Guidance on Voriconazole

Active ingredient: Voriconazole

Form/Route: Suspension/ Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 200 mg/ 5 mL
Subjects: Normal healthy males and females, general population. Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.
Additional Comments:

Analytes to measure (in appropriate biological fluid): Voriconazole in plasma.

Bioequivalence based on (90% CI): Voriconazole

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.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.