Active Ingredient: Sildenafil citrate

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 10 mg base/mL at the dose of 20 mg (2 mL EQ 10 mg base/mL)
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 10 mg base/mL at the dose of 20 mg (2 mL EQ 10 mg base/mL)
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

Analytes to measure (in appropriate biological fluid): Sildenafil and its active metabolite, piperazine N-desmethylsildenafil, in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, you should submit the following data: 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): Sildenafil

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). The dissolution information for this product is available at this Web site. A dosage unit is based on the labeled concentration of the suspension product. Use the dosage unit (1 ml). Test a total of 12 units from 12 different bottles. Specifications will be determined upon review of the abbreviated new drug application (ANDA).