Contains Nonbinding Recommendations

Draft Guidance on Zafirlukast

Active ingredient: Zafirlukast

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 20 mg
Subjects: Normal healthy males and females, general population.
Additional Comments:

Analytes to measure (in appropriate biological fluid): Zafirlukast in plasma.

Bioequivalence based on (90% CI): Zafirlukast

Waiver request of in-vivo testing: 10 mg based on acceptable (i) bioequivalence studies on the 20 mg tablet, and (ii) proportional similarity of the formulations 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.