Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Probenecid; Sulopenem Etzadroxil

November 2025

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Active Ingredients: Probenecid; Sulopenem etzadroxil

Dosage Form: Tablet

Route: Oral

Strength: 500 mg; 500 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 500 mg; 500 mg
   Subjects: Healthy non-pregnant, non-lactating females
   Additional comment: Exclude subjects with a history of drug hypersensitivity (e.g., hypersensitivity to beta-lactams) to prevent serious hypersensitivity reactions.

Waiver request of in vivo testing: Not applicable

Analytes to measure: Probenecid and sulopenem[1] in plasma

Bioequivalence based on (90% CI): Probenecid and sulopenem

[1] Sulopenem etzadroxil is not able to be reliably measured in whole blood or plasma.

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 the test product and reference listed drug (RLD).[2] Specifications will be determined upon evaluation of the abbreviated new drug application.

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