

Draft Guidance on Sildenafil Citrate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

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 C_{max}.

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/>. 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).