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Draft Guidance on Gepotidacin Mesylate

December 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

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Active Ingredient: Gepotidacin mesylate

Dosage Form: Tablet

Route: Oral

Strength: EQ 750 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: EQ 750 mg Base
   Subjects: Healthy non-pregnant, non-lactating females
   Additional comments:
   - Exclude subjects with known risk factors for prolonged QTc interval and Torsades de Pointes.
   - If there are gastrointestinal tolerability concerns on this product, a fed study can be conducted as an alternative approach.

Analyte to measure: Gepotidacin in plasma

Bioequivalence based on (90% CI): Gepotidacin

Waiver request of in vivo testing: Not applicable

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).[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 guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.