Draft Guidance on Vardenafil Hydrochloride

Active ingredient: Vardenafil Hydrochloride

Form/Route: Tablets/Orally Disintegrating

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 10 mg
   Subjects: Normal healthy males, general population
   Additional comments: The drug should be placed on the tongue where it will disintegrate. The drug should be administered without water.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 10 mg
   Subjects: Normal healthy males, general population
   Additional comments: The drug should be placed on the tongue where it will disintegrate. The drug should be administered without water.

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

Bioequivalence based on (90% CI): Vardenafil

Waiver request of in vivo testing: Not Applicable

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/. 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

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