Contains Nonbinding Recommendations

Draft Guidance on Pimozide

Active ingredient: Pimozide

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two way crossover *in-vivo*
Strength: 2 mg
Subjects: Normal healthy males and females, general population
Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

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:

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.