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Draft Guidance on Alosetron Hydrochloride

October 2024

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Active Ingredient: Alosetron hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 0.5 mg Base, EQ 1 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 1 mg Base
   Subjects: Healthy non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Alosetron in plasma

Bioequivalence based on (90% CI): Alosetron

Waiver request of in vivo testing: EQ 0.5 mg Base strength based on (i) acceptable bioequivalence study on the EQ 1 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportionally similarity of the formulations between both 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 both strengths of the test product and reference listed drug (RLD) products.[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 FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*