

Guidance on Sildenafil Citrate

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Active ingredient: Sildenafil Citrate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 100 mg
Subjects: Normal, healthy males
Additional comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 100 mg
Subjects: Normal, healthy males
Additional comments:

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

Bioequivalence based on (90% CI): Sildenafil

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 C_{max}.

Waiver request of in-vivo testing: 25 mg and 50 mg based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) proportionally similar 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.