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Draft Guidance on Sulfamethoxazole; Trimethoprim

October 2024

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Active Ingredients:	Sulfamethoxazole; Trimethoprim
Dosage Form:	Tablet
Route:	Oral
Strengths:	400 mg; 80 mg, 800 mg; 160 mg
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 800 mg; 160 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analytes to measure: Sulfamethoxazole and trimethoprim in plasma

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

Waiver request of in vivo testing: 400 mg; 80 mg strength based on (i) an acceptable bioequivalence study on the 800 mg; 160 mg strength, (ii) acceptable dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.