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Draft Guidance on Neratinib Maleate

November 2025

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Active Ingredient: Neratinib maleate

Dosage Form: Tablet

Route: Oral

Strength: EQ 40 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 40 mg Base at the dose of 240 mg (6 x EQ 40 mg Base)
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: Males with female partners of reproductive potential should use effective contraception during the study and for 3 months after the last dose.

Analyte to measure: Neratinib in plasma

Bioequivalence based on (90% CI): Neratinib

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 guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.