Contains Nonbinding Recommendations

Draft Guidance on Paroxetine Mesylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Paroxetine mesylate

Dosage Form; Route: Tablet; Oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base
   Subjects: Males and non-pregnant females, general population
   Additional Comments: Women of child-bearing potential should practice abstention or contraception during the study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base
   Subjects: Males and non-pregnant females, general population
   Additional Comments: See above.

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

Bioequivalence based on (90% CI): Paroxetine

Waiver request of in-vivo testing: Eq 10, 20 and 30 mg base based on (i) acceptable bioequivalence studies on the 40 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: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).