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Draft Guidance on Valsartan

October 2024

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Active Ingredient: Valsartan

Dosage Form: Tablet

Route: Oral

Strengths: 40 mg, 80 mg, 160 mg, 320 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: 320 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Include provisions for appropriate monitoring and intervention in the case of possible drug-related adverse events (e.g., subjects complaining of dizziness/ lightheadedness should have blood pressure/heart rate assessed). Female subjects of reproductive potential should practice abstention or contraception during the study.

Analyte to measure: Valsartan in plasma

Bioequivalence based on (90% CI): Valsartan

Waiver request of in vivo testing: 40 mg, 80 mg, and 160 mg strengths based on (i) acceptable bioequivalence study on the 320 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.

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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*.