

Draft Guidance on Sulfamethoxazole; Trimethoprim

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Active Ingredient: Sulfamethoxazole; Trimethoprim

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg/5 mL; 40 mg/5 mL
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg/5 mL; 40 mg/5 mL
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

Analyte 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: Not Applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).