Contains nonbinding Recommendations

Draft Guidance on Phentermine Hydrochloride

Active ingredient: Phentermine Hydrochloride

Form/Route: Orally disintegrating tablet

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 37.5 mg
   Subjects: Healthy males and non pregnant females, general population.
   Additional Comments: 1. The whole tablet should be placed on top of the tongue and allowed to disintegrate for 30 seconds then swallowed without water. 2. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. It is not known if Suprenza is excreted in human milk; however, other amphetamines are present in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 37.5 mg
   Subjects: Healthy males and non pregnant females, general population.
   Additional Comments: Please see the comments above.

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

Bioequivalence based on (90% CI): Phentermine

Waiver request of in vivo testing: 15 mg and 30 mg based on (i) acceptable bioequivalence studies on the 37.5 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of 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.