**Active ingredient:** Zolmitriptan

**Dosage Form/Route:** Tablet/Oral

**Recommended studies:** 2 studies

1. **Type of study:** Fasting
   - **Design:** Single-dose, two-way crossover in-vivo
   - **Strength:** 5 mg
   - **Subjects:** Healthy males and nonpregnant females, general population
   - **Additional Comments:**

2. **Type of study:** Fed
   - **Design:** Single-dose, two-way crossover in-vivo
   - **Strength:** 5 mg
   - **Subjects:** Healthy males and nonpregnant females, general population
   - **Additional Comments:**

**Analytes to measure (in appropriate biological fluid):** Zolmitriptan and its active metabolite, N-desmethylzolmitriptan in plasma

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

**Bioequivalence based on (90% CI):** Zolmitriptan

**Waiver request of in-vivo testing:** 2.5 mg based on (i) acceptable bioequivalence studies on the 5 mg strength, (ii) acceptable in vitro dissolution testing for 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/](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 Feb 2010*