

Guidance on Escitalopram Oxalate

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Active ingredient: Escitalopram Oxalate

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: Normal healthy males and females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 20 mg
Subjects: Normal healthy males and females, general population.
Additional comments:

Analytes to measure: Escitalopram, using an achiral assay

Bioequivalence based on (90% CI): Escitalopram

Waiver request of in-vivo testing: 5 mg and 10 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) proportionally similar 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.