: PSG_219008

[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*.