Active ingredient: Tizanidine Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 4 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 4 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments:

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

Bioequivalence based on (90% CI): Tizanidine

Waiver request of *in-vivo* testing: 2 mg based on (i) acceptable bioequivalence studies on the 4 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.accessdata.fda.gov/scripts/cder/dissolution/](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 Nov 2010