Contains Nonbinding Recommendations

Draft Guidance on Disopyramide Phosphate

Active ingredient: Disopyramide Phosphate

Form/Route: Extended Release Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 150 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 150 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

Analytes to measure: Disopyramide in plasma

Bioequivalence based on (90% CI): Disopyramide

Waiver request of in-vivo testing: 100 mg based on (i) acceptable bioequivalence studies on the 150 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:

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.