Contains Nonbinding Recommendations

Guidance on Vardenafil Hydrochloride

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Vardenafil Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 20 mg
   Subjects: Normal healthy males, general population
   Additional comments:

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2. Type of Study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 20 mg
   Subjects: Normal healthy males, general population
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Vardenafil in plasma

Bioequivalence based on (90% CI): Vardenafil

Waiver request of in-vivo testing: 2.5 mg, 5 mg, and 10 mg, based on (i) acceptable bioequivalence studies on the 20-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.