Draft Guidance on Topiramate

Active ingredient: Topiramate

Form/Route: Sprinkle Capsule /Oral

Recommended studies: 2 studies

1.   Type of study: Fasting
      Design: Single-dose, two-treatment, two-period crossover *in-vivo*
      Strength: 25 mg
      Subjects: Normal healthy males and females, general population
      Additional Comments: Females must have a negative baseline pregnancy test within 24 hours
      prior to receiving the drug. Females should not be pregnant or lactating, and if applicable, should
      practice abstention or contraception during the study.
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2.   Type of study: Fed
      Design: Single-dose, two-treatment, two-period crossover *in-vivo*
      Strength: 25 mg
      Subjects: Normal healthy males and females, general population
      Additional comments: Please see comments above.
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Analytes to measure (in appropriate biological fluid): Topiramate in plasma.

Bioequivalence based on (90% CI): Topiramate

Waiver request of in-vivo testing: 15 mg based on (i) acceptable bioequivalence studies on the 25 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.