Contains Nonbinding Recommendations

Draft Guidance on Pimozide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Pimozide

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 2 mg
   Subjects: Adult males and non-pregnant, non-lactating females, general population.
   Additional Comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 2 mg
   Subjects: Adult males and non-pregnant, non-lactating females, general population.
   Additional Comments: None

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

Pimozide has a long terminal elimination half-life. Please ensure adequate washout periods between treatments in the crossover studies. You may also consider using a parallel study design due to pimozide's long half-life. For long half-life drug products, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or AUC_{inf}. Please collect sufficient blood samples in the bioequivalence study to adequately characterize the peak concentration (Cmax) and time to reach peak concentration (tmax).

Bioequivalence based on (90% CI): Pimozide

Waiver request of in-vivo testing: 1 mg based on (i) acceptable bioequivalence studies on the 2 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of 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).