

Guidance on Donepezil Hydrochloride

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Active ingredient: Donepezil Hydrochloride

Form/Route: Orally Disintegrating Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 10 mg
Subjects: Normal healthy males and females, general population
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 10 mg
Subjects: Normal healthy males and females, general population
Additional comments:

Analytes to measure: Donepezil in plasma

Bioequivalence based on (90% CI): Donepezil

Waiver request of in-vivo testing: 5 mg based on (i) acceptable bioequivalence studies on the 10 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.