Contains Nonbinding Recommendations

Draft Guidance on Sulfamethoxazole; Trimethoprim

Active ingredient: Sulfamethoxazole; Trimethoprim

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 800 mg/160 mg
Subjects: Normal healthy males and females, general population
Additional Comments:

Analytes to measure (in appropriate biological fluid): Sulfamethoxazole and trimethoprim in plasma.

Bioequivalence based on (90% CI): Sulfamethoxazole and trimethoprim

Waiver request of in-vivo testing: 400 mg/80 mg based on (i) acceptable bioequivalence studies on the 800 mg/160 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.