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Draft Guidance on Amoxicillin; Vonoprazan Fumarate

October 2024

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Active Ingredients: Amoxicillin; Vonoprazan fumarate

Dosage Forms: Capsule; Tablet

Route: Oral

Strength: 500 mg; EQ 20 mg Base

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: 500 mg; EQ 20 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Specific recommendations are provided below.

Analytes to measure: Amoxicillin and vonoprazan in plasma

Bioequivalence based on (90% CI): Amoxicillin and vonoprazan

Waiver request of in vivo testing: Not applicable

Additional comments regarding the pharmacokinetic endpoint bioequivalence studies: Since this drug product is co-packaged with amoxicillin capsules and vonoprazan fumarate tablets, abbreviated new drug application (ANDA) applicants may: (1) conduct one bioequivalence study under fasting conditions by co-administering amoxicillin capsules and vonoprazan fumarate tablets; (2) conduct a total of two bioequivalence studies, separately for amoxicillin capsules and vonoprazan fumarate tablets under fasting conditions; or (3) cross-reference approved applications, such as new drug application or ANDA for the individual components of this co-packaged drug product.

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 ANDA.

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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*.