

Guidance on Tamoxifen Citrate

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Active ingredient: Tamoxifen Citrate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 20 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments: Due to the long elimination half-life of tamoxifen, the firm may consider a parallel study design.

2. Type of study: Fed
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 20 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional comments: Please see comment above.

Analytes to measure: Tamoxifen in plasma

Bioequivalence based on (90% CI): Tamoxifen

Waiver request of in-vivo testing: 10 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.accessdata.fda.gov/scripts/cder/dissolution/>. 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.