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Draft Guidance on Mavorixafor

November 2025

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Active Ingredient: Mavorixafor

Dosage Form: Capsule

Route: Oral

Strength: 100 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: 100 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments:
   - Exclude subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Males with female partners of reproductive potential should use effective contraception during the study and for three weeks after the last dose.
   - Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of mavorixafor. Alternatively, a parallel study design may be considered.

Analyte to measure: Mavorixafor in plasma

Bioequivalence based on (90% CI): Mavorixafor

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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Unique Agency Identifier: PSG_218709

[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.*