Contains Nonbinding Recommendations

Guidance on Citalopram Hydrobromide

This guidance represents 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: Citalopram hydrobromide

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 40 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comment: Females should not be pregnant, and if applicable, 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: 40 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comment: Please see comment above.

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

Bioequivalence based on (90% CI): Citalopram

Waiver request of in vivo testing: 20 mg and 10 mg 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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).