

Guidance on Dofetilide

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Active Ingredient: Dofetilide

Form/Route: Capsules/Oral

Recommended Studies: 2 studies

1. Type of Study: Fasting
Design: Single dose, two-way crossover, in vivo
Strength: 0.5 mg
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study
Additional Comments: A Black Box warning concerns the risk of drug-induced arrhythmia. The study should be conducted in a facility that can provide continuous cardiac monitoring in the presence of personnel trained in management of serious ventricular arrhythmias. Any subject that develops a prolonged QTc interval should be monitored until the QTc is within normal limits.

2. Type of Study: Fed
Design: Single dose, two-way crossover, in vivo
Strength: 0.5 mg
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study
Additional Comments: Please see comments above.

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

Bioequivalence based on (90% CI): Dofetilide

Waiver request of in vivo testing: 0.25 mg, 0.125 mg based on (i) acceptable bioequivalence studies on the 0.5 mg strength, (ii) proportionally similar to the 0.5 mg strength, and (iii) acceptable in vitro dissolution testing.

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.