Contains Nonbinding Recommendations

Guidance on Erlotinib Hydrochloride

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Active ingredient: Erlotinib Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 150 mg
Subjects: Normal healthy males and females, general population.
Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study. Any subject experiencing an adverse event should be followed until the adverse event has completely resolved.

Analytes to measure (in appropriate biological fluid): Erlotinib in plasma

Bioequivalence based on (90% CI): Erlotinib

Waiver request of in-vivo testing: 100 mg and 25 mg based on (i) acceptable bioequivalence studies on the 150 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.