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Draft Guidance on Flutamide

October 2024

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Active Ingredient: Flutamide

Dosage Form: Capsule

Route: Oral

Strength: 125 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: 125 mg at a dose of 250 mg (2 x 125 mg)
   Subjects: Healthy males
   Additional comments: None

Analytes to measure: Flutamide and active metabolite, hydroxyflutamide in plasma

Bioequivalence based on (90% CI): Flutamide

If flutamide plasma concentrations can be reliably measured and its pharmacokinetic parameters accurately determined, applicants should analyze the flutamide data using the confidence interval approach. The hydroxyflutamide data can be used to provide supportive evidence of comparable therapeutic outcome.

If flutamide cannot be reliably measured, applicants should analyze the hydroxyflutamide data obtained from the study using the confidence interval approach.

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.

Document History: Recommended April 2013; Revised October 2024

Unique Agency Identifier: PSG_018554

[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*.