Contains Nonbinding Recommendations

Guidance on Desipramine Hydrochloride

Active Ingredient: Desipramine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 100 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments: None.

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 100 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None.

Analytes to measure (in appropriate biological fluid): Desipramine in plasma.

Bioequivalence based on (90% CI): Desipramine

Waiver request of in-vivo testing: 10 mg, 25 mg, 50 mg, 75 mg, and 150 mg based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity 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 website, 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).