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Draft Guidance on Lapatinib Ditosylate

November 2022

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Active Ingredient: Lapatinib ditosylate

Dosage Form; Route: Tablet; oral

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 250 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with abnormal liver function tests prior to the study. Monitor liver function during the study. Female subjects of reproductive potential and male subjects with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose. Ensure an adequate washout period between treatments in the crossover study to minimize the potential risk of hepatoxicity.

Analyte to measure: Lapatinib in plasma

Bioequivalence based on (90% CI): Lapatinib

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 and reference products. Specifications will be determined upon evaluation of the Abbreviated New Drug Application (ANDA).

Revision History: Recommended May 2010; Revised July 2010, November 2022

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