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Draft Guidance on Abemaciclib

October 2024

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Active Ingredient: Abemaciclib

Dosage Form: Tablet

Route: Oral

Strengths: 50 mg, 100 mg, 150 mg, 200 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: 200 mg
   Subjects: Healthy females not of reproductive potential
   Additional comments: None

Analyte to measure: Abemaciclib in plasma

Bioequivalence based on (90% CI): Abemaciclib

Waiver request of in vivo testing: 50 mg, 100 mg, and 150 mg strengths based on (i) acceptable bioequivalence study on the 200 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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 all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended September 2018; Revised October 2024

Unique Agency Identifier: PSG_208716

[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.*