Contains Nonbinding Recommendations

Draft Guidance on Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate

Active ingredient: Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 7.5 mg; 7.5 mg; 7.5 mg; 7.5 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 7.5 mg; 7.5 mg; 7.5 mg; 7.5 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Analytes to measure (in appropriate biological fluid): D-amphetamine and l-amphetamine, measured separately in plasma

Bioequivalence based on (90% CI): D-amphetamine and l-amphetamine

Waiver request of in vivo testing: (1. 25 mg; 1.25 mg; 1.25mg; 1.25 mg), (1.875 mg, 1.875 mg; 1.875 mg: 1.875 mg), (2.5 mg, 2.5 mg. 2.5 mg, 2.5 mg), (3.125 mg, 3.125 mg, 3.125 mg, 3.125 mg), (3.75 mg, 3.75 mg, 3.75 mg, 3.75 mg), (5 mg, 5 mg, 5 mg, 5 mg) strengths based on (i) acceptable bioequivalence studies on the (7.5 mg, 7.5 mg, 7.5 mg, 7.5 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.accessdata.fda.gov/scripts/cder/dissolution/. 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.