Active ingredient: Methylphenidate Hydrochloride

Form/Route: Chewable Tablet

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 10 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comment:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 10 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comment:

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

Bioequivalence based on (90% CI): Methylphenidate

Waiver request of in-vivo testing: 5 mg and 2.5 mg tablets, based on (i) acceptable bioequivalence studies on the 10 mg strength tablet, (ii) proportional similarity of the formulations across the 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.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.

Recommended Dec 2009