

Draft Guidance on Paroxetine Mesylate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Paroxetine Mesylate

Form/Route: Capsule/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single dose, two way crossover, in vivo
Strength: 7.5 mg (base)
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: Females should practice abstention or contraception during the study.

2. Type of study: Fed
Design: Single dose, two way crossover, in vivo
Strength: 7.5 mg (base)
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: Please see above.

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

Bioequivalence based on (90% CI): Paroxetine

Waiver request of in vivo testing: N/A

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.